

## The contributions of lay workers in providing home-based treatment adherence support to patients with AIDS in urban settings: Lessons from the field in Tanzania and Zambia

Godfather D. Kimaro<sup>1,2\*</sup>, Christian Bottomley<sup>2</sup>, Amos Kahwa<sup>1</sup>, Lorna Guinness<sup>3</sup>, Sokoine Kivuyo<sup>1</sup>, Victoria Simms<sup>2</sup>, Bernard Ngowi<sup>1</sup>, Duncan Chanda<sup>4</sup>, Shabbar Jaffar<sup>5</sup>, Godfrey S. Mfinanga<sup>1</sup>

<sup>1</sup>National Institute for Medical Research, Muhimbili Medical Research Centre, Tanzania

<sup>2</sup>Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, UK

<sup>3</sup>Department of Global Health and Development, London School of Hygiene and Tropical Medicine, UK

<sup>4</sup>Institute for Medical Research and Training, University Teaching Hospital, Lusaka, Zambia

<sup>5</sup>Department of International Public Health, Liverpool School of Tropical Medicine, Liverpool, UK.

### Abstract

**Introduction:** In 2018, there were appropriately 20.6 million [18.2 million–23.2 million] people living with HIV in Eastern and Southern Africa, and an estimated 67% of them were on antiretroviral therapy (ART). A major challenge in the scale-up of ART services in Sub-Saharan Africa is the severe shortage of clinical staff.

**Methods:** We conducted a randomised trial in Tanzania and Zambia to test an innovative intervention that involved the use of lay health workers and screening for cryptococcal meningitis and tuberculosis. Here we describe the model of care with a particular focus on the trained lay worker component. Lay workers carried out home visits to patients in the intervention arm to deliver antiretroviral drugs, provide adherence counselling, and conduct simple monitoring for treatment side effects and other medical conditions. Lay workers were responsible for referring patients with conditions that might require further medical attention as well as discouraging self-referral. A total of 1999 participants were enrolled in the trial. Lay workers were recruited through public advertisements.

**Results:** Six lay workers were recruited in each country and trained for two weeks. Each lay worker was paid a monthly salary of US\$ 487.61 in Zambia and US\$ 524.61 in Tanzania. They were also paid communication and transport expenses for home visits. The median number of visits per patient was 3 for Tanzania and 4 for Zambia. On average a lay worker was responsible for 72.3 patients in Tanzania and 94.5 in Zambia for 1 year. Referrals were made in 9% of the home visits and self-referral was discouraged in 64% of visits.

**Conclusion:** The use of paid lay workers to provide HIV/AIDS services in urban settings where there is a shortage of clinical staff may help to identify ART related side effects/adverse reactions and prevent unnecessary referrals.

**Keywords:** HIV/AIDS, Lay workers, Antiretroviral therapy (ART), REMSTART Trial

### Background

In 2018, there were appropriately 20.6 million [18.2 million–23.2 million] people living with HIV in Eastern and Southern Africa, and an estimated 67% of them were on antiretroviral therapy (ART)(1). A major challenge in the scale-up of ART services in Sub-Saharan Africa is the severe shortage of clinical staff. The number of health personnel per 100,000 population in Africa is low compared to developed countries (2). For example, in Tanzania in 2012 there were an estimated 310 physicians per 100,000 population and 436 nursing and midwifery personnel per 100,000 population (3), and the health workforce is expected to reduce further(4–6). In Zambia, according to the most recent figures, there are 173 physicians per 100,000 population and 784 nursing and midwifery personnel per 100,000 population. A further challenge is the cost of transport to access health services (7–12). These costs can be difficult to afford for patients receiving long-term care, particularly if they have to attend the clinic regularly.

\* Corresponding E-mail: [fatherdk@yahoo.com](mailto:fatherdk@yahoo.com)

As a result of the staff shortages, patients may not receive sufficient advice on detecting and responding to ART-related side effects and this is known to affect adherence to ART (8,13). Findings of a cluster randomised trial showed that home-based care delivered by trained lay workers was as effective as standard clinic-based care (11). These findings suggest that one way to overcome the shortage of the clinical staff might be to utilise trained lay workers to help patients identify side effects and refer them to the clinic whenever necessary. In addition, trained lay workers might help discourage unnecessary self-referrals and thereby reduce patients' direct and indirect costs.

Additionally, in most of the low income countries, including Tanzania and Zambia, use of lay workers such as social welfare assistants and community health workers in the provision of some of HIV related services is already being implemented as a pragmatic response to health workforce shortages to various degrees (14–16). For instance, in Tanzania it is recommended that lay workers be involved in the provision of antiretroviral drugs, adherence monitoring, and support, maintaining HIV/AIDS registers, and referring HIV-infected individuals to HIV/AIDS care and treatment centres (14).

We recently conducted a large randomised-controlled trial among HIV-infected patients starting ART with CD4 count <200 cells / $\mu$ l in Dar es Salaam, Tanzania and in Lusaka, Zambia, known as the REMSTART trial (17). The intervention comprised i) screening for cryptococcal infection using serum cryptococcal antigen (CrAg) combined with pre-emptive fluconazole therapy for patients testing CrAg positive; and ii) weekly home visits for the first 4 weeks for patients on ART by trained lay workers to provide adherence support. This package was compared with standard care. To our knowledge, our study was the first randomised controlled trial evaluating the use of trained lay workers in government health facilities in an urban setting. Therefore, to help explain the success of the trial, which reduced all-cause mortality by 28%, compared with standard clinic-based care. Here, we describe the REMSTART model of care with a particular focus on the trained lay worker component. We, additionally, analysed lay workers' records and reports including lay workers' field notes, monitoring data, financial and training records to identify adverse reactions, disease progression, and advice given to the patients as well as lay worker costs.

## Methods

### **The REMSTART trial**

The REMSTART trial was implemented in Dar es Salaam (Tanzania) and Lusaka (Zambia). In 2012, the population of Dar es Salaam was 4,364,541(18) and the population of Lusaka was 1,715,032 (19). The HIV prevalence in these cities was 7%(20) and 17%(21) respectively. The average number of clinic visits by patients on ART, each month, at the sites where the REMSTART trial was implemented was 1856 for Dar es Salaam (3 clinics) and 5000 for Lusaka (3 clinics). When the trial was implemented, patients presenting with a diagnosis of HIV-infection were offered ART if they had CD4 count  $\leq$  350 cells/ $\text{mm}^3$  or if they were at WHO clinical stages 3 or 4. The REMSTART trial initially targeted those patients with CD4<100cells/ $\text{mm}^3$  (later revised to <200cells/ $\text{mm}^3$ ). At the study sites, HIV was managed from primary care clinics through monthly follow-up clinic visits.

The trial enrolled 1,999 patients, who were individually randomised to receive either standard care or the REMSTART intervention and followed them up for 12 months. The primary outcome was all-cause mortality within 1 year of starting ART. The REMSTART intervention comprised i) screening for cryptococcal infection using serum cryptococcal antigen (CrAg) combined with pre-emptive fluconazole therapy for patients testing CrAg positive; and ii) weekly home visits for the first 4 weeks for patients on ART by trained lay workers to provide adherence support. This package was compared with standard care and basic monitoring for signs and symptoms of drug toxicity and disease progression using a checklist.

Information on side effects/adverse reactions was collected by the lay workers from among the trial participants in the intervention arm during home visits. This information was not collected for the participants in the control arm as the trial was designed to look at the impact of the intervention on mortality. The trial was completed in September 2014 and intervention led to a reduction of all-cause mortality of 28% relative to standard care (17).

The REMSTART trial protocol was approved by the ethics committee of the London School of Hygiene & Tropical Medicine, the Ethics and Research Science committee in Zambia, and the National Health Research Ethics Sub-Committee in Tanzania. This trial is registered with the International Standard Randomised Controlled Trial Number registry, number ISCRTN 20410413. Informed written consent was obtained from each trial participants (17).

### **Lay workers recruitment and payment<sup>1</sup>**

Lay workers were recruited through public advertisements in local newspapers. Six lay workers, all with an undergraduate degree in Tanzania and six, all with a college diploma in Zambia were recruited and trained for two weeks in both countries. In Zambia, each lay worker was paid a monthly salary of US\$ 487.61 plus transport costs for home visits up to US\$ 6.78 per visit. In Tanzania, each lay worker was paid a monthly salary of US\$ 524.61 and an additional fixed amount of US\$ 43.72 to cover travel expenses and airtime to communicate with patients and health facility staff. In both countries, lay workers were provided with a cellular phone to communicate with health facility staff and patients. On average a lay worker was responsible for 72.3 patients in Tanzania and 94.5 in Zambia for 1 year. Table 1 reports the characteristics of the lay workers and participants who received the intervention.

**Table 1: Characteristics of the lay workers and participants in the intervention arm**

	Tanzania (%)	Zambia (%)
Proportion of study participants in the intervention arm	434/870 (50)	567/1129 (50)
Proportion of Female participants in the intervention arm	273/434 (63)	279/567 (49)
Median age of study participants in the intervention arm in years (IQR)	38 (32–45)	35 (30–41)
Number of lay workers	6	6
Number of women lay-workers	4	4
Lay workers' age in years, median (min, max)	26 (23-27)	34(18-63)
Gross monthly income per lay worker (in US\$)	504.43	446

### **Training of lay workers**

Following recruitment, the lay workers in both countries received two weeks of classroom training, before trial enrolment began in December 2011. The training module was the same in both countries, and was delivered by counsellors approved by the Ministries of Health. The emphasis in the training was on adherence to ART. Four days of training were on ways of promoting adherence, three days were on monitoring patients for HIV disease progression and signs of adverse effects from antiretroviral drugs using a checklist, and the remaining three days were on definitions of major opportunistic infections and research ethics. The training modules were developed after reviewing the Tanzania and Zambia HIV home-based care manuals for people living with HIV and also the manual used by The AIDS Support Organisation (TASO) group in Uganda (11). We arranged for the trainees to meet with nurses experienced in home-based care for people living with HIV, and for them to visit patients who were lost from HIV care (clients who had missed at least three consecutive clinic appointments). The mean cost of training per lay worker was US\$ 35.01 in Tanzania and US\$ 56.63 in Zambia (all costs are

<sup>1</sup> all costs are presented in 2018US\$

in 2018 US\$). This cost covered a number of expenses include: training materials and venue, allowance for trainers, transport (home-training centre-home) costs for the lay workers, and lunch and refreshments during the training.

Tanzania started recruiting trial participants on 9 February 2012 and Zambia started on 16 February 2012. Lay workers worked with minimal supervision on field trips but were encouraged to telephone the nurse or clinicians at the site or the study coordinator for advice. The lay workers had daily feedback meetings with nursing staff and monthly meetings with the trial team members (trial coordinator, nurses, and clinicians) to share their experiences and discuss difficult cases.

### **Mode of transport**

Most home visits were made using public transport because taxis were not affordable within the budget of the trial, and motorbikes and bicycles, which are widely used in the study areas, were not acceptable to the lay workers. In Tanzania, travel costs were paid for out of a monthly fixed travel allowance (98,183.80Tanzania shillings = 43.72US\$). In Zambia, travel costs were reimbursed; the average monthly expenditures per lay worker on travel were approximately 506,087.27Zambian kwacha (equivalent to US\$ 97.52). This cost covered transport fares and airtime for the lay worker to call his/her patients before home visits and phone charges.

### **Home visits**

Each participant in the intervention arm was assigned a lay worker who visited him/her at home or an agreed location. Information to locate the participant's home including address, phone number, and map cues was collected at enrolment. The number of home visits made by a lay worker, missed home visit appointments, type, and number of medical conditions, and number of referrals that were either discouraged or encouraged were recorded by the lay workers.

The lay workers were expected to make a minimum of four scheduled home visits, one week apart. At each home visit, the lay worker delivered antiretroviral drugs, provided adherence counselling, and conducted simple monitoring for treatment side effects and other medical conditions using a checklist. They referred participants to the clinic, when this was necessary, and phoned a clinician or nurse based at the clinic when they were uncertain about the referral. ART management for the patients remained unchanged and was the same for intervention and control arms. A quarter of patients in Tanzania and almost half in Zambia requested to meet the lay worker away from home. The reasons patients gave for meeting the lay worker away from home, included the fear of stigma and not wanting to disclose their HIV status to their spouse (Table 2).

Overall, the majority of patients had all four visits (660/1001; 66%). Lay workers telephoned participants about two days in advance to arrange the visit, and the number of missed appointments was likely low as a consequence of this (172/1254; 13.7% in Tanzania and 89/1991; 4.5% in Zambia). Of the 172 missed appointments in Tanzania, in 79 (45.9%) the patient could not be contacted by phone, in 25 (14.5%) they had died, in 23 (13.4%) they had travelled out of town, in 6 (3.5%) they had decided to withdraw from the trial, in 5 (2.9%) they had been admitted to hospital, in 16 (9.3%) they were at work and in 18 (10.5%) they had provided incorrect contact details. In Zambia, 48 (54.0%) appointments were missed because the patient had died and the remainder were missed because the patient had been admitted to hospital (n=18; 20.2%), or had decided to withdraw from the trial (n=21; 23.6%) or could not be contacted by phone (n=2; 2.2%).

**Table 2: Characteristics of the home visits<sup>§</sup>**

	Tanzania	Zambia
Number of patients in intervention arm	434	567
Number of home visits made in the intervention arm	1254	1991
Number of patients not visited at all	44	34
Number of patients visited once	36	24
Number of patients visited twice	48	16
Number of patients visited three times	98	41
Number of patients visited more than three times	207	453
Median (min, max) time in minutes taken to travel from the study site to the patient's home	44 (5-22)*	60 (30-90) <sup>#</sup>
Median (range) time (in minutes) spent with each participant per appointment	28 (12-62)**	30 (15-45) <sup>##</sup>
Median (range) number of missed appointments per participant (i.e. when no-one was seen).	1 (1-4)	2(1-4)

<sup>§</sup>Lay-worker visited participants in the intervention arm only, so this information was not collected for the participants in the standard care

\* Based on seven home visits conducted between 1 – 14 November 2012. The observations were done during these visits only.

<sup>#</sup>estimate from a sample of furthest and nearest participants

\*\*Based on nine patients visited between 1 – 14 November 2012. The observations were done during these visits only.

<sup>##</sup>estimated from a sample of new and sick against well (final visit) participants

\*\*\*Top-down method was used to obtain the estimates (we divided the total amount spent by lay-workers on transport and communication by a total number of home visits conducted).

<sup>^</sup>The meeting took place at a location near the participant's or family member's home or the workplace

Lay workers were responsible for referring patients with conditions that might require further medical attention as well as discouraging self-referral. Referrals were made in 9.3% of the home visits and self-referral was discouraged in 63.6% of the home visits (Table 3). Referral rates were higher in Tanzania (1 in every 7.4 visits) than in Zambia (1 in every 14.8 visits). The referral was encouraged if the participant had at least one of the following; numbness and burning sensation in the limbs, bad dreams, body itching, cough, swelling and joint pains, difficulty breathing, chest pain, diarrhoea and vomiting. On the other hand, lay workers discouraged referral if participants had either general body weakness or abdominal discomfort/fullness and loss of appetite.

Overall, the most common side effects/adverse reactions identified during study visits were: general body weakness (n=750), abdominal discomfort/fullness (n=403), loss of appetite (n=398), numbness and burning sensation of the limbs (n=205), bad dreams (n=97), body itching (n=74), cough (n=57), swollen and joint pains (n=44), difficulty in breathing and chest pain (n=26) and diarrhoea and vomiting (n=17).

**Table 3: referrals made by lay-workers during home visits<sup>§</sup>**

	Tanzania	Zambia
Number of patients in intervention arm	434	567
Number of visits at which participants were referred to the health centre or hospital	169*(13%)	134* (7%)
Number of visits at which participants were advised that their symptoms would not require a referral	1063** (85%)	1002**(50%)
Number of visits during which lay-worker phoned the health centre for advice	111 (9%)	105 (5%)

	Tanzania	Zambia
Number of referrals following phone call discussion with a nurse	45 (5%)	37 (2%)

<sup>§</sup>Lay-worker visited participants in the intervention arm only, so this information was not collected for the participants in the standard care

\*Includes referrals made by lay-workers with or without telephone discussions with a nurse.

\*\*include self-referrals discouraged by the lay-workers with and without telephone discussion with the nurse. A total of 1885 referrals were discouraged without discussions with a nurse and 180 were discouraged following phone call discussions with a nurse

In Tanzania, retention of the lay workers was difficult. Between June 2013 and February 2014 five out of six lay workers left the study and had to be replaced. The replacement lay workers received on-job training from the study nurses and coordinator and were mentored by experienced lay workers who were still working on the trial. Four of those who left got a new job with a longer period of employment and one got married and moved upcountry. Retention was better in Zambia where only one lay worker left the trial after being offered a job in the government sector.

### **Cost of the lay workers**

The mean per-participant costs of the lay worker component for Tanzania and Zambia were USD 58.62 and USD 77.30, respectively. Estimation of these costs included recurrent costs (personnel, transport, and communication costs) and capital costs (mobile phone handsets and training costs).

### **Discussion**

We have previously shown that the REMSTART intervention reduced all-cause mortality by 28% compared with standard care in two countries where there is a severe shortage of health workers(17). Although there has been informal adoption of some forms of task sharing in response to staff shortages in resource-limited countries(14,22–24), this is the first randomised controlled trial to show that trained lay workers can be used in government health centres in an urban setting. Here we describe the component of the REMSTART intervention that was delivered by lay workers and that contributed to its success.

A high proportion of participants in the REMSTART intervention arm received all four scheduled home visits. Telephoning participants 1-2 days before a home visit was scheduled may have helped patients to keep appointments since almost all missed appointments among participants who were still alive occurred when the person could not be contacted in advance. We also found that a significant number of home visits occurred away from the home. This might be because patients were afraid to disclose their HIV status to family members. In light of this stigma, and since telephoning patients was effective in our study, an important future research question is whether it is possible to provide adherence support and monitoring by phone.

Lay worker visits had important consequences for referrals. Most referrals made by lay workers occurred within 1 month of treatment initiation and they may have substantially improved health outcomes since HIV-related mortality is highest during the first month of treatment (25–28). In addition, by using a checklist and knowledge they had acquired in training, lay workers may have been able to prevent unnecessary clinic visits. Preventing unnecessary clinic visits is important because it improves the efficiency of the ART programme by reducing unnecessary health resource utilisation at the clinic, and it reduces the costs incurred by patients in accessing health services, which in turn improves utilization of HIV services (7–10,12) and clinical outcomes (29,30).

Retention of the lay workers was difficult in Tanzania. This might have been because the Tanzanian lay workers were younger or because they had university degrees and were, therefore, offered alternative employment more frequently than their Zambian counterparts, who had college diplomas. Each lay worker who left was replaced. The replacements were given on-the-job training by the trial team members (nurses and clinicians) and were also paired with experienced lay workers and were left to work independently after they had become competent. No additional expenditures incurred in training the newly recruited lay workers. For sustainability, should these modes of care be scaled up, we would recommend using lay workers with a lower level of education, as Zambia did, to minimize turnover and salary costs.

Findings from this analysis suggest that the cost of employing lay workers will not be a major challenge to scaling up the lay worker intervention as the cost per patient for the first year of ART (i.e., annual cost of a lay worker divided by the average number of patients) is US\$ 7.28 in Tanzania and US\$ 5.25 in Zambia. Additionally, we anticipate that if this approach was rolled out to all patients, many patients would be on therapy and the increased density would reduce travel distances, which will in-turn reduce cost per patient.

We are currently evaluating the cost-effectiveness of the intervention as a whole, including the lay worker component. Preliminary findings from this evaluation show that the additional cost of a lay worker is small relative to the overall cost of care in the first year of ART. The full RESMSTART intervention cost was USD 89 (95% CI 84.68–93.31) per person in Tanzania and USD 83.7 (81.8–85.6) per person in Zambia (17).

When the trial was implemented, HIV-infected individuals were offered ART if they had CD4 count  $\leq 350$  cells/mm<sup>3</sup> or if they were at WHO clinical stages 3 or 4. Since 2014 after the REMSTART trial was concluded various treatment recommendations have been reviewed such that in 2015 the cut-off point for ART initiation was CD4 count  $< 500$  cells/mm<sup>3</sup> (31), and now the policy is to test and treat regardless of the WHO clinical stages or CD4 levels. Despite these policy changes, we think that the REMSTART research findings are relevant. Firstly, in the ongoing project “Translating the REMSTART Research Findings into Practice” in Tanzania, we are still seeing HIV-infected individuals presenting with CD4 count  $< 200$  cells/mm<sup>3</sup>. Secondly, these policy changes will substantially increase the number and volume of HIV-infected individuals initiating on ART. This will further overstretch the few available medical personnel which in-turn may affect the quality of ART services. Trained lay workers may be a very valuable resource and may be a cost-effective way of helping cope with the increased burden, in the current changing policy environment.

Two further limitations of our study are: 1) it may be difficult to apply our findings to rural and semi-urban settings; 2) lay workers did not visit participants in the standard care, hence information related to home visit, referrals and ART related side effects/adverse reactions are not available for this group.

## Conclusion

The use of paid lay workers to provide HIV/AIDS services in urban settings where there is a shortage of clinical staff may help to identify ART related side effects/adverse reactions and prevent unnecessary referrals.

## Declarations

**Ethics:** We use data from a large trial (ISCRTN 20410413) which was approved by the ethics committee of the London School of Hygiene & Tropical Medicine, the Ethics and Research Science committee in Zambia, and the National Health Research Ethics Sub-Committee in Tanzania.

**Conflict of interests:** The authors declare that they have no competing interests.

**Consent for publication:** Not applicable

**Acknowledgments:** We thank the study participants and staff involved with the REMSTART trials and our funder, EDCTP (European and Developing Countries Clinical Trials Partnership).

**Authors' Contributions:** Conceived and designed the study: GDK, CB, AK, LG, SK, VS, BN, DC, SJ, GM. Performed the study: GDK, CB, AK, LG, SK, VS, BN, DC, SJ, GM. Analysed the data: GDK, CB, AK, LG, SK, VS, BN, DC, SJ, GM. GDK and AK wrote the first draft of the paper and subsequent drafts with inputs from CB, LG, SK, VS, BN, DC, SJ, GM. All authors have given final approval of the version to be published.

**Funding:** This study was part of the REMSTART trial which was funded by the European and Developing Countries Clinical Trials Partnership (IP.2009.33011.003). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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