Task-Shifting of Antiretroviral Delivery From Health Care Workers to Persons Living With HIV/AIDS: Clinical Outcomes of a Community-Based Program in Kenya

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Objectives: To assess whether community-based care delivered by people living with HIV/AIDS (PLWAs) could replace clinic-based HIV care.

Design: Prospective cluster randomized controlled clinical trial.

Setting: Villages surrounding 1 rural clinic in western Kenya.

Subjects: HIV-infected adults clinically stable on antiretroviral therapy (ART).

Intervention: The intervention group received monthly Personal Digital Assistant supported home assessments by PLWAs with clinic appointments every 3 months. The control group received standard of care monthly clinic visits.

Main Outcomes Measured: Viral load, CD4 count, Karnofsky score, stability of ART regimen, opportunistic infections, pregnancies, and number of clinic visits.

Results: After 1 year, there were no significant intervention-control differences with regard to detectable viral load, mean CD4 count, decline in Karnofsky score, change in ART regimen, new opportunistic infection, or pregnancy rate. Intervention patients made half as many clinic visits as did controls ($P < 0.001$).

Conclusions: Community-based care by PLWAs resulted in similar clinical outcomes as usual care but with half the number of clinic visits. This pilot study suggests that task-shifting and mobile technologies can deliver safe and effective community-based care to PLWAs, expediting ART rollout and increasing access to treatment while expanding the capacity of health care institutions in resource-constrained environments.

Key Words: antiretroviral therapy, healthcare delivery, HIV/AIDS, health information technology, sub-Saharan Africa, task-shifting

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INTRODUCTION

Multiple studies have documented the effectiveness of antiretroviral therapy (ART) in sub-Saharan Africa.[1–6] This evidence notwithstanding, ART rollout in resource-constrained settings has been slow. More than 5 million of the 9.5 million people living in low-income and middle-income countries in need of ART are still without access to treatment.[7] Delays in rollout are in part due to the substantial financial and human resources necessary to establish and maintain an HIV care delivery infrastructure. Sub-Saharan Africa is a case in point: it is the home of two thirds of persons living with HIV/AIDS (PLWAs) but only 3% of the world's health care workers and commands less than 1% of the world's health expenditures.[8,9]

Task shifting has been advocated as one strategy for addressing the health care worker shortages impeding scaling up of ART programs in resource-constrained settings.[10–12] The World Health Organization (WHO) guidelines advocate task-shifting from physicians and nurses to community health workers, including PLWAs, to provide HIV services at the community level.[11] However, the evidence that task-shifting can be done safely and effectively is limited to a handful of small programs from Haiti, Uganda, South Africa and where community health workers and PLWAs have been incorporated into local HIV care delivery systems.[13–15]

Mobile health technology as a component of an overall task-shifting strategy has the potential to be an effective tool in assisting the efficient and cost-effective provision of care in

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resource-limited settings. Such technology seems to have been effective in at least 1 program in Uganda, where PLWAs have used mobile phones to monitor patients on ART.[16] Given the paucity of data on the effectiveness of task-shifting in this setting, it has not yet been possible to identify the optimal care delivery structure for HIV programs.

To assess the impact of task-shifting on the clinical outcomes of HIV-infected patients, we performed a pilot study that was integrated into an extensive HIV/AIDS care network maintained by the United States Agency for International Development and the Academic Model for Providing Access to Healthcare programs (USAID-AMPATH) partnership. Our goal was to evaluate the clinical outcomes of patients enrolled in an innovative HIV care delivery system which utilized PLWAs as Community Care Coordinators (CCCs), aided by an electronic decision support tool, to deliver medications and provide follow-up care to patients on ART in the community.

METHODS

Study Design

Details of the development of the community-based ART delivery model that was tested in this trial, including particulars of the CCC curriculum, the onsite mentoring program and the Personal Digital Assistant (PDA) programming have been published elsewhere.[17] This pilot prospective community randomized clinical trial was conducted between March 2006 and April 2008. This study was approved by the Indiana University School of Medicine Institutional Review Board and the Moi University Institutional Research and Ethics Committee.

Setting

Founded in 2001, the USAID-AMPATH Partnership currently manages 23 parent clinics and 23 satellite clinics in western Kenya with the main clinic located on the grounds of Moi Teaching and Referral Hospital in Eldoret, Kenya.[18] At the close of this study in April of 2008, the system provided care for 64,000 adults and children with HIV, of which there were approximately 28,000 adults on ART. This study was conducted within the HIV Clinic and the community surrounding the Mosoriot Rural Health Center (30 Km southwest of Eldoret). The Mosoriot HIV Clinic serves Kosirai Division, a community of 60,000 in a province with an estimated HIV prevalence of 7.4%.[19] At the time of study closure, the center cared for nearly 4000 HIV-infected adults, over half of whom were receiving ART. Kosirai Division is parceled into 24 geographic and administrative areas called sublocations. The average sublocation has a diameter of 4 km and can be traversed by foot in a matter of 1–2 hours making these sublocations the ideal size to be managed by an individual CCC. As such they were chosen as the unit of randomization. Community randomization was stratified based on distance from the road with sublocations situated directly adjacent to the tarmac road being randomized separately from those that were not adjacent to the road (a minimum of 2 Km from the road). For each stratum, community names were placed in sealed opaque envelopes with 2 envelopes being assigned to the control group for every envelope assigned to the intervention group. Envelopes were then opened, and the list of intervention and control sublocations was generated.

Study Population

HIV patients enrolled at the Mosoriot HIV clinic were eligible for this study if they were at least 18 years old, clinically stable on ART for a minimum of 3 months with no adherence issues (defined answering the following question "during the last 7 days how many of his/her pills did the patient take?" as "all" during the majority of the patients clinic visits and by "most" at the remaining visits), had household members who were aware of the patients' HIV-status (to minimize the potential for negative social impacts of the study), lived in Kosirai Division (or in bordering sublocations within 4 km of the Kosirai border), and were willing to consent to participate. Patients were excluded if they had an active WHO stage 3 or 4 condition, were pregnant (by patient self-report), had been hospitalized in the previous 3 months, or were unable to understand the informed consent process due to mental or physical incapacity.[20]

Standard of Care

At the time this study was conducted, the standard of care within the USAID-AMPATH system was for patients on ART to visit the clinic monthly. During these visits, patients were seen by a nurse who triaged and obtained vital signs and a clinical officer (equivalent to a physician's assistant in the United States) or physician (approximately 10% of visits) who took an interim medical history, addressed any acute concerns, reviewed medications and medication adherence by self-report, and prescribed ART and opportunistic infection prophylaxis. Patients then presented to the pharmacy where they were provided with a 1-month supply of all medications. This model requires contact with a minimum of 3 heath care providers and when transportation and wait times are taken into account is very time consuming and expensive for the patient.

Description of the Intervention

CCCs were chosen from the HIV clinic population at Mosoriot. All CCCs chosen had a secondary education.[17] To be considered for this position, a patient had to be clinically stable with self-reported 100% adherence to ART over the 6 months before recruitment and considered by the clinic staff to be a good role model and mentor for other patients. Once recruited, CCCs underwent structured didactic training, which included the use of a PDA that was preprogrammed to collect a symptom review, vital signs (temperature, weight, and pulse oximetry), adherence, food security, and domestic violence information. Decision support in the form of preprogrammed alerts was triggered if specified parameters were met. Alerts included prompts for the CCCs to return the next day to re-evaluate the patient, transport the patient to the clinic for urgent evaluation, or call the clinical officer for consultation. After the didactic training, each CCC underwent 2 months of clinical mentoring.[17] After completing mentoring, CCCs entered the field where they conducted home visits with patients within their assigned sublocations. Intervention patients received monthly home assessments by the CCC. During home visits, CCCs obtained and entered data

concerning patient's symptoms into their PDAs along with vital signs and an assessment of adherence to ART and opportunistic infection prophylaxis (derived from in-home pill counts). They were encouraged to comply with all alerts from their PDAs and to dispense a one-month supply of the patient's medications (from a prefilled kit) if the visit triggered no alerts that would require the patient to be seen immediately in clinic.

Data Collection

In addition to the scheduled clinical visits (control group—monthly; intervention group—every 3 months), each enrolled patient was seen at Mosoriot for a research visit at enrollment and every 3 months until the closeout visit at 12 months. Research visits were coscheduled with clinic visits. At the enrollment visit, a clinical officer and research assistant reviewed and abstracted historical data from the patient's medical chart, assessed WHO stage, Karnofsky score, ART adherence history, herbal medication use, and opportunistic infection prophylaxis and treatment.[21] At follow-up research visits, the above information was supplemented by data on interim hospitalizations, intervening health issues, ART adherence, and toxicity from the clinic charts. In the catchment area for this study, the Mosoriot clinic is the only option for free HIV care. It is possible that patients could seek care in the private sector, however, in our experience this is rare and so we feel that our patient records capture all outpatient encounters with the health care system. All data were entered into standard case report forms for study enrollment and follow-up visits. At all visits, the research assistant administered an adherence survey (initial or follow-up). An HIV viral load and CD4 count were obtained at the initial and closeout research visits, and an additional CD4 count was obtained at the 6-month visit. Data from the Case Report Forms were entered into a Microsoft Access Database (Microsoft, Inc, Redmond, WA). Data from the Adherence Assessment Forms were entered into the AMPATH Medical Record System.[22] Data entered into the case report form was validated with data from AMPATH Medical Record System and review of the patient's chart when results were found to be discrepant. Clinical data and adherence data were linked and analyzed using SAS version 9.1 (SAS Inc, Cary, NC).

Statistical Analysis

At the design stage for estimating sample size, we projected that the intervention group was able to achieve the AMPATH target of 95% adherence to medications and control group with 80% adherence (as per historical rates). We also assumed that the annual loss-to-follow-up rates would be 5% and 15% for the intervention and control arm, respectively. Based on these assumptions, a total of 320 subjects with 160 in each arm would achieve a $>95\%$ power to detect significant differences in adherence to medications. Given, we had 87 and 102 subjects in the intervention and control arm at the end of 12 months, a post hoc power calculation indicates that we retained $>80\%$ power to detect the projected difference in adherence.

Analysis was by intention to treat, in which all study participants were regarded as randomly assigned to their respective study arm based on their sublocation. The outcomes of interest for this study included adherence (to drugs and to clinic visits), clinical outcomes (ie, viral load responses, intercurrent opportunistic infections, hospitalization, loss to follow-up, change to second-line therapy and mortality). Continuous variables were expressed as the mean $\pm$ SD, and categorical variables were summarized by frequency and percentages. We used 2-sample Student t test to compare continuous variables if the distributions were approximately normal and the Wilcoxon rank-sum test for skewed variables. Comparisons of proportions for dichotomous variables were performed using Fisher exact test. We estimated event-free survival using Kaplan–Meier methods and compared the time with various events between the 2 treatment arms using the log-rank test. Cox proportional hazard regression model was used to adjust the analyses for covariates not well balanced between the treatment arms. The assumption of proportional hazard was tested by the method proposed by Lin et al.[23] For all tests, a P value <0.05 was considered statistically significant. All analysis was performed by SAS version 9.1 (SAS Inc).

RESULTS

There were 239 patients evaluated for possible enrollment. Thirty-one patients were excluded for the reasons identified in the enrollment flow chart (Fig. 1). All of the remaining 208 patients were enrolled, with 96 randomly assigned to the intervention group and 112 to the control group. Demographic characteristics did not differ between the intervention and control groups. The mean age for both groups was in the late thirties, and approximately three quarters were female (Table 1). Enrollment clinical status also did not differ between the 2 groups, with no significant differences in the percent of individuals with a history of WHO Stage 3/4 disease, detectable viral load, or mean Karnofsky score. There was a slight trend toward a higher mean CD4 count in the intervention group at enrollment, with a mean of 305 cells per microliter in the intervention group versus 278 cells per microliter in the control group, respectively ($P = 0.09$). With regard to composition of ART regimen, more than 90% of patients in both groups were receiving a nonnucleoside reverse transcriptase inhibitor–based regimen. The percent of patients receiving tuberculosis and cryptococcal prophylaxis or treatment were also similar between the 2 groups.

At completion of the study, there were 87 patients in the intervention group and 102 patients in the control group for a total of 189 patients with evaluable 12-month endpoints. Eight patients had withdrawn from study and 10 were lost to follow-up. At 12 months, there were no significant intervention–control differences in the percent withdrawn from study or lost to follow-up (Table 2, Fig. 2). Of the 8 patients withdrawn, 3 were in the intervention group and 5 in the control group with the predominant reason for withdraw being intention to move residence outside of the catchment area of the study. Of the 10 patients lost to follow-up, half were in the intervention group. The reasons for lost to follow-up were available for 8 patients, 4 were pregnant (intervention group = 2; control group = 2) and 3 had moved outside of the catchment area (intervention group = 1; control group = 2). One patient in the control group quit taking his medications

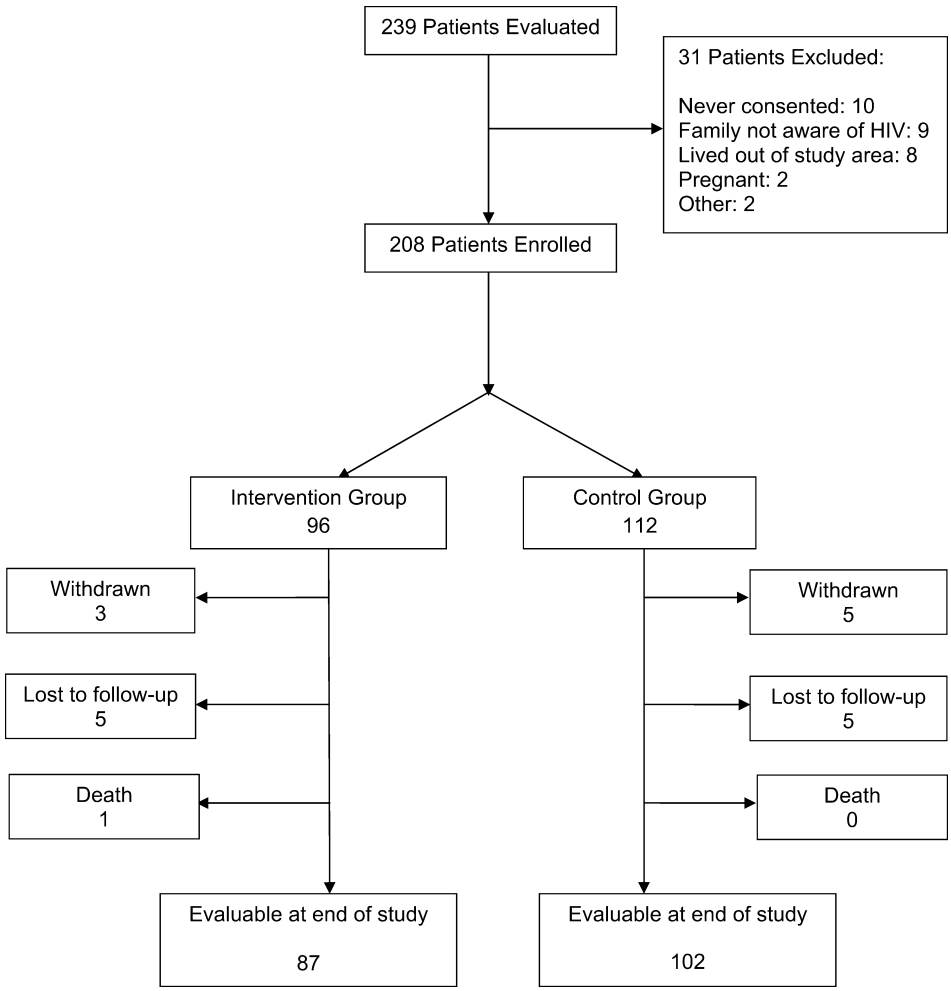

FIGURE 1. Study enrollment.

and did not return to clinic because he believed that God would cure him. There was one death in the intervention group, which was unrelated to HIV care and attributed to the use of herbal abortofacients.

During the study period, the intervention group had significantly fewer clinic visits (6.2) than the control group (12.4) ($P < 0.001$). However, the CCC group undertook 64% more clinic visits than were originally scheduled for this group. Despite fewer clinic visits for the intervention group, clinical outcomes between the 2 groups were not significantly different. At 12 months, there were no significant intervention–control differences in decline in Karnofsky score, complete change in antiretroviral regimen, pregnancy incidence, worsened WHO stage, or rate of opportunistic infections (Table 2, Fig. 3). Intervention–control differences in median CD4 count and percent with detectable viral load at 12 months were also not significantly different (Table 2). The gap between CD4 counts seen at enrollment (not statistically significant), and the overall CD4 counts for both groups, increased over the 12 months. Both groups demonstrated high levels of self-reported medication adherence, and there were no statistical differences between the intervention and control groups.

DISCUSSION

Our study found similar clinical and laboratory outcomes for those patients treated in the traditional manner (monthly clinic visits with a nurse, clinical officer, or a physician) and patients followed by the CCCs who required half the clinic visits as compared with controls. In addition, to our knowledge, this is the first randomized control trial assessing the efficacy of utilizing HIV-infected individuals educated at the secondary school level to provide antiretrovirals and monitor HIV therapy. Several previous studies have shown equivalent outcomes with task-shifting components of HIV care from physicians to other health care worker cadres including nurses and mid-level practitioners.[5,10,13,14,24–28] Only one other published study has assessed a model of HIV care that shifts the majority of responsibility for HIV-care provision from health care providers to lay workers (nonhealth care providers).[15] In this cluster-randomized trial from Uganda, 1453 patients received either home-based care by lay workers or routine facility based care. Similar to our study, the Ugandan study found no differences in virologic, immunologic, or clinical outcomes. The major difference between the studies was the educational level of the lay workers. In the Ugandan study, lay workers were

TABLE 1. Baseline Patient Characteristics

Characteristics	Intervention Group, (n = 96)	Control Group, (n = 112)	*P*
Gender, male no. (%)	25 (26)	31 (27.7)	0.87
Age, mean (SD)	38.7 (9.9)	37.5 (9.5)	0.86
WHO stage, no. (%)			
1	34 (35.4)	43 (38.4)	0.94
2	12 (12.5)	11 (9.8)	
3	31 (32.3)	36 (32.1)	
4	19 (19.8)	22 (19.6)	
Karnofsky score median (minimum, maximum)	100 (100, 100)	100 (90, 100)	0.4
First-line regimen (3TC, D4T, NVP), no. (%)	76 (79.2)	96 (85.7)	0.27
Regimen backbone, no. (%)			
Nonnucleoside reverse transcriptase	87 (90.6)	104 (92.9)	0.62
Protease inhibitor	9 (9.4)	8 (7.1)	
Receiving PCP prophylaxis, no. (%)			
Any (dapsone or TMP-sulfa)	31 (32.6)*	46 (41.4)‡	0.20
TB prophylaxis, no. (%)	10 (10.6)†	14 (12.6)‡	0.83
TB treatment, no. (%)	1 (1.1)*	3 (2.7)	0.63
Cryptococcal treatment/prophylaxis, no. (%)	4 (4.2)*	2 (1.8)‡	0.41
Detectable VL, no. (%)	8 (8.5)†	13 (12.6)§	0.49
CD4 cell count, mean (interquartile range)	305 (227, 430)	278 (186, 397)‡	0.09

*n = 95.
†n = 94.
‡n = 111.
§n = 107.
TB, tuberculosis.

individuals with college degrees or diplomas unlike our CCCs who were educated at a secondary school level. In rural areas, the ability to decentralize HIV care to lay persons, the majority of whom will only have a secondary education, is of critical importance.

Our study demonstrated that task-shifting can decrease the number of clinic visits, thus helping to decongest the clinic and increase the number of patients receiving care with fixed clinic resources. The patients who were enrolled in the CCC group required half the number of clinic visits (6.2 vs. 12.4) of those patients receiving the standard of care monthly clinic visits. The CCC group undertook 64% more clinic visits than were originally scheduled for this group due to clinic referral triggered by the identification of acute medical and social issues during home evaluations by the CCCs. A significantly lower number of clinic visits in the home-based care group was also seen in the Ugandan study where the home-based care group had a mean of 8 clinic visits per patient over 30 months (3.2 clinic visits per year) as compared with the standard of care clinic group who had a mean of 26 visits per patient over 30 months (10.4 clinic visits per year).[15] Similar to our study, the Ugandan study also showed that the home-based care group had 75% more visits than originally scheduled. Based on the findings of both studies, one can anticipate that a home-based care program will significantly decrease the number of patient visits to the clinic but that these patients will also have a substantial number of required acute care visits.

We found that the CCCs were in a unique position to recognize psychosocial issues that may not have been apparent at clinic visits. This was exemplified by the identification of issues that negatively affected HIV care such as food insecurity, domestic violence, alcohol abuse, and HIV disclosure issues. It is likely that the identification of these problems at home visits led to earlier intervention, which may improve overall patient care in the long run. The health care team considered the CCCs to be a trusted and reliable linkage between patients and themselves (including the pharmacy team), thus facilitating communication related to changes in regimen and dosage of drugs.[17] Descriptions of the roles played by community health workers (accompagnateurs) within the Partners in Health program in Haiti support our findings that these individuals not only serve as active members of the health care team but also provide social linkages and support for their patients.[13]

One key to the CCCs being able to coordinate care in the community was the decision-support program built into their PDAs. This allowed their training to focus on data collection (eg, symptoms, vital signs, adherence, etc) and implementing needed interventions. Because the CCCs are not qualified to interpret these data and make decisions about treatment, use of PDAs promoted effective task-shifting by allowing the medical decision making to be done by the clinical officers and physicians. In addition the CCCs always had the option of calling the clinical officer for advice even if the PDA program did not recommend this action. Wireless communication is becoming widely adopted in sub-Saharan Africa, and health care applications are being programmed into cellular telephones, which makes such technology potentially widely applicable to health care settings. However, a recent review of mobile health technologies found that use within the health care system has usually been restricted to physicians' offices,

TABLE 2. Patient Outcomes at 6 and 12 Months

Characteristics	Intervention Group, (n = 96)	Control Group, (n = 112)	95% Confidence Interval	*P*
Median days in study, (IQR)				
6 months	175 (168–177)	168 (168–176)	—	0.10
12 months	343 (336–349.5)	343 (336–364)	—	0.20
New WHO stage 3 or 4 event, no. (%)				
6 months	6 (8.2)*	7 (8.1)†	(0.30, 5.65)	1.0
12 months (cumulative)	11 (14.9)‡	14 (16.1)†	(0.18, 4.80)	
Decline in Karnofsky score, no. (%)				
6 months	1 (1.1)§	0 (0)‖	N/A	0.46
12 months (interval)	0 (0)¶	0 (0)#	N/A	N/A
Complete regimen change, no. (%)				
6 months	1 (1.1)§	0 (0)‖	N/A	0.46
12 months (cumulative)	2 (2.3)¶	1 (1.0)#	(0.04 to 4.92)	0.6
CD4 cell count: mean (IQR)				
6 months	354 (232–451)**	306 (214–410)††	(−19 to 74)‡‡	0.24
12 months	404 (265–527)†	358 (240–522)§§	(−38 to 77)	0.50
Detectable VL at 12 months, no. (%)	9 (10.5)‖‖	13 (13.5)§§	(0.54 to 3.31)	0.65
OI rate per 100 person-years	13.6	19.8	(0.37 to 1.34)	0.42
LTFU at study closure, no. (%)	5 (5.2)	5 (4.5)	(0.24 to 3.03)	1.0
Pregnancy, no. (%)	12 (12.7)##	11 (9.9)***	(0.27 to 2.07)	0.62
Number of clinic visits, 12 months, mean (SD)	6.4 (2.5)	12.6 (3.4)	(−7.0 to −5.4)	<0.001
Never missed medications (self-reported)				
6 months, no. (%)	85 (96)†††	98 (97)‡‡‡	(0.14)	0.71
12 months, no. (%)	79 (94)§§§	95 (97)‖‖‖	(0.12)	0.47

Due to specimen loss and incomplete data, the n available at each time point for each variable are as follows: *n = 73; †n = 87; ‡n = 74; §n = 90; ‖n = 104; ¶n = 88; #n = 99; **n = 89; ††n = 103; ‡‡Hodges–Lehmann location shift confidence interval; §§n = 96; ‖‖n = 86; ¶¶Uses Incidence Rate Ratio for interval calculation; ##n = 71; ***n = 81; †††n = 89; ‡‡‡n = 101; §§§n = 84; ‖‖‖n = 98; ¶¶¶n = 80; ###n = 81; ****n = 103; ††††n = 86.

with few examples of use in resource-poor settings, and no data on their use by nonmedical personnel to support the provision of health care.[29] Another review found evidence to both support and refute the potential effectiveness of mobile phones for health care interventions.[30] Similar to our program design, PLWAs have been incorporated into an HIV care delivery system in Uganda using mobile phones to monitor patients at their home with the perception that the intervention improved adherence and overall patient care.[16] Based on our findings, it seems that mobile health technologies show promise for assisting in the expansion of ART access in resource-poor settings with limited human resources.

Given the 12-month duration of this study, an average Kenyan Birth rate of 39.72 per 100,000 in 2006 and that our population was HIV infected and had recently been initiated on ART, we anticipated the pregnancy rate in our population to be less than 5%.[31] We, however, had much higher pregnancy

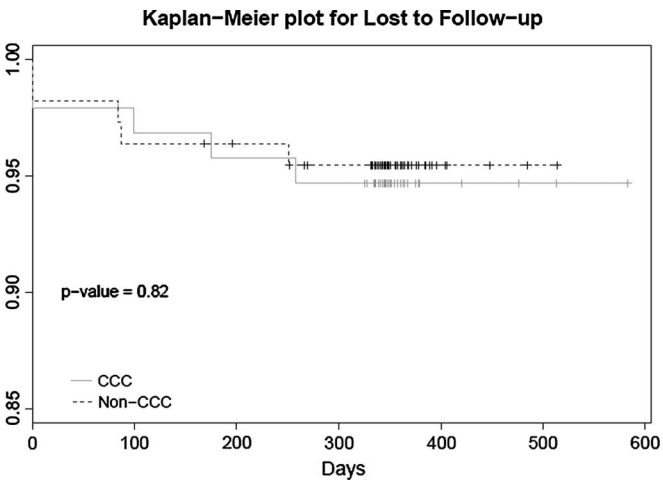

FIGURE 2. Kaplan-Meier plot for lost to follow-up.

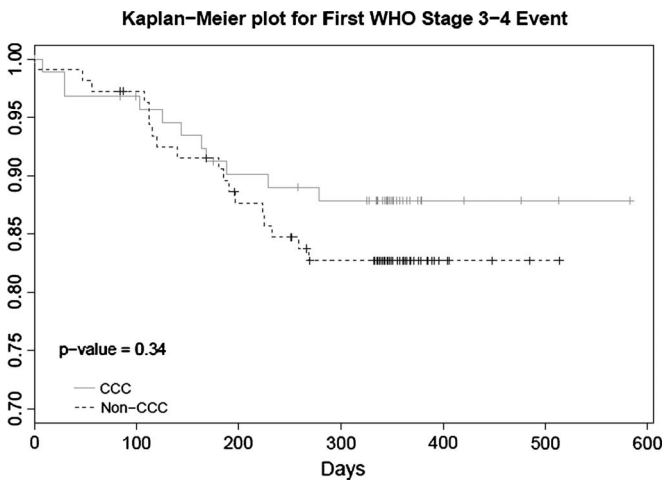

FIGURE 3. Kaplan-Meier plot for first WHO stage 3–4 event.

rates for both the control group (10%) and intervention group (13%). Pregnancy intentions were discussed at enrollment, and patients were aware that the intention to become pregnant was an exclusion criterion for entering the study. This suggests to us that most of the pregnancies were unintended, however, it is also possible that patients were uncomfortable sharing their pregnancy intentions with the team. With future home-based care projects, we plan to build in questions related to family planning desires along with alerts that would be triggered to refer patients to family planning. In addition, we would also like to build and test a module that would allow for the majority of pregnancy care for HIV-infected women to take place in the home. Our experience highlights the need for home-based HIV care programs to have a mechanism built into their system to effectively deal with reproductive health issues including family planning and pregnancy.

The most significant limitation of this study is the small sample size in part due to recruitment restrictions based on residence. The original sample size calculation had a power of >95%. Although we still had >80% power to detect differences based on 189 subjects total, we would prefer a higher threshold for power in order to claim noninferiority of the CCCs vs. clinic-based care in the absence of statistically significant intergroup differences. There may also be unmeasured differences between the sublocations designated as control or intervention that potentially bias the results of this study. Because patients had to be stable on ART for at least 3 months before enrollment in this study, the findings from this study cannot be generalized to populations who are newly initiating ART. In addition, because a high level of adherence was part of the inclusion criteria, this study was not optimally designed to assess the impact of the CCC intervention on adherence. We must also acknowledge that the Karnofsky score has not been validated in Africa and as such is a limitation in this study. The major strength of this study was the use of a community-randomized design which allowed for real-time comparison of the control and the intervention groups. This type of approach is uncommon in implementation and operations research, where historical controls are the most frequently used construct for a control group, and as such is subject to confounding by other changes that occur in the health care environment.

CONCLUSIONS

We found that CCCs with secondary school education and mobile computer-based decision support can provide safe and effective HIV care. These results support WHO's recommendation that PLWAs be used as part of an HIV-care model that shifts specified care tasks away from health care providers to lay individuals. This innovative model of ART delivery has the potential to facilitate ART rollout and allow health care systems in resource-constrained settings to care for more patients. However, larger scale studies will be needed to confirm our findings.

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REFERENCES

1. Coetzee D, Hildebrand K, Boulle A, et al. Outcomes after two years of providing antiretroviral treatment in Khayelitsha, South Africa. *AIDS*. 2004;18:887–895.
2. Laurent C, Ngom Gueye NF, Ndour CT, et al. Long-term benefits of highly active antiretroviral therapy in Senegalese HIV-1-infected adults. *J Acquir Immune Defic Syndr*. 2005;38:14–17.
3. Weidle PJ, Malamba S, Mwebaze R, et al. Assessment of a pilot antiretroviral drug therapy programme in Uganda: patients' response, survival, and drug resistance. *Lancet*. 2002;360:34–40.
4. Wools-Kaloustian K, Kimaiyo S, Diero L, et al. Viability and effectiveness of large-scale HIV treatment initiatives in sub-Saharan Africa: experience from Western Kenya. *AIDS*. 2006;20:41–48.
5. Stringer JS, Zulu I, Levy J, et al. Rapid scale-up of antiretroviral therapy at primary care sites in Zambia: feasibility and early outcomes. *JAMA*. 2006; 296:782–793.
6. Sow PS, Otieno LF, Bissagnene E, et al. Implementation of an antiretroviral access program for HIV-1–infected individuals in resource-limited settings: clinical results from 4 African Countries. *J Acquir Immune Defic Syndr*. 2007;44:262–267.
7. WHO, UNAIDS. Towards universal access: scaling up priority HIV/AIDS interventions in the health sector. Progress Report 2009. Available at: http://www.who.int/hiv/pub/tuapr_2009_en.pdf. Accessed October 13, 2009.
8. WHO, UNAIDS. *Progress on Global Access to HIV Antiretroviral Therapy. A Report on 3 by 5 and Beyond*. Geneva, Switzerland: World Health Organization; 2006.
9. WHO. *Treat, Train, Retain. The AIDS and health workforce plan. Report on the Consultation on AIDS and Human Resources for Health*. Geneva, Switzerland: WHO; May 11–12, 2006.
10. Ivers LC, Jerome JG, Cullen K, et al. Task-shifting in HIV care: a nurse-centered, community-based model of care in rural Haiti. Oral Abstract Session: Presented at: AIDS 2008-XVII International AIDS Conference. August 6, 2008; Mexico City, Mexico. Abstract no. WEAX0103.
11. World Health Organization.Task shifting: rational redistribution of tasks among health workforce teams, global recommendations and guidelines. Available at: http://data.unaids.org/pub/Manual/2007/ttr_taskshifting_en.pdf. Accessed December 8, 2008.
12. Mullan F, Frehywot S. Non-physician clinicians in 47 sub-Saharan African countries. *Lancet*. 2007;370:2158–2163.
13. Koenig SP, Leandre F, Farmer PE. Scaling-up HIV treatment programmes in resource-limited settings: the rural Haiti experience. *AIDS*. 2004,18(Suppl 3):S21–S25.
14. Bedelu M, Ford N, Hilderbrand K, et al. Implementing antiretroviral therapy in rural communities: the Lusikisiki model of decentralized HIV/AIDS care. *J Infect Dis*. 2007;196(Suppl 3):S464–S468.
15. Jaffar S, Amuron B, Foster S, et al. Rates of virologic failure in patients treated in a home-based versus a facility-based HIV-care model in Jinja, southeast Uganda: a cluster-randomised equivalence trial. *Lancet*. 2009; DOI:10.1016/S1040-6736(09)61674-3.
16. Chang LW, Kagaayi J, Nakigozi, et al. Responding to the human resource crisis: peer health workers, mobile phones, and HIV care in Rakai, Uganda. *AIDS Patient Care STDS*. 2008;22:173–174. doi:10.1089/apc.2007.0234.
17. Wools-Kaloustian K, Sidle J, Selke H, et al. A model for extending antiretroviral care beyond the rural health center. *J Int AIDS Soc*. 2009;12:22.
18. Einterz RM, Kimaiyo S, Mengech HN, et al. Responding to the HIV pandemic: the power of an academic medical partnership. *Acad Med*. 2007;82:812–818.
19. National AIDS and STI Control Programme, Ministry of Health, Kenya. July 2008. *Kenya AIDS Indicator Survey 2007: Preliminary Report*. Nairobi, Kenya. Available at: http://www.usaid.gov/ke/ke.buproc/AIDS_Indicator_Survey_KEN_2007.pdf. Accessed July 6, 2009.
20. WHO Department of HIV/AIDS. WHO Case Definitions of HIV for Surveillance and Revised Clinical Staging and Immunological Classification of HIV-Related Disease in Adults and Children. 2007. Available at: www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf. Accessed November 25, 2009.
21. Tierney WM, Beck EJ, Gardner RM, et al. A pragmatic approach to constructing a minimum dataset for care of patients with HIV in developing countries. *J Am Med Informat Assoc*. 2006;13:253–260.

22. Tierney WM, Rotich JK, Hannan TJ, et al. The AMPATH medical record system: creating, implementing, and sustaining an electronic medical record system to support HIV/AIDS care in western Kenya. *Stud Health Technol Inform*. 2007;129(Pt 1):372–376.
23. Lin D, Wei L, Ying Z. Checking the Cox model with cumulative sums of Martingale-based residuals. *Biometrika*. 1993;80:557–572.
24. Sherr K, Pfeiffer J, Mussa A, et al. The role of nonphysician clinicians in the rapid expansion of HIV care in Mozambique. *J Acquir Immune Defic Syndr*. 2009;52:S20–S23.
25. Cohen R, Lynch S, Bygrave H, et al. Antiretroviral treatment outcomes from a nurse-driven, community-supported HIV/AIDS treatment programme in rural Lesotho: observational cohort assessment at two years. *J Int AIDS Soc*. 2009;12:23.
26. Harries AD, Schouten EJ, Libamba E. Scaling up antiretroviral treatment in resource-poor settings. *Lancet*. 2006;367:1870–1872.
27. Ferradini L, Jeannin A, Pinoges L, et al. Scaling up of highly active antiretroviral therapy in a rural district of Malawi: an effectiveness assessment. *Lancet*. 2006;367:1335–1342.
28. Miles K, Clutterbuck DJ, Seitio O, et al. Antiretroviral treatment roll-out in a resource-constrained setting: capitalizing on nursing resources in Botswana. *Bull World Health Organ*. 2007;85:555–560.
29. Lu YC, Xiao Y, Sears A, et al. A review and a framework of handheld computer adoption in healthcare. *Int J Med Inform*. 2005;74:409–422.
30. Kaplan WA. Can the ubiquitous power of mobile phones be used to improve health outcomes in developing countries? *Global Health*. 2006;2:9. doi:10.1186/1744-8603-2-9.
31. CIA World Factbook. Kenya Demographics Profile 2010. Available at: http://www.indexmundi.com/kenya/demographics_profile.html Accessed May 19, 2010.