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## The effect of Community ART Groups on retention-in-care among patients on ART in Tete Province, Mozambique: a cohort study

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1     **The effect of Community ART Groups on retention-in-care among patients on ART in Tete Province,**  
2     **Mozambique: a cohort study**

3     Tom Decroo<sup>1,a</sup>, Barbara Telfer<sup>1</sup>, Carla Das Does<sup>2</sup>, Richard A White<sup>3</sup>, Natacha Dos Santos<sup>1</sup>, Alec  
4     Mkwamba<sup>1</sup>, Sergio Dezembro<sup>1</sup>, Mariano Joffrisse<sup>1</sup>, Tom Ellman<sup>4</sup>, Carol Metcalf<sup>4</sup>

5     <sup>a</sup>Corresponding author : tomdecroo2@gmail.com

6     1 Médecins Sans Frontières, Tete, Mozambique

7     2 Direcção Provincial de Saúde Tete, Moçambique

8     3 Department of Infectious Disease Epidemiology and Modelling, Norwegian Institute of Public Health,  
9     Oslo, Norway

10    4 Médecins Sans Frontières, Southern Africa Medical Unit, Cape Town, South Africa

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## Abstract

**Objectives:** Estimate the effect of participation in Community ART Groups (CAG) versus individual care on retention-in-care on antiretroviral therapy (ART).

**Design:** Retrospective cohort study.

**Setting:** High levels of attrition (death or loss-to-follow-up (LTFU) combined) on ART indicate that delivery models need to adapt in sub-Saharan Africa. In 2008, patients more than six months on ART began forming CAG, and took turns to collect ART refills at the health facility, in Tete Province, Mozambique,.

**Participants:** 2406 adult patients, retained-in-care for at least six months after starting ART, during the study period (date of CAG introduction at the health facility-30 April 2012).

**Methods:** Data up to 30 April 2012 was collected from patient records at eight health facilities. Survival analysis was used to compare retention-in-care among patients in CAG and patients in individual care, with joining a CAG treated as an irreversible time-dependent variable. Multivariable Cox regression was used to estimate the effect of CAG on retention-in-care, adjusted for age, sex, and health facility type, and stratified by calendar cohort.

**Results:** Twelve-month and 24-month retention-in-care from the time of eligibility were respectively 89.5% and 82.3% among patients in individual care and 99.1% and 97.5% among those in CAGs ( $p < 0.0001$ ). CAG members had a greater than five-fold reduction in risk of dying or being lost-to-follow-up (adjusted hazard ratio [aHR]: 0.18, 95% CI: 0.11-0.29).

**Conclusions:** Among patients on ART, retention-in-care was substantially better among those in CAGs than those in individual care. This study confirms that patient-driven ART distribution through CAGs results in higher retention-in-care among patients who are stable on ART.

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36 **Key words:** HIV; community participation; health services accessibility; peer support; treatment outcome

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38 **Strengths and limitations of this study**

- 39 • Community ART Groups (CAG) were piloted first in Tete province, Mozambique. The effect of  
40 participation in CAG versus individual care on retention-in-care on ART was not yet assessed in  
41 this pilot project.
- 42 • A large number of patients, with diverse characteristics, were included in the analysis. The  
43 findings are representative of “real life” programmatic conditions.
- 44 • Another strength is that through our methodological approach we minimized the potential for  
45 survival bias by starting follow-up 6 months after ART initiation in order to exclude patients who  
46 had not yet stabilized on ART; and treating CAG status as a time-dependent variable to ensure  
47 that retention-in-care prior to joining a CAG was taken into account.
- 48 • However, the applied exclusion criteria may have resulted in some selection bias, making the  
49 findings less generalizable. Moreover, patients who opted to join a CAG and those who remained  
50 in individual care may have differed with respect to factors which we did not take into  
51 consideration in the analysis.

## Introduction

Currently an estimated 36.7 million people are living with HIV (PLHIV), of whom 17 million were on antiretroviral therapy (ART) at the end of 2015.<sup>1</sup> Will it be feasible to achieve the UNAIDS target of having 73% of all PLHIV on ART and virologically-suppressed by 2020? Such an unprecedented undertaking will require innovative approaches, especially in sub-Saharan Africa (SSA), where the HIV burden is the highest, and health workforce gaps and other challenges hamper response.<sup>2</sup> In addition, high levels of attrition (death or loss-to-follow-up (LTFU) combined) undermine the proven benefits of early treatment for individuals and the prevention of onward transmission of HIV.<sup>3</sup> A recent systematic review reported attrition rates in ART programs in African countries of 18%, 24%, and 31% after six months, one year, and two years of ART, respectively.<sup>3</sup> Distance to health facilities, transport costs, long waiting times at the health facilities, work responsibilities, and family commitments have been reported as reasons for defaulting treatment.<sup>4</sup> ART delivery closer to patients' homes is effective at improving retention-in-care.<sup>4</sup>

To enrol and retain millions of PLHIV on ART, health systems have had to adapt during the past decade. Several policies have been implemented to increase the capacity of understaffed health systems. Treatment has been decentralized from specialized HIV clinics to peripheral primary health care facilities.<sup>5</sup> Tasks have been shifted from doctors to nurses, from nurses to lay health-workers, and from lay health-workers to patients.<sup>6</sup> Additionally, in some countries delivery models have become increasingly patient-centered, allowing patients to combine lifelong ART refills with a normal social and economic life.<sup>4,7</sup>

Mozambique is one of the countries that have adopted a patient-centered ART delivery model. However, despite decentralization of ART provision, starting in 2006, LTFU rates remained unacceptably high.<sup>8,9</sup> Strategies, such as home visits to patients LTFU, had been unsuccessful in bringing patients back to

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76 care.<sup>10</sup> Patients reported long distances, lack of information, queuing at health facilities, and stigma  
77 associated with regular clinic attendance, as barriers to retention-in-care.<sup>11</sup>  
78 To overcome these barriers associated with the standard, clinic-based, individual-care approach to ART  
79 delivery, and drawing on published accounts of patient involvement in chronic disease care,<sup>12</sup> the Health  
80 Directorate of Tete Province and Médecins Sans Frontières proposed that clinically stable patients on  
81 ART be given the option of forming peer groups and becoming involved in ART delivery and monitoring.  
82 Patients on ART are given the option of joining a peer group, or remaining in clinic-based individual care,  
83 and can move between the two models of care, according to their preference. These peer groups are  
84 named Community ART Groups (CAGs). To join a CAG, patients are required to be at least 15 years old,  
85 and to have been on ART for at least six months, and to be stable on treatment. Each CAG has a  
86 maximum of six members. Members take turns to travel to the clinic to collect monthly ART refills for all  
87 group members. Every month, before the CAG representative attends the health facility to collect the  
88 ART refills, the group meets in their community to discuss each member's current health and treatment  
89 status and any travel plans. The CAG representative whose turn it is to collect the monthly ART refills has  
90 a clinical consultation and reports on the status of the other group members (retained on ART in the  
91 group, died, travelled, etc.). This information is recorded on a group monitoring card, which is kept in the  
92 clinic, and updated each month. CAG members are advised to make unscheduled visits to the health  
93 facility between ART refill appointments if they develop health problems, as do other patients who  
94 develop health problems during the intervals between scheduled appointments. Giving patients a high  
95 level of autonomy, the CAG model is the most patient-driven, community-based ART delivery model  
96 described to date.<sup>13</sup>  
97 The CAG model has previously been described in more detail.<sup>14</sup> CAG members reported several benefits  
98 including time and cost savings. They reported that less frequent clinic visits was associated with reduced

experiences of stigma in the community, and viewed the CAG as a protective environment where they could share treatment experiences confidentially. Patients considered counsellors, lay health-workers trained in the basics of HIV care and psychosocial care, to be approachable. These counsellors played an important role in forming and monitoring CAGs.<sup>15</sup> Four year retention-in-care was 92%.<sup>16</sup> Despite this high retention-in-care on ART among patients in CAGs, these previous studies did not assess the relative effectiveness of the CAG model and the standard, clinic-based, individual care approach in retaining patients on ART, in Tete province, where CAG were piloted. We conducted a study to estimate the effect of the CAG model relative to standard individual care, on retention-in-care among patients on ART.



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**Methods**

*Study design*

We conducted a retrospective cohort study using programme data.

*Study setting*

Mozambique has a population of 23.9 million inhabitants, of whom more than 70% live in rural areas.<sup>17</sup>

HIV prevalence among sexually-active people is estimated to be 10.5%. Over 1.5 million people in

Mozambique are living with HIV.<sup>18</sup> The government began providing ART in 2003.<sup>9</sup> Due to an extreme

shortage of human resources and limited infrastructure, it took more than a decade to attain 50% ART

coverage, according to the ART eligibility criteria in effect at the time. By the end of 2015, ART coverage

was about 53%.<sup>18</sup>

The rural Province of Tete, in Mozambique, has a population of two million. An estimated 36% of the

population has access to a health facility within 30 minutes of their home.<sup>17</sup> The province has 105 health

facilities, spread across 15 districts. By mid-2012 only 32 of the 105 (30.5%) facilities in Tete Province

offered ART.<sup>9</sup> Decentralization of ART provision towards peripheral clinics, in order to increase

accessibility of ART, has been hampered by infrastructural constraints, a shortage of medically-qualified

staff, organizational challenges, and a lack of regulation to push for task-shifting from nurses to lay

health-workers.<sup>19</sup>

Of the 32 facilities in Tete Province that were providing ART in 2012, 12 (37.5%) implemented the CAG

model in 2008 or 2009. Differences in the management of patients in standard individual care and those

in CAGs are summarized in Table 1.

## 128 *Study sites and population*

129 Of 12 health facilities that had implemented the CAG model by the end of 2009, eight (Manje, Changara,  
130 Songo, Chitima, Mutarara, Moatize, Zobue, and Boroma) were included in this study. The other four  
131 facilities were excluded because the majority of patients on ART (>80%) were enrolled in CAGs, leaving  
132 few patients in standard individual care to serve as a comparison group.

133 Patients included in the study were known to be 15 to 59 years of age at ART commencement and had  
134 started ART 6 or less months prior to or after the CAG model was introduced at the health facility . In  
135 order to minimize survival bias, patients who started ART more than 6 months before the CAG model  
136 was introduced at the health facility that they were attending, and patients who transferred to the  
137 health facility more than 6 months after starting ART, were excluded from the analysis. Patients younger  
138 than 15 years, 60 years and older, with an unknown age at ART initiation, were also excluded from the  
139 analysis. Patients who remained in care for less than 6 months after starting ART were excluded because  
140 patients are required to be stable on ART in order to be eligible to join a CAG, and mortality is highest in  
141 the first 6 months after starting ART.<sup>20,21</sup>

## 142 *Study period*

143 The start of the study period varied by health facility, starting on the date that the first CAGs were  
144 formed at the facility. Patients at all 8 study facilities were followed-up until the end of April 2012. For  
145 the purpose of this analysis, patients entered the cohort on the date on which they became eligible to  
146 join a CAG, defined as 6 months after starting ART.

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*Data collection and definition of variables*

Patient-files and clinic-held copies of CAG cards were used as data sources. Data was abstracted during the second half of 2012 and 2013, and entered into a Microsoft Access database. CAG monitoring tools and processes have been described elsewhere.<sup>14</sup>

The information collected included patient socio-demographic characteristics (sex, age at ART initiation, date of ART initiation, CD4 results, date of joining a CAG, and date of returning to individual care, if applicable), treatment outcomes and dates. The following treatment outcomes were recorded: retained-in-care at the end of the study period (30 April 2012), dead, lost to follow-up (LTFU), and transferred out. LTFU was defined as being more than 2 months overdue for the most recent appointment or scheduled ART refill. Health facilities were categorized as peri-urban or rural based on the geographical setting in which they are located. The two peri-urban facilities (Moatize and Songo) have medical specialists, a referral laboratory and radiology facilities available, and the rural facilities (Manje, Changara, Chitima, Mutarara, Zobue, and Boroma) are primary health care facilities run by nurses.

*Data analysis*

The analysis was performed using Stata Version 14 (StataCorp, College Station, Texas, USA).

Some numeric variables were categorized to facilitate the analysis. Median and interquartile ranges (IQR) were calculated for numeric variables and proportions for categorical variables.

Survival analysis was used to compare retention-in-care among patients in CAG and patients in individual care. Joining a CAG was treated as an irreversible time-dependent variable, with patients included in the “not in a CAG” group until they joined a CAG, and in the CAG group from the date that they joined a CAG. CAG members who returned to individual care (n = 11), were retained in the CAG group in the survival analyses. Univariable and multivariable Cox regression were used to estimate crude hazard ratios (HRs)

169 and adjusted hazard ratios (aHR) for attrition. The aHRs were adjusted for age, sex, and health facility  
170 type, and stratified by calendar period of ART initiation (six-month intervals).

171 Patients who remained in care at the end of the study period had their follow-up censored on 30 April,  
172 2012. Patients who were LTFU, or who died during the study period, were considered as having  
173 experienced the outcome event (attrition), with the outcome date defined as the most recent date of  
174 contact with the health facility, either in the form of an individual clinic visit, or an ART refill collected by  
175 another CAG member on the patient's behalf. Patients who were transferred to another facility were  
176 censored on the date of transfer.

### 177 *Ethics*

178 This study was approved by the Ethics Review Board of Médecins Sans Frontières (Geneva, Switzerland)  
179 and the Mozambican National Bioethics Committee (Comite Nacional De Bioetica para a Saúde).

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**Results**

During the study period, between 1 February 2008 and 30 April 2012, 9,266 patients were provided with ART in the eight health facilities. Of these patients, 2,406 were included in the analysis and 6,860 were excluded for reasons shown in Figure 1.

Of the 2,406 patients who satisfied the inclusion criteria, 901 (37.5%) joined a CAG during the study period (Table 2). Patients who joined a CAG were also more likely to be female (CAG: 70.3%; 631/901; non-CAG: 59.9%; 883/1505), and attending a rural clinic (CAG: 64.8%; 584/901; non-CAG: 57.3%; 862/1505). Patients who joined a CAG had a longer follow-up time (median: 26 months, IQR: 18 to 33 months) from the date that they entered the cohort and the end of the study (30 April 2012) than those who did not join a CAG (median: 16 months, IQR: 7 to 27 months).

CAG patients joined a CAG after a median of 8.3 (IQR 3.6 to 16.7) months from the time of eligibility (6 months after starting ART). Overall, 279 out of 2406 (12%) patients died or were LTFU by the end of the study period (30 April, 2012).

Overall, 12-month retention-in-care (RIC) from the date of eligibility was 90.8% (95%CI: 89.5% to 92.0%) and 24-month RIC was 86.0% (95%CI: 84.2% to 87.6%). RIC was significantly greater among patients in CAGs than those not in CAGs (stratified log-rank test:  $p < 0.0001$ ) (Figure 2). Twelve-month RIC was 99.1% (95% CI: 97.3 to 99.7%) among those in CAGs and 89.5% (95% CI: 87.9 to 90.8%) among those not in CAGs (Table 3).

Adjusted for age, gender, health facility type, and stratified by calendar period of ART initiation, patients in CAG had a more than five-fold lower rate of attrition (aHR: 0.18, 95% CI: 0.11 – 0.29) (Table 3). The risk of attrition was higher among patients younger than 25 years compared to those aged 30 – 39 years

202 (aHR: 1.65, 95%CI: 1.17 –2.32); and among males compared to females (aHR: 1.80, 95%CI: 1.41 – 2.30)

203 (Table 3).

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**Discussion**

We found that RIC among patients in CAGs was substantially higher than among patients in individual care. After adjustment for age, gender, health facility type, and after stratification by calendar period of ART initiation, patients in CAG were more than five times less at risk to die or to be LTFU. Other studies on RIC in CAG and individual care showed similar findings. Reports of high retention-in-care in CAG in Tete province informed CAG pilots, in Mozambique, and in Lesotho. The Mozambique national pilot showed 91.4% and 82.9% RIC in CAG and individual care, respectively. This study included patients from 68 health facilities in 7 different provinces (not Tete province), a mix of urban and rural, and high and low volume ART clinics.<sup>22</sup> The MSF supported pilot in Lesotho showed 98.7% and 90.2% RIC in CAG and individual care, respectively.<sup>23</sup>

Overall, 12-month RIC from the date of eligibility (6 months after starting ART) was 90.8% and 24-month RIC was 86.0%. These findings are similar to what is reported by other studies conducted in Mozambique. In a study conducted in rural Mozambique, two-year attrition among patients more than 12 months on ART was 16.2%.<sup>24</sup> Another Mozambican study showed late attrition rates (after 6 months on ART) of 15 patients per 100 person-years in urban clinics, and 23 patients per 100 person-years in rural clinics.<sup>8</sup> A systematic review analyzed data from eight Mozambican studies and found attrition of 17% at 6 months, 28% at 12 months, and 44% at 24 months.<sup>3</sup>

A strength of this study is the large number of patients, with diverse characteristics included in the analysis. Another strength is that all the study facilities gave patients the option between individual, clinic-based care and CAG, thus enabling the models of care to be compared under “real life” programmatic conditions. Therefore our findings are representative of the reality of the program in Tete. Another strength is our methodological approach. Patients entered the cohort after being on ART for 6 months, thus excluding patients who had not yet stabilized on ART. Among patients on ART, attrition has

228 been found to be highest immediately after ART initiation, gradually declining over the following year.<sup>3</sup>

229 We minimized the potential for survival bias by excluding patients who had started ART more than 6

230 months before CAGs were introduced at the facility; starting follow-up 6 months after ART initiation in

231 order to exclude patients who had not yet stabilized on ART; treating CAG status as a time-dependent

232 variable to ensure that retention-in-care prior to joining a CAG was taken into account; and stratifying

233 the Cox regression analyses by calendar period of entry into the cohort to take into account potential

234 interaction between CAG status and calendar period with respect to attrition. Finally, we adhered to the

235 STROBE guidelines for cohort studies.

236 However, there are also limitations to this study. The exclusion criteria that we chose may have resulted

237 in some selection bias, making the findings less generalizable. Moreover, patients who opted to join a

238 CAG and those who remained in individual care may have differed with respect to hidden confounding

239 factors which we did not take into consideration in the analysis. Potential confounders for which we

240 were unable to adjust in the analysis, due to a lack of data, include distance of the patients' homes from

241 the clinic, psychosocial characteristics, and health prognosticators such as CD4. There may thus be some

242 residual confounding in the estimated risk of attrition associated with CAG status and the other factors

243 (age, sex, facility type) that we considered in the analysis. Moreover, due to the very nature of the CAG

244 model as described in Table 1, ascertainment of being LTFU was likely more accurate among those in

245 CAG compared with those who remained in standard, individual care, which may have resulted in

246 measurement bias. Finally, we were unable to use viral suppression as an outcome because routine viral

247 load monitoring was not available during the study period. Although we found high retention-in-care

248 among patients in CAGs, we were unable to assess adherence to treatment. Further research is needed

249 to compare viral load outcomes of patients in CAGs and patients in individual care.



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3 250 The finding that attrition may be reduced by a patient-driven ART distribution model has important  
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5 251 implications, especially in rural contexts. The high retention-in-care among patients who joined CAGs can  
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8 252 be attributed to a combination of factors including: a reduced time spent travelling to and from the  
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10 253 facility and queuing at the facility; reduced health care-related transport costs; and enhanced  
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12 254 information-sharing within the community and between the community and health-care workers.<sup>15</sup> Peer  
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14 255 support and higher levels of self-efficacy have been identified as important enablers of successful  
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16 256 lifelong HIV care.<sup>25</sup> Peer support enhances utilization of health care services, and has a positive effect on  
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18 257 quality of life.<sup>26</sup> Rasschaert et al found that relationships between patients and healthcare providers  
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20 258 changed profoundly after the CAG model was implemented. CAG members were perceived by clinic and  
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22 259 community staff as co-providers because they took responsibility for medical tasks, served as a channel  
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24 260 of communication between community members and healthcare providers, and reduced the workload  
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26 261 of healthcare workers, especially in rural health facilities.<sup>27</sup>  
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31 262 In 2008, when the CAG model was introduced, clinicians and healthcare workers were concerned about  
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33 263 whether medical tasks such as ART distribution could be delegated to patients. The results of this study  
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35 264 confirm that ART distribution can be delegated to patients, and demonstrates that patients can take  
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37 265 responsibility for their lifelong HIV care, especially when supported by their peers. Earlier studies have  
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39 266 shown the benefit of involving patients in peer-to-peer activities without remuneration, including  
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41 267 counselling, tracing of patients LTFU, administrative tasks in health facilities, and income-generation  
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43 268 projects.<sup>28,29</sup> But none of these community-based ART delivery models was driven by the voluntary  
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45 269 engagement of PLHIV, motivated by their own health needs. Other community-based ART delivery  
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47 270 models in Uganda and Kenya, have introduced ART delivery to patients' homes by paid lay healthcare  
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49 271 workers, who are recognized and accountable as formal healthcare workers, and equipped with  
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51 272 motorbikes and cell phones.<sup>30-32</sup>  
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To achieve and sustain high ART coverage, health programs need to differentiate and adapt to the specific needs of different subgroups, including virologically suppressed patients on ART, clinically unstable patients, HIV/TB co-infected patients, and adolescents.<sup>33,34</sup> For those stable on ART less frequent clinic visits and out-of-clinic ART refill are recommended to reduce maximally the burdens on patients and rationalize the use of the scarce health workforce.<sup>35</sup>

Currently CAG are rolled out nationally in Mozambique, and in neighboring countries such as Lesotho, Zimbabwe, and Malawi.<sup>22,23</sup> In Tete Province the daily management of CAG strongly depended of facility-based lay counsellors.<sup>15,26</sup> Adaptation of this patient-driven delivery model, which was rooted in the rural community of central Mozambique, will be needed to be adapted to local contexts, needs of specific patient groups, available resources and national policies.

## Conclusion

RIC was substantially higher among patients on ART in CAG than among those in individual care. Exclusion of the first six months on ART from the follow-up period, and the exclusion of patients who had been on ART for more than 6 months at the time that CAGs became available at the facility that they were attending, reduced the potential for survival bias but, as the study was observational in design, residual or unmeasured confounders may have contributed to the differences observed. Nevertheless this study confirms that patient-driven ART distribution through CAGs results in high RIC, and supports the Mozambique Ministry of Health in rolling out CAG nationally.

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**Competing interests:** None declared.

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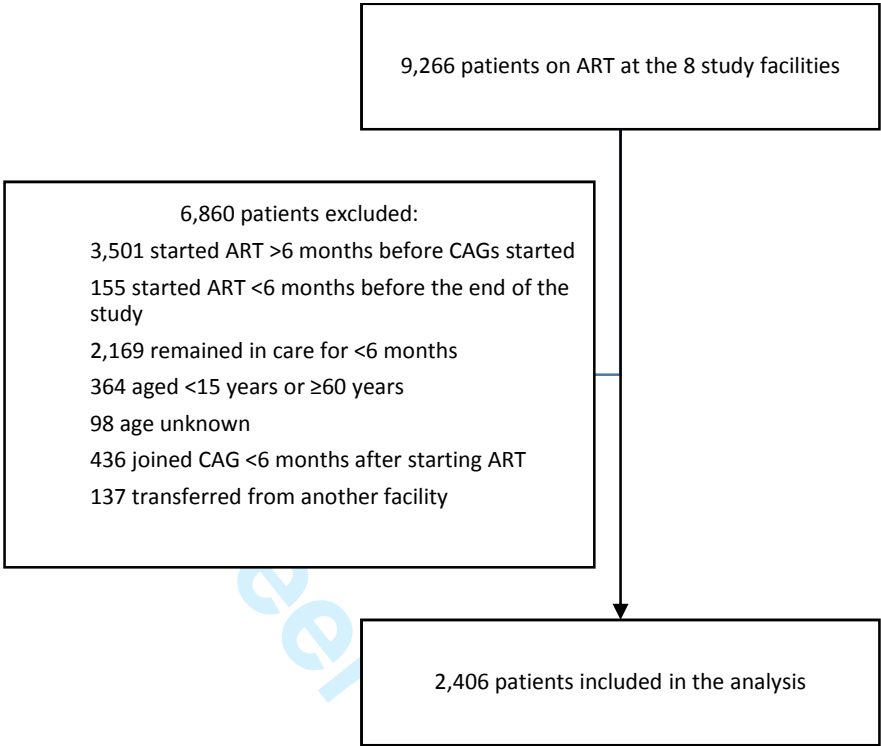
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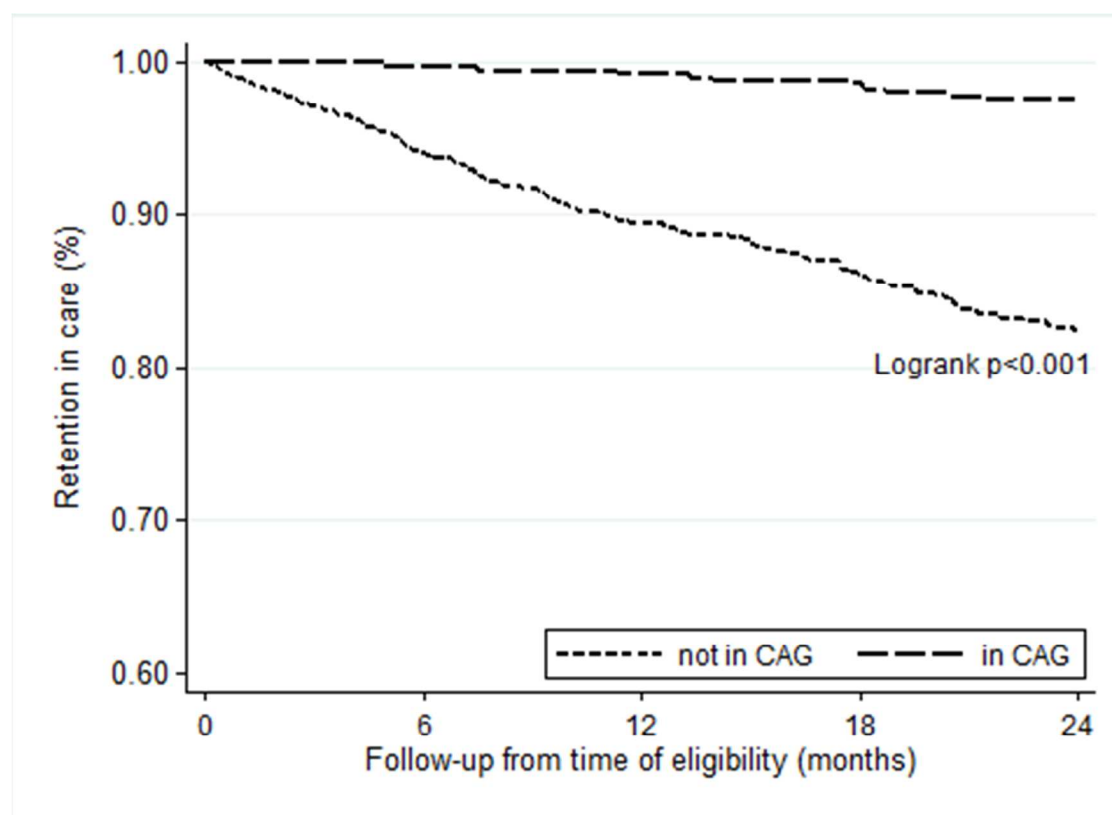


**Figure 1: Study flow diagram: inclusion of patients on ART in the study**



CAG: Community ART groups; ART: antiretroviral therapy

**Figure 2 Retention-in-care by CAG status among 2406 patients on ART, between 2008 and 2012, in Tete, Mozambique**



ART: antiretroviral therapy; CAG: Community ART Group

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Table 1. Description of individual clinic-based care and the CAG model, between 2008 and 2012, in Tete, Mozambique

	Individual clinic-based model	Community ART group model
Providers	Health authorities and clinicians	Health authorities, clinicians and patients
Location for ART delivery	Health facility	Health facility and community
Involvement of patient	Passive	Active
Target group	All patients with HIV	Patients stable on ART
Voluntary counselling and testing	Voluntary or referred by clinician	Voluntary or referred by clinician or CAG members
Pre-ART patients	No monitoring	Social network of CAG extends into broader community and creates link with pre-ART patients
ART Initiation	Clinical officer/ medical doctor	Clinical officer/ medical doctor
ART refill	All patients must come to the clinic monthly for ART refills, with/without a consultation by a nurse and/or counsellor. Stable patients have a consultation every 6 months.	One member of each CAG comes to the clinic monthly on a rotational basis, has a consultation with a nurse and/or counsellor, and collects ART refills for all members of the group
Indirect cost of ART	Each patient bears the cost of transport to/from the clinic Each month several hours in the queue	Cost of transport to/from the clinic shared among all members of the CAG One patient in queue for 6 CAG members. CAG representatives are prioritized, because they are perceived as co-providers
Monitoring of patients on ART	No monitoring of patients between clinic visits, no information on the health status or whereabouts of patients between clinic visits, or on their adherence to treatment	CAG members actively prevent loss to follow-up, and monitor the health status and whereabouts of group members through informal and formal monitoring, using a group card. Information on the status of all members in the group is reported monthly to the health facility by the CAG representative.
Active search (tracing and recapture)	When a patient is identified as late or lost to follow-up: <ul style="list-style-type: none"><li>No or few resources for tracing patients</li><li>Often the physical address of the patient is incorrect or missing</li><li>Distance to the house of the patient can be too far for physical tracing to be feasible</li></ul> Therefore true outcomes of patients LTFU are difficult to ascertain.	CAG members trace other group members in the community immediately if the member misses a meeting. Information is obtained through the social network of other patients, family, and neighbours. CAG members are usually aware when another group member is non-adherent or stops taking ART and can usually maintain contact with other members through family networks when travelling outside the area.
Reasons for non-adherence or LTFU	No systematic understanding or addressing of the problem	Reasons known in detail and systematically through the social network, and reported to the health care workers

ART: antiretroviral therapy; CAG: Community ART Group; LTFU: lost to follow-up

Table 2: Characteristics of patients included in the analysis, by CAG status

	Did not join a CAG	Joined a CAG	Total cohort
Total (n, column %)	1505 (100)	901 (100)	2406 (100)
Sex <sup>a</sup> (n, column %)			
Female	883 (59.9)	631 (70.3)	1514 (63.1)
Male	617 (41.1)	267 (29.7)	884 (36.9)
Age at ART initiation (years) (median, IQR)	32 (26 – 39)	33 (27 – 40)	32 (27 – 39)
Health facility type (n, column %)			
Peri-urban	643 (42.7)	317 (35.2)	960 (39.9)
Rural	862 (57.3)	584 (64.8)	1446 (60.1)

CAG: Community ART Group

<sup>a</sup> 8 (0.3%) patients did not have their sex recorded.

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415 Table 3: Retention in care from the time of eligibility to join a CAG, and factors associated with retention  
416 in care, among 2406 patients on ART, between 2008 and 2012, in Tete, Mozambique

Characteristic	12-month RIC % (95% CI)	24-month RIC % (95% CI)	HR (95% CI)	aHR (95% CI)
All (n = 2,406)	90.8 (89.5 – 92.0)	86.0 (84.2 – 87.6)	—	—
CAG status				
Not in a CAG (n = 2,406)	89.5 (87.9 – 90.8)	82.3 (79.9 – 84.5)	1.00 (reference)	1.00 (reference)
In a CAG (n = 901)	99.1 (97.3 – 99.7)	97.5 (95.4 – 98.6)	0.17 (0.10-0.28)	0.18 (0.11 – 0.19)
Age (years)				
15 – 24 (n = 371)	87.7 (83.5 – 90.9)	81.4 (75.9 – 85.8)	1.52 (1.09-2.11)	1.65 (1.17 – 2.32)
25 – 29 (n = 515)	92.7 (89.9 – 94.7)	87.1 (83.0 – 90.2)	0.98 (0.71-1.36)	1.04 (0.75 – 1.45)
30 – 39 (n = 945)	90.8 (88.6 – 92.6)	87.3 (84.6 – 89.6)	1.00 (reference)	1.00 (reference)
40 – 59 (n = 575)	91.2 (88.3 – 93.4)	85.8 (82.0 – 88.8)	1.09 (0.80-1.49)	0.98 (0.72 – 1.34)
Sex				
Female (n = 1,514)	92.4 (90.8 – 93.7)	88.9 (86.9 – 90.7)	1.00 (reference)	1.00 (reference)
Male (n = 854)	88.2 (85.6 – 90.3)	80.8 (77.4 – 83.8)	1.78 (1.41 – 2.26)	1.82 (1.42 – 2.33)
Facility type				
Peri-urban (n = 960)	90.9 (89.2 – 92.3)	85.6 (83.3 – 87.7)	1.00 (reference)	1.00 (reference)
Rural (n = 1,446)	90.8 (88.5 – 92.6)	86.6 (83.7 – 89.0)	0.97 (0.76 – 1.25)	0.90 (0.70 – 1.16)
Cohort				
2008 (n = 148)	93.1 (87.5 – 96.2)	88.0 (81.4 – 92.4)	1.00 (reference)	—
Jan – Jun 2009 (n = 229)	92.5 (88.1 – 95.2)	85.1 (79.7 – 89.2)	1.27 (0.77 – 2.10)	—
Jul – Dec 2009 (n = 389)	93.7 (90.8 – 95.7)	88.8 (85.1 – 91.6)	0.94 (0.57 – 1.56)	—
Jan – Jun 2010 (n = 352)	92.4 (89.0 – 94.8)	87.4 (83.3 – 90.5)	1.06 (0.63 – 1.78)	—
Jul – Dec 2010 (n = 382)	92.2 (88.9 – 94.5)	84.4 (80.2 – 87.8)	0.95 (0.55 – 1.64)	—

RIC: Retention in care; CI: Confidence interval; HR: Hazard ratio; Adjusted hazard ratio. Hazard ratios were adjusted for the other variables shown, and stratified by calendar cohort in 6-month categories;

<sup>a</sup> CAG status was a time-dependent variable. Patients were in the “not in CAG” group until they joined a CAG.

<sup>b</sup> Cohorts were defined as the semesters of each year within the study period (restricted to 2010 to allow for at least 12 months follow-up), and patients were categorized into each cohort by date at which they became eligible for the study (i.e. date at which they reached 6 months on ART). The multivariable Cox regression was stratified by cohort, so aHR's were not determined.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-10
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	8
		(b) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	5,6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9-10
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	9-10
		(b) Describe any methods used to examine subgroups and interactions	9-10
		(c) Explain how missing data were addressed	8
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11, Figure 1
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11, Table 2
		(b) Indicate number of participants with missing data for each variable of interest	Figure 1
		(c) Summarise follow-up time (eg, average and total amount)	11
Outcome data	15*	Report numbers of outcome events or summary measures over time	11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-12, Table 3
		(b) Report category boundaries when continuous variables were categorized	Table 2
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	13
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).



# BMJ Open

## The effect of Community ART Groups on retention-in-care among patients on ART in Tete Province, Mozambique: a cohort study

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<b>Primary Subject Heading</b>:	HIV/AIDS
Secondary Subject Heading:	Patient-centred medicine
Keywords:	HIV, community participation, health services accessibility, peer support, treatment outcome

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1     **The effect of Community ART Groups on retention-in-care among patients on ART in Tete Province,**  
2     **Mozambique: a cohort study**

3     Tom Decroo<sup>1,a</sup>, Barbara Telfer<sup>1</sup>, Carla Das Does<sup>2</sup>, Richard A White<sup>3</sup>, Natacha Dos Santos<sup>1</sup>, Alec  
4     Mkwamba<sup>1</sup>, Sergio Dezembro<sup>1</sup>, Mariano Joffrisse<sup>1</sup>, Tom Ellman<sup>4</sup>, Carol Metcalf<sup>4</sup>

5     <sup>a</sup>Corresponding author : tomdecroo2@gmail.com

6     1 Médecins Sans Frontières, Tete, Mozambique

7     2 Direcção Provincial de Saúde Tete, Moçambique

8     3 Department of Infectious Disease Epidemiology and Modelling, Norwegian Institute of Public Health,  
9     Oslo, Norway

10    4 Médecins Sans Frontières, Southern Africa Medical Unit, Cape Town, South Africa

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## Abstract

**Objectives:** Estimate the effect of participation in Community ART Groups (CAG) versus individual care on retention-in-care on antiretroviral therapy (ART).

**Design:** Retrospective cohort study.

**Setting:** High levels of attrition (death or loss-to-follow-up (LTFU) combined) on ART indicate that delivery models need to adapt in sub-Saharan Africa. In 2008, patients more than six months on ART began forming CAG, and took turns to collect ART refills at the health facility, in Tete Province, Mozambique,.

**Participants:** 2406 adult patients, retained-in-care for at least six months after starting ART, during the study period (date of CAG introduction at the health facility-30 April 2012).

**Methods:** Data up to 30 April 2012 was collected from patient records at eight health facilities. Survival analysis was used to compare retention-in-care among patients in CAG and patients in individual care, with joining a CAG treated as an irreversible time-dependent variable. Multivariable Cox regression was used to estimate the effect of CAG on retention-in-care, adjusted for age, sex, and health facility type, and stratified by calendar cohort.

**Results:** Twelve-month and 24-month retention-in-care from the time of eligibility were respectively 89.5% and 82.3% among patients in individual care and 99.1% and 97.5% among those in CAGs ( $p < 0.0001$ ). CAG members had a greater than five-fold reduction in risk of dying or being lost-to-follow-up (adjusted hazard ratio [aHR]: 0.18, 95% CI: 0.11-0.29).

**Conclusions:** Among patients on ART, retention-in-care was substantially better among those in CAGs than those in individual care. This study confirms that patient-driven ART distribution through CAGs results in higher retention-in-care among patients who are stable on ART.

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36 **Key words:** HIV; community participation; health services accessibility; peer support; treatment outcome

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38 **Strengths and limitations of this study**

- 39 • Community ART Groups (CAG) were piloted first in Tete province, Mozambique. The effect of  
40 participation in CAG versus individual care on retention-in-care on ART was not yet assessed in  
41 this pilot project.
- 42 • A large number of patients, with diverse characteristics, were included in the analysis. The  
43 findings are representative of “real life” programmatic conditions.
- 44 • Another strength is that through our methodological approach we minimized the potential for  
45 survival bias by a) starting follow-up 6 months after ART initiation in order to exclude patients  
46 who had not yet stabilized on ART, and b) treating CAG status as a time-dependent variable to  
47 ensure that retention-in-care prior to joining a CAG was taken into account.
- 48 • However, the applied exclusion criteria may have resulted in some selection bias, making the  
49 findings less generalizable. Moreover, patients who opted to join a CAG and those who remained  
50 in individual care may have differed with respect to factors which we did not take into  
51 consideration in the analysis.

## Introduction

Currently an estimated 36.7 million people are living with HIV (PLHIV), of whom 17 million were on antiretroviral therapy (ART) at the end of 2015.<sup>1</sup> The World Health Organization (WHO) endorses the 90-90-90 UNAIDS targets: by 2020, 90% of people living with HIV should know their HIV status. Of those, 90% should be on ART, and 90% of people on ART should be virologically suppressed. Or, when combined as a single indicator, 73% of all PLHIV should be virologically suppressed.<sup>2</sup>

Will it be feasible to achieve 73% of all PLHIV on ART and virologically-suppressed by 2020? Such an unprecedented undertaking will require innovative approaches, especially in sub-Saharan Africa (SSA), where the HIV burden is the highest, and health workforce gaps and other challenges hamper response.<sup>3</sup>

In addition, high levels of attrition (death or loss-to-follow-up (LTFU) combined) undermine the proven benefits of early treatment for individuals and the prevention of onward transmission of HIV.<sup>4</sup> A recent systematic review reported attrition rates in ART programs in African countries of 18%, 24%, and 31% after six months, one year, and two years of ART, respectively.<sup>4</sup> Distance to health facilities, transport costs, long waiting times at the health facilities, work responsibilities, and family commitments have been reported as reasons for defaulting treatment.<sup>5</sup> ART delivery closer to patients' homes is effective at improving retention-in-care.<sup>5</sup>

To enrol and retain millions of PLHIV on ART, health systems have had to adapt during the past decade. Several policies have been implemented to increase the capacity of understaffed health systems. Treatment has been decentralized from specialized HIV clinics to peripheral primary health care facilities.<sup>6</sup> Tasks have been shifted from doctors to nurses, from nurses to lay health-workers, and from lay health-workers to patients.<sup>7</sup> Additionally, in some countries delivery models have become increasingly patient-centered, allowing patients to combine lifelong ART refills with a normal social and economic life.<sup>5,8</sup>

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3 76 Mozambique is one of the countries that have adopted a patient-centered ART delivery model. However,  
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5 77 despite decentralization of ART provision, starting in 2006, LTFU rates remained unacceptably high. One  
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8 78 study showed an overall attrition rate of 37 per 100 person-years.<sup>9</sup> Another Mozambican study showed  
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10 79 that half of those who started ART were either dead or LTFU at 3 years follow-up.<sup>10</sup> Strategies, such as  
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12 80 home visits to patients LTFU, had been unsuccessful in bringing patients back to care.<sup>11</sup> Patients reported  
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14 81 long distances, lack of information, queuing at health facilities, and stigma associated with regular clinic  
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16 82 attendance, as barriers to retention-in-care.<sup>12</sup>  
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20 83 To overcome these barriers associated with the standard, clinic-based, individual-care approach to ART  
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22 84 delivery, and drawing on published accounts of patient involvement in chronic disease care,<sup>13</sup> the Health  
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24 85 Directorate of Tete Province and Médecins Sans Frontières proposed that clinically stable patients on  
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26 86 ART be given the option of forming peer groups and becoming involved in ART delivery and monitoring.  
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30 87 Patients on ART are given the option of joining a peer group, or remaining in clinic-based individual care,  
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32 88 and can move between the two models of care, according to their preference. These peer groups are  
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34 89 named Community ART Groups (CAGs). Giving patients a high level of autonomy, the CAG model is the  
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36 90 most patient-driven, community-based ART delivery model described to date.<sup>14</sup> Lay counsellors played  
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38 91 an important role in forming and monitoring CAGs.<sup>15</sup> The CAG model has previously been described in  
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40 92 more detail.<sup>16</sup>  
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45 93 Four year retention-in-care was 92%.<sup>17</sup> Despite this high retention-in-care on ART among patients in  
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47 94 CAGs, these previous studies did not assess the relative effectiveness of the CAG model and the  
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49 95 standard, clinic-based, individual care approach in retaining patients on ART, in Tete province, where  
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51 96 CAG were piloted. We conducted a study to estimate the effect of the CAG model relative to standard  
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53 97 individual care, on retention-in-care among patients on ART.  
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## 99 **Methods**

### 100 *Study design*

101 We conducted a retrospective cohort study using programme data.

### 102 *Study setting*

103 Mozambique has a population of 23.9 million inhabitants, of whom more than 70% live in rural areas.<sup>18</sup>

104 HIV prevalence among sexually-active people is estimated to be 10.5%. Over 1.5 million people in

105 Mozambique are living with HIV.<sup>19</sup> The government began providing ART in 2003.<sup>20</sup> By the end of 2015,

106 ART coverage was about 53%.<sup>19</sup>

107 The rural Province of Tete, in Mozambique, has 105 health facilities, spread across 15 districts. By mid-

108 2012 only 32 of the 105 (30.5%) facilities in Tete Province offered ART.<sup>20</sup> Decentralization of ART

109 provision towards peripheral clinics, in order to increase accessibility of ART, has been hampered by

110 infrastructural constraints, a shortage of medically-qualified staff, organizational challenges, and a lack of

111 regulation to push for task-shifting from nurses to lay health-workers.<sup>21</sup>

### 112 *Community ART Groups*

113 Community ART Groups (CAGs) are peer groups in which members take turns to travel to the clinic to

114 collect monthly ART refills for all group members. To join a CAG, patients are required to be at least 15

115 years old, and to have been on ART for at least six months, and to be stable on treatment. Each CAG has

116 a maximum of six members. Members take turns to travel to the clinic to collect monthly ART refills for

117 all group members. Every month, before the CAG representative attends the health facility to collect the

118 ART refills, the group meets in their community to discuss each member's current health and treatment

119 status and any travel plans. The CAG representative whose turn it is to collect the monthly ART refills has

120 a clinical consultation and reports on the status of the other group members (retained on ART in the

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3 121 group, died, travelled, etc.). This information is recorded on a group monitoring card, which is kept in the  
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5 122 clinic, and updated each month. The group monitoring card includes the name of the CAG, the names of  
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8 123 the CAG members, their ART regimen, and the monthly pill count.<sup>16</sup> CAG members are advised to make  
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10 124 unscheduled visits to the health facility between ART refill appointments if they develop health  
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12 125 problems, as do other patients who develop health problems during the intervals between scheduled  
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14 126 appointments.  
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18 127 Of the 32 facilities in Tete Province that were providing ART in 2012, 12 (37.5%) implemented the CAG  
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20 128 model in 2008 or 2009. Differences in the management of patients in standard individual care and those  
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22 129 in CAGs are summarized in Table 1.  
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26 130 *Study sites and population*  
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29 131 Of 12 health facilities that had implemented the CAG model by the end of 2009, eight (Manje, Changara,  
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31 132 Songo, Chitima, Mutarara, Moatize, Zobue, and Boroma) were included in this study. The other four  
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33 133 facilities were excluded because the majority of patients on ART (>80%) were enrolled in CAGs, leaving  
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35 134 few patients in standard individual care to serve as a comparison group.  
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39 135 Patients included in the study were known to be 15 to 59 years of age at ART commencement and had  
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41 136 started ART 6 or less months prior to or after the CAG model was introduced at the health facility. In  
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43 137 order to minimize survival bias, patients who started ART more than 6 months before the CAG model  
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45 138 was introduced at the health facility that they were attending, and patients who transferred to the  
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47 139 health facility more than 6 months after starting ART, were excluded from the analysis. Patients younger  
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49 140 than 15 years, 60 years and older, with an unknown age at ART initiation, were also excluded from the  
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51 141 analysis. Patients who remained in care for less than 6 months after starting ART were excluded because  
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53 142 patients are required to be stable on ART in order to be eligible to join a CAG, and mortality is highest in  
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55 143 the first 6 months after starting ART.<sup>22,23</sup>  
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## 144 *Study period*

145 The start of the study period varied by health facility, starting on the date that the first CAGs were  
146 formed at the facility. The CAG starting dates were respectively 23/08/2008, 24/09/2008, 10/10/2008,  
147 8/01/2009, 13/05/2009, 15/09/2009, 16/09/2009, and 14/12/2009 for health facility Zobue, Manje,  
148 Changara, Boroma, Moatize, Songo, Mutarara, and Chitima. Patients at all 8 study facilities were  
149 followed-up until the end of April 2012. For the purpose of this analysis, patients entered the cohort on  
150 the date on which they became eligible to join a CAG, defined as 6 months after starting ART.

## 151 *Data collection and definition of variables*

152 Patient-files and clinic-held copies of CAG cards were used as data sources. Data was abstracted during  
153 the second half of 2012 and 2013, and entered into a Microsoft Access database. CAG monitoring tools  
154 and processes have been described elsewhere.<sup>16</sup>

155 The information collected included patient socio-demographic characteristics (sex, age at ART initiation,  
156 date of ART initiation, CD4 results, date of joining a CAG, and date of returning to individual care, if  
157 applicable), treatment outcomes and dates. For patients in CAG the source for the treatment outcome  
158 and date was the CAG card and the patient-file. All other variables were solely retrieved from the  
159 patient-files. The following treatment outcomes were recorded: retained-in-care at the end of the study  
160 period (30 April 2012), dead, lost to follow-up (LTFU), and transferred out. LTFU was defined as being  
161 more than 2 months overdue for the most recent appointment or scheduled ART refill. Similarly, CAG  
162 members who didn't collect the scheduled ART refill within their CAG were defined as LTFU. Health  
163 facilities were categorized as peri-urban or rural based on the geographical setting in which they are  
164 located. The two peri-urban facilities (Moatize and Songo) have medical specialists, a referral laboratory  
165 and radiology facilities available, and the rural facilities (Manje, Changara, Chitima, Mutarara, Zobue, and  
166 Boroma) are primary health care facilities run by nurses.

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3 167 *Data analysis*  
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6 168 The analysis was performed using Stata Version 14 (StataCorp, College Station, Texas, USA).  
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9 169 Some numeric variables were categorized to facilitate the analysis. Median and interquartile ranges (IQR)  
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11 170 were calculated for numeric variables and proportions for categorical variables.  
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15 171 Survival analysis was used to compare retention-in-care among patients in CAG and patients in individual  
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17 172 care. Joining a CAG was treated as an irreversible time-dependent variable. Patients were “not in a CAG”,  
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19 173 until they joined a CAG, and “in a CAG” from the date that they joined a CAG. CAG members who  
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21 174 returned to individual care (n = 11), were retained in the CAG group in the survival analyses. Univariable  
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23 175 and multivariable Cox regression were used to estimate crude hazard ratios (HRs) and adjusted hazard  
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25 176 ratios (aHR) for attrition. The aHRs were adjusted for age, sex, and health facility type, and stratified by  
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27 177 cohort (calendar period of ART initiation, by six-month intervals). Cohorts were restricted to 2010 to  
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29 178 allow for at least 12 months follow-up.  
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34 179 Patients who remained in care at the end of the study period had their follow-up censored on 30 April,  
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36 180 2012. Patients who were LTFU, or who died during the study period, were considered as having  
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38 181 experienced the outcome event (attrition), with the outcome date defined as the most recent date of  
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40 182 contact with the health facility, either in the form of an individual clinic visit, or an ART refill collected by  
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42 183 another CAG member on the patient’s behalf. Patients who were transferred to another facility were  
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44 184 censored on the date of transfer.  
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49 185 *Ethics*  
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52 186 This study was approved by the Ethics Review Board of Médecins Sans Frontières (Geneva, Switzerland)  
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54 187 and the Mozambican National Bioethics Committee (Comite Nacional De Bioetica para a Saúde).  
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## Results

During the study period, between 1 February 2008 and 30 April 2012, 9,266 patients were provided with ART in the eight health facilities. Of these patients, 2,406 were included in the analysis and 6,860 were excluded for reasons shown in Figure 1.

Of the 2,406 patients who satisfied the inclusion criteria, 901 (37.5%) joined a CAG during the study period (Table 2). Patients who joined a CAG were also more likely to be female (CAG: 70.3%; 631/901; non-CAG: 59.9%; 883/1505), and attending a rural clinic (CAG: 64.8%; 584/901; non-CAG: 57.3%; 862/1505). Patients who joined a CAG had a longer follow-up time (median: 26 months, IQR: 18 to 33 months) from the date that they entered the cohort and the end of the study than those who did not join a CAG (median: 16 months, IQR: 7 to 27 months).

CAG patients joined a CAG after a median of 8.3 (IQR 3.6 to 16.7) months from the time of eligibility (6 months after starting ART). Overall, 279 out of 2406 (12%) patients died or were LTFU by the end of the study period.

Overall, 12-month retention-in-care (RIC) from the date of eligibility was 90.8% (95%CI: 89.5% to 92.0%) and 24-month RIC was 86.0% (95%CI: 84.2% to 87.6%). RIC was significantly greater among patients in CAGs than those not in CAGs (stratified log-rank test:  $p < 0.0001$ ) (Figure 2). Twelve-month RIC was 99.1% (95% CI: 97.3 to 99.7%) among those in CAGs and 89.5% (95% CI: 87.9 to 90.8%) among those not in CAGs (Table 3).

Adjusted for age, gender, health facility type, and stratified by calendar period of ART initiation, patients in CAG had a more than five-fold lower rate of attrition (aHR: 0.18, 95% CI: 0.11 – 0.29) (Table 3). The risk of attrition was higher among patients younger than 25 years compared to those aged 30 – 39 years

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210 (aHR: 1.65, 95%CI: 1.17 –2.32); and among males compared to females (aHR: 1.80, 95%CI: 1.41 – 2.30)  
211 (Table 3).  
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## Discussion

We found that RIC among patients in CAGs was substantially higher than among patients in individual care. After adjustment for age, gender, health facility type, and after stratification by calendar period of ART initiation, patients in CAG were more than five times less at risk to die or to be LTFU. Other studies on RIC in CAG and individual care showed similar findings. Reports of high retention-in-care in CAG in Tete province informed CAG pilots, in Mozambique, and in Lesotho. The Mozambique national pilot showed 91.4% and 82.9% RIC in CAG and individual care, respectively. This study included patients from 68 health facilities in 7 different provinces (not Tete province), a mix of urban and rural, and high and low volume ART clinics.<sup>24</sup> The MSF supported pilot in Lesotho showed 98.7% and 90.2% RIC in CAG and individual care, respectively.<sup>25</sup> CAG members reported several benefits including time and cost savings. They reported that less frequent clinic visits was associated with reduced experiences of stigma in the community, and viewed the CAG as a protective environment where they could share treatment experiences confidentially.<sup>15,25</sup>

Overall, 12-month RIC from the date of eligibility (6 months after starting ART) was 90.8% and 24-month RIC was 86.0%. These findings are similar to what is reported by other studies conducted in Mozambique. In a study conducted in rural Mozambique, two-year attrition among patients more than 12 months on ART was 16.2%.<sup>26</sup> Another Mozambican study showed late attrition rates (after 6 months on ART) of 15 patients per 100 person-years in urban clinics, and 23 patients per 100 person-years in rural clinics.<sup>9</sup> A systematic review analyzed data from eight Mozambican studies and found attrition of 17% at 6 months, 28% at 12 months, and 44% at 24 months.<sup>4</sup>

A strength of this study is the large number of patients, with diverse characteristics included in the analysis. Another strength is that all the study facilities gave patients the option between individual, clinic-based care and CAG, thus enabling the models of care to be compared under “real life”

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236 programmatic conditions. Therefore our findings are representative of the reality of the program in Tete.

237 Another strength is our methodological approach. Patients entered the cohort after being on ART for 6

238 months, thus excluding patients who had not yet stabilized on ART. Among patients on ART, attrition has

239 been found to be highest immediately after ART initiation, gradually declining over the following year.<sup>4</sup>

240 We minimized the potential for survival bias by excluding patients who had started ART more than 6

241 months before CAGs were introduced at the facility; starting follow-up 6 months after ART initiation in

242 order to exclude patients who had not yet stabilized on ART; treating CAG status as a time-dependent

243 variable to ensure that retention-in-care prior to joining a CAG was taken into account; and stratifying

244 the Cox regression analyses by calendar period of entry into the cohort to take into account potential

245 interaction between CAG status and calendar period with respect to attrition. Finally, we adhered to the

246 STROBE guidelines for cohort studies.

247 However, there are also limitations to this study. The exclusion criteria that we chose may have resulted

248 in some selection bias, making the findings less generalizable. Moreover, patients who opted to join a

249 CAG and those who remained in individual care may have differed with respect to hidden confounding

250 factors which we did not take into consideration in the analysis. Potential confounders for which we

251 were unable to adjust in the analysis, due to a lack of data, include distance of the patients' homes from

252 the clinic, psychosocial characteristics, and health prognosticators such as CD4. There may thus be some

253 residual confounding in the estimated risk of attrition associated with CAG status and the other factors

254 (age, sex, facility type) that we considered in the analysis. Moreover, due to the very nature of the CAG

255 model as described in Table 1, ascertainment of being LTFU was likely more accurate among those in

256 CAG compared with those who remained in standard, individual care, which may have resulted in

257 measurement bias. Finally, we were unable to use viral suppression as an outcome because routine viral

258 load monitoring was not available during the study period. Although we found high retention-in-care

among patients in CAGs, we were unable to assess adherence to treatment. Further research is needed to compare viral load outcomes of patients in CAGs and patients in individual care.

The finding that attrition may be reduced by a patient-driven ART distribution model has important implications, especially in rural contexts. The high retention-in-care among patients who joined CAGs can be attributed to a combination of factors including: a reduced time spent travelling to and from the facility and queuing at the facility; reduced health care-related transport costs; and enhanced information-sharing within the community and between the community and health-care workers.<sup>15</sup> Peer support and higher levels of self-efficacy have been identified as important enablers of successful lifelong HIV care.<sup>27</sup> Peer support enhances utilization of health care services, and has a positive effect on quality of life.<sup>28</sup> Rasschaert et al found that relationships between patients and healthcare providers changed profoundly after the CAG model was implemented. CAG members were perceived by clinic and community staff as co-providers because they took responsibility for medical tasks, served as a channel of communication between community members and healthcare providers, and reduced the workload of healthcare workers, especially in rural health facilities.<sup>29</sup>

In 2008, when the CAG model was introduced, clinicians and healthcare workers were concerned about whether medical tasks such as ART distribution could be delegated to patients. The results of this study confirm that ART distribution can be delegated to patients, and demonstrates that patients can take responsibility for their lifelong HIV care, especially when supported by their peers. Earlier studies have shown the benefit of involving patients in peer-to-peer activities without remuneration, including counselling, tracing of patients LTFU, administrative tasks in health facilities, and income-generation projects.<sup>30,31</sup> But none of these community-based ART delivery models was driven by the voluntary engagement of PLHIV, motivated by their own health needs. Other community-based ART delivery models in Uganda and Kenya, have introduced ART delivery to patients' homes by paid lay healthcare

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3 282 workers, who are recognized and accountable as formal healthcare workers, and equipped with  
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5 283 motorbikes and cell phones.<sup>32-34</sup>  
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9 284 To achieve and sustain high ART coverage, health programs need to differentiate and adapt to the  
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11 285 specific needs of different subgroups, including virologically suppressed patients on ART, clinically  
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13 286 unstable patients, HIV/TB co-infected patients, and adolescents.<sup>35-36</sup> For those stable on ART less  
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15 287 frequent clinic visits and out-of-clinic ART refill are recommended to reduce maximally the burdens on  
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17 288 patients and rationalize the use of the scarce health workforce.<sup>37</sup>  
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21 289 Currently CAG are rolled out nationally in Mozambique, and in neighbouring countries such as Lesotho,  
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23 290 Zimbabwe, and Malawi.<sup>24-25</sup> In Tete Province the daily management of CAG strongly depended of facility-  
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25 291 based lay counsellors.<sup>15,29</sup> Adaptation of this patient-driven delivery model, which was rooted in the rural  
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28 292 community of central Mozambique, will be needed to be adapted to local contexts, needs of specific  
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30 293 patient groups, available resources and national policies.  
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33 294 **Conclusion**  
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36 295 RIC was substantially higher among patients on ART in CAG than among those in individual care.  
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38 296 Exclusion of the first six months on ART from the follow-up period, and the exclusion of patients who had  
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40 297 been on ART for more than 6 months at the time that CAGs became available at the facility that they  
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42 298 were attending, reduced the potential for survival bias but, as the study was observational in design,  
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44 299 residual or unmeasured confounders may have contributed to the differences observed. Nevertheless  
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46 300 this study confirms that patient-driven ART distribution through CAGs results in high RIC, and supports  
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48 301 the Mozambique Ministry of Health in rolling out CAG nationally.  
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**Ethics approval:** This study was approved by the Ethics Review Board of Médecins Sans Frontières (Geneva, Switzerland) and the Mozambican National Bioethics Committee (Comite Nacional De Bioetica para a Saúde).

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411 **Figure 1: Study flow diagram: inclusion of patients on ART in the study**

412 (Uploaded separately)

413 CAG: Community ART groups; ART: antiretroviral therapy

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416 **Figure 2 Retention-in-care by CAG status among 2406 patients on ART, between 2008 and 2012, in**  
417 **Tete, Mozambique**

418 (Uploaded separately)

419 ART: antiretroviral therapy; CAG: Community ART Group

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422 Table 1. Description of individual clinic-based care and the CAG model, between 2008 and 2012, in Tete,  
423 Mozambique

	Individual clinic-based model	Community ART group model
Providers	Health authorities and clinicians	Health authorities, clinicians and patients
Location for ART delivery	Health facility	Health facility and community
Involvement of patient	Passive	Active
Target group	All patients with HIV	Patients stable on ART
Voluntary counselling and testing	Voluntary or referred by clinician	Voluntary or referred by clinician or CAG members
Pre-ART patients	No monitoring	Social network of CAG extends into broader community and creates link with pre-ART patients
ART Initiation	Clinical officer/ medical doctor	Clinical officer/ medical doctor
ART refill	All patients must come to the clinic monthly for ART refills, with/without a consultation by a nurse and/or counsellor. Stable patients have a consultation every 6 months.	One member of each CAG comes to the clinic monthly on a rotational basis, has a consultation with a nurse and/or counsellor, and collects ART refills for all members of the group
Indirect cost of ART	Each patient bears the cost of transport to/from the clinic Each month several hours in the queue	Cost of transport to/from the clinic shared among all members of the CAG One patient in queue for 6 CAG members. CAG representatives are prioritized, because they are perceived as co-providers
Monitoring of patients on ART	No monitoring of patients between clinic visits, no information on the health status or whereabouts of patients between clinic visits, or on their adherence to treatment	CAG members actively prevent loss to follow-up, and monitor the health status and whereabouts of group members through informal and formal monitoring, using a group card. Information on the status of all members in the group is reported monthly to the health facility by the CAG representative. Periodically meetings between CAG members and counsellors are held either in the community or the health facility, which help to ascertain treatment outcomes.
Active search (tracing and recapture)	When a patient is identified as late or lost to follow-up: <ul style="list-style-type: none"><li>No or few resources for tracing patients</li><li>Often the physical address of the patient is incorrect or missing</li><li>Distance to the house of the patient can be too far for physical tracing to be feasible</li></ul> Therefore true outcomes of patients LTFU are difficult to ascertain.	CAG members trace other group members in the community immediately if the member misses a meeting. Information is obtained through the social network of other patients, family, and neighbours. CAG members are usually aware when another group member is non-adherent or stops taking ART and can usually maintain contact with other members through family networks when travelling outside the area.
Reasons for non-adherence or LTFU	No systematic understanding or addressing of the problem	Reasons known in detail and systematically through the social network, and reported to the health care workers

424 ART: antiretroviral therapy; CAG: Community ART Group; LTFU: lost to follow-up

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Table 2: Characteristics of patients included in the analysis, by CAG status

	Did not join a CAG	Joined a CAG	Total cohort
Total (n, column %)	1505 (100)	901 (100)	2406 (100)
Sex <sup>a</sup> (n, column %)			
Female	883 (59.9)	631 (70.3)	1514 (63.1)
Male	617 (41.1)	267 (29.7)	884 (36.9)
Age at ART initiation (years) (median, IQR)	32 (26 – 39)	33 (27 – 40)	32 (27 – 39)
Health facility type (n, column %)			
Peri-urban	643 (42.7)	317 (35.2)	960 (39.9)
Rural	862 (57.3)	584 (64.8)	1446 (60.1)

CAG: Community ART Group

<sup>a</sup> 8 (0.3%) patients did not have their sex recorded.

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432 Table 3: Retention in care from the time of eligibility to join a CAG, and factors associated with retention  
433 in care, among 2406 patients on ART, between 2008 and 2012, in Tete, Mozambique

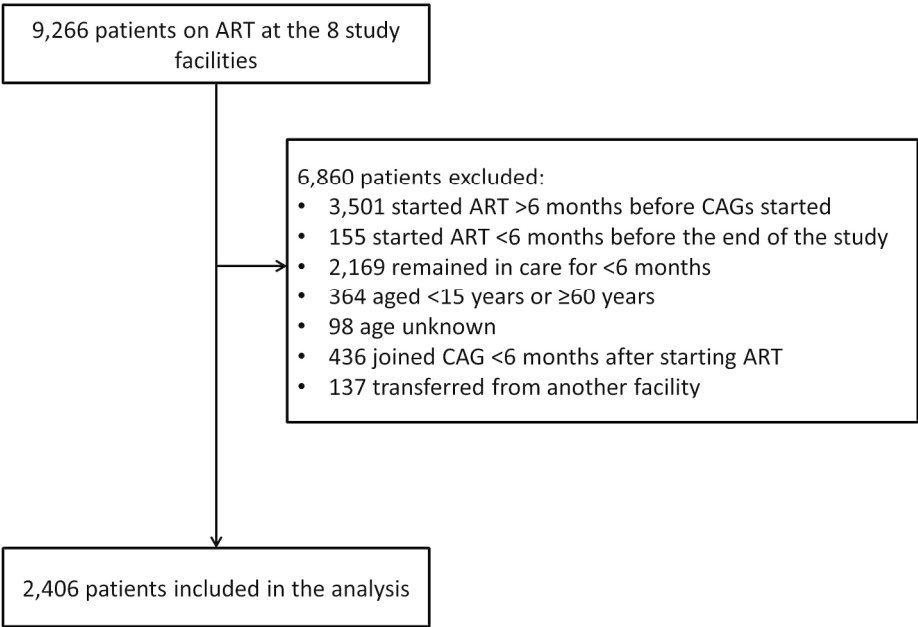
Characteristic	12-month RIC % (95% CI)	24-month RIC % (95% CI)	HR (95% CI)	aHR (95% CI)
All (n = 2,406)	90.8 (89.5 – 92.0)	86.0 (84.2 – 87.6)	—	—
CAG status				
Not in a CAG (n = 2,406)	89.5 (87.9 – 90.8)	82.3 (79.9 – 84.5)	1.00 (reference)	1.00 (reference)
In a CAG (n = 901)	99.1 (97.3 – 99.7)	97.5 (95.4 – 98.6)	0.17 (0.10-0.28)	0.18 (0.11 – 0.19)
Age (years)				
15 – 24 (n = 371)	87.7 (83.5 – 90.9)	81.4 (75.9 – 85.8)	1.52 (1.09-2.11)	1.65 (1.17 – 2.32)
25 – 29 (n = 515)	92.7 (89.9 – 94.7)	87.1 (83.0 – 90.2)	0.98 (0.71-1.36)	1.04 (0.75 – 1.45)
30 – 39 (n = 945)	90.8 (88.6 – 92.6)	87.3 (84.6 – 89.6)	1.00 (reference)	1.00 (reference)
40 – 59 (n = 575)	91.2 (88.3 – 93.4)	85.8 (82.0 – 88.8)	1.09 (0.80-1.49)	0.98 (0.72 – 1.34)
Sex				
Female (n = 1,514)	92.4 (90.8 – 93.7)	88.9 (86.9 – 90.7)	1.00 (reference)	1.00 (reference)
Male (n = 854)	88.2 (85.6 – 90.3)	80.8 (77.4 – 83.8)	1.78 (1.41 – 2.26)	1.82 (1.42 – 2.33)
Facility type				
Peri-urban (n = 960)	90.9 (89.2 – 92.3)	85.6 (83.3 – 87.7)	1.00 (reference)	1.00 (reference)
Rural (n = 1,446)	90.8 (88.5 – 92.6)	86.6 (83.7 – 89.0)	0.97 (0.76 – 1.25)	0.90 (0.70 – 1.16)
Cohort				
2008 (n = 148)	93.1 (87.5 – 96.2)	88.0 (81.4 – 92.4)	1.00 (reference)	—
Jan – Jun 2009 (n = 229)	92.5 (88.1 – 95.2)	85.1 (79.7 – 89.2)	1.27 (0.77 – 2.10)	—
Jul – Dec 2009 (n = 389)	93.7 (90.8 – 95.7)	88.8 (85.1 – 91.6)	0.94 (0.57 – 1.56)	—
Jan – Jun 2010 (n = 352)	92.4 (89.0 – 94.8)	87.4 (83.3 – 90.5)	1.06 (0.63 – 1.78)	—
Jul – Dec 2010 (n = 382)	92.2 (88.9 – 94.5)	84.4 (80.2 – 87.8)	0.95 (0.55 – 1.64)	—

RIC: Retention in care; CI: Confidence interval; HR: Hazard ratio; Adjusted hazard ratio. Hazard ratios were adjusted for the other variables shown, and stratified by calendar cohort in 6-month categories;

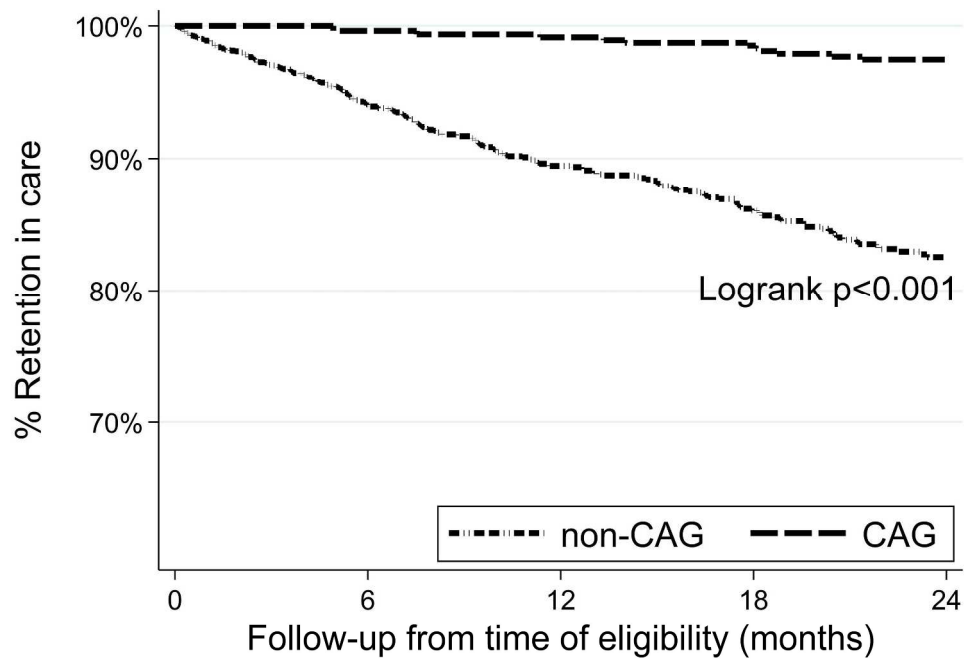
<sup>a</sup> CAG status was a time-dependent variable. Patients were in the “not in CAG” group until they joined a CAG.

<sup>b</sup> Cohorts were defined as the semesters of each year within the study period (restricted to 2010 to allow for at least 12 months follow-up), and patients were categorized into each cohort by date at which they became eligible for the study (i.e. date at which they reached 6 months on ART). The multivariable Cox regression was stratified by cohort, so aHR's were not determined.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-10
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	8
		(b) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	5,6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9-10
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	9-10
		(b) Describe any methods used to examine subgroups and interactions	9-10
		(c) Explain how missing data were addressed	8
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11, Figure 1
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11, Table 2
		(b) Indicate number of participants with missing data for each variable of interest	Figure 1
		(c) Summarise follow-up time (eg, average and total amount)	11
Outcome data	15*	Report numbers of outcome events or summary measures over time	11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-12, Table 3
		(b) Report category boundaries when continuous variables were categorized	Table 2
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	13
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).