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## Loss to Care and Death Before Antiretroviral Therapy in Durban, South Africa

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### Abstract

**Objective**—To examine the loss to care and mortality rates before starting antiretroviral therapy (ART) among ART eligible HIV-infected patients in Durban, South Africa.

**Design**—Retrospective cohort study.

**Methods**—We reviewed data from ART eligible adults ( $\geq 18$  years) at an urban HIV clinic that charges a monthly fee from July to December 2006. ART eligibility was based on CD4 count  $\leq 200$  cells per microliter or clinical criteria and a psychosocial assessment. Patients who did not start ART and were lost within 3 months were phoned. Correlates of loss to care were evaluated using logistic regression.

**Results**—During the study period, 501 patients registered for ART training. Mean time from initial CD4 count to first ART training was 3.6 months (interquartile range 2.3–3.9 months). Four hundred eight patients (81.4%) were in care and on ART at 3-month follow-up, and 11 (2.2%) were in care but had not initiated ART. Eighty-two ART eligible patients (16.4%) were lost before ART initiation. Of these, 28 (34.1%) had died; two thirds of deaths occurred before or within 2 months after the first ART training. Despite multiple attempts, 32 patients (39%) were unreachable by phone. Lower baseline CD4 counts ( $\leq 100$  cells/ $\mu$ L) and unemployment were independently associated with being lost.

**Conclusions**—Loss to care and death occur frequently before starting ART at an HIV clinic in Durban, South Africa. This delay from CD4 count to ART training, even among those with the lowest CD4 counts, highlights the need for interventions that improve linkage to care and prioritize ART initiation for those with low baseline CD4 counts.

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## Keywords

Africa; HIV healthcare; linkage to care; lost to follow-up; pre-ART mortality

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## INTRODUCTION

South Africa has been devastated by the AIDS epidemic: nearly 20% of the adult population was estimated to be HIV infected in 2006, with a projected 837,000 adults in need of treatment.<sup>1-4</sup> The South African Department of Health began implementing its HIV/AIDS Operational Plan in 2004 with a rapid scale-up of antiretroviral therapy (ART) in the public sector. Its current 5-year strategic plan is to provide access to care and treatment for 80% of its citizens living with HIV by 2011.<sup>3,5</sup> With the assistance of the US President's Emergency Plan for AIDS Relief (PEPFAR), which supports the delivery of HIV treatment to over 3 quarters of South Africans on treatment, South Africa has the largest ART treatment program in the world.<sup>6,7</sup>

Despite major strides in initiating HIV care with improved access to treatment, there are often delays from determination of eligibility for ART to its initiation. Data from South Africa show that these delays result in substantial mortality. In the Gugulethu outpatient ART program in Cape Town, 66% of deaths occurred within 90 days of enrollment among patients awaiting ART.<sup>8</sup>

In South Africa, patients who are eligible for ART based on CD4 count  $\leq 200$  cells per microliter or World Health Organization (WHO) stage 4 disease are typically given a date in the future for initiating a clinical evaluation and treatment preparation process which takes a minimum of 3 weeks and often longer.<sup>9,10</sup> The pretreatment preparation includes baseline clinical evaluation and HIV education and is a time when patients may be lost from care. Reasons for failure to complete this pretreatment process and begin therapy, despite eligibility for ART, are not currently collected as part of routine monitoring and evaluation of South African ART or PEPFAR programs. Our objective was to examine the pre-ART loss and mortality rates among ART eligible patients who have not yet started therapy at an urban HIV clinic in South Africa.

## METHODS

### Study Setting and Population

The Sinikithemba HIV clinic at McCord Hospital has been treating patients with ART since 1999; in 2004, the clinic became a PEPFAR-funded site which enabled it to rapidly expand its clinical care services. McCord is a semi-private hospital in an urban setting. The HIV clinic has initiated over 5000 patients on ART, serving a predominantly African, Zulu-speaking population.<sup>11</sup> Patients presenting for CD4 counts are referred from the McCord Hospital outpatient care sites, from other sites in the Durban region, or self-refer. HIV-infected patients with a CD4 cell count  $\leq 200$  cells per microliter or who meet clinical criteria for ART (WHO stage 3 or 4) are referred at the same visit for a psychosocial assessment to evaluate readiness for ART initiation.<sup>9</sup> Patients who are interested in receiving care at Sinikithemba and who are deemed psychosocially eligible for ART are given a date to begin the ART literacy training process, which includes clinical evaluation and baseline laboratory work. They are also scheduled for 3-group educational sessions taught approximately 1 week apart by trained HIV counselors. Patients are started on ART at the third ART literacy training visit, unless they require further medical work-up; if so, they are scheduled for subsequent pre-ART clinic visits (Fig. 1). The study population was limited to adults ( $\geq 18$  years old) who met CD4 count or clinical criteria (WHO stage 3 or 4) for ART eligibility, underwent psychosocial assessment,

and were interested into pursuing HIV care at McCord, including paying a monthly fee (140 South African Rand [2AR]). If they met these criteria, patients were assigned a future date for their first ART literacy training visit. Although the standard of care at the clinic is to actively pursue reasons for missed appointments in patients who have started ART, the current study focused on patients who were eligible but were lost to care after obtaining a CD4 count/psychosocial assessment but before ART initiation. Such patients would not have been followed up as part of routine care by clinic staff.

### Data Collection

We obtained a list of all HIV-infected adults who met CD4 count or clinical criteria, received their CD4 count results, underwent a psychosocial assessment, and were scheduled for ART training at Sinikithemba from July through December 2006. A physician, a nurse, and a trained premedical student performed retrospective chart reviews for all patients using a standardized data extraction tool. Charts were reviewed for baseline demographic and clinical information, including baseline CD4 count. We also determined whether patients had attended ART trainings, had started ART, and had remained in care for 3 months after the final ART training date. If patients had continued with their scheduled clinic appointments, they were defined as being “in care,” even if they had not started ART. ART eligible patients scheduled for ART training who did not start ART and were lost to care before or within 3 months of the final ART training visit were deemed “pre-ART losses”; the date and purpose of their last clinic contact were recorded. We define pre-ART loss specifically as loss before ART initiation; the term “lost to follow up” has been used frequently in the literature to imply loss after starting treatment.<sup>12</sup> These pre-ART loss patients were phoned to ascertain their status. Patients were called a minimum of 3 times by a research nurse using contact details provided by the patient to the clinic. Patients were designated as deceased, changed service provider, unreachable, or moved away from the McCord Hospital catchment area. Pre-ART loss patients who were contacted and expressed the desire to return to clinical care were referred to clinic staff to be included in subsequent training sessions.

The study was approved by both the McCord Hospital Ethics Committee (Durban, South Africa) and the Partners Institutional Review Board (Boston, MA).

### Statistical Analysis

We compared baseline cohort characteristics of the “in care” and pre-ART loss groups using the  $\chi^2$  test for categorical data and the Student *t* test for continuous variables. We used the Wilcoxon rank sum test to compare variables with non-normal distributions. Bivariate analysis was used to examine correlates of loss to care during the intervention period, including demographic characteristics, baseline CD4 count, and time from CD4 count to first training date. Independent correlates of pre-ART loss were evaluated using multivariate logistic regression. Associations were examined at a  $P < 0.05$  significance level (2-sided test).

All study data were double entered into a Microsoft ACCESS Database. Statistical analyses were performed using SAS software (version 9.1; SAS Institute, Cary, NC).

## RESULTS

### Cohort Characteristics

During the 6-month study period, 501 adults were deemed ART eligible based on CD4 count, WHO clinical stage, and psychosocial assessment and were registered for ART literacy training. Twenty-three of these patients had CD4 count  $>200$  cells per microliter and were ART eligible based on clinical criteria (WHO stage 3 or 4). The median age was 35 years

[interquartile range (IQR) 31–42 years], and 281 patients (57%) were female. The median baseline CD4 count for the cohort was 96 cells per microliter (IQR 39–158 cells/ $\mu$ L).

### Cohort Follow-Up

Of the 501 adults eligible for ART training at study entry, 408 (81.4%) were in care and on ART at the 3-month follow-up after the final ART literacy training. An additional 8 patients (1.6%) were in care and attending the clinic monthly but had not initiated ART due to tuberculosis or other medical conditions; 3 patients who had regularly attended clinic but had not initiated ART died by the 3-month follow-up (Fig. 2).

In total, 82 eligible patients (16.4%) were lost during the time following a CD4 count/ psychosocial assessment and before ART initiation (pre-ART loss). Fifty-four patients (65.8%) were lost to care after a CD4 count but before ART training; 13 patients (15.8%) were lost during ART training, and 15 patients (18.3%) were lost just after ART training during clinical evaluation but still before ART initiation (Fig. 2). Two of the 82 pre-ART loss patients (2.4%) were ART eligible based on clinical criteria; the remainder were ART eligible based on CD4 count  $\leq$ 200 cells per microliter. Mean time from CD4 count to first clinic training date was 3.6 months (IQR 2.3–3.9 months); mean time was 3.1 months for those with CD4 count  $\leq$ 100 cells per microliter and 4.3 months for those with CD4  $>$ 100 cells per microliter ( $P < 0.0001$ ).

### Characteristics of Patients Lost to Care Before Treatment

We compared the baseline characteristics of pre-ART loss patients with those who remained in care (Table 1). The pre-ART loss group were more likely to be male compared with the in-care group (53.7% versus 41.4%,  $P = 0.04$ ), more likely to be unemployed (59.8% versus 47.2%,  $P = 0.04$ ), and more likely to have a baseline CD4 count  $\leq$ 100 cells per microliter (64.6% versus 50.1%,  $P = 0.02$ ). The median CD4 count for the pre-ART loss group was 67 cells per microliter (IQR 34–136 cells/ $\mu$ L) compared with a median of 100 cells per microliter (IQR 40–164 cells/ $\mu$ L) for those who remained in care at 3 months ( $P = 0.05$ ).

### Status of Patients Lost Pre-ART

Of the 82 patients not in care and lost before initiating ART, 28 (34.1%) were known to have died. The majority of deaths occurred among these pre-ART loss patients before the first ART training visit (Fig. 2). Two thirds of deaths (19 of 28) among the lost patients occurred before or within 2 months after their assigned date of ART training (data not shown). The remaining 9 deaths occurred from 3 to 5 months after the patients' assigned first ART training date. The median baseline CD4 count among the 28 patients known to have died was 56 cells per microliter (18–92 cells/ $\mu$ L) compared with 98 cells per microliter (IQR 51–154 cells/ $\mu$ L) among patients lost from care for other reasons or who were unreachable ( $P < 0.0001$ ).

Other reasons provided by patients or family members for not remaining in care at the clinic included change of service provider, moving away from the area or feeling unready for ART (Table 2). Three patients (3.7%) requested reentry into the program; they subsequently completed training and have started ART. Many of the pre-ART loss patients (32 of 82, 39.0%) were unreachable by telephone, despite multiple attempts. This was due to disconnected mobile phone lines or patients not answering the phone.

### Factors Associated With Pre-ART Loss

In bivariate analyses, patients who were lost pre-ART were more likely to be unemployed [odds ratio (OR) 1.88, 95% CI 1.11 to 3.17] and to have a CD4 count  $\leq$ 100 cells per microliter (OR 1.86, 95% CI 1.09 to 3.16) (Table 3). Controlling for gender, age, marital status, and time from CD4 count to date of ART training in multivariate analysis, patients with lower baseline

CD4 count ( $\leq 100$  cells/ $\mu\text{L}$ ) were more than twice as likely to be lost from care before ART initiation compared with those with baseline CD4  $> 100$  cells per microliter (OR 2.13, 95% CI 1.22 to 3.71) (Table 3). Multivariate analysis also showed that unemployment was independently associated with loss from care before ART initiation (OR 1.88, 95% CI 1.09 to 3.23).

## DISCUSSION

This study examines the magnitude of pre-ART loss from care and mortality among ART eligible patients before initiation of therapy in Durban, South Africa. In a cohort of 501 adults who were eligible for ART based on CD4 count or WHO criteria and were referred for ART literacy training, 16.4% (82 of 501) of patients were lost to care before ever starting ART. One third of pre-ART loss patients (28 of 82) were confirmed dead, with the majority of deaths occurring before or within 2 months of the assigned ART literacy training date. More than one third patients lost before ART initiation (32 of 82, 39.0%) were unreachable by telephone despite multiple attempts. Most HIV treatment programs do not typically measure or report pre-ART losses, therefore, these data highlight the substantial early losses from care and deaths that occur after baseline CD4 counts but before ART initiation in a high-burden setting with a rapid ART program scale-up.

Closely mirroring other low-income settings, the median baseline CD4 count for the entire cohort was 96 cells per microliter, illustrating the state of severe immune suppression at the time that most patients are diagnosed and referred for HIV care in South Africa.<sup>13</sup> Patients with CD4 counts  $\leq 100$  cells per microliter were more than twice as likely to be lost to care before starting ART compared with those with CD4 counts  $> 100$  cells per microliter. Those who were lost had a median baseline CD4 count of 67 cells per microliter; deaths and losses among patients waiting for ART with evidence of advanced disease have also been seen at a community-based ART cohort in Cape Town, supporting the notion that our results might be generalizable and that this problem has been inadequately described and addressed.<sup>8</sup> The average time from obtaining a CD4 count to initiation of ART training in this program was over 3 months, even for those with CD4 counts  $\leq 100$  cells per microliter. This was also the period of highest mortality. Interventions targeted at shortening programmatic delays from CD4 count to ART initiation and at facilitating earlier HIV diagnosis and linkage to care are paramount to improving patient linkage and preventing deaths. As a result of these findings, at McCord Hospital, patients are now able to attend ART literacy training visits in a shorter time frame than during the study period to facilitate earlier ART initiation. Prioritizing patients for ART initiation based on low CD4 count or other clinical parameters may improve patient outcomes, however, prioritization may also lead to referral of some patients who are so ill that they will die despite treatment.<sup>8,14</sup> Facilitating earlier HIV diagnosis at higher CD4 counts is therefore critical; this may be accomplished through provider-initiated HIV testing in health care settings and increased testing in non-health care venues.

Unemployment may represent a marker of more advanced illness, or unemployed patients may struggle with transport costs and fees for clinic visits. We found that patients who were unemployed were nearly twice as likely to be lost from care before ART initiation. This may reflect that patients were required to pay a 140 ZAR (~US \$20 in 2006) monthly fee for HIV care at McCord during the study period, a substantial financial burden among the unemployed. A large meta-analysis of patient retention in sub-Saharan Africa found that programs that required full or partial payment had lower rates of retention at 6 months of follow-up compared with those that required no payment.<sup>12</sup> This highlights the importance of minimizing out-of-pocket patient expenses in HIV programs; in our setting, the hospital now offers baseline CD4 counts at the time of HIV diagnosis free of charge to patients.



This study has several limitations. A large proportion (nearly 40%) of patients lost pre-ART could not be reached by telephone to ascertain their status after leaving the care of the clinic. As such, our mortality estimate of one third of patients in the pre-ART loss group is likely conservative; disconnected mobile phone service may often indicate patient deaths. Incorrect contact details, lost telephones, and disconnected mobile phone lines are common in resource-scarce settings and may hamper adequate follow-up of patients.<sup>15</sup> This limitation highlights the need for ART clinics to update contact information regularly and check for accuracy to facilitate follow-up. We did not control for certain factors which might affect patients' ability to follow-up. These factors, such as hemoglobin,<sup>11</sup> body mass index,<sup>16</sup> history of tuberculosis,<sup>8</sup> and distance from clinic,<sup>17</sup> may also serve as markers of disease severity. In addition, McCord Hospital is a semi-private hospital which may not be representative of public sector hospitals in South Africa where many HIV-infected patients seek care free of charge. However, the ART literacy training program and ART eligibility criteria are similar in both settings and are derived from the South African Operational Plan.<sup>3,9</sup>

Loss to care and death occur frequently after baseline CD4 count but before starting ART in Durban, South Africa. Substantial mortality occurs during the 3-month average delay from CD4 count to initiation of ART literacy training among patients with severe immune suppression. This pre-ART attrition is not typically recorded in treatment programs in resource-limited settings, leading to an underestimate of overall loss to follow-up. Most studies of lost to follow-up focus on patients who are lost after starting ART, however, there is substantial morbidity and mortality pre-ART. Our study highlights a pressing need for attention to linkage to care issues, from the time of an HIV diagnosis through the initiation of ART. Resources should be devoted to patients lost before ART initiation to find strategies that minimize the loss and its attendant morbidity and mortality. Interventions that improve linkage to care after HIV diagnosis and prioritize ART initiation for those with low baseline CD4 counts in resource-limited settings are urgently needed.

## ACKNOWLEDGMENTS

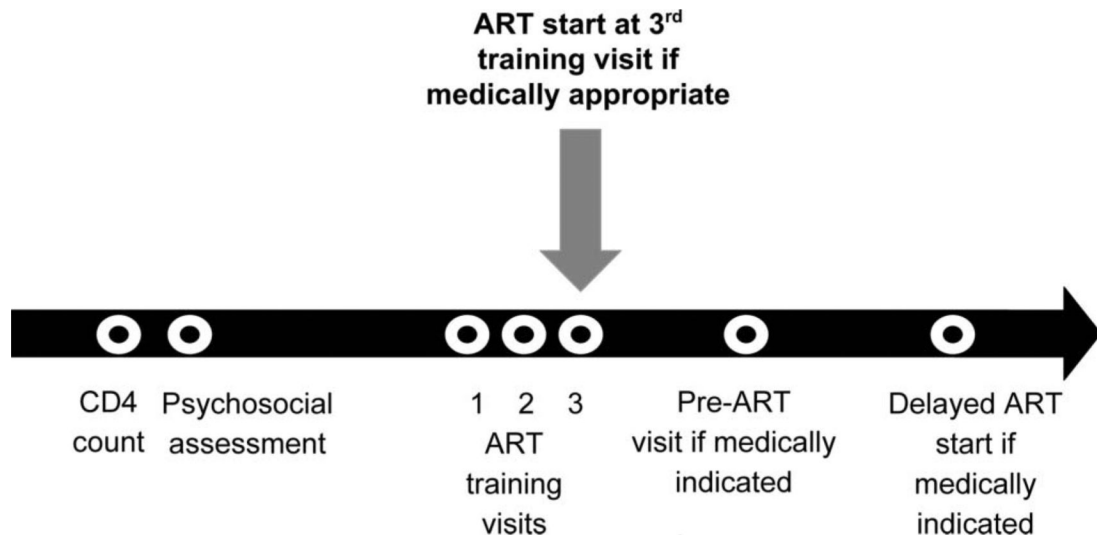
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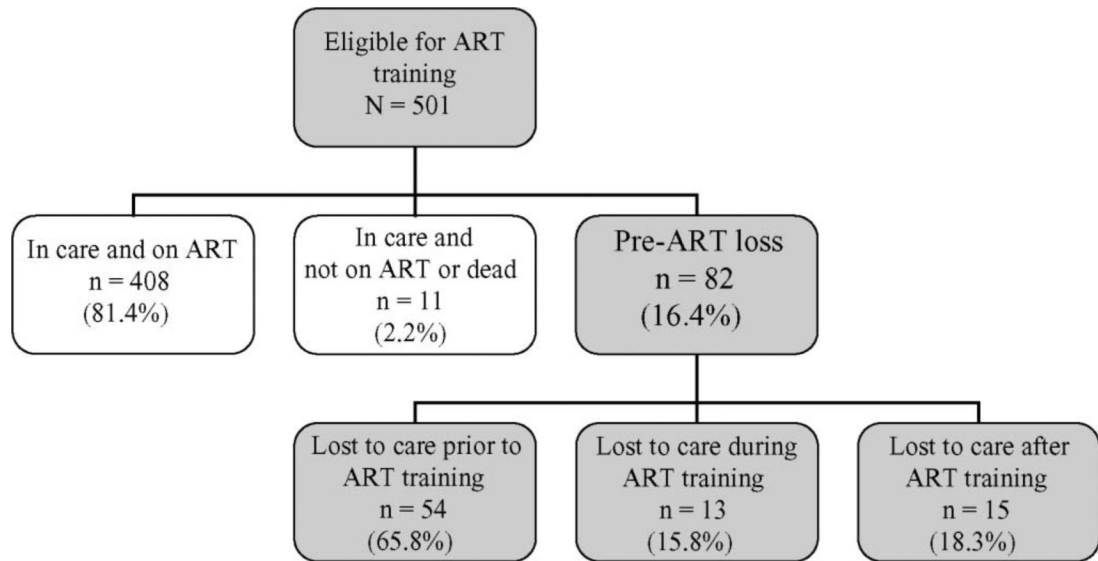
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**FIGURE 1.**  
Schematic of Pathway to ART Start.





**FIGURE 2.** Cohort flow diagram showing patient outcomes at 3-month time point after last ART literacy training visit.

**TABLE 1**

Baseline Characteristics of ART Eligible Patients Who Remained in Care and Who Had Pre-ART Loss in an HIV Treatment Program in Durban, South Africa

	In Care n = 419, n (%)	Pre-ART Loss n = 82, n (%)	P
Male gender	172 (41.4)	43 (53.7)	0.04
Age, median in years (IQR)	35 (31–42)	35 (32–42)	0.33
Married	95 (22.7)	26 (32.1)	0.07
Unemployed	197 (47.2)	49 (59.8)	0.04
Time from CD4 to first scheduled training visit, mean in months (IQR)	3.6 (2.3–3.9)	3.8 (2.3–3.7)	0.86
Baseline CD4 count, median (IQR)	100 (40–164)	67 (34–136)	0.05
Baseline CD4 count <100 cells/ $\mu$ L	210 (50.1)	53 (64.6)	0.02

Data are No. (%) of patients in each category, unless otherwise indicated.

**TABLE 2**

Status of Patients With Pre-ART Loss to Care (n = 82)\*

	<b>n</b>	<b>% of Pre-ART Loss Patients</b>
Died	28	34.1
Changed service provider	15	18.3
Moved away	3	3.7
Signed up to return	3	3.7
Patient decided not ready	1	1.2
Unreachable	32	39.0

\* As ascertained by repeated telephone calls (see Methods).

**TABLE 3**

Predictors of Pre-ART Loss in a Cohort of ART Eligible Patients At an HIV Treatment Program in Durban, South Africa

Variable	Crude OR (95% CI)	<i>P</i>	Adjusted OR (95% CI)	<i>P</i>
Male gender (versus female)	1.64 (0.98 to 2.7)	0.06	1.40 (0.82 to 2.38)	0.21
Age	1.01 (0.98 to 1.04)	0.41	1.00 (.97 to 1.04)	0.95
Married (versus single)	1.56 (0.90 to 2.73)	0.12	1.57 (0.85 to 2.89)	0.15
Unemployed (versus employed)	1.88 (1.11 to 3.17)	0.02	1.88 (1.09 to 3.23)	0.02
CD4 $\leq$ 100 cells/ $\mu$ L	1.86 (1.09 to 3.16)	0.02	2.13 (1.22 to 3.71)	0.008
Time from CD4 to training date	1.02 (0.96 to 1.09)	0.55	1.04 (0.98 to 1.11)	0.23