Distribution of Antiretroviral Treatment Through Self-Forming Groups of Patients in Tete Province, Mozambique

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Background: As antiretroviral treatment cohorts continue to expand, ensuring patient retention over time is an increasingly important concern. This, together with capacity and human resource constraints, has led to the consideration of out-of-clinic models for the delivery of antiretroviral therapy (ART). In 2008, Médecins Sans Frontières and the Provincial authorities launched a model of ART distribution and adherence monitoring by community groups in Tete Province, Mozambique.

Programme Approach: Patients who were stable on ART for 6 months were informed about the community ART group model and invited to form groups. Group members had 4 key functions: facilitate monthly ART distribution to other group members in the community, provide adherence and social support, monitor outcomes, and ensure each group member undergoes a clinical consultation at least once every 6 months. Group members visit the health centre on a rotational basis, such that each group member has contact with the health service every 6 months.

Results: Between February 2008 and May 2010, 1384 members were enrolled into 291 groups. Median follow-up time within a group was 12.9 months (IQR 8.5–14.1). During this time, 83 (6%) were transferred out, and of the 1301 patients still in community groups, 1269 (97.5%) were remaining in care, 30 (2%) had died, and 2 (0.2%) were lost to follow-up.

Discussion: The Community ART Group model was initiated by patients to improve access, patient retention, and decongest health services. Early outcomes are highly satisfactory in terms of mortality and retention in care, lending support to such out-of-clinic approaches.

INTRODUCTION

The number of people receiving antiretroviral therapy (ART) in low-income countries continues to increase, with an estimated 5 million people on treatment as of July 2010. As treatment cohorts continue to expand and age, the question of how to ensure that patients initiated on ART are supported to remain in care is becoming an increasingly important concern. A recent systematic review of programs in sub-Saharan Africa reported that on average almost a third of patients were lost to follow-up (LTFU) within 2 years of being initiated on to ART.[1]

Several studies have indicated that practical challenges—distance to services and transport costs, work responsibilities, and family commitments—are associated with defaulting from care.[2,3] Barriers at the health facility level such as long waiting times, patient experience with the health system, stigma and discrimination, and lack of social support and information for adherence have also been reported as reasons for defaulting.[1] Thus, ensuring that ART services are accessible as close as possible to the community is an important way to improve access to and retention in care.[4–6]

ART is a lifelong therapy, and the number of patients entering treatment continues to increase, leading to concern that conventional health systems will become increasingly overwhelmed. The limited health workforce in high HIV prevalence settings together with the need to provide ART at the community level has led to consideration of out-of-clinic models of care that would engage patients in essential tasks including ART distribution and peer support for adherence and social support.[7]

Mozambique faces many problems common to high HIV burden countries in southern Africa. The government began providing ART in 2003, but the dire lack of human resources and infrastructure for heath care provision has limited coverage: in 2007, it was estimated that only around one third of people in need of ART were receiving treatment,[8] whereas overall, only around half of the population have access to an acceptable level of health care.[9] Access to and

retention in care is a major challenge in many parts of the country due to distances to health facility, transportation costs, and long waiting times.[10]

In 2008, in collaboration with patients and local health authorities, Médecins Sans Frontières (MSF) piloted a model of ART distribution and adherence monitoring by community groups to supplement the conventional mode of ART delivery in health clinics and hospitals. The model was initially proposed during problem-solving discussions between counselors and ART patients as a potential way to improve retention while giving patients greater responsibility for certain aspects of service provision.

In this article, we describe the implementation of the community ART group (CAG) model and report preliminary outcomes.

PROGRAM DESCRIPTION

Project Setting

Tete Province lies in central Mozambique and borders Malawi, Zambia, and Zimbabwe. Approximately 85% of the province's 1.8 million inhabitants live in rural areas. Adult HIV prevalence is estimated at 13%.[11] MSF has been supporting the health authorities in Tete Province since 2002 in the implementation and scale-up of HIV care and treatment. ART provision began in May 2003 at Tete Provincial hospital and was decentralized to selected peripheral health centres in 2006.[12] By mid-2010, 1 quarter of health facilities in Tete Province (28 of 105) were authorized to initiate ART. Despite significant progress in increasing access to ART services through decentralization of HIV care and task shifting, about 1 in 5 ART patients in Tete are LTFU, and at least half of those LTFU are estimated to be dead.[12]

Stakeholder Consultation

Group discussions were conducted between patients and counselors at health facilities supported by MSF. Patients reported that the main barriers to ART access and retention on ART were transport costs and perceived stigmatization by attending health facilities and time lost waiting in long queues at clinics, often just for refills.

Ministry of Health Guidelines state that patients stable on ART only need a clinical consultation once every 6 months, but ART supplies can only be given monthly. The practical consequence is that patients often travel long distances to pick up medications every month. The CAG approach was proposed in consultation with patients as a way for patients to utilize existing social networks and pool resources to reduce the individual requirement to travel and queue at health centers each month for ART prescriptions and provide mutual support for adherence and social needs.

Participating Clinics and Group Formation

CAGs were established in 12 health facilities in 6 districts (Chiuta, Changara, Moatize, Tete City, Cahora Bassa, and Mutarara) of Tete Province. The estimated population of the 6 districts with CAGs was 900,666. As of May 2010, 11,052 people were active on ART, among whom

half (5772) were attending health centers at which CAGs were established.[13]

Participating health facilities were required to have the following minimum package of services: HIV counseling and testing, a clinician authorized to prescribe ART, a guaranteed supply of ART and opportunistic infection prophylaxis, and transport for CD4 samples and results.

At the group level, members had 4 key practical functions as follows: to collect and distribute ART each month to group members in the community; to provide community-based adherence support and treatment outcome monitoring; to establish a community-based treatment social support network; and to ensure each group member undergoes a clinical consultation at least once every 6 months. The group elected a group leader who facilitates monthly group meetings, conducts monthly pill counts, and monitors group attendance.

CAGs were promoted in clinic waiting areas, during consultation and counseling sessions and through information distributed within the community. To join a group, patients needed to be clinically stable on ART for a minimum of 6 months and have CD4 ≥200 cells per cubic millimeter. Interested patients were advised to form groups of up to 6, elect a group leader, and present to their nearest clinic for eligibility assessment by a clinician. Counselors trained newly formed groups in the approach and in the roles and responsibilities of patients in a group, conducted monthly monitoring of groups of group representatives, and conducted group counseling and education sessions.

Community ART Groups

Each month, a group representative visits the nearest health facility to collect medicines for the group. Every member is expected to serve as the group representative on a rotational basis such that each patient has contact with a health centre every 6 months. Group members could still visit the health centre at any other time, for any reason, if required.

A group meeting is held in the community before each clinic visit, and the designated group leader counts each members' pills (adherence check). Any new signs or symptoms, adherence problems, or intention to relocate to another area or interrupt treatment are discussed and documented for each patient on the group-held group monitoring form. The group chooses a member who will represent and report on the group and collect medications at health facility level, for that month. The patients give their appointment cards to the group representative to take them to the health facility.

At facility level, the group representative discusses each group member with a counselor or clinician, covering such issues as adherence (self-report and pill count), clinical status, and any action to be taken such as requesting a patient to attend the health facility for consultation, bloods, or adherence counseling. The group monitoring form is jointly reviewed. The group representative then meets with a clinician who prescribes ART and prophylactic drugs for each group member. The patient-held appointment cards are updated by the clinician or counselor. The group representative also undergoes a clinical consultation at this visit. The group representative then returns to the community and distributes ART and other medicines to each patient, returns the patient-

held appointment cards, and, where necessary, requests a group member to go to the health facility for follow-up.

All members from different CAGs linked to the same health facility are invited 6 monthly for a group session at the health facility or in the community. Health education and information updates on topics such as CAG dynamic, adherence, when to come for an unplanned consultation, tuberculosis, prevention of mother to child transmission, opportunistic infections, and treatment issues are provided. A blood sample for CD4 is taken at the end of the session for all who are present (Table 1).

Monitoring and Evaluation

Three paper-based tools are used to monitor CAGs: the national patient-held appointment card, the clinic-based patient file, and a group monitoring form.

The patient-held appointment cards are given to the group representative before the health facility visit and brought

TABLE 1. Summary of CAG Implementation Steps

Consult stakeholders	Hold group discussions with patients, health authorities, and health facility staff
Select project sites	Select sites according to, for example, size of ART cohort (urban sites), geographical isolation of surrounding population (rural sites), and whether a facility had the following features:
	HIV counseling and testing
	Transport for CD4 samples & results
	A clinician authorized to prescribe ART, follow patients, draw blood from patients for CD4 counts, and familiar with procedures for CAG project
	A person to manage the groups (counselor, clinician, other)
	A person to dispense ART and a secure supply of ART and opportunistic prophylaxis
Prepare health facilities to manage CAGs	Design a guideline with health authorities, tailored to reality of each facility
	Train facility staff in the CAG model and their flexible roles and responsibilities
Promote CAG model as voluntary option to conventional care for stable ART patients	Provide patients with information on CAGs in health facility waiting areas, during consultations and counseling sessions
	Ask patients who attended the health facilities to inform other ART patients known to them in their local area, about CAGs
	Request patients to form groups of a maximum of 6, and elect a group leader
	Request groups to present to a facility to be screening for eligibility to join CAGs
Screen interested ART patients	Eligibility criteria:
	Followed on ART at least 6 months
	Taking first line ART with weight greater than 25 kg
	Taking an alternative first line regimen containing Efavirenz with weight > 40 kg
	Be clinically stable and without any active WHO Stage III or IV clinical condition
	Have a CD4 count in last three months greater than 200 mm^3
	Screening: By clinician or counsellor. Documentation in patient file
Train group members once screened	Train and educate group members in the CAG model, the practical functions of group members, and the responsibilities of the group leader and group representative
	Open 2 copies of the group monitoring form, 1 for the group, 1 for the facility
Every month groups meet in community, a group representative attends the health facility to report on the group and collect antiretrovirals, to distribute in the community	Groups meet in community each month to count pills, monitor adherence and outcomes, update the group monitoring form, and elect a group representative
	The group representative for the month attends the facility to report on the group, collect antiretrovirals for each group member, and to have an individual clinical consult
	Clinicians prescribe ART each month for individual patients in standard manner. The group monitoring form is updated
	Group representative distributes ART to members in community
	Patients can attend the facility at any other time they need, for any reason
Monitor patients and ART groups and provide ongoing support and quality improvement	Monthly group meeting in community (intragroup monitoring)
	Monthly feedback from group representative to facility (group-facility monitoring)
	Monthly update of information on ART group monitoring form
	Patient file, consultation registers, and other standard monitoring tools updated
	Monthly standard reports to health authorities and analysis of database
	Every 6 months all group members attend the facility for a group meeting/training, and to have blood collected for CD4 count
	Activities conducted to audit the quality of functioning of CAGs, such as follow-up of patients who died, were LTFU or have adherence problems

together with the group monitoring form to the health facility. The next CAG refill dates are updated on appointment cards and then returned to each group member in the community along with a 1-month supply of ART.

Paper-based patient files are kept in all health facilities and contain essential information on each patient: unique patient ID, name, contact details, age, sex, clinical history, CD4 results, clinical consultation findings, medications prescribed, adherence and counseling information, and other details.

The group monitoring form includes information on ART prescription and pill counts for all group members and acts as a group-specific cohort register. The group monitoring form contains basic background information including patient identification number, sex, age, date initiated ART, CD4 at ART initiation, count and date of last CD4, monthly dates of ART collection, monthly pill counts, date of next consultation, and a basic health check. One side of the form is updated by the group representative and group members (pill count and patient signature of approval) each month. The group representative takes this form (along with the patient-held cards) to the facility each month, where it is reviewed with clinic staff and updated with information such as number of ART dispensed to the group representative for each patient, date to next collect ART for the group and new CD4 results. A copy of the group monitoring form is held at the clinic.

Information from the 3 monitoring tools are encoded in an electronic database (Excel) by a trained data manager to evaluate the following program-level information: demographic and other baseline information, date of ART initiation, CD4 count at ART initiation, date each patient joined ART group, name of ART group, dates of ART distribution, dates of 6 monthly CD4 blood collection and individual consultation, CD4 results, pill count at time of each ART distribution, number of pills dispensed, and standard patient outcomes. Data are analyzed each month to track enrollment, patient follow-up and outcomes, undertake data cleaning, and generate aggregate health centre outcome reports for CAGs.

Patient Consent and Protections

CAGs were started as a programatic response as solution to respond to the many obstacles patients encountered in accessing their monthly treatment and to alleviate over-burdened health centers. A number of basic securities were put in place to ensure voluntary participation and patient data protection. From the beginning, participation in CAG care has been voluntary. At the start of the program, basic information about the CAG approach, including eligibility criteria and roles and responsibilities of group members was made available in the local language through information sessions in health facility waiting areas and in discussion with patients who had defaulted from care. At any time, patients in CAG care could opt and return to standard care and follow-up. No financial or material incentive was provided. The CAG electronic database is password-protected and locked and stored in a secure room according to normal standards. The program was formally approved by local health authorities.

A number of processes were established to ensure the proper functioning of the groups. CAG members were encouraged to report to their clinician or counsellor any serious problem experienced within a group, such as diversion or non-receipt of antiretrovirals. Regular meetings were held with members at community and health facility level to identify any problems and counsellors conducted ad hoc audits through brief structured interviews with group members at facility level. All adverse events such as death or defaulting were investigated and documented.

RESULTS

The first CAG was established in February 2008. By May 31, 2010, 1384 members had been enrolled into 291 groups (Table 2). Group members had been on ART for a median of 22.3 months (interquartile range: 9.7–34.2) at enrollment. Median age at enrollment into a group was 36 years, and the majority (70%) were female, consistent with demographic characteristics of adults in conventional ART care in Tete province[12] Median follow-up time within a group was 12.9 months (interquartile range: 8.5–14.1) (Table 3).

A review of documentation and meetings with facility staff and CAG leaders confirmed that all doses of ART were collected from the facility and delivered to patients. Adherence monitoring was successful, with 92% of patients (1173 of 1269 members as 31 May 2010) had their last 2 pill counts recorded correctly on the group monitoring form.

Adverse outcomes were reviewed for all patients. Of the 1384 patients who had enrolled into a CAG, 83 (6%) had been transferred either back to conventional care or to another treatment centre, in general due to patients changing place of residence. Of the remaining 1301 patients, 1269 (97.5%) were remaining in care, 30 (2%) had died, and 2 (0.2%) were LTFU. Of 48 members that returned to standard care, 27 left due to change of residence, 3 due to poor adherence to ART, 12 for medical reasons, and 6 for social reasons unrelated to the group. Among the 30 CAG member who died, 3 died of acute, unknown circumstances at home, whereas the remainder had all had at least 1 clinical consultation related to their illness leading to death: 21 deaths due to HIV-related causes, the remaining 6 due to non–HIV-related illness. The 2 instances of defaulting were due to change of residence and social reasons unrelated to CAGs or their care.

Finally, in terms of workload reduction, staff at health facilities reported that CAGs resulted in an approximately 4-fold reduction in consultations among patients in CAGs.

DISCUSSION

The CAG approach was designed together with patients in response to patient reported barriers to retention on treatment, and as such was a highly acceptable alternative mode of service delivery for stable ART patients. For patients, CAGs represent a way to decrease the financial and economic/social costs of their treatment, take greater responsibility for the management of their own health, and be active partners in health care delivery. Beyond simply reducing transport costs, the groups provides a means of encouraging greater patient responsibility for their own health and building and reinforcing social networks and peer support, which have been identified as important ways to support adherence to treatment.[14,15]

TABLE 2. Baseline Characteristics of CAG Patients

Category	Value
Total	1384
Number of facilities with CAGs	12
Number of groups	291
Average number per group	5
Female, number (%)	968 (70)
Age at enrollment (years), median (IQR)	36 (30–43)
CD4 count at ART initiation, median (IQR)*	176 cells/mm^3 (105–247)
Months on ART pre-CAG, median (IQR)	22.3 (9.7–34.2)

*Data missing for 86 patients.
IQR, interquartile range.

The proportion of patients LTFU were lower than reported in the literature, in which rates of LTFU at 12 months range from 1.2% to 26%.[1] For Mozambique, the national average rate of defaulting at 12 months is 15%.[16] However, the data presented are programatic data and as such are subject to a number of limitations common to observational studies that threaten the validity and generalizability of the findings. In particular, survivorship bias resulting from the eligibility criteria that requires patients to be clinically stable and to have been on ART for 6 months before being able to join the program may limit generalizability. Nevertheless, the current low rate of defaulting and mortality in this program suggests that the approach described herein has clear potential in supporting long-term ART management, at least for stable patients.

Around 5 million people are currently receiving ART in developing countries, and another 10 million people are currently estimated to be in need of treatment.[17] The growing number of patients on ART is not, however, being met by a commensurate increase in the numbers of clinics and clinic staff. High HIV burden settings are usually chronically under resourced to meet current needs: it is estimated that a 7-fold increase in health personnel is required in Mozambique to meet the health needs of the population.[18]

TABLE 3. Outcomes at May 31, 2010, of CAG Patients, Tete Province, Mozambique

Outcome	Value
Total	1384
Months in CAGs, median (IQR)	12.9 (8.5–14.1)
Died: n, % (95% CI)	30, 2.2% (1.5% to 3.1%)
LTFU: n, % (95% CI)	2, 0.1% (0% to 0.5%)
Transferred out to other health facility: n, % (95% CI)	35, 2.5% (1.8% to 3.5%)
Transferred back to conventional care: n, % (95% CI)	48, 3.5% (2.6% to 4.6%)
Active in CAG: n, % (95% CI)	1269, 91.7% (90.1% to 93.1%)
CD4 gain since initiation, median (IQR)*	478.5 cells/mm^3 (313.5–642)

*Data available for 78% (836) of patients: patients in CAGs at least 9 months and who had a CD4 in last 6 months.
CI, confidence interval; IQR, interquartile range.

For ART delivery to be sustainable and successful in the long term, there is a need for models of care that separate clinical patient management (which requires trained health workers) and the dispensing of medicines (which does not), and address patient-reported barriers to treatment access and retention. A shift from acute to chronic care implies a greater emphasis on self-management of disease outside of a clinical setting, with patients assuming an active and informed role in managing physical, psychological, and social aspects of health.[19]

In Western countries, chronic disease self-management programs are accepted as a way to improve patient outcomes and reduce the burden on healthcare systems for a range of chronic diseases including asthma,[20] diabetes,[21] arthritis,[22] chronic obstructive pulmonary disease,[23] and cancer.[24] Non-physician-led approaches such as repeat prescriptions[25] and patient held records[26] have been found to be of benefit to patients and health services. For HIV care, the concept of chronic disease self-management has been proposed for over a decade but has been largely confined to adherence support.[27] More recently, out-of-clinic approaches to ART care have been piloted as a way to decongest overburdened health services and simplify treatment for patients. A recent cluster randomized trial in Uganda found that home-based ART delivery was equivalent to facility-based ART delivery in terms of survival and virological suppression.[28] In Tanzania, community-based volunteers and trained medical workers support mobile drug distribution by refilling prescriptions in the community, and this has anecdotally led to reduced LTFU.[29] In western Kenya, people living with HIV/AIDS have been trained and salaried to provide follow-up to clinically stable HIV patients in their communities and distribute ART and prophylaxis for opportunistic infections.[30] The positive early outcomes of the CAG approach presented here lend support to such out-of-clinic approaches.

Improving retention in care is just one challenge to health services in high-HIV prevalence settings. Substantial attrition has also been reported among patients diagnosed HIV positive and awaiting ART initiation, both in Mozambique[31] and elsewhere.[32] Innovative approaches are also needed across the care cascade from HIV diagnosis to long-term retention. The future refinement of the CAG approach in Mozambique will include reflection on how this approach can support the health service and improving outcomes across the treatment cascade. For example, many CAGs have members who are not yet eligible for ART who join monthly group meetings in the community and benefit from the social support and education. In this way, the CAG model may also help to minimize pre-ART defaulting, an issue of growing concern in ART programs in southern Africa.[32] Another challenge lies in the need to develop adapted approaches for vulnerable subgroups as children, adolescents, pregnant woman, commercial sex workers, and HIV/TB-coinfected patients. Finally, the CAG program requires long-term follow-up and formal evaluation comprising both qualitative and quantitative approaches to determine its effectiveness, acceptability, sustainability, and generalizability.

Although there remains an urgent need to continue to enroll patients onto ART as a medical priority, program implementers must also begin to take the long view, including from the patients' perspective. HIV/AIDS is a chronic disease

requiring lifelong treatment. With successful treatment, patients initiated on ART in resource-limited settings can expect to live around 30 years on treatment.[33] The long-term management of ART in resource-limited settings will require out-of-clinic solutions, with patient-clinic partnerships, in particular for patients who are stable on ART. Community-based approaches represent an important dimension in this approach.

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