

Peer Health Workers and AIDS Care in Rakai, Uganda: A Mixed Methods Operations Research Evaluation of a Cluster-Randomized Trial

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Abstract

Settings with limited health care workers are challenging environments for delivery of antiretroviral therapy. One strategy to address this human resource crisis is to task shift through training selected patients as peer health workers (PHWs) to provide care to other individuals receiving antiretroviral therapy. To better understand processes of a cluster-randomized trial on the effect of these PHWs on AIDS care, we conducted a mixed methods operations research evaluation. Qualitative methods involved patients, PHWs, and clinic staff and included 38 in-depth interviews, 8 focus group discussions, and 11 direct observations. Quantitative methods included staff surveys, process, and virologic data analyses. Results showed that task shifting to PHWs positively affected structural and programmatic functions of care delivery—improving clinical organization, medical care access, and patient-provider communication—with little evidence for problems with confidentiality and inadvertent disclosure. Additionally, this evaluation elucidated trial processes including evidence for direct and indirect control arm contamination and evidence for mitigation of antiretroviral treatment fatigue by PHWs. Our results support the use of PHWs to complement conventional clinical staff in delivering AIDS care in low-resource settings and highlight how mixed methods operations research evaluations can provide important insights into community-based trials.

Introduction

HUMAN RESOURCE LIMITATIONS pose a significant challenge to the delivery of antiretroviral therapy (ART) in rural, low-resource settings such as Rakai, Uganda.^{1,2} In 2007, the World Health Organization (WHO) published a report on task shifting in AIDS care, emphasizing the need for the rational distribution of responsibilities among health work force teams.³ Peer health workers (PHWs) are people living with HIV (PLHIV) and may potentially be a valuable type of community health worker (CHW) to assist with task shifting.⁴ Recent studies in Uganda and other resource poor areas in Africa have shown successes for home and community-based HIV/AIDS services in identifying those with HIV/AIDS and

improving ART adherence.^{5,6} However, there have been few rigorous evaluations of the effects and processes of PHWs on AIDS care outcomes.

From 2006 to 2008, the Rakai Health Sciences Program (RHSP) and collaborators conducted a cluster-randomized trial among 15 mobile AIDS clinics to determine whether PHWs improved ART care outcomes. Details of this intervention and main trial results are reported elsewhere.⁷ In brief, trained PHWs provided adherence monitoring and psychosocial support to fellow patients at clinic sites and during periodic home visits and assisted with triaging sick patients. The PHW intervention was found to decrease virologic failure rates among patients on ART for 96 weeks or more. It was also associated with decreased loss to follow-up

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but had no effect on adherence measures or on shorter term virologic outcomes.⁷

This trial was pragmatically oriented, meaning a general framework for PHW tasks and monitoring was developed, but the intervention was allowed to adapt to needs and problems as they arose.⁸ Additionally, this trial occurred in the setting of a rapidly evolving ART program. Mixed methods and operations research has been called for as critical to understanding complex interventions studies and moving study findings to programs and policy.^{9,10} We therefore conducted a mixed methods operations research evaluation to better understand PHW trial results and the underlying processes that led to those results.^{9,11}

Methods

Study setting and participants

In June 2004, RHSP began providing ART through a President's Emergency Plan for AIDS Relief (PEPFAR)-funded mobile clinic program operating in multiple sites throughout the rural Rakai District in southwestern Uganda. The PHW trial took place from May 2006 to July 2008. The mixed methods evaluation took place throughout the trial period and during a 5-month period following trial completion.

Qualitative methods

The qualitative portion of this study used in-depth interviews, focus groups, and direct observations methods. Study participants were sampled purposively to ensure a broad range of perspectives.

In-depth interviews. In the intervention arm ($n=10$ clinics), we conducted 10 interviews with PHWs (one from each clinic, out of 29 total PHWs) and 12 interviews with patients (6 female, 6 male; age range 32–52). In the control arm ($n=5$ clinics) we conducted 6 interviews (3 female, 3 male; age range, 32–42). Ten RHSP clinic staff were also interviewed.

Focus groups. We conducted four patient focus groups (two male, two female) in the intervention arm, and two focus groups (one male, one female) in the control arm. All the focus group participants were drawn from rural-based clinics and were selected to be representative of the patient population. These focus groups were composed of 7–10 patients each. Two mixed gender PHW focus groups were conducted consisting of seven participants each.

Direct observations. Three direct observation shadowing sessions were carried out during PHW home visits. Eight direct observations were carried out at mobile clinics in both intervention and control arms to learn about daily clinic operations of the RHSP ART team and to note relevant differences between arms.

Data collection procedures. Written informed consent was obtained from all participants. Study investigators and the qualitative data collection team reviewed and edited semistructured data collection guides after conducting pilot interviews. Interview questions were open-ended. Interviews and focus groups focused on personal experiences with ART and the PHW program, and how these experiences changed

over time. In control hubs, the interview and focus group guides were more generally focused on ART care and support and information networks, and the experience of living with HIV. All in-depth interviews and focus groups were tape recorded and transcribed. All interviews and focus groups with patients and PHWs were conducted in Luganda, the predominant local language. Translation and transcription was done in a single step by the interviewer or note taker. Interviews with clinic staff were conducted in English. Observation notes were recorded on site and later expanded to a detailed write-up by the researcher.

Data analysis. After transcription, data were entered into NVivo software for coding and analysis (NVivo 8, QSR International, Victoria, Australia). Transcript review began while focus groups and interviews were still underway and participant responses were used to shape questions for future interviews. After completing line-by-line coding for interviews and focus groups, we developed a codebook by categorizing responses into thematic categories. Quotes from coded transcripts were triangulated with the original transcripts to ensure appropriate contextualization.

Quantitative methods

Quantitative methods included trial process data analyses, a Likert scale survey of clinic staff, and patient virologic outcome data analyses.¹²

Process data evaluations. Process indicators were collected throughout the trial, including number and frequency of PHW home visits to patients, number of patients refusing home visits, and number of patients assigned to PHWs. Additionally, significant programmatic changes were recorded and summarized to provide contextual information. These data were all analyzed descriptively.

Likert scale surveys. A Likert scale survey (1=agree strongly, 3=neutral, 5=disagree strongly) was administered to clinical staff near the end of the trial to assess their views on the PHW program. These data were analyzed descriptively.

Virologic outcomes analyses. We conducted *post hoc* analysis of virologic failure rates of patients at weeks 24 and 48 of ART comparing pretrial to trial time periods. Viral loads (failure defined as detectable viremia greater than 400 copies per milliliter) were measured using the Amplicor Monitor Assay, version 1.5 (Roche Diagnostics, Branchburg, NJ) with a lower limit of detection of less than 400 copies per milliliter. Virologic outcome analyses were by intention to treat using log-binomial regression with generalized estimating equations, an exchangeable correlation structure, and robust variance estimates appropriate for cluster-randomized trials.¹³ Data were analyzed using SAS 9.2 (SAS Institute Inc., Cary, NC).

Ethical review

The trial was approved by Institutional Review Boards at the Uganda Virus Research Institute's Safety and Ethics Committee, the Uganda National Council for Science and Technology, and Johns Hopkins University.

Results

Evidence for direct contamination of control arm

The main trial showed a lack of PHW effect on virologic outcomes of patients on ART less than 96 weeks or on cumulative risk of virologic failure. Qualitative results suggested that contamination between the trial arms was a possible explanation for these findings. In the control clinics, some of the PHWs' clinic-based tasks were being performed by untrained and uncompensated patient volunteers. For example, at one clinic, a patient would register other patients as they arrived and helped organize triage:

In this area there are some people who have turned out to work like PHWs. For example, like in Kibaale [control] hub. There is a gentleman, he really works like a PHW. So when we reach there that man we find that he has already done registration for the patients, which also the PHW do here...So you find, Kibaale is also like a [intervention] hub. (Clinic Staff Interview)

Clinic staff expressed how, after seeing subjective logistical improvements in the intervention arm, staff appointed volunteer patients in control arms to register other patients and to serve as a point person to interact with other patients. These patients' clinic-based tasks appeared to be mostly administrative, but they did occasionally give health talks as well.

There was also evidence of modest contamination in home visit-based tasks. Clinic staff mentioned that self-appointed individuals in the control arm occasionally offered information about missing patients' whereabouts and status. One patient in the control arm even began making home visits to other patients:

As I told you earlier, health workers had told me that PHWs have to visit patients in their homes to offer them reassurance and to see what challenges they have. When they talked about this issue I also decided to take it up. Some patients usually ask me to forward their challenges/problems to the health workers. I thereby decided to visit patients and identify challenges which they experience. So by the time we get to the clinic day I already have something which I can tell to the health workers. (Male Control Patient Interview)

Evidence for task shifting and indirect contamination

Qualitative findings found that PHWs contributed greatly to organization in the clinic through task shifting. Clinic staff noted that before the PHW program, they struggled to organize patients and address their questions and concerns. PHWs alleviated confusion by registering patients and helping organize clinic flow. As PHWs began addressing basic patient care issues, clinic staff reported they had more time to attend to other patient needs. PHWs would also field questions from

patients who expressed discomfort in approaching the clinical staff:

There are certain conversations that we hold with PHWs which are very helpful to one's health but we may not be able to share this with health workers. During such sessions the PHW would be able to advise you about certain issues which the health workers may not be able to help about because you feared him/her. You will be able to share all this with the PHW freely because he is a friend. Indeed you may not be so free to share all this with a health worker who comes in once in a while. (Male Patient Focus Group)

In the community, PHWs' home visits provided an opportunity to assess personal factors such as alcohol use that might affect adherence and not be as apparent in a clinic setting. Additionally, PHWs were able to address various concerns about ART that promoted patient adherence and saved patient time and money traveling to health facilities for support. For example, PHWs were able to counsel patients on correct medication taking and adherence strategies:

The patient I got failed to differentiate between Nevirapine and Septrin. She could instead take two tablets of Septrin thinking it is Nevirapine...So I talked to her mother...and I told her to separate the drugs for her...I told her to give her every morning and in the evening. She is now fine and was even able to help other patients on how to go about with the drugs. (Female PHW Focus Group)

Before the PHW program began, several clinic staff noted they would spend significant time and resources (e.g., fuel for transport) personally going out in to the field to address similar types of issues. PHWs were perceived to reduce the overall workload for clinic staff and allowed them to provide better overall patient care. While these task shifting effects were most noticeable in the intervention arm, there did appear to be indirect contamination of the control arm through a generalized improvement in program-wide efficiency.

Virologic evidence for global programmatic improvements

Table 1 compares 24 and 48 week virologic failure rates before and during the trial period. Notably, the 24 and 48 week failure rates were significantly decreased during the trial period in both arms compared to before. Contextual process data showed that a number of other programmatic improvements were implemented during the study period besides the PHW intervention. These improvements included the use of viral load results to guide care, more focused ART-related messaging, enhanced adherence counseling, chart stickers to help identify treatment failures, and second-line ART provider talks. Qualitative results also suggested that

TABLE 1. VIROLOGIC FAILURE RATES WITHIN STUDY ARM BEFORE AND DURING STUDY PERIOD

<i>Weeks from ART initiation</i>	<i>Arm</i>	<i>Before study % failing (n/N)</i>	<i>During study % failing (n/N)</i>	<i>RR (95% CI)</i>	<i>p Value</i>
24 weeks	PHW	44.5% (85/191)	9.8% (39/397)	0.22 (0.16–0.30)	<0.0001
	Control	35.4% (23/65)	10.5% (16/152)	0.30 (0.27–0.33)	<0.0001
48 weeks	PHW	28.1% (36/128)	10.0% (32/321)	0.35 (0.24–0.50)	<0.0001
	Control	33.3% (12/46)	13.2% (15/114)	0.39 (0.19–0.81)	0.01

ART, antiretroviral therapy; PHW, peer health worker; RR, risk ratio; CI, confidence interval.

clinic staff gained experience and effectiveness over the course of the study period in better delivering ART. These global programmatic improvements resulted in lower than initially anticipated rates of virologic failures.

Impact on long-term ART patients

The trial showed that the PHW intervention decreased virologic failure rates among long-term patients on ART for 96 weeks or more.⁷ The early ART-related difficulties cited by patients included stigma, side effects, and technical understanding of how to take the therapy. Months or years after ART initiation, different adherence challenges emerged, including a sense that they were “cured,” “treatment fatigue,”¹⁴ or difficulty maintaining their drug schedule at work. PHWs appeared to positively impact many of these later adherence barriers:

If he [PHW] takes a month without visiting, you certainly become reluctant. This is because you still have AIDS though you have no pain and no boils. Certainly you might withdraw from drugs feeling that you are fully cured. In fact there are so many patients who withdraw from using drugs because they now feel they have cured up completely. In fact a PHW has a very big role to play during such a situation. He comes in to encourage you to take your drugs. They are doing an important job. (Male Patient Interview)

Impact on loss to follow-up

In the trial, fewer patients were lost to follow-up in the PHW intervention arm than in the control arm. Some PHWs noted patient mobility which created difficulties in following through with treatment⁷:

You just see a person asking for drugs, when you ask her, she says I came from this community, people tell you that she is staying somewhere at her place. When you reach her place, they tell you that she shifted and went back to the other side. (Peer Health Worker Interview)

Qualitative analyses showed that PHWs were able to locate missing patients due to their presence in the community, which facilitated patient tracing and retention in care.

Impact on confidentiality and stigma

Qualitative findings supported the concept that PHWs had a direct role in many patients' lives, providing psychosocial support and combating stigma. As one patient noted:

People in the community can stigmatize to an extent that you even fear to leave the house and are very worried. You can tell the PHW that I fear to leave the house because people stigmatize me...and the PHW tells you that you should be firm, people will talk and get tired, if you keep taking your drugs your health will improve and people will no longer have anything to say about you. (Female Patient Focus Group)

Many patients also felt that PHWs were able to help protect confidentially rather than putting them at risk for unwanted disclosure:

Before the PHW came in we had a problem because you had to tell each and everyone about your health problem until you get to someone who could provide you with assistance. By so doing everyone got to know your problem, even those who cannot assist you and those who would go around gossiping

about your problem to other people. So this was a big problem. After the coming of the PHW, we tell all our health problems to the PHWs. (Male Patient Focus Group)

Impact on adherence

Clinic staff responses to the Likert scale survey (Table 2) and qualitative interviews showed that staff believed PHWs were positively impacting adherence.

The program has been of great help to us the medical people and to the patients themselves. In most cases the PHWs have come out to tell us the truth behind every patient we interact with. Most patients deceive us as far as adherence is concerned but the PHWs have always come to our rescue. (Clinic Staff Interview)

Patients themselves also noted improved engagement in care in their community. As patients saw relatives, friends, and other peers recovering from illness, patients developed hope that their own health would also improve and thus re-dedicated efforts to attend clinic sessions and adhere to ART.

In the past, the PHW could go to a patient's home and they could not know that he or she is a PHW but now they see the PHW going to a very ill person and after a short period of time they see a person walking normally. This prompts them to join us after seeing the importance of it. (Female Patient Focus Group)

Areas for improvement

A number of areas for improvement of the PHW program were identified. Clinic staff suggested increasing the numbers of PHWs, more frequent retraining on drug regimen adjustments, and a more generous stipend system (referred to

TABLE 2. CLINIC STAFF RESPONSES TO PHW PROGRAM SURVEY^a

Statement	n	Mean (SD) [range]
The PHW program improved the overall care of the clinic patients.	38	1.54 (0.55) [1–3]
Patients who talked to a PHW before initiating ART had a better understanding of the importance of adhering to ART.	37	1.59 (0.63) [1–3]
Review of PHW home visit forms was helpful in identifying patients with special adherence counseling needs.	37	1.54 (0.59) [1–3]
Review of PHW home visit forms was helpful in identifying patients with special clinical concerns (e.g., side effects, new illnesses, etc.).	36	1.72 (0.72) [1–3]
The PHW program made my job easier.	39	1.72 (0.71) [1–3]
The PHW program should be scaled up to all the hubs.	39	1.15 (0.48) [1–3]
The PHW program should be discontinued.	39	4.75 (0.37) [4–5]

^a1 = agree strongly; 2 = agree, 3 = neutral, 4 = disagree, 5 = disagree strongly.

PHW, peer health worker; SD, standard deviation; ART, anti-retroviral therapy.

locally as “facilitation”). Many PHWs also commented on the need for increased stipends, noting how PHW home visiting took time away from other gainful work. Clinic staff and PHWs both suggested refresher trainings and more frequent discussions on the ideal interactions between staff and PHWs.

Concerns with intervention intensity were also noted. PHWs were initially charged with performing biweekly home visits, but by study end there were about 25–30 patients per PHW, significantly higher than the initial 15:1 goal. As one staff member noted:

Some [PHWs] have many more patients to see and we don't know whether it will reduce the effectiveness of the program....And well, we are looking at patients coming from different directions all over, although we have a PHW in each geographic region, but sometimes we want to take care of a patient who is on the other side of the geographical region and that means the PHW has to travel long distances to get to see the patient. (Clinic Staff Interview)

Process indicators showed that PHWs eventually averaged monthly rather than biweekly contacts. Inclement weather, absent patients, and transportation challenges were cited as common obstacles to more frequent visitation.

Clinic staff survey results

Likert Scale survey results (Table 2) largely echoed results from the qualitative evaluation. Clinic staff generally had positive impressions of the PHW program and felt it improved adherence, clinical management, retention in care, and eased their own work. They felt the PHW program should be scaled up and continued after the study period.

Discussion

A mixed methods operations research evaluation of a cluster-randomized trial on the impact of PHWs on AIDS care revealed several themes from qualitative analyses which helped improve understanding of trial findings and underlying processes. Quantitative analyses from this evaluation largely complimented these qualitative results. HIV/AIDS programs and future operations/implementation research endeavors in similar settings may benefit from these study methods and insights.

A key discovery of this evaluation was evidence for both direct and indirect contamination of the control arm. Direct contamination occurred when some patients began voluntarily taking up PHW tasks in the control arms. Indirect contamination occurred through task shifting which resulted in overall gains in program quality. Such contamination could have reduced the ability of the study to detect intervention effects, and may help explain why no differences were seen in early virologic outcomes between arms or in cumulative risk of virologic failure.

In comparisons of before and during trial 24 and 48 week virologic failure rates within arms, both study arms demonstrated dramatic improvement during the trial. These results could have been due to a secular trend, but could also be evidence for the PHW program positively impacting both the intervention arm as well as control arm through task shifting. From a study rigor perspective, possible contamination was not desirable in that between arm differences may have been attenuated, but programmatically it may have been beneficial

in improving overall viral suppression. This finding demonstrates the tensions which will be inherent in many operational and implementation studies which must balance study design with pragmatic, programmatic considerations.^{10,15,16}

Interestingly, the adherence challenges and PHW processes in dealing with these challenges appeared to differ between patients on ART for short compared to longer amounts of time. These different adherence barriers may help explain why PHWs were found to have a significant effect on patients on longer term ART. “Treatment fatigue” is an increasingly important public health issue, and PHWs may be an effective intervention to sustain ART.² Future studies may also seek to further explore the relationship between adherence perception, adherence reporting, and virologic outcomes.

The processes by which PHWs contributed to decreasing lost to follow-up rates appeared straightforward. PHWs were present in and knowledgeable about the community and could ably assist with tracking down patients. Retention in care is critical to successful ART programs and the role of PHWs in addressing this issue may be significant.^{17,18} Additionally, PHWs were noted to be consistent and reputable sources of information and motivation both in the clinic and in the communities. PHWs did not have any obvious deleterious effects on disclosure and confidentiality. Some of these potential benefits of peers have been noted before, although typically in observational studies and rarely regarding ART in low-resource settings.^{1,19,20}

Process indicators showed that while PHWs generally fulfilled their tasks, they did not visit patients as frequently as initially planned, and intervention efficacy may have been blunted. The optimal work load and patient ratios for PHWs remains unclear. However clinic staff and PHWs largely endorsed the end of study PHW to patient ratios as being manageable. Another challenge was determining appropriate PHW stipends. Recent WHO guidance suggests compensation should outweigh opportunity costs for health workers to encourage retention.¹ No PHWs quit during this study, suggesting their compensation was sufficient.

Study limitations included limited generalisability of some study findings as the evaluation and intervention were implemented in the setting of a relatively atypical, mobile clinic approach within a program with longstanding research experience.²¹ Since this trial was carried out within an evolving ART delivery program, it was difficult to have a control arm that could isolate the secular trends while remaining representative of the patient population. Optimizing controls for operational research trials is a challenging issue for the field, and they should be carefully and pragmatically selected in future trials. Although researchers attempted to use a variety of data collection methods to reduce response bias and informed consent emphasized participant protections, study participants may have withheld criticism out of respect for the program or fear of retribution. Also, translation and transcription was done in a single step, which could introduce bias, and field notes were written up after observations and could be subject to recall bias. Finally, parts of this evaluation were carried out over a short period of time and may not have fully captured the changes that were occurring over the entire length of the trial.

This mixed methods operations research study supports strategies to task shift medical care and may have relevance to other ART programs and operations/implementation

research. Future research should further detail the capabilities of PHWs to improve clinical productivity in delivery of HIV/AIDS care, and how to best optimize their effectiveness. Mixed methodology should be pursued when assessing randomized trial outcomes to understand trial results and processes, and to best ensure the effective translation of study findings into policy and programs.

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