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Can self-management improve HIV treatment engagement, adherence, and retention? A mixed methods evaluation in Tanzania and Uganda

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Abstract

This paper presents the evaluation results of a self-management support (SMS) initiative in Tanzania and Uganda, which used quality improvement to provide self-management counseling, nutritional support, and strengthened linkages to community-based services for highest-risk patients (those with malnutrition, missed appointments, poor adherence, high viral load, or low CD4 count). The evaluation assessed improvements in patient engagement, ART adherence, and retention. Difference-in-difference models used clinical data (n=541 in Tanzania, 571 in Uganda) to compare SMS enrollees to people who would have met SMS eligibility criteria had they been at intervention sites. Interviews with health care providers explored experiences with the SMS program and were analyzed using codes derived deductively from the data. By end-line, SMS participants in Tanzania had significantly improved visit attendance (odds ratio 3.53, 95% confidence interval 2.15, 5.77); a non-significant improvement was seen in Uganda (odds ratio 1.62, 95% confidence interval 0.37, 7.02), which may reflect a dose-response relationship due to shorter program exposure there. Self-management can improve vulnerable patients' outcomes -- but maximum gains may require long implementation periods and accompanying system-level interventions. SMS interventions require long-term investment and should be contextualized in the systems and environments in which they operate.

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Keywords

Adherence; retention; engagement; ART

INTRODUCTION

The global community has made great progress in the fight against HIV/AIDS, with substantial recent improvements in prevention, diagnosis, and treatment (1). Despite these achievements, many challenges remain across the HIV care continuum (2).

Patients with low engagement with and retention in care are particularly vulnerable to poor adherence, which can lead to increased drug resistance and worse morbidity and mortality outcomes (as well as increased likelihood of HIV transmission to uninfected individuals) (3–5). Interventions targeting low-engagement groups have used a range of in-clinic and community-based approaches (6), including peer counseling (7), and new approaches for care delivery (8–10) that incorporate promotion of patient self-management (11) and use of communication technology (12–14) -- but there is relatively little rigorous evidence on the effectiveness of such interventions, particularly in lower-income countries (4, 15–18).

The USAID Applying Science to Strengthen and Improve Systems Project (ASSIST) implemented a self-management support (SMS) initiative in Tanzania and Uganda, which used a quality improvement approach to target highest-risk patients. This project built on prior nutrition assessment, counseling, and support (NACS) experience (19, 20). The goal of the SMS initiative was to improve patient engagement in care in order to improve adherence to medications, retention in care, and health status. This paper presents the results of the SMS evaluation. The main research questions were: (1) Was the SMS initiative successful in achieving its objectives? In particular, was this an effective model for improving patient outcomes? (2) What lessons can be learned from this initiative that might inform implementation of future SMS programs?

METHODS

Program overview:

The SMS initiative was designed within the context of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Partnership for HIV-Free Survival (PHFS), which used quality improvement methodologies and multi-country learning platforms to bolster implementation of guidelines for prevention of mother-to-child HIV transmission (21). The SMS initiative adopted many of the same design approaches as the PHFS, including targeting of high-volume health facilities, learning and sharing lessons from implementation, and attention to data collection and monitoring – with the goal of diffusing successful program components to other sites. The SMS initiative (Table 1) targeted adults (over 18 years of age) who were receiving HIV treatment but demonstrated vulnerability, which was defined as being clinically high-risk or having poor adherence behaviors. At participating facilities, these patients received an intensified support intervention (beyond the standard care provided to all patients which was adherence counseling upon ART initiation plus group education

throughout treatment). The intervention provided additional self-management counseling, nutritional support, and strengthened linkages to community-based services such as livelihood and food security programs. The project provided training for health care providers at implementation sites, on how to effectively provide self-management counseling and nutritional support; and supported them to form quality improvement teams to continuously review clinic processes, identify areas requiring improvement, apply changes to those areas, and analyze performance indicators to determine if the changes resulted in improvement. Applying an improvement approach, changes that were proven effective were adopted, and changes that were less effective were either adapted or discarded (22). During SMS counseling with patients, the trained providers (clinicians in Uganda, expert clients in Tanzania) encouraged patients to identify relevant challenges with nutrition, adherence, or visit attendance, and discuss how patients could take a lead role in addressing these problems. At the end of the counseling session, the patient was encouraged to develop specific goal(s) and a plan of action, as well as a follow-up date for assessing progress toward the goal(s).

Nine implementation sites in Tanzania and Uganda (both participating countries in the PHFS) began implementing the SMS initiative between late 2015 and early 2016. Implementation sites were selected in partnership with the PEPFAR team and the Ministry of Health in each country. In both countries, eligible sites were facilities that provided HIV counseling and testing services (and had data available for these patients) and had high patient volume. In Uganda, additional criteria were the availability of equipment for on-site CD4 testing and experience with nutrition programs and management of malnourished HIV patients. Facilities in the two countries represented different levels of the health system and were similar in patient volume, but there were some important baseline differences: facilities in Tanzania saw a slightly higher percentage of their patients attending scheduled HIV care appointments (approximately 70% of patients, versus 66% in Uganda); and Uganda needed to develop and implement systems for identifying eligible patients (such as routine documentation of nutritional status and improved appointment tracking) whereas Tanzania already had these systems in place before SMS implementation.

Data collection:

The evaluation data were collected from facilities that implemented the SMS initiative (“intervention sites,” n=4 in Tanzania and n=5 in Uganda) and facilities that did not (“comparison sites,” n=5 in Tanzania and n=5 in Uganda). Data were collected between June and September 2017 by experienced researchers who were trained on the goals and methods of the evaluation.

Quantitative: Data were abstracted from records of adult patients on ART (initiated on or before January 2015). Selection proceeded in two steps. First, to ensure that the sample would include high-risk patients, a random subset of patients who had been diagnosed as moderately or severely acutely malnourished during calendar year 2016 was selected. The target size of this subset was 100 patients per country, but if this could not be attained, then each facility contributed as many records as possible towards this goal. Next, additional records were selected at random from the remaining eligible pool of patients (adults on ART

who initiated on or before January 2015) at each facility, to reach between 575-600 records per country (split between intervention and comparison sites). The SMS initiative should have enrolled all qualifying patients at intervention sites, but patient-level exposure to the intervention was assigned based on clinical records of whether each patient was enrolled in SMS.

The data elements extracted from each record included: patient age, sex, HIV clinical history (date of diagnosis, date of ARV initiation), and panel data on appointment-keeping (all dates of scheduled appointments and whether attended on this day), ARV pick-up behavior (all dates of scheduled refills and whether obtained), exams (including dates, CD4 and viral load tests, weights, nutrition assessments), and SMS-related activities (enrollment dates, reasons, progress toward goals). Data were collected via tablets using SurveyCTO software.

Qualitative: Interviews were conducted at participating facilities (both intervention and, whenever possible, comparison sites) with health workers who routinely provide HIV care, of any cadre including doctors, nurses, and counselors. The qualitative data collection instruments included both open- and close-ended questions about topics related to experiences with care delivery and with the SMS initiative (see Appendix 1 for list of interview questions). Qualitative data collection aimed to elucidate lessons from implementation.

Data analysis

Quantitative: The patient record data were analyzed using Stata v14. Data were first cleaned to remove incomplete records. Basic descriptive analyses were conducted to obtain a snapshot of the patient population and of clinical activities. Multivariable analyses were conducted to compare outcomes at intervention and comparison sites within each country. Outcomes for the subgroup of SMS-enrolled patients (those actually enrolled in the program at participating sites) were also analyzed and compared to patients who would have been enrolled during the “post” period had they been at intervention sites in that country (i.e., met the eligibility criteria but were at comparison sites). Comparative analyses were constructed using difference-in-difference models to compare changes over time (pre versus post period) at intervention versus comparison sites. The key outcome of interest was change in patient on-time appointment-keeping during the post period compared to the pre period (engagement in care).

Qualitative: All interview data were transcribed and translated into English. Semi-structured/open-ended data were analyzed using grounded theory—i.e., themes emerged from the data itself (with no analysis framework imposed *ex ante*), and these were used to create a codebook with categories and sub-categories (see Appendix 1 for list of codes). All interview data were coded using this codebook.

Ethical review:

The The Harvard T.H. Chan School of Public Health Institutional Review Board reviewed this study protocol and classified it as exempt from full IRB review as it analyzed only fully de-identified data.

RESULTS

The dataset contained exam and appointment data (January 2015 and July 2017) on 541 patients in Tanzania and 571 patients in Uganda. This included information on 11,503 clinical visits in Tanzania (21.3 on average per patient over this period) and 6529 clinical visits in Uganda (11.3 on average per patient over this period). (For context, at the time of this study, Uganda had implemented multi-month dispensing of ARVs for stable adult patients, while Tanzania continued to do monthly refills for most patients.)

Participants were on average 44-45 years old in both countries (Table 2). Most respondents were female in both countries, and had been diagnosed in 2012 in Tanzania and during 2009-10 in Uganda. Patients in Tanzania initiated ART sooner after diagnosis than those in Uganda. First-ever CD4 level in Tanzania was approximately 200-250 and was approximately 300-400 in Uganda.

There were 12 provider interviews conducted in Tanzania, and 11 provider interviews in Uganda. Providers who participated in qualitative interviews were mostly nurses, doctors, and clinical officers in both countries (data not shown), and had been in this position for an average of approximately 5 years.

SMS initiative implementation

Detailed clinical information was collected from 51 Tanzanian patients who participated in the SMS initiative and 88 SMS participants in Uganda (Table 3). Just over half of all enrollees were female in both countries. These patients were enrolled on average 14 months before the date of data collection in Tanzania and 8 months prior in Uganda; and on average 3-4 years after they had initiated ART (data not shown). The primary reasons for SMS enrollment were malnutrition (41.2% of enrolled patients in Tanzania and 22.7% in Uganda), poor appointment-keeping (17.6% in Tanzania and 23.9% in Uganda), and/or high viral load in Uganda (51.1% of enrolled patients). By the date of data collection in mid-2017, most of these patients in Tanzania had already graduated from the SMS initiative (90.2%), but less than half (44.3%) in Uganda had done so.

Providers at facilities implementing the SMS initiative were asked about its implementation during qualitative interviews. They described how it functions: “*Before [SMS] patients were being counseled in general. But self-management handles a patient individually, according to his or her needs. Which is proper. Because when you talk to them in general, you may not know their needs. But self-management identifies the need of the patient individually.*” (Uganda); “*Health care staff sit with patients and help them set goals. The health workers then follow him or her to determine if those goals are met*” (Tanzania). Providers in Uganda mentioned some challenges with implementation, including reluctance to adopt this new counseling approach, particularly with little orientation/training, and the increased burden on already-busy health workers: “*It needs a lot of time, which I may not have ... If I have to draw a self-management plan with somebody, this can take an hour. If there are 60 patients, and 10 are on self-management, that’s like 10 hours...*” (Uganda).

When asked how the SMS initiative could be improved/strengthened, providers had a number of suggestions, including: more training (including refresher trainings) and guidelines for SMS participants (“*All health care providers dealing with HIV patients should be trained on self-management*” [Tanzania]); more time for counseling and educating patients; and improved follow-up and monitoring mechanisms, including mentorship and coaching (“*I say we can [strengthen] by ongoing mentorship and coaching, and review meetings*” [Uganda]). Additional suggestions included enhanced experience-sharing with other implementation sites, and extending the program to more patient groups.

All respondents at intervention sites in both countries (except one provider in Tanzania) said the SMS initiative was making a difference in patient outcomes; they cited examples of improvement including patient outcomes, adherence patterns, and provider-patient communication: “*Self-management is a very good activity because it gives you time to interact with the patient. That is when they will understand exactly what they are supposed to do in order to make themselves well.*” (Uganda); “*After introducing self-management, health workers help patients to deal with their problems. Loss to follow-up has decreased and there is improved adherence*” (Tanzania). Providers at some non-intervention sites mentioned that they wished the SMS initiative was implemented at their facility. In Uganda where all interviewees were asked this close-ended question, 8 providers said the SMS initiative was helping their patients, and 3 felt it was somewhat helping.

SMS initiative results

Table 4 displays the results of the difference-in-difference models, which compare changes between the pre and post periods (difference 1) for eligible patients at intervention and comparison sites (difference 2). In Tanzania, there were 119 people at comparison sites who would have been classified as high-risk and enrolled in the SMS initiative had these sites been implementing SMS; in Uganda, 51 such patients at comparison sites met these criteria.

In both countries, SMS-enrolled patients were more likely to attend scheduled appointments during the post period than eligible patients at comparison sites, although this difference was only significant in Tanzania where enrolled patients were much more likely to attend (adjusted odds ratio 3.53) than those at comparison sites. The result was similar in magnitude and significance for men and women in both countries. There was no significant change found in patient weight, likelihood of being classified as malnourished, or CD4 level (the latter was examined only in Tanzania) (data not shown).

On average across all sampled patients at both intervention and comparison sites in Tanzania, on-time visit attendance improved (not significantly) across all patients at intervention sites while worsening significantly at comparison sites (Appendix 2). Among the full sample at both intervention and comparison sites in Uganda, on-time visit attendance worsened significantly between the pre and post periods.

DISCUSSION

This analysis presents evaluation results for an intervention aimed at improving engagement, adherence, and retention among the subset of most-vulnerable patients receiving treatment

for HIV in Tanzania and Uganda. The intervention used a quality improvement approach to implement enhanced counseling and self-management support for high-risk patients. The program was implemented at 4 high-volume sites in Tanzania and 5 high-volume sites in Uganda. This evaluation used a quasi-experimental design to compare changes for patients at these implementing facilities versus those at comparison sites that did not deliver the SMS intervention.

These results indicate that patients in Tanzania who were enrolled in the SMS initiative had significantly and greatly improved visit attendance compared to those who were also high-risk but at comparison (nonintervention) sites. The lack of statistically significant results in Uganda may have been due to the fact that patients who enrolled in the initiative were exposed for a shorter duration on average, and far fewer had “graduated” from SMS in Uganda by the time of end-line data collection (44.3% versus 90.2% who had graduated in Tanzania). A recent randomized control trial of a self-management program for people on HIV treatment in the Netherlands found significantly improved clinical outcomes (viral load, CD4 count, and treatment failure) for patients enrolled in the intervention after a 15-month follow-up period (11) so perhaps a longer follow-up period is necessary for identifying robust effects. As noted above, the SMS program had a longer start-up period in Uganda; this may have affected the rate at which participants were enrolled as well as overall implementation. The program was also implemented by clinicians in Uganda (versus expert clients in Tanzania), which may have affected the “dose” of intervention delivered, given time constraints and workload. Additionally, because patients in the Uganda sample contributed fewer visits on average across the study period (only 7.7 compared to an average of 11.7 visits in Tanzania) the smaller sample size reduced our power to detect statistically significant differences in Uganda particularly given the clustered data structure (visits within patients, within facilities).

According to these clinical record data, more SMS patients in Uganda than in Tanzania experienced adverse outcomes during the follow-up period, including not returning for clinical care (23.8% of the sample in Uganda, versus less than 1% in Tanzania), malnutrition (10.2% of the sample in Uganda, versus 3.5% in Tanzania), and few referrals to community services (less than 1% in Uganda versus 14.5% in Tanzania). During qualitative interviews (data not shown), patients and providers in Uganda also discussed nutrition-related adherence challenges and structural access to care barriers. Providers also discussed their frustration with weak connections to support programs/services in the community. Although these challenges were outside the scope of this intervention, they merit further exploration if policymakers, program managers, and clinicians wish to improve engagement, adherence, and retention outcomes.

The results suggest that an intervention using quality improvement methods may be promising for improving engagement and retention in care – but that significant and sustained improvements in health outcomes may necessitate a longer implementation period and robust accompanying interventions at the system level. By employing a mixed-methods approach, this evaluation not only analyzed changes in quantitative indicators, but also explored issues related to implementation. Additional qualitative data highlight important determinants of engagement, adherence, and retention in care, and represent important areas

for further intervention and research. The differences in health status between intervention participants at baseline in these two countries – longer delay from HIV diagnosis to ART initiation in Uganda, generally better visit attendance and higher weights among patients in Tanzania – may also suggest important complementary areas that may need attention to maximize intervention effects for SMS programs.

Some limitations to these results should be noted. First, few outcome indicators could be explored due to limitations in clinic record data (including many missing data elements). Second, although qualitative interviewers were well-trained in good data collection practices, there is the possibility of social desirability and other response bias. Third, although mortality endpoints were rare in this dataset, loss to follow-up was more common, particularly in Uganda, so there may be some censoring, including potential survivorship bias, in the clinical data collected. Lastly, the intervention may have had spillover effects to other non-eligible/-enrolled patients at the intervention sites, and we did not investigate these changes.

CONCLUSIONS

Retention and engagement in care are critical within the HIV treatment cascade, as they influence adherence to medication, medication side effects and resistance, transmission of HIV infection to others, and morbidity and mortality outcomes. This analysis adds to an emerging evidence base of approaches to improve engagement and retention, particularly in low-resource settings. It presents results from a two-country study and presents evaluation results and information about implementation. The self-management intervention showed promise for improving clinic attendance for the most vulnerable patients at these treatment sites. The results also underscore how HIV interventions must be contextualized in the systems and environments in which they operate, and how many factors, including those beyond the scope of a specific program, may influence outcomes.

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Appendix 1:

Interview questions about SMS program

- Have you ever participated in any self-management activities? Give us your view about it.
- Is there a “self-management” program at this facility?
- If yes:
 - Who in the clinic participates in this program?
 - How does your facility implement this program?
 - Do you feel that the self-management tools and protocols your clinic is using are making a difference in your patients’ clinical outcomes? Why or why not?
- If no:
 - Do you feel there is a role for increased patient self-management? Why or why not?
- How can we make self-management services better and more acceptable in this facility?
- Is there anything you would like to see done differently in this facility? If yes, what?

Codebook for qualitative data analysis

- Service delivery
 - Challenges to providing care
 - Impact of care on patients’ health – HIV
 - Impact of care on patients’ health – nutrition
 - Impact of care on patients’ empowerment
 - Perceived patient satisfaction with care
- Self-management program
 - Benefits/role of the program
 - Drawbacks of the program
 - Program details
 - Suggestions for program improvement
 - Other comments about SMS

Appendix 2:: Patient outcomes, by country and site type, pre versus post periods

Table A1:

Full patient population outcomes at intervention and comparison sites, pre versus post periods

	Tanzania				Uganda			
	Intervention		Comparison		Intervention		Comparison	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Visits attended on scheduled day, %	66.5%	69.2% (n/s)	83.8%	79.1% ***	79.9%	75.5% **	80.2%	71.8% ***
Within-person attendance change, %	+3.3%		-5.0%		-5.1%		-6.3%	
CD4 level, average	383	470 ***	477	550 ***	n/a		n/a	
Within-person CD4 change, average	+79		+95					
Weight (kg), average	59.3	58.7 **	57.4	59.0 ***	56.0	54.9 **	55.4	55.3 (ns)
Within-person weight change (kg), average	-0.59		+1.59		-0.97		-0.13	

Asterisks indicate level of significance on t-test of difference between pre and post sites:

n/s: not significant

*

p < 0.05

**

p < 0.01

p < 0.001

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Table 1:

Overview of the SMS initiative

<p>Description: Self-management support (SMS) is a patient-centered counseling approach for people living with HIV and other chronic conditions. In this program, healthcare providers and/or expert patients identify HIV-positive patients who meet established high-risk criteria, and provide individualized information and decision-making support to help these patients better understand their condition and be actively engaged in their treatment and overall health outcomes (23). Facility teams received SMS training and employed a quality improvement approach to integrate the SMS design into the existing care system, and to create an enabling environment by restructuring clinic flows to introduce a system for identifying, enrolling, and supporting high-risk patients through SMS. With the guidance of healthcare providers, SMS-enrolled patients worked toward achieving measurable, manageable, and practical goals between their clinic appointments. These goals were developed collaboratively between patients and providers, and targeted personal health challenges such as neglecting to take ARVs daily due to forgetfulness, work/travel schedules, or other factors.</p>	
<p>Enrollment criteria:</p>	
<p><u>Tanzania:</u></p> <ul style="list-style-type: none"> - Missed appointments (no attendance during same calendar month as scheduled date) - Poor ARV adherence (less than 90% of pills taken according to pill count) - Malnourished (classified MAM or SAM) - Low CD4 count (200 or less) - Recent weight loss (over 2kg between appointments) 	<p><u>Uganda:</u></p> <ul style="list-style-type: none"> - Missed appointments (no attendance within 2 weeks of scheduled date) - Poor ARV adherence (less than 95% of pills taken according to pill count) - Malnourished (classified MAM or SAM) - Classified as WHO stage 3 or 4 - High viral load (more than 1000 copies) - Has an opportunistic infection

Table 2:

Description of the quantitative patient record sample

	Tanzania (n=541)	Uganda (n=571)
Age, mean (range)	45 (20-76)	44 (18-79)
Female, n (%)	318 (59.1%)	342 (61.0%)
Diagnosed at current facility (yes), n (%)	496 (91.9%)	452 (82.9%)
Year of HIV diagnosis, mean (median)	2012 (2012)	2010 (2009)
Months between diagnosis and ART initiation, mean (median; range)	8.8 (2.0; 0-118)	23.4 (15.8; 0-123)
Year of ART initiation, mean (median)	2012 (2012)	2012 (2012)
First CD4 level, mean (median; range) ^a	244 (197; 1-1917)	372 (312; 8-1754)
First viral load ^a		
Undetected, n (%)	128 (100%) ^a	382 (78.4%)
Detected, n (%):	0	93 (19.1%)
Log ₁₀ (Copies/ml), mean (median; range)	n/a	5.02 (4.25; 2.74-6.74)

^aSubset of patients with this data element. Some values may not sum to 100% due to missing data

Table 3:

SMS initiative enrollment and activity at intervention sites

	Tanzania (n=258)			Uganda (n=284)		
SMS enrolled, n (%)	51 (19.8%)			88 (31.0%)		
Female, n (%)	29 (56.9%)			48 (55.8%)		
Reasons for enrollment, n (%) ^a						
	All	Females	Males	All	Females	Males
Malnutrition	21 (41.2%)	14 (48.3%)	7 (31.8%)	19 (22.1%)	9 (18.8%)	10 (26.3%)
Poor adherence	12 (23.5%)	3 (10.3%)	9 (40.9%)	5 (5.7%)	3 (6.3%)	2 (5.3%)
Poor appointment-keeping	9 (17.6%)	7 (24.1%)	2 (9.1%)	21 (23.9%)	10 (20.8%)	11 (29.0%)
Other ^b	6 (11.8%)	3 (10.3%)	3 (13.6%)	1 (1.1%)	1 (2.1%)	0
Low CD4 count	5 (9.8%)	3 (10.3%)	2 (9.1%)	0	0	0
Clinical stage	1 (2.0%)	1 (3.5%)	0	4 (4.7%)	2 (4.2%)	2 (5.3%)
High viral load	0	0	0	44 (51.2%)	27 (56.3%)	17 (44.7%)
Patient graduated from program, n (%)	46 (90.2%)	27 (93.1%)	19 (86.4%)	39 (44.3%)	22 (45.8%)	17 (44.7%)

^aPercentages sum to more than 100% since some patients were enrolled for more than one reason.

^bOther enrollment reasons included: weight loss, smoking, alcoholism, opportunistic infections, gender-based violence (GBV)

Table 4:SMS initiative effects ^{a,b}

	Tanzania			Uganda		
	Total	Females	Males	Total	Females	Males
Attended appointment on scheduled day (odds ratio)	3.53 *** (0.89)	3.17 *** (0.90)	3.96 *** (1.08)	1.62 (1.21)	1.64 (1.57)	1.65 (0.91)
n	3416	1789	1627	1650	1023	608

^a Table reports coefficient on the difference-in-difference estimator (i.e., interaction of post [vs pre] * intervention [vs comparison]).

^b All models include individual-level fixed effects for each patient, and appointment-year fixed effects. Standard errors, clustered at facility level, in parentheses. Asterisks indicate level of significance:

† p < 0.1;

* p < 0.05;

** p < 0.01;

*** p < 0.001