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The effectiveness and efficiency of implementing the chronic care model for HIV care in Uganda

MARCH 2016

This research report evaluating the chronic care model for HIV care in Uganda was prepared by University Research Co., LLC (URC) for review by the United States Agency for International Development (USAID) and authored by Edward I. Broughton, Martin Muhire, Esther Karamagi, and Herbert Kisamba of URC and Sarah Smith Lunsford of EnCompass LLC through the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project. The USAID ASSIST Project is made possible by the generous support of the American people through USAID. The project's support for the application of the chronic care model for HIV in Uganda was supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

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DISCLAIMER

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Acknowledgements

The authors thank the health workers and managers at the participating facilities and the Ugandan MOH for their support. The authors acknowledge the review provided by Dr. Mirwais Rahimzai, Chief of Party, USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project, University Research Co., LLC (URC); Dr. M. Rashad Massoud, Director, USAID ASSIST Project, URC; Ms. Lani Marquez, Knowledge Management Director, USAID ASSIST Project, URC; and Dr. James Heiby, Medical Officer, US Agency for International Development.

This report was prepared by University Research Co., LLC (URC) under the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project, which is funded by the American people through USAID's Bureau for Global Health, Office of Health Systems. Support for the chronic care model implementation in Uganda was provided by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The project is managed by URC under the terms of Cooperative Agreement Number AID-OAA-A-12-00101. URC's global partners for USAID ASSIST include: EnCompass LLC; FHI 360; Harvard University School of Public Health; HEALTHQUAL International; Initiatives Inc.; Institute for Healthcare Improvement; Johns Hopkins Center for Communication Programs; and WI-HER, LLC.

For more information on the work of the USAID ASSIST Project, please visit www.usaidassist.org or write assist-info@urc-chs.com.

Recommended citation

Broughton EI, Muhire M, Karamagi E, Kisamba H, Lunsford SS. 2016. The effectiveness and efficiency of implementing the chronic care model for HIV care in Uganda. *Research and Evaluation Report*. Published by the USAID ASSIST Project. Bethesda, MD: University Research Co., LLC (URC).

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Acronyms

ART	Antiretroviral therapy
ASSIST	USAID Applying Science to Strengthen and Improve Systems Project
CCM	Chronic Care Model
CD4	Cluster of differentiation 4
CEA	Cost-effectiveness analysis
HC	Health center
IRB	Institutional Review Board
MOH	Ministry of Health
NGO	Non-governmental organization
OI	Opportunistic infection
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PQS	PEPFAR Quality Strategy
URC	University Research Co., LLC
USAID	US Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Introduction

The chronic care model (CCM), is an integrated, population-based approach to providing health care for those with chronic diseases that involves patient self-management support, delivery system design and decision-support for clinicians and patients to ensure evidence-based guidelines are integrated into practice. In Uganda, the CCM was used as the basis of providing care for patients with HIV on antiretroviral therapy with technical assistance from the United States Agency for International Development (USAID) Applying Science to Strengthen and Improve Systems (ASSIST) Project. We sought to determine the effectiveness and efficiency of the implementing the CCM in Uganda.

Methods

In this controlled pre/post-intervention study in two districts, we collected data on CD4 and patient adherence from a random sample of clients receiving HIV services at any one of six sites. The intervention included learning sessions and monthly coaching visits from improvement experts over one year. We used a difference-in-differences analysis controlling for potential confounders. Qualitative data were gathered using pre-tested semi-structured interview guides.

Results

The odds of an increase in CD4 in the intervention group was 3.2 times higher than in the control group ($p=0.022$). About 9% of clients had clinician-reported adherence to ART the same or better at end line compared to baseline in the intervention group ($p<0.001$). A greater proportion of the patients in the intervention group reported being more responsible for their health and feeling in better health. The intervention cost the project \$11,740 and there was a total of 7,016 patients enrolled for ART care in the participating clinics for a total of \$1.67 per patient served in the clinics. The incremental cost-effectiveness ratios of the intervention compared to business-as-usual was \$ 8.88 per additional ART patient with an improved CD4 and \$ 2.07 per additional ART patient with the same or better adherence to ART.

Qualitatively, provider knowledge had increased in intervention sites compared to controls and there was a perception of increased efficiency and organization which led to positive impressions of the services provided among workers at those sites. Overall, providers experienced improvements delivering care and clients experienced improvement in the care they received.

Conclusion

The findings suggest that for a modest expenditure, it is possible to improve process and outcome indicators of the quality of care by implementing the CCM. Qualitative improvements in the intervention sites were observed in areas beyond the focus of the activity, such as task-shifting of triage responsibilities to expert patients and managing inventory to prevent stock-outs. It is recommended that the method of implementing the chronic care model described here be implemented widely in Uganda and it may be suitable for application in other similar settings.

I. INTRODUCTION

In the past decades with the advent and wide availability of effective antiretroviral drug regimens, HIV has become increasingly considered a chronic disease even in low-resource settings [1]. The chronic care model (CCM) is an integrated, population-based approach to providing health care for those with chronic diseases in primary care settings. It primarily involves the following components of care: self-management support (patients given the necessary skills to play an active and constructive role in their own care); delivery system design (clinic systems such as staffing and appointments are organized to provide high quality, support and patient-centered care) and; decision support for clinicians and patients to ensure that evidence-based guidelines are integrated into clinician practice to facilitate the best health and well-being outcomes possible [2]. It is also important to maximize the accuracy of the data use to track patient outcomes because of the centrality of these data to inform management of the patient as well as drive the process of health system improvement [3].

In Uganda, the CCM is being used as the basis of providing care and support for patients with HIV who are on antiretroviral therapy (ART). The United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), which support improvement of the Ugandan health care system for the benefit of HIV-infected people, were interested in determining the effectiveness and efficiency of using process improvement to introduce the CCM to improve retention, adherence and outcomes in persons living with HIV/AIDS in this setting. Technical assistance from the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project provided an opportunity to examine the effects of implementation of changes in the system of care based on the CCM on clients seeking HIV services in Uganda. This research evaluated this implementation in one district in Uganda. It compares the health status and treatment history of clients receiving treatment in this one district to those from an adjacent district where there was no specific implementation of changes based on the CCM. The evaluation addressed the following questions:

- 1) Are clients who are HIV-positive and receiving care from clinics undergoing changes based on the CCM more likely to remain in the continuum of care than clients treated in clinics that are not undergoing such changes?
- 2) Are clients receiving care in clinics using the CCM more likely to be more compliant with taking their HIV medications (ART and cotrimoxazole preventive therapy)?
- 3) Are clients receiving care in clinics using the CCM more likely to have better clinical outcomes as measured by an increase in CD4counts, a decrease in reported opportunistic infections, maintenance or improvement in body weight?
- 4) If adherence to treatment and outcomes are better among clients receiving care from clinics implementing the CCM compared to those receiving care in clinics not using the CCM, what is the incremental cost-effectiveness of the CCM implementation in this setting?
- 5) How does the client experience in clinics implementing CCM differ from the experience in clinics not using CCM?
- 6) How do providers experience implementing CCM?

Improving the effectiveness and efficiency of service delivery to people with HIV in low- and middle-income countries is of great importance to the overall public health in those countries. In countries that receive support from PEPFAR, there is an increasing focus on transparency, accountability for impact, and accelerating core interventions for epidemic control [4]. PEPFAR and other external partners of the Ugandan Ministry of Health (MOH) have acknowledged that the current heavy reliance on external financial and technical partnerships with the MOH in response to the HIV epidemic is unsustainable and different models of delivery of care are needed as the availability of treatment expands [4]. Evaluating the effectiveness and the resources required to change the system of care delivery to utilize the CCM, and how it functions, is important to give stakeholders in the MOH, external donors such as PEPFAR, and other interested parties within and beyond Uganda an objective evidence base to guide decisions about allocation of resources for programs to address HIV.

II. METHODS

A. Study Design

We conducted a controlled pre/post-intervention study in two neighboring districts, Mityana and Nakaseke in Central Uganda, chosen as representative of mixed rural/township districts in the country. We collected quantitative data from a random sample of clients receiving HIV services at any one of the six sites participating in the study, three in the intervention district of Mityana and three in the control district of Nakaseke. Mityana was randomly selected to be the intervention district and Nakaseke was chosen as the control district. Both districts were receiving technical assistance from the same Ugandan NGO and were considered comparable in size, economy and HIV burden. The sole district hospitals from each were chosen as well as one outpatient center (Health Center III) from each district and one smaller hospital (Health Center IV) with inpatient, outpatient and basic surgery facilities from each district. These were chosen because of their geographical proximity to the district hospital and their similarities in patient volume and staffing levels. The unit of analysis for client self-management and client status indicators was the individual client.

B. Sampling

Clients were selected using systematic random sampling from all clients receiving services for HIV in the selected facilities and who met the following inclusion criteria:

- 1) Receiving HIV services for at least the previous four months
- 2) Over the age of 18 years
- 3) Full-time residents of either Mityana or Nakaseke district and do not have plans to seek treatment at another facility for at least 12 months
- 4) Consent to be participants in this study

Client participants were selected from among all those who meet the selection criteria. The sample was randomly selected by their randomly assigned identification number. The sample size was determined in order to detect a difference in adherence in an indicator of 15% with a starting point of 50% with a power of 0.8, alpha of 0.05 and using a design factor of two to account for clustering by facility. For differences in changes in CD4 counts, calculations were based on the ability to detect a differences in the CD4 change of 15 with a standard error of 20 (determined from a previous study in another district in Uganda), a power of 0.8 and a design effect of two to account for clustering by facility.

Fifty patients were randomly selected from each arm to participate in interviews. The intent was to interview the same 100 participants at baseline and end line, but some patients from the baseline were not able to be traced at end line (**Table 1**). Facility-based providers were also interviewed. Due to staff turnover, interviewing the same providers was not possible. To capture reflections on the improvement activity, at end line in the intervention facilities we purposively selected providers who had worked at the facility for at least six months.

Table 1: Patient and provider interview respondents

	Intervention Sites				Control Sites			
	Baseline		Endline		Baseline		Endline	
	Patients	Providers	Patients	Providers	Patients	Providers	Patients	Providers
Hospital	29	4	29	5	28	6	24	6
Health Center III	10	2	10	5	12	3	11	1
Health Center IV	9	2	9	2	8	4	6	1

C. Intervention

Initially, a three-day orientation training was conducted in June 2013 by two experts in process improvement from the USAID-funded project and two clinicians from similar health facilities previously involved in a pilot intervention implementing the CCM. The audience for the orientation were two staff members from the Mityana district health office of the MOH and 25 staff members from the three intervention facilities. Material covered included identifying service delivery problems and implementing changes to address them, collecting and maintaining accurate clinical data to be able to track performance, reorganizing care at the facilities to improve efficiency and empowering patients to play a more active role managing their condition.

This was followed by eight monthly visits by an improvement expert, a district health office staff member and a clinician from the pilot intervention facility to each of the three participating clinics individually. At the Health Centers III and IV, the first morning of each visit was used to review patient charts, registers and drug dispensary logs, and observe clinic operations. The afternoon were used to provide feedback to the improvement team. At the main district hospital (DH) where there were larger numbers of patients, the first day was used to review records and on the following day, the coaches provided feedback to clinic staff on successful practices as well as gaps in performance and ideas on how to address them. Also, during the coaching visits, one staff member from one facility would visit another participating site to learn what changes were successful or otherwise at the different site. This was meant to accelerate learning among sites.

In addition to the orientation session, the project convened two meetings of representatives of the three intervention facility teams and district health office staff, one in October 2013 and a second and final collaborative learning meeting in February 2014. These meetings were designed to allow the sites to share successful changes introduced to implement the CCM, learn from each other, and identify actions that each site would take to continue to apply the CCM. Such shared learning is an important part of collaborative process improvement wherein all sites working toward the same improvement aims share and learn from each other. The second such meeting, which involved three district health office staff members from Mityana and 29 participants from the three Mityana health facilities, served to consolidate all the successful changes implemented and document details of how they were implemented, as well as identify challenges faced during the course of improving HIV chronic care.

Changes implemented at some clinics include the provision of clinical job aids so clinicians had visual reminders of recommended practices in the care of HIV patients, provision of written appointment reminders for patients to ensure they knew when to come for their next visit, more fastidious tracking of patient CD4s and ensuring that these tests were done at appropriate intervals and their findings were acted on, and early identification and prompt treatment for tuberculosis co-infection. Patients as beneficiaries of care also embarked on changes such as a change in dietary habits to ensure they ate a balanced diet. Some patients began planting vegetable under the direction of the self-management groups to facilitate their consumption of nutritious food. Other patients ceased behaviors such as alcohol consumption and having multiple sex partners while on ART.

D. Quantitative Data Collection

Quantitative data were primarily collected from client medical records in both the intervention and control sites. These include CD4 counts if they were taken within 30 days prior to baseline data collection. For patients without recent CD4 counts, baseline measures were collected so a pre-intervention to post-intervention change in the intervention group could be compared to the change between the two periods in the control group.

Adherence to ART data were collected from the patient treatment charts for sampled patients enrolled in HIV care at any one of the six participating facilities. Data collection was done by trained data abstractors who referenced the columns on the treatment charts on where adherence was recorded. Clinicians

completed these columns once they had conducted pill counts for both cotrimoxazole and antiretroviral medications and adherence was determined as either: good (patients had taken all pills as expected or missed taking not more than two), fair (patients who missed taking 2-4 pills) or poor (patients who missed taking more than 5 pills). Before the start of baseline data collection, health workers were coached to collect reliable and valid adherence data and instructed to remind patients to return with pill balances so pill counts could be conducted and recorded on the patient card.

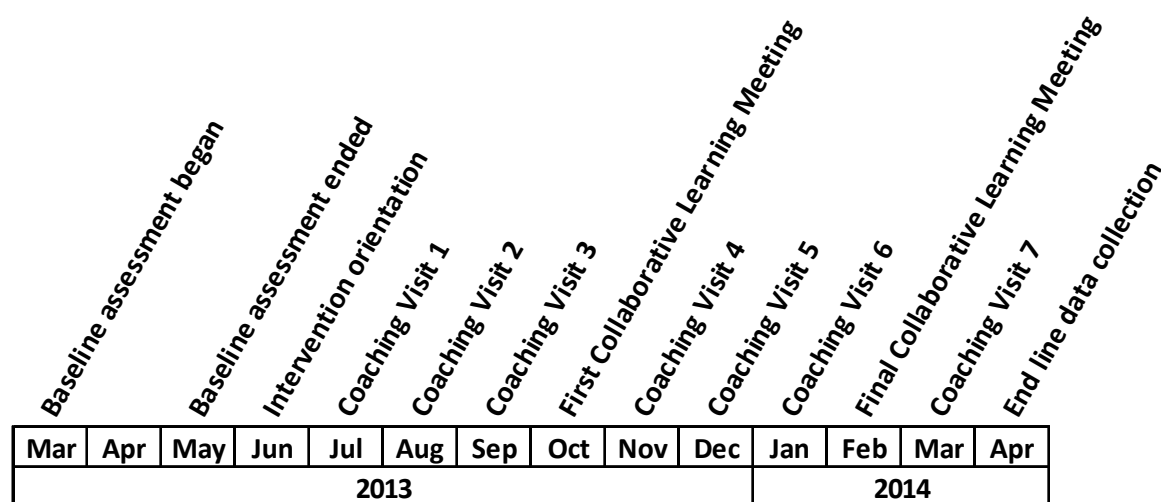
Appointment adherence was calculated by subtracting the date the patient came into the clinic for his or her most recent appointment, and the time noted on the register as the date they were scheduled for the visit that month. In accordance with the Uganda MOH definition, if the client was last at the clinic for consultation within seven days of his or her scheduled visit, they were considered compliant with their scheduled appointment.

Data on opportunistic infections (OIs) and WHO clinical stage relied on the clinical judgment of the attending health care worker and them writing this down accurately in the clients individual medical record and then for the trained data abstractors to collect these data and record them in the study's database. Body weights were measured using the body weight scales available in the facility and it was assumed that the clients would be weighed using the same scale each time they came in for their visit. The importance of obtaining these data and correct recording them was emphasized by the coaches to the front line health workers in the facilities. It was also discussed with the NGO providing technical assistance to Nakaseke that even in these control sites, these data needed to be collected assiduously and accurately.

These data were different from the routine data collection that occurred every month as part of the implementation of the improvement activities in the intervention sites, even though many were the same indicators. The data used to inform the health care delivery system improvement were generally collected by the quality improvement teams in the facilities rather than the trained data collectors who were sent to the same facilities at the beginning and end of the implementation periods. These quality improvement teams were coached by members of the coaching teams on how to collect, analyze and interpret the routine monthly data for use in informing the intervention.

Figure 1 shows the timeline for data collection and implementation of the intervention and the evaluation data collection points.

Figure 1: Timeline for the intervention



E. Qualitative Data Collection

Qualitative data were gathered using pre-tested semi-structured interview guides. Patient interviews included topics on adherence, retention, managing their health and any problems, support from health care providers and others in their social network, and perceptions of the quality of care. Provider interviews covered service delivery systems, decision support, information systems, and healthcare organization and included a knowledge test on current Ugandan HIV care and treatment guidelines and enrollment criteria. Patient interviews were conducted in Luganda and provider interviews were conducted in English. Interviewers were trained in interviewing and data capture techniques, and human subjects research ethics, including informed consent. Data were captured through interviewer field notes including direct quotes and observations [5].

F. Cost Data Collection

The perspective taken for the cost-effectiveness analysis was the payer for the improvement activity, USAID. Cost data were collected from the accounting records of the USAID HCI and ASSIST Projects. They include the time of the personnel facilitating the learning sessions and conducting the coaching visits and the transportation, venue, refreshments and incidental expenses. It also includes the transportation costs and per diems for clinic staff participating in the collaborative learning meetings and coaching visits. We did not include the time participants took from their regular activities because we considered it part of the usual allowance that clinic workers have for continuing education activities and other work not directly with patients and the MOH did not incur any additional costs to support participation of their clinical staff in their improvement activities. Discounting and inflation were not applied to the costs or effects because most were incurred within a year of the beginning of the implementation. Costs were recorded in Uganda Shillings and converted into US dollars at the January 2015 exchange rate.

G. Ethics

The study was approved by the University Research Co., LLC Institutional Review Board (IRB), based in the US, and the IRB of the implementing partner based in Uganda and registered with the Uganda National Council for Science and Technology – registration number HS 1375.

H. Data Analysis

1. Quantitative data

Two separate analyses were conducted on the proxy outcome measures used to evaluate the effectiveness of the intervention.

In the first, we used data from patient records on adherence with appointments, OIs, body weight, adherence to ART and cotrimoxazole, and WHO clinical stage. For each variable, we separated out those clients for whom both baseline and end line data were collected then determined if there was any change in them. We considered each variable separately controlling for potential confounders (**Table 2**).

Table 2: Baseline characteristics of sample – completeness of data collected

Variable	Intervention		Control		p-value
	n	%	n	%	
Female	227	63	226	70	0.0053
Adherent to appointment	240	68	262	77	0.008
Both weights reported	106	29	177	54	<0.001
Both adherence	306	84	291	90	0.044
Baseline adherence	315	90	236	74	<0.001

Variable	Intervention		Control		p-value
Good functional status (BL)	348	99	280	100	0.698
Both OI data reported	87	24	158	49	<0.001
OI report at baseline	16	5	53	20	<0.001
Both WHO Clinical Stage reported	290	89	305	84	0.047
Both CPT adherence	302	83	291	90	0.017

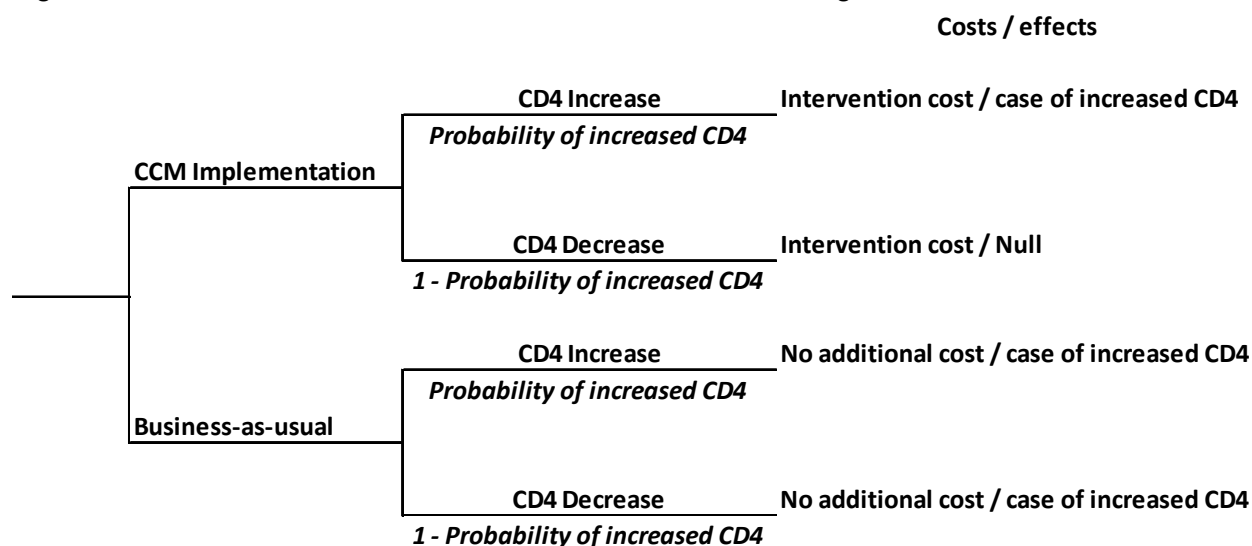
In the second, we analyzed baseline characteristics such as age, sex and time since HIV diagnosis to determine differences between the intervention and control samples. We also analyzed these potential confounding variables to determine their association with the main outcome variables, improvement in CD4 counts and adherence to ART comparing the baseline period to the end line after the intervention was completed. We considered changes in CD4s as a continuous and dichotomous variable (improved or not). To determine the change attributable to the intervention, we used both linear and logistic regression both as univariate analysis and controlling for potential confounders (**Table 3**).

Table 3: Change in outcome indicator attributable to CCM intervention

Variable	Intervention		Control		Change attributable to intervention (%)	p-value
	n	%	n	%		
Improved adherence with appointments	75	21	48	15	6	0.013
OI cured	3	3	21	13	-10	0.021
Developed OI	11	13	43	27	-14	0.010
No weight loss	41	39	58	33	6	0.313
ART adherence same or better	99	32	159	55	-23	<0.001
CPT adherence same or better	122	40	156	54	-14	0.001
WHO Stage not worse	271	89	262	90	-1	0.552

For the cost-effectiveness analysis component, we used decision-tree analysis to compare the efficiency of the intervention relative to the counterfactual of the situation in the control group over the same period (**Figure 2**). We used the logistic regression output controlling for confounders and transformed this into a probability to use in the model. Results of the economic analysis are reported in terms of the incremental cost per additional patient with an improvement in their CD4 count or per additional patient reported to have the same or better compliance to ART.

Figure 2: Decision tree for cost-effectiveness model for increasing CD4 outcome



2. Qualitative data

Interview data were entered into an Excel database to allow for quantification of closed-ended questions and coding of open response questions. Differences in changes were calculated by subtracting the difference in control baseline and end line from difference in intervention baseline and end line. Due to the small sample, more rigorous statistical analysis was not possible. A deductive coding scheme was applied to the open responses based on the CCM components and topics covered in the interview guide. Comparison between responses from intervention and control participants was performed.

III. RESULTS

A. CD4 Improvement

There were 46 participants in the control group and 54 in the intervention group who provided samples for baseline CD4 testing and two in the intervention group and nine in the control group could not be traced to obtain end-line samples. The majority in both groups were women and the factor that was the most dissimilar between the two groups was the time since HIV diagnosis and the proportion of patients who transferred out of the facility to receive care in another facility (**Table 4**). For data on adherence to ART, 363 patient charts in the intervention group and 325 in the control group were collected. This was the larger group from which the subset of those who had the two measures of their CD4s to detect changes were selected.

Table 4: Baseline characteristics of sample

Variable	Intervention	Control	p-value
Number of participants	54	46	-
Age (years)	41.7	39.7	0.304
Females (%)	61	65	0.672
Months since HIV diagnosis	55	43	0.06
Months since starting ART	36	33	0.523

Variable	Intervention	Control	p-value
Baseline CD4	430	466	0.464
Lost to follow-up n (%)	2 (4%)	5 (11%)	0.162
Transferred out n (%)	0 (0%)	4 (11%)	0.027

The effect of immutable characteristics on the primary outcome was determined using univariate logistic regressions (**Table 5**). The interpretation of the first data row in the table is that for a patient who is one year older than another, he or she has a 6% decrease ($0.94 - 1$) in the odds of having an improvement in CD4 over the 12 month period. For the second row, the interpretation is that females had a 30% higher odds of improvement in CD4 count ($1.3 - 1$) compared to men. Age, the number of months on ART and baseline CD4 counts had the greatest effect on the likelihood of improvement in CD4.

Table 5: Association of baseline characteristics with improvement in CD4 counts

Variable	Odds Ratio	p-value
Age	0.94	0.013
Female	1.3	0.538
Months on ART	0.98	0.044
Months since HIV diagnosis	0.99	0.419
Baseline CD4	0.998	0.03

The average increase in CD4 counts was about 71 cells higher in the intervention group compared to the control group with the p-value lower for the multivariate model than the univariate model ($p=0.079$ and $p=0.149$ respectively) (Table 6). The odds of an increase in CD4 in the intervention group when controlling for potential confounders was 3.2 times higher than in the control group ($p=0.022$) and this attributable difference is the input used for the cost-effectiveness model. Clinician reported adherence to ART was approximately 60% ($p = 0.001$) less likely to be lower in the intervention group compared to controls (Table 6).

Table 6: Change in CD4 and adherence to ART attributable to improvement intervention

Variable	Intervention	Control	p-value
CD4 counts			
Number of participants	54	46	-
Increase in CD4 (univariate model)	86	15	0.149
Increase in CD4 (multivariate model)	235	146	0.077
Odds ratio of increased CD4 (univariate model)	2.6	1	0.033
Odds ratio of increased CD4 (multivariate model)	3.2	1	0.022
End line CD4	517	519	0.983
Clinician-reported adherence			
Number of participants	306	291	
Odds ratio of same or better adherence (univariate)	2.32	1	0.001
Odds ratio of same or better adherence (multivariate)	2.34	1	0.001

B. Cost-effectiveness

The overall cost of the intervention from the perspective of the implementing party was Ugandan shillings 33,525,000 or \$ 11,740 and here was a total of 7,016 patients enrolled for ART care in the participating clinics for a total of \$1.67 per patient served in the clinics. The incremental cost-effectiveness ratios of the intervention compared to the business-as-usual scenario in terms of CD4 count changes is \$ 8.88 per additional ART patient with an improved CD4 count (95% CI: 6.12 – 18.20) and \$ 2.07 per additional ART patient with the same or better adherence reported on their ART card (95% CI: 2.00 – 2.16). Therefore, from the total additional expenditure, there were 1,300 more patients with improvements in their CD4 counts and 6,700 more patients with the same or better adherence to ART reported on their ART cards.

C. Qualitative Data

1. Patient Self-management

Over half of patients reported having treatment supporters across both arms and at both times of data collection with no change between data collection points. Treatment supporters were often family or close friends. However, in the intervention sites at end line, patients also indicated using expert patients or fellow patients as their supporters, which was not found to be the case in the control sites. There was a notable increase in the number of patients reporting being responsible for their own health in both arms, with a corresponding decrease in health workers or family cited as responsible for the patients' health (**Table 7**). When probed for who was included in the "other" category, respondents cited close friends or family. The decline observed in both arms may be as a result of counseling and awareness raising village health teams conducted in both districts, which took place independent of the intervention.

Table 7: Patients indicating who was responsible for their health and self-reported health status

	Intervention Sites		Control Sites		Difference in Change
	Baseline (n=48)	Endline (n=50)	Baseline (n=48)	Endline (n=41)	
Who is responsible for my health?					
I am	33% (16)	74% (37)	38% (18)	71% (29)	8%
Health Worker	27% (13)	10% (5)	23% (11)	17% (7)	-11%
Other (family, close friend)	40% (19)	16% (8)	40% (19)	12% (5)	4%
Compared to last month, I feel...					
Better	56% (27)	86% (43)	77% (37)	85% (35)	22%
Same	29% (14)	12% (6)	6% (3)	12% (5)	-23%
Worse	15% (7)	2% (1)	17% (8)	5% (2)	-1%

Similar changes were observed in self-reports of how patients felt at the time of data collection compared to the previous month. When asked to explain their self-reported health status responses extended beyond the physical to their social and financial wellbeing. One patient explained: "Last month I was sick with stress. I had lost 200,000 [Ugandan Shillings] for my business. That's why I missed my appointment" (female patient, intervention hospital, end line).

When asked if they had a plan to improve their health, respondents in both arms and across data collection times reported they did (baseline: 85% in both arms; end line: 78% in the control and 94% in the intervention). Plans included but were not limited to adhering to treatment regimens, attending appointments, or limiting alcohol or tobacco consumption. They almost universally involved some form of income generating activity such as growing produce or rearing livestock to sell or establishing a shop.

2. Provider knowledge and decision support

Presence of reference materials in facilities was universal, though access at baseline in both arms was challenged. Materials were locked in offices, not readily accessible by facility staff. By the end of the intervention, intervention sites had materials displayed in consultation and clinic rooms, facilitating access during patient assessments; control sites, in contrast, did not have reference materials freely available. Providers in both arms reported having access to continuing medical education. Many reported these sessions were conducted during their weekly or monthly staff meetings when a fellow staff member would present on their area of specialty. Attending more formal education sessions outside the facility was less common across both arms.

On a knowledge test of ART initiation guidelines and WHO staging criteria, providers in the intervention group appear to have increased their knowledge over the course of the project (**Table 8**). The greatest improvements in provider knowledge at intervention sites were observed in knowledge of ART initiation among patients with pulmonary tuberculosis or extra-pulmonary tuberculosis and WHO Clinical Stage I or II (0%-50%), and patients with hepatitis B co-infection (0% to 58%), as well as the WHO Clinical Staging Criteria for HIV-positive pregnant women (12% to 92%). Providers in control sites maintained or declined in most knowledge areas with the exception of ART initiation guidelines for all HIV-positive pregnant women (85% to 100%) and WHO Clinical Staging Criteria for HIV-positive pregnant women (46% to 57%).

Table 8: Provider respondents who correctly stated ART initiation guidelines and WHO Clinical Staging Criteria

	Intervention Sites		Control Sites		Difference in Change
	Baseline (n=8)	Endline (n=12)	Baseline (n=13)	Endline (n=7)	
ART Initiation Guidelines					
All exposed children under 2 years	25% (2)	33% (4)	38% (5)	57% (4)	10%
Children between 2-5 years if CD4 <25% (<750 cells/mm3)	12% (1)	50% (6)	8% (1)	0% (0)	34%
All positive pregnant women	50% (4)	83% (10)	85% (11)	100% (7)	43%
Patients with PTB or extra-pulmonary TB and WHO Clinical Stage I and II	0% (0)	50% (6)	0% (0)	0% (0)	50%
Hepatitis B co-infected patients in WHO Clinical Stage I and II	0% (0)	58% (7)	0% (0)	0% (0)	58%
WHO Clinical Staging Criteria					
Initiate ART in all patients who have WHO stage III disease and are co-infected with TB	62% (5)	83% (10)	85% (11)	57% (4)	82%
Initiate all HIV+ pregnant women	12% (1)	92% (11)	46% (6)	57% (4)	86%
Initiate all patients who have WHO Clinical Stage IV disease	87% (7)	92% (11)	77% (10)	57% (4)	67%

In the intervention sites, improvement work focused on improving provider knowledge through an initial knowledge assessment to understand where the knowledge gaps were, followed by development of a facility-specific action plan. Plans included holding continuing medical education sessions, providing one-on-one support, displaying prescription charts in the facility, and having peers provide support to colleagues. The declines in knowledge in control sites may be in part due to staff turnover which prevented effective peer-to-peer learning and the lack of medical education sessions focused on improving HIV-related knowledge, while the improvements may be due to other implementing partner or MOH activities not accounted for in this study.

3. Delivery system design

Assisting patients in moving through the facility was done by posting flow charts, signage, and using expert patients as guides at intervention sites. The use of expert patients in aiding patients in their movement through the facility also served as a triage mechanism. Expert patients escorted patients with complaints to the doctor's office; those with no complaints would be directed to nurse. Control sites also utilized expert patients, though clinical staff played a larger role in triage and moving patients through the facility.

Making improvements in retention and adherence was challenging for providers in both intervention and control sites. One indicator of retention was appointment keeping. Locating patients who missed appointments presented an ongoing challenge for providers who expressed there was not much to be done once a patient missed appointments and efforts were better spent on educating patients and preventing missed appointments: "I have their phone numbers and when they miss we call them. We don't call them immediately because calling is difficult because the number is big, we try to prevent clients from missing appointments through pre-ART counselling and also health education session" (Medical Officer, intervention hospital).

Reducing drug stock-outs and improving referral and laboratory processes were not objectives of this improvement work, but providers did comment on how these areas were affected by the collaborative improvement process. Drug stock-outs were a challenge at all facilities at both baseline and end line though the reasons differed. In control sites, issues with stock-outs at both baseline and end line centered around delayed ordering from the National Medical Stores. Intervention sites had the same challenges at baseline, but at end line the issue was delayed delivery from the National Medical Stores, especially of second line drugs which, according to respondents could take up to one month.

In contrast, referral and laboratory processes, both of which involved aspects of the health system outside the facilities' locus of control, were not improved according to providers. In all sites referrals were made to higher or specialized facilities using a referral form or letter. Counter-referrals were far less common in both arms, with little change in the referral system at the end of the intervention period. Similarly, challenges with obtaining laboratory results remained in facilities in both arms, and was especially noted by providers from facilities which had to utilize hospital laboratory services for CD4 counts and sputum tests. One provider indicated that receiving sputum test results from the hospital laboratory could take up to a month.

Providers also felt service delivery was improved by establishing a functional system for managing patient files. At baseline, individual ART cards were stored in a file room but there was no organizational system across all facilities. This resulted in delays or the inability to locate an ART card in advance of the patient's visit, impacting quality and continuity of care. Intervention sites spent time organizing these files by ART number to facilitate retrieval and returning the files. Additionally, intervention facilities shifted the task of retrieving and returning files to expert patients, freeing time for clinicians to spend in direct contact with patients. Patients observed and experienced reduced waiting time.

"These days we no longer delay a lot as opposed to previously before you people interviewed us last year." (male intervention hospital patient)

“Those days, they would delay us. Now we spend less time unlike those days. You can spend four hours and leave by 2:00pm. People go one by one until they are finished by 2:00pm.”
(female intervention HCIV patient).

However, one patient (male intervention HCIII) did comment that providers “mix up the files and they do not see us in the order expected” indicating that the system did not function every time. Providers also noticed and were pleased with the reduced waiting time for patients and the overall improved efficiency. *“Clients used to wait for so long that could some time lead to some of them not coming knowing they will have to spend the whole day at the facility but now days things changed.”* (Enrolled nurse, intervention HCIV). Similar improvements were not observed in control sites.

4. Health care organization

In both arms the number of providers reporting the existence of improvement teams at their facilities increased; however the form and function of these teams differed between the intervention and control sites notably. The collaborative improvement approach to applying the chronic care model enhanced staff cohesion and working relationships: “this has strengthened the teamwork” (clinical officer, intervention HCIV). Similar experiences were not expressed by providers in the control sites.

Organization extended beyond the improvement teams. One challenge patients observed in both arms was inconsistent hours of facility staff and their late arrival, which led to extended wait times. Intervention facilities set regular arrival hours for facility staff which was noticed and appreciated by patients in the intervention sites. There were no such changes in the control sites and the complaints among the patients remained consistent from baseline to end line.

IV. DISCUSSION

This study found that patients receiving HIV care from clinics that were delivering care using the chronic care model were more likely to have increases in their CD4 counts and more likely to have clinician-report adherence to their prescribed therapy. Improvements in client perspectives of being responsible for their own health along with improved perceived health status and having plans for managing their health may have contributed to improved CD4 counts, and increased adherence to treatment and retention into care. Patients’ views on self-management extended beyond clinical care, often focusing on a need to ensure their financial wellbeing through agriculture or other business activities as a mechanism for promoting their health and wellbeing. This finding is consistent with another study from Uganda which suggested that “people need to pursue meaningful economic and social lives if they are to incorporate HIV as a long-term chronic condition into their lives and adhere to treatment” [6]. While addressing social and economic aspects of patient wellbeing is often outside the scope of healthcare improvement activities, it is important to recognize that for patients they are inherently linked to adherence, retention, and ultimately clinical outcomes.

Qualitative improvements in the intervention sites were observed in areas beyond the focus of the activity, such as task shifting of triage responsibilities to expert patients and managing inventory to prevent stock-outs. These qualitative changes highlight two key strengths of the improvement approach; first, the process enables improvement teams to address concerns pertinent to their context; and second, there is a spill-over effect, as teams observe improvements in one area they are motivated to apply improvement methods to other areas, which is best captured through qualitative methods. It may also indicate the early stages of institutionalizing the capacity to apply improvement methods to areas that did not receive direct external support. That no qualitative changes were observed in the referral process or obtaining laboratory results, also not the focus of this activity, may indicate the need for continued assistance or more time for teams to address those areas. Alternatively, the facility improvement teams may not have viewed referral or laboratory processes as priority areas and elected to focus their attentions elsewhere.

These improvements were achieved for less than \$2 expenditure per patient enrolled in HIV care at the participating facilities. Uganda had 23 external donors funding HIV-related activities in the country in 2013 [7]. Donor funding has stagnated in recent years in general and the lower levels of resourcing require a greater emphasis on efficiency in programs that address HIV [8]. This program, with its modest cost, appears to be good value. It would be beneficial for external donors to have analyses of more programs being implemented in donor-recipient countries so decisions can be informed but objective evaluations of efficiency.

The need to develop effective and efficient models for service delivery to those with chronic conditions is a major public health need. Pharmacologic advances and expanding access to treatment have made the 35 million with HIV infections now people with a potentially chronic condition rather than the acute and fatal one it was about 2 decades ago and about two thirds of these people live in LMICs [9]. This has happened at a time when the burden of chronic diseases from other causes in these settings has also increased significantly and is projected to continue to do so [10]. Therefore health systems in LMICs such as Uganda must implement programs that keep people with HIV adherent to treatment and playing a major role in managing their chronic condition to achieve good health outcomes at low costs.

Several authors have reported the evolution of managing people infected with HIV from treating them as acute clinical cases to managing them as patients with a chronic condition, and the need to change the health care delivery system to accommodate the phenomenon [1, 11, 12]. However, there are few reports of implementing changes at the service delivery level in low-income settings to implement the chronic care model. A review of chronic care model decision support and clinical information systems identified three studies from low-income settings and their finding overall across all settings was that the interventions had modest impacts on improving the care of people with HIV [13]. None of the three low-income setting studies examined implementation of comprehensive chronic care model but rather tested components of it [14-16]. This is the first study from a low-income country to report the effectiveness and efficiency of implementing the chronic care model as a more complete package. However, this intervention did not include community support, one of the six components of the chronic care model. Given that much self-management takes place outside of the clinic, it is possible that we would have observed greater improvement had the intervention also taken place at the community level.

The US Government is expected to spend \$6.3 billion on global efforts to HIV, about the same as it has spent annually since 2010 [17]. PEPFAR's pivot to scaling resources and services towards health service delivery sites with moderate and high patient numbers and geographic areas with high burden of HIV means that more attention will be paid to service delivery in high-volume facilities such as those in these two high HIV burden districts in Uganda. With the emphasis on making all resources spent on the effort go toward the maximum impact in reducing the HIV burden, reporting on the efficiency of health system interventions provides valuable information to make informed resource allocation choices. It could be considered a detriment of objective decision-making that there are few studies in the published literature of the sort presented here. In their review of cost-effectiveness analyses of interventions on the HIV continuum of care, Nosyk [18] identified 10 studies conducted in Africa but none were examined using the chronic care model and none focused on interventions to improve the systems of care. There are two studies underway that will provide cost-effectiveness data on implementation conducted in similar settings with which the results reported here can be compared [19, 20].

Uganda is one of the 18 African countries required to operationalize PEPFAR's Quality Strategy (PQS). The PQS is a framework for implementing quality improvement while facilitating country ownership and sustainability [21]. It is based on the understanding that improving health processes is a collective responsibility involving everyone from individual patients to health systems, managers and clinicians, and it recognizes that the productivity and efficiency of health care processes in HIV care need attention. This evaluation indicates that implementing the CCM in this setting should be considered as part of the PQS.

A. Limitations

There were several limitations to this study. First, the time frame for the analysis did not allow determination of the difference between patient outcomes at control and intervention facilities over a longer period. Data on difference in morbidity and mortality that may have been captured had the study continued for several years would have allowed reporting of more compelling outcomes than changes in CD4 and clinician-reported proxy outcomes. CD4 counts are generally recognized as an acceptable measure of the HIV disease [22, 23]. However, other health outcomes would also have allowed results to be reported as disability-adjusted life years (DALYs) or similar measures so that the effectiveness and efficiency of this program could have been compared to interventions for other health conditions.

Some health outcome indicators results seem contradictory. For example, the proportion of clients for whom OIs were reported at baseline then not reported at end line (the “OI cured” data in Table 2) was higher in the control group than the intervention group. This may have been a reflection of examination or recording errors by front line clinicians rather than a reflection of the true state of changes in OI between the two groups. Information on what the OIs were was not available for this evaluation. More accurate data collected by clinicians independently examining participating clients would have avoided this problem but was beyond the scope of the study. Similarly, the proportion of clients reportedly adherent to their ART regimen improved in the intervention group more than the control group but the opposite was seen for CPT adherence.

It was assumed that the effects of the intervention would only have lasted for the period of the analysis. It is likely that the effects of the intervention’s positive effects seen in this evaluation would have lasted at least some period into the future even without further intervention. This was not considered because the rate of attenuation of the effects without further intervention were not known. This is highly likely that this attenuated the positive effect of the intervention and led to an underestimation of the efficiency of the program.

The perspective taken for the analysis was that of the program funder, USAID, and can be useful for other external donors to make resource allocation decisions. However, it does not provide information to the MOH or other in-country stakeholders about the program’s efficiency with which that could be aided in making such decisions. We could have modeled the effectiveness and efficiency of the program if implemented by MOH personnel and other indigenous Ugandan resources but this would have involved making assumptions about the effectiveness of the program when implemented with those local resources rather than with the external technical assistance which was the case observed here. Also, capturing all opportunity costs of the intervention by taking the societal perspective, including the financial consequences for patients, may have given a result of more utility to in-country decision-makers so that they could estimate the cost of implementing the CCM without donor support to Ugandan societal overall.

To ensure that adherence was accurately reported by the clinicians in the participating facilities, clinicians there were reminded to performing pill-counts with all patients. Given that this occurred just before the baseline data collection, it may having increase the attention clinician were giving to informing the patients of the importance of remaining compliant with medication prescripts. If so, this would have led to an underestimation of the magnitude of change in adherence attributed to the intervention.

The sample size for the provider knowledge test was quite small so the findings are not generalizable and the data did not lend themselves to more rigorous statistical analysis. In addition, not all the same providers were interviewed at baseline and end line which may have impacted findings from their perspective on applying the chronic care model.

V. CONCLUSION

The findings suggest that for a modest expenditure, it is possible to improve process and outcome indicators of the quality of care while improving provider and client experiences in delivering and receiving care. It is recommended that the method of implementing the CCM described here be implemented widely in Uganda and it may be suitable for application in other similar settings. At the time of writing, this intervention had been implemented in the control sites in Nakaseke and preliminary data indicate that similar positive results were found.

A study with a longer follow-up period may have been able to capture the long-term health outcomes such as deaths, disability, secondary infections and or disability adjusted life years averted. This would have allowed expressing the effectiveness and efficiency of the intervention in more meaningful terms and allowed comparison to interventions targeting other health problems.

Any other studies on effectiveness on health outcomes of interventions to improve quality of care should have a cost-effectiveness component if in similar settings to so policy-makers can decide among different interventions knowing their relative efficiency.

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