

## Lost to follow up and clinical outcomes of HIV adult patients on antiretroviral therapy in care and treatment centres in Tanga City, north-eastern Tanzania

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**Abstract:** Scaling up of Antiretroviral (ARV) drugs is crucial and should be a perpetual venture in developing countries in-order to increase the survival period of HIV/AIDS individuals. In Tanzania, information on the rate of patients considered as lost to follow up during treatment with ARVs is scarce. The objective of this study was to determine the rate of lost to follow up and treatment outcome among patients attending two care and treatment clinics (CTCs) in Tanga City in north-eastern Tanzania. A descriptive observational study was carried out on cohorts from Tanga AIDS Working Group and Bombo Regional Hospital. The total number of patients identified as "lost to follow up" were 89 of which 14 (15.7%) died. Among those who died, 3 (21.4%) died between the second week and 3 months after ARV initiation. Of those still alive (84.3%; 75/89), 25% (19/75) were still on ARVs, whereas 47 (62.7%) self transferred to other CTCs. Proper patient documentation with actual residence address is a crucial aspect for adherence. Similarly, frequent prompt tracing of patient should be part of any drug interventional programme linking facility and communities.

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**Key words:** Lost to follow up, clinical outcomes, HIV, antiretroviral therapy, Tanzania

### Introduction

To attain retention of patients in the treatment programmes, adherence to therapy is an important aspect. However, little attention has been paid on this aspect especially in East Africa countries (Mugusi *et al.*, 2002; Karcher *et al.*, 2007). Scaling up of antiretroviral therapy (ART) is crucial and should be a perpetual venture in the developing countries in-order to increase the survival period of HIV/AIDS victims (Matida *et al.*, 2007). Following the introduction of ARTs in 1995 a total of 2.5 million deaths have been averted in low and middle income countries (UNAIDS, 2011). Existing data show that, there are 34 million people living with HIV worldwide, majority of them are from Sub-Saharan Africa (UNAIDS, 2011). It has been shown in some studies that, the outcome of ART in care and treatment centres (CTC) in the developing world has been better compared with those reported in developed countries (Calmy *et al.*, 2006; Wools-Kaloustian *et al.*, 2006; Braitstein *et al.*, 2006). However, in some studies it has been reported that, there has not been a difference between these two settings in terms of ART outcome in treatment and care centres (Braitstein *et al.*, 2006). On the other hand, it has been shown that, mortalities triggered by HIV-1 infections in low-income countries have been higher than high income countries (Egger *et al.*, 2006).

A number of ART programmes have used different modalities to classify attrition of patients from antiretroviral treatment. Some of these modalities included death of patients as "loss to follow-up", whereas in other studies they were reported as early mortalities (Karcher *et*

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*al.*, 2007). It is important to catch all types of patients who missed scheduled clinic visits or medication pickups for specific period of time. Some patients remain in the programmes but stop taking ART (Fox & Rosen, 2010) while others can be transferred to other facilities and continue to take ART (Mocroft *et al.*, 1997). In accordance with criteria set by each clinic, patients are classified as lost to follow-up (LTFU) if they have not attended scheduled clinic for two or more consecutive visits (Rosen *et al.*, 2007) or did not attend completely for at least two or three months ("drop out") (Calmy *et al.*, 2006; Ferradini *et al.*, 2006). Whereas in Tanzania according to the National AIDS Control Programme these patients are classified as LTFU if two-to-three attempts to track them failed within three months (NACP, 2005). It has been observed that the rates of patients LTFU varies between different CTCs, ranging from 5% (Calmy *et al.*, 2006) to 25% (Wools-Kaloustian *et al.*, 2006). On the other hand, in Tanzania a program known as *TUNAJALI* (literary meaning "We Care") has shown that a facility with over 5,000 patients on ART were reported to have LTFU of between 30-40% of the enrolled patient (Mpangile *et al.*, 2010). Observations in three ART programme clinics, one each in Africa, Asia and South America, with active follow-up did experience a lower proportion of LTFU of 12% in the first year. For those programmes without active follow-up a higher proportion of 19% LTFU (Braitstein *et al.*, 2006) has been observed.

Tanzania is among the resource constraints countries with an estimated population of about 43.6 million people of which 1.4 million are living with HIV/AIDS, 70.5% being of age 25-49 and 15% being 15-24 years old (UNAIDS, 2011). By December 2010, a total of 740,040 people living with HIV (PLHIV) had been enrolled at 11,000 health facilities countrywide, and 76.2% of 440,000 eligible clients are on ART (NACP, 2012). Thus, in order to get the benefits of ART there is a need for more efforts to reduce LTFU of patients on ART so that early death, high morbidity and drug resistance are minimized or stopped in Tanzania. In this study, therefore, we analyzed the LTFU and treatment outcomes of patients between two care and treatment clinics during a period of 12 months, of follow up post ART initiation. This would enable proper documentation of the magnitude of problem of LTFU and treatment outcome in order to assist policy markers and programme managers addressing the challenges encountered in LTFU of patients on ART care and treatment programmes.

## **Materials and Methods**

### ***Study area and patients***

This descriptive and observational study was conducted at two adjacent care and treatment centres (CTC), namely the Tanga AIDS Working Group (TAWG=I) and Bombo Regional Hospital (BRHT=II) in Tanga City of north-eastern Tanzania. Data collection was effected between June 2006 and July 2008. Study participants came within the realms of Tanga City, namely Sahare, Mikanjuni, Ngamiani, Mabawa, Majengo, Nguvumali and Pongwe. The participants were recruited upon consent and after fulfilling the criteria for receiving ART, according to the National AIDS Clinical Management Guidelines (NACP, 2009). Only those with CD4 cell counts below 200/ $\mu$ l and not taking ART were included in this study. Follow up was conducted on monthly basis for a period of 12 months during which clinical and laboratory

assessments were performed together with collection of ART by the study participants. A fixed drug combination regimen was provided for a period of 2 weeks as tolerance test, and thereafter a full monthly therapeutic course was prescribed according to individual's body weight.

For this study, lost to follow up is defined as patient has not attended scheduled clinic for three months consecutively and their vital status is unknown. At the same time, two-three attempts to track those patients have failed. For this study clinical outcome is defined as treatment outcome, and includes CD4 T Lymphocytes, CD8 T lymphocytes, haemoglobin levels, body weight and death.

#### ***Follow up procedures by counsellor nurses***

Study participants were provided with a blue identity (ID) card to produce every time they visit the clinic and another card for the prescription of ART drugs, clinic dates and monitoring through the drug facility register provided by the Ministry of Health and Social Welfare. At baseline, counsellor nurses and area community assistants were provided with client ID and area residential numbers and where possible house numbers. The purposes were to help weekly follow up to collect adverse drug events and clinical assessment.

#### ***Data collection***

Data were collected on structured questionnaires and entered into a computer and managed using Microsoft Access 2003. Then the data were imported into STATA version 8.0 software programme for analysis. Patients from TAWG (CTC I) and Bombo Regional Hospital (CTC II) were compared.  $\chi^2$  test with relative risks (RR) and 95% confidence intervals (CI) were used for clinical /treatment outcomes, and the student's t-test was used for time periods between start of ARV, LTFU and patient tracing, with differences at the level of 0.05 considered as significant.

#### ***Ethical consideration***

Ethical clearance of the study was approved by the Medical Research Coordinating Committee of the National Institute for Medical Research. Informed consents both oral and written were obtained from study participants.

#### **Results**

A total of 155 individuals were recruited from both care and treatment centres during the study period. Registration of patients began at CTC I between March 2006 and May 2008 after establishing ARV treatment programme. The services were later extended to CTC II. 106 (68.4%) and 49 (31.6%) patients were recruited from CTC I and CTC II respectively. During the follow up period, 89 (57.4%) patients were reported to have lost to follow-up from the study with high proportion being females 58 (65.2%) as compared to males 31(34.8%). However, this loss to follow up was not statistically significant ( $P=0.5$ ) among males and females. Of the studied individuals, 57.3% (51/89) were from CTC I, and 42.7% (38/89) were from CTC II. There was high rate of lost to follow up at CTC II as compared to CTC I (Table 1). It was observed that,

individuals who enrolled at CTC II were four times more likely to lost to follow-up as compared to those enrolled at CTC I (Odds 4.1, 95%CI: 1.74-9.83,  $P<0.001$ ).

**Table 1: Characteristics and outcome status of study cohort who were categorized as lost to follow-up between the two CTCs clinics**

Variable	TAWG	Bombo
Patient initiated ARV	106 (68.4%)	49 (31.6%)
Age(median, IQR)	37.9 (33.9 - 51.0)	37.4 (32. - 43)
No. of patient dropped out/lost to follow up	51 (57.3%)	38 (42.7%)
Mean(95%CI) time between starting ARV and diagnosis of loss to follow up in months	1.2 (0.1 - 1.4)	1.0 (1.0 - 1.1)
Median( range) time between Diagnosis of lost to follow up and home visits in months	0.9	1.7
Actual outcome status at the lost to follow up tracing visit of alive	41	34
Alive on ARV at the same clinic	0 (0.0)	0 (0.0)
Alive on ARV at different clinics	10 (24.4%)	9 (26.5%)
Alive but had stopped ARV	1 (2.4%)	3 (8.8%)

Key: ARV =antiretroviral therapy

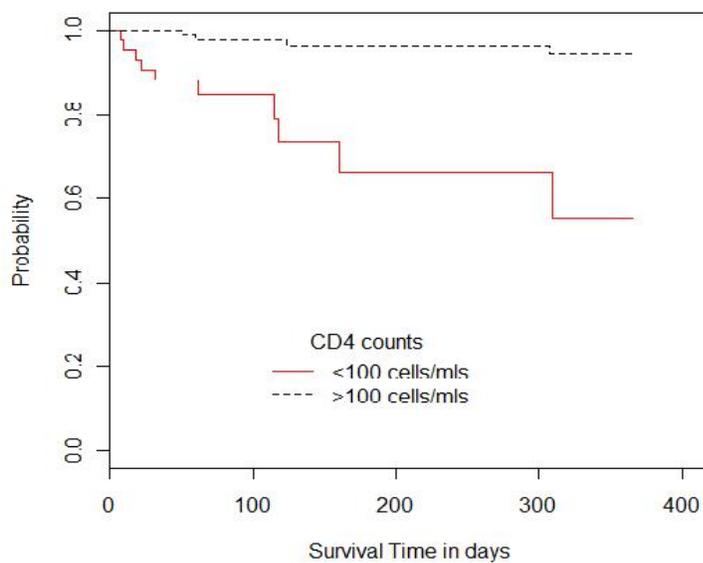
There was a statistical significance difference between the number of individuals LTFU at CTC II and CTC I ( $P =0.0002$ ) with OR of 0.21 at 95% (CI 0.15-0.52). It was observed that, in all LTFU, the mean time between start of ARV and date of LTFU was 1.2 (0.1-1.4) for CTC I while that for CTC II was 1.0 (0.1-1.4) months. On the other hand, the date between the LTFU and home visiting, the median time was 0.9 and 1.7 months for CTCs I and for II, respectively. The general median with inter-quintile range (IQR) time between initiation of ARV and LTFU for both males and females was 1.3 months (range 1.0-2.0 months). The major reason for LTFU observed was death, with 11 (21.6%) from CTC I and 3 (7.9%) from CTC II. However, the median time between initiation of ARV and death was 1.2 months. Seventy five (84.3%) of the LTFU were still alive; and 47(62.7%) of them had moved/transferred themselves to another CTC elsewhere without prior information to the clinic where they were registered initially. On the other hand about 6 (15.0%) and 3 (8.6%) individuals in CTC I and II, respectively had stopped ARV treatment. The reasons stopping of ARV from the 9 patients included the high bus fare to the health facility (2 patients; 22.2%) spiritual believe that were "served" and cured of the HIV/AIDS (3 patient; 33.3%) and changed ARV into local herbs (4 patients; 44.4%). The time between lost to follow up and home visits was significantly longer for patients recruited at CTC II than those recruited at CTC I ( $P<0.002$ ).

Although the number of patients recruited at CTC II were fewer than those recruited at CTC I, it appears that, the latter patients were more immune-compromised with low CD4 and CD8 T lymphocytes as compared to those of CTC I (Table 2). However, the haemoglobin levels of the two groups were similar at recruitment period [ $t=0.3$ ;  $P =0.733$ ] (Table 2). The same pattern was observed with body mass index of the two groups.

**Table 2: Bio-characteristic features of individuals who lost to follow up**

Variable	TAWG (CTC I)	BRHT (CTC II)
Total lost to follow up	51 (57.3%)	38(42.7%)
CD4 ,mean(95% CI)	177(113-240.4)	123(67.2-180.5)
CD8 ,mean(95% CI)	1069(684-1455)	725(538-913)
Haemoglobin(SD)	9.9(9.1-10.6)	9.8(8.7-10.8)
Mass body w index(BMI)	19(4.1)	18.6(2.8)
Sex ratio (Male: Female)	0.8:1	0.4:1

Survival-rate as estimated by the Kaplan-Meier survival analysis has shown a survival benefit among individuals on ART with CD4 (>100 cell/ $\mu$ l) ( $P<0.001$ ) at enrolment period (Figure 1). Similar pattern of survival benefit was observed among individuals with haemoglobin ( $\geq 11$ g/dL) at recruitment ( $P=0.003$ ) also (Figure 2).



**Figure 1: Survivorships among the individuals with CD4 counts (<100 and >100) at enrolment**

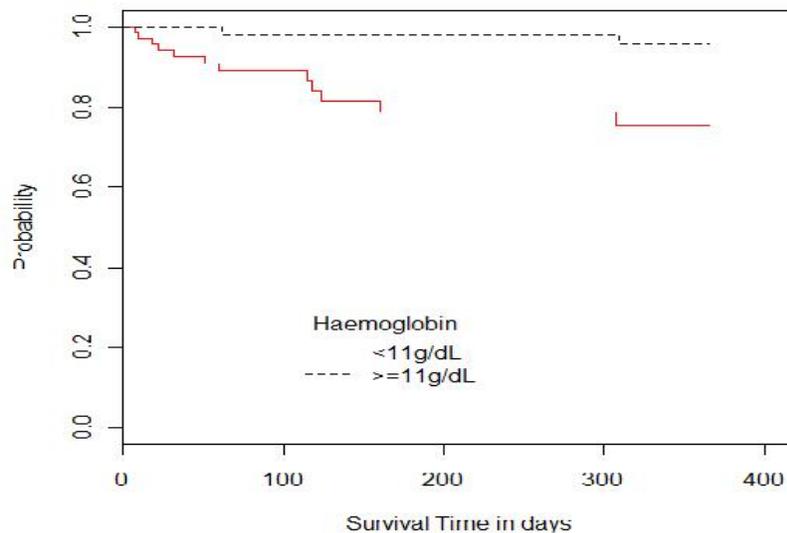


Figure 2: Survivorship among the individuals with haemoglobin (<11g/dL and ≥11g/dL) at enrolment

## Discussion

This current study has shown that, more than half of patients under ARV treatment at two CTC clinics, were considered as lost to follow-up. The lost to follow up occurred within the period of three months after initiation of ART despite having being counselled and accepted adherence to treatment schedule. A large proportion of lost to follow was among women possibly because majority of the recruited patients were also women. This might be the case because women are more sensitive with health status that triggers them to test earlier for HIV (Somi *et al.*, 2009; Ochieng-Ooko *et al.*, 2010). On the other hand why men delay access to care and subsequently a bad clinical outcome remains unclear.

This study has also identified that, LTFU was more frequent before ARVs initiation which is during the two weeks of counselling and functional tests processing. Similar observation has been reported in studies conducted in Kenya and Malawi (Hodes, 2010). Our findings identifies two scenarios; (i) individuals who are having signs and symptoms of disease who will consult for care and treatment, however, they will unlikely return back to the clinic unless their health status begins to worsen; (ii) those who are very sick might come back because they are too sick. It is important therefore to have a mechanism to increase the uptake in terms of voluntary counselling, testing, and retention within the programme mostly when checking for functional tests and the tolerance dose provision period before ARVs initiation. It is to be noted that, the overall, loss-to-follow-up rates in this study was lower than the average reported in a systematic review of ART programmes in sub-Saharan Africa (Rosen *et al.*, 2007). This could have been attributed to a small sample size of our study. Some of those patients considered as LTFU might have decided to transfer themselves to different CTC clinics without prior information to their original CTC clinic where they registered initially for proper

recording and transfer. They might have done this because of disclosure problems or travelling costs to the clinic, or having identified a better package offered by programme operating within the vicinity or and confidentiality reasons. LTFU was higher at CTC II as compared to CTC I although individuals recruited at CTC II were fewer in number. It is likely that the number of patients enrolled at CTC II was lower because it was a newly established centre within the hospital whereby the issue of addressing stigma and confidentiality was at its infancy. The other reason for the high LTFU at the CTC II could be that, the regional referral health facility has many patients and the chances that an HIV client will be seen by several people is high as compared to CTC I which is situated strategically to attend HIV/AIDS patients only. It is also possible that, at CTC II less attention is paid to HIV/AIDS patients due to a large number of patients attending the regional health facility for other conditions. Therefore the well-being of HIV/AIDS patients at CTC II could have been compromised hence leading to less recruitment as compared to CTC I.

Our findings do not show any difference between the mean time since initiation of ARV and LTFU in the two CTCs. Similarly no difference was observed in terms of LTFU and home visit by the nurse counsellors. The reason might be because the home visiting nurse counsellors in both CTCs were conducted at the same date and time. The common reason for LTFU in both CTCs was death occurring in the first three months of ARV initiation. This could have been due to the late consulting when these patients were critically ill with very low level of haemoglobin and CD4 glycoprotein of the helper T lymphocytes hence suffering opportunistic infections. This has been observed other in ART programmes in Sub-Saharan Africa (Mocrofit *et al.*, 1997; Luebbert *et al.*, 2010). In Sub-Saharan Africa and the rest of developing world many HIV clients would consult when having a typical clinical syndrome of immune-suppression whereas at this point in time no fear of stigma but fear of death. The early death among such individuals in our study is likely to be attributed to the low CD4, CD8 T lymphocytes and haemoglobin levels. Similar observations have been reported in a study in Malawi (Tenthani *et al.*, 2010).

When we compared ART and survival benefits of individual with CD4 <100 cells/mLs in our study, it was observed that, the chance of dying was higher in this group as compared to those with CD4 >100 cells/mLs and haemoglobin >11g/dl. These results suggest that, the crucial parameters to consider when a survival benefit is to be promoted are CD4 of  $\geq 100$  cell/ml and haemoglobin levels  $\geq 11$ g/ml at recruitment or at pre-ARVs. These phenomena correspond well with the time when many clients default from the programme as observed in another study carried out in Tanzania (Bupamba *et al.*, 2010). Our findings are supported by observations of Morgan *et al.* (2002) which reported that once a patient was diagnosed to be immune compromised; the median survival is less than a year in Africa setting.

It is a fact that, in high income countries, the ART programmes are well financed and organized in terms of follow ups at both pre-ART and during ART as compared to developing countries where resources are scarce. Scaling up such programmes without considering financial, human resources, together with adherence and sustainability is also calling for high rates of LTFU and early mortalities among individuals already on treatment and those waiting to initiate treatment. The low rate of LTFU at CTCI is likely to be because it was providing food supplements and nutrients as compared to CTCII. This could have influenced and attracted

clients to remain within the programme longer. This is also true for studies conducted in well funded programmes where food and nutrients supplements were provided in order to optimize clinical outcome in people living with HIV (Mills *et al.*, 2006; Rosen *et al.*, 2007). However, the problem LTFU attrition during treatment with ART varies widely, depending on the knowledge in managing of ART and funding of such programmes (Nachega, 2010). The longer the follow up, the high proportion of LTFU, similar findings have been reported in studies conducted in Sub-Saharan Africa (Rosen *et al* 2007). The small proportion of death reported in this study could have been contributed to the short period of follow up. Possibly if the follow up period was longer than a year, the effects of severity of those LTFU could have increased the mortalities. In this study, some of the patients who were alive could not be traced, possibly due to intentional wrong address in the register. This type of attitude could have been a reflection of patient feelings before their relatives and friends since they do not want to disclose their HIV-seropositivity status because of possible stigma. Whether patients gave a wrong address or not, details recorded at the CTC clinic were inadequate and difficult to explore.

In conclusion, frequent prompt tracing of patient should be part of any drug interventional programme linking facility and communities. These findings are also recommending that, individuals suspecting to have acquired HIV infection should attend CTC early for CD4 T lymphocytes and haemoglobin levels checking to avoid late consulting at critical stage when they have the actual AIDS. This will reduce death at early stages of the disease.

### **Competing interests**

The authors declare that they have no conflict of interests.

### **Authors Contributions**

WHM formulated the idea, hypothesis, data analysis and writing of the manuscript. MLK formulated the idea, hypothesis and data analysis. FF and BPM performed the data cleaning, editing, analysis and writing the manuscript. HAM and CIM conducted clinical examination, evaluated and assessed the progress of clinical aspects of those patients and their welfare. AMR supervised and carried out the laboratory examinations and writing this manuscript.

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