

## Predictors of survival in HIV-infected patients under antiretroviral treatment in selected hospitals of Ethiopia

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### Abstract

**Introduction:** In spite of the availability of large number of researches that address issues about HIV/AIDS in Ethiopia, evidence on survival and mortality indicators are insignificant.

**Objective:** To assess survival and indicators for mortality of HIV-positive patients receiving ART in Ethiopia.

**Method:** A retrospective facility-based register review was done in 31 purposively selected hospitals across the country. A 15 years data from medical records were included in the analysis. Cox proportional hazards regression was done to identify factors independently associated with survival. Relative risks (hazard ratio) with 95% CI and two-sided test of significance was used to measure the association between dependent and independent variables.

**Result:** From the total 83,876 (56.12%) patient records reviewed, 65,333 (43.71%) were females and the rest were males. Among the total patient records, 10.91% were record of dead people, 47.1% were alive, 22.84% were transferred out, and 13.3% were lost to follow up. About three fourth of patients (77.6 %) were actively working, while 11.65% and 6.71% were ambulatory and bed ridden patients respectively. Death rate among patients on ART was 11.1 per 1,000 Person-year while it is 12.2 per 1,000 Person-year among patients on Pre ART. According to the Kaplan Meier Life Table, the survival probability of patients on ART in the first four years was greater than 95%, and gradually decreased to 78% survival by the end of the 15 years follow-up. Cox proportional hazard model shows that Region, sex, CD4 cell count at ART initiation, functional status, CD4 count at outcome, weight, and age were independent factors associated with death.

**Conclusion:** The overall survival rate in this study was high. Low rate of survival was predicted by sex, region, CD4 count at ART initiation, functional status, and CD4 count at outcome, weight, and age.

**Key words:** Predictors of survival, HIV infected, antiretroviral

### Introduction

HIV/AIDS is a worldwide pandemic (Cohen 2008). All inclusive, roughly 36.7 million individuals were living with HIV/AIDS in 2016 (UNAIDS 2016). There were around 1 million deaths from AIDS in 2016, down from 1.9 million in 2005 (UNAIDS 2016). The 2015 Global Burden of Disease Study published in Lancet, reported that worldwide the number of new HIV infections topped in 1997 at 3.3 million. Worldwide the number of new infection fell from 3.3 in 1997 to 2.6 million in 2005, then remained stable from 2005 to 2015 (Wang 2015). Sub-Saharan Africa is the region hardest hit by the pandemic. According to UNAIDS 2011 report, an estimated 68% (22.9 million) of all HIV cases and 66% of all deaths (1.2 million) happened in this region. This implies around 5% of the grown-up population are infected. East and Southern Africa is home to 6.2% of the total population but home for 19.4 million individuals living with HIV i.e. more than half of the aggregated number of individuals living with HIV on the planet. In 2016, there were 790,000 new HIV infections, 43% of the worldwide aggregate (Avert 2018).

The new HIV infection in sub-Saharan African nations has demonstrated a decrease trend by over 33% from an estimated 2.2 million in 2005 to 1.5 million in 2013 and yet it is still high. The scale up of Antiretroviral therapy/treatment (ART) has brought significant decreases in the HIV incidence. HIV exposed people living in areas with ART coverage of 30 to 40% were 38% less likely to acquire new HIV infection than those living in areas where ART coverage was less than 10% (Ayesha 2016). ART is used to combat HIV infection by controlling viral replication. ART programs have been scaled-up drastically in East and Southern Africa over the past decades. With expanded access to ART, the number of AIDS related deaths have consistently declined globally and in sub-Saharan Africa there was a 39% decrease between 2005 and 2013 (UNAIDS 2014). In East and Southern Africa, about 11.7 million individuals were on ART in 2016, which means 79% of the individuals living with HIV. Around the same time, pediatric treatment coverage expanded to 51% from 19% in 2010 (Avert 2018).

In spite of the availability of large number of researches that address issues about HIV/AIDS in Ethiopia, evidence on survival and mortality indicators are insignificant. The objective of this study is to evaluate survival and indicators for mortality of HIV-positive patients receiving ART in Ethiopia.

## Materials and Methods

A cross sectional facility-based patient record review was done on register of patients who had started ART and who had been followed in 31 purposively selected government hospitals of Ethiopia during the period of (2001/2 – 2015/16). The review was undertaken in all People Living with HIV (PLHIV) records, a total of 149,454 those initiated ART and assessed for trend analysis. Follow-up time until death and death from all causes obtained from patient medical records in the ART clinics of hospitals were the main outcome measure and outcome variable in this study, respectively. The independent variables were socio-demographic characteristics, baseline clinical, laboratory and ART information. Patients were censored on the date of any one of the following events, irrespective of its order of occurrence: if lost to follow-up, if transferred to another health facility, or if alive at the end of follow up. Time to event data (survival times) was calculated by subtracting date of treatment started ( $t_0$ ) from date of event occurred ( $t_1$ ).

To compile the required information, need based data collection form was designed and developed from the national ART intake and follow-up forms. A standardized data collection tools or/and checklists were prepared to collect information on individual patients from hospital registers. The data were collected by reviewing patients register. Health professionals working in ART clinics of the respective hospitals were assigned as data collectors and the hospital head as supervisor/team leader. Besides, timely supervision had been made by co-investigators.

Although the field staff members had exposure and knowledge of patients' data organization at hospital level, two days intensive orientation was given on the objectives of the assessment, methodological approaches, data tracking tools and procedures to be followed. All completed data collection forms were examined for completeness, consistency and clarity during data management, and analysis. Data were analyzed using the STATA Statistical package, Version 14.2. Relative risks (hazard ratio) with 95% CI and two-sided test of significance was used to

measure the association of dependent and independent variables. Survival curves were compared between different exposure groups using log-rank test (Chi-square test with 1 df under  $H_0$ ).

Survival trend over the follow uptime was calculated using the Kaplan Meier (KM) method and covariates were fitted to Cox proportional hazard regression model. An assumption to Cox-proportional hazard model that is the hazards remaining proportionately constant is checked using graphical representation (Log-log plot) and a statistical test. No violation of the assumption was found, therefore no stratified Cox model or incorporate a time-dependent term were not used. Ethical approval was obtained from scientific and ethical review office of EPHI.

## Results

**Socio-demographic and clinical factors:** From the total records reviewed, 83,876 (56.12%) were females and the rest 65,333 (43.71%) were males; 15,302 (10.91%) were dead while 65,908 (47.1%) were alive. Regarding to patients functional status, 83,817 (77.6%), 12,584 (11.65%), 7,250 (6.71%) were actively working, ambulatory and bed ridden, respectively. From total records reviewed 86% of the patients were on ART. Patients mean age and CD4 count at ART initiation were 33 years and 201 cells/mm<sup>3</sup> respectively. The highest proportion of patients were from Amhara region (26.9%), followed by Oromia region (20.69%) and Addis Ababa (14.94%) (Table 1).

**Incidence, mean survival time, and Log rank Test:** The death rate among patients on ART is 11.1 per 1000 person-year while it was 12.2 per 1000 Person-year among patients on Pre ART. The mean survival time was about 14 years (Table 2). The log rank test for equality of survivor function shows p-value of greater than 0.05, indicating that there is no significant difference between the survival function of patients on ART and pre ART (Table 2).

**Life Table:** According to the Kaplan Meier Life Table and curve, probability of survival in the first four years was greater than 95%, and gradually decreased to reach its minimum value of 78% survival at the end of follow-up at year 15<sup>th</sup> (Table 3). Survival was higher among patients on ART than pre ART from follow up period of 6 to 10 years but the difference was not statistically significant (P-value=0.7946).

**Table 1: Socio demographic and clinical factors of patients on ART (N=149,454)**

| Characteristics       | Frequency, (%)  | Mean (95%CI)                    |
|-----------------------|-----------------|---------------------------------|
| Outcome               |                 |                                 |
| Alive                 | 65908 (47.01)   |                                 |
| Died                  | 15302 (10.91)   |                                 |
| Transferred out       | 32028 (22.84)   |                                 |
| Lost to follow up     | 18676 (13.32)   |                                 |
| Functional status     |                 |                                 |
| Working               | 83,817 ( 77.60) |                                 |
| Bed ridden            | 7,250 (6.71) s  |                                 |
| Ambulatory            | 12,584 (11.65)  |                                 |
| Sex                   |                 |                                 |
| Male                  | 65,333 (43.71)  |                                 |
| Female                | 83,876 ( 56.12) |                                 |
| Age                   |                 | 33.16164 (33.10032 - 33.22297)  |
| Region                |                 |                                 |
| Tigray                | 12,839 (8.59)   |                                 |
| Afar                  | 2,669 (1.79)    |                                 |
| Amhara                | 40,205 (26.90)  |                                 |
| Oromia                | 30,915 (20.69)  |                                 |
| Somali                | 2,755 (1.84)    |                                 |
| Benshangul Gumuz      | 4,665 (3.12)    |                                 |
| SNNP                  | 19,651 (13.15)  |                                 |
| Gambella              | 84 (0.06)       |                                 |
| Harari                | 1,274 (0.85)    |                                 |
| Addis Ababa           | 22,319 (14.94)  |                                 |
| Dire Dawa             | 6,339 (4.24)    |                                 |
| Weight                |                 | 54.31097 (54.12425 - 54.49769)  |
| ART status            |                 |                                 |
| On ART                | 126,892 (86.11) |                                 |
| Pre ART               | 20,468 (13.89)  |                                 |
| CD4 at ART initiation |                 | 201.3281 ( 184.7869 - 217.8693) |

**Table 2: Incidence rate and mean survival time and log rank test among patients on pre ART and ART**

| ART status                                       | Time at risk | Incidence rate | Restricted mean in year (CI 95% ) |          | No. of subjects |
|--------------------------------------------------|--------------|----------------|-----------------------------------|----------|-----------------|
| On ART                                           | 366943       | 0.0110971      | 13.84598 (13.7064                 | 13.9856) | 68230           |
| Pre ART                                          | 656          | 0.0121951      | 10.33404 (9.8922                  | 10.7759) | 122             |
| Total                                            | 371102       | 0.0113203      | 13.84588 (13.7063                 | 13.9855) | 69257           |
| Log-rank test for equality of survivor functions |              |                |                                   |          |                 |
| ART_STATUS                                       |              | Events         |                                   |          |                 |
| On ART                                           |              | observed       | expected                          |          |                 |
| Pre_ART                                          |              | 4072           | 4072.7                            |          |                 |
| Total                                            |              | 8              | 7.3                               |          |                 |
|                                                  |              | 4080           | 4080                              |          |                 |
|                                                  |              | chi2(1)        | 0.07                              |          |                 |
|                                                  |              | Pr>chi2        | 0.7946                            |          |                 |

**Table 3: Life table of patients under ART**

| Time in Year | Beg. Total | Net Fail | Lost | Survivor Function | Std. Error | [95% Conf. Int.] |        |
|--------------|------------|----------|------|-------------------|------------|------------------|--------|
| 1            | 69257      | 1048     | 8871 | 0.9849            | 0.0005     | 0.9839           | 0.9858 |
| 2            | 59338      | 643      | 7576 | 0.9742            | 0.0006     | 0.9729           | 0.9754 |
| 3            | 51119      | 526      | 6125 | 0.9642            | 0.0008     | 0.9627           | 0.9656 |
| 4            | 44468      | 527      | 5749 | 0.9527            | 0.0009     | 0.951            | 0.9545 |
| 5            | 38192      | 388      | 5092 | 0.9431            | 0.001      | 0.9411           | 0.945  |
| 6            | 32712      | 331      | 5525 | 0.9335            | 0.0011     | 0.9313           | 0.9357 |
| 7            | 26856      | 250      | 5596 | 0.9248            | 0.0012     | 0.9224           | 0.9272 |
| 8            | 21010      | 219      | 6165 | 0.9152            | 0.0014     | 0.9124           | 0.9179 |
| 9            | 14626      | 130      | 5899 | 0.9071            | 0.0016     | 0.904            | 0.9101 |
| 10           | 8597       | 95       | 5225 | 0.897             | 0.0018     | 0.8934           | 0.9006 |
| 11           | 3277       | 36       | 2041 | 0.8872            | 0.0024     | 0.8823           | 0.8919 |
| 12           | 1200       | 6        | 762  | 0.8827            | 0.003      | 0.8767           | 0.8886 |
| 13           | 432        | 0        | 415  | 0.8827            | 0.003      | 0.8767           | 0.8886 |
| 14           | 17         | 2        | 14   | 0.7789            | 0.069      | 0.6061           | 0.8828 |
| 15           | 1          | 0        | 1    | 0.7789            | 0.069      | 0.6061           | 0.8828 |

**Cox Regression:** In multivariate Cox proportional hazard regression (Table 4), factors independently associated with survival after adjusting for patient characteristics were living area in Benishangul

Gumuz, and SNNP regions, functional status, being ambulatory and bed ridden, baseline CD4 count, weight at baseline and CD4 count at outcome.

**Table 4: Cox regression analysis (Breslow method) to determine predictors of mortality among HIV infected patients on ART, (N=23,025)**

| Variables             | Hazard Ratio | [95% Conf. Interval] |           | Std. ERR  | P> z    |
|-----------------------|--------------|----------------------|-----------|-----------|---------|
| Region                |              |                      |           |           |         |
| Tigray                | 1            |                      |           |           |         |
| Afar                  | 5.66E-16     | 0                    |           | 1.21E-08  | 1       |
| Amhara                | 1.269976     | 0.460063             | 3.50569   | 0.6579305 | 0.645   |
| Oromiya               | 1.24402      | 0.4423177            | 3.49881   | 0.6563436 | 0.679   |
| Somali                | 2.58E-18     | 0                    |           | 6.49E-09  | 1       |
| Benshangul Gumuz      | 3.407435     | 1.205727             | 9.629555  | 1.806108  | 0.021   |
| SNNP                  | 4.047552     | 1.307089             | 12.53371  | 2.33422   | 0.015   |
| Gambella              | 3.87E-17     | 0                    |           | 6.09E-09  | 1       |
| Addis Ababa           | 0.9829875    | 0.3594711            | 2.688017  | 0.5045239 | 0.973   |
| Dire Dawa             | 1.636225     | 0.5421536            | 4.938143  | 0.9221446 | 0.382   |
| Sex                   |              |                      |           |           |         |
| Male                  | 1            |                      |           |           |         |
| Female                | 0.827394     | 0.6824332            | 1.003147  | 0.0813125 | 0.054   |
| CD4 at ART initiation | 0.9993429    | 0.9985739            | 1.000112  | 0.0003925 | 0.094   |
| Functional status     |              |                      |           |           |         |
| Working               | 1            |                      |           |           |         |
| Bed ridden            | 29.88609     | 22.43869             | 39.80528  | 4.370256  | < 0.001 |
| Ambulatory            | 7.376144     | 5.758566             | 9.4481    | 0.9316791 | < 0.001 |
| Weight                | 0.9742606    | 0.9670315            | 0.9815437 | 0.0037021 | < 0.001 |
| Height                | 1.000447     | 0.9978708            | 1.00303   | 0.0013161 | 0.734   |
| CD4 at outcome        | 0.9979449    | 0.9974893            | 0.9984007 | 0.0002325 | < 0.001 |
| Age                   | 0.9997562    | 0.9982883            | 1.001226  | 0.0007495 | 0.745   |

## Discussion

This 15-years retrospective document review of HIV infected patients has given insight in survival and its determinants in 31 selected hospitals of Ethiopia. The overall mortality on ART and pre-ART were 11.1 per 1000 person years and 12.2 per 1000 person years respectively. Region, sex, CD4 at ART initiation and at the outcome period, weight, height and functional status of individuals were identified as a predictor for the death of the patient.

ART has a positive impact on improved survival of HIV-infected patients. However, there is high mortality rate among patients in resource-poor countries. Overall in this study, 10.91% of the cases were dead, similarly, closer results (10.74%) death had been shown in the studies done in Debreworkos hospital (8.85%) (Fekade 2017); Aksum Hospital (14.8%) (Abeba 2017); Adama (7.6%) (Tadesse 2014); and in seven University Teaching Hospitals (10.3%) (Seyoum 2017; Kedir 2014). It also coincides with the finding with systematic review done in Ethiopia that reported 5 -15% of the patients died within the respective follow-up periods (Ayalew 2017) and the overall deaths (11.8%) in Nepal (NCASC 2011). The average age of HIV patients was found to be 33 years which is comparable with studies conducted across African countries. Similar studies done in Cameroun with a median age of 35 years

(Sieleumou 2009); and (Wang 2015), in Zambia with mean age of patients of 31 years (Amanzi 2016) and median age of 32 in Ethiopia (Abebe 2016). The overall death rate in this study was 1.1 per 100 person-year and is higher than the 3.2 per 100 person-years noted in other studies (Tadesse 2014); and (Mengesha 2014).

A study done by Nurilign and his colleagues revealed the overall estimated survival duration after ART initiation is to be 65.22 months (Nurilign 2014). However, in our study the mean survival time was 14 years. In the present study, the median survival time was not determined because the largest observed analysis time was censored, the survivor function does not go to zero; in this case the restricted mean might be underestimated but it is still the best estimate of survival time. This study brought better estimate as it considers most of the hospitals that provide ART treatment service in the country.

In Cox Regression model; living in Benishangul Gumuz, and SNNP region, functional status of being ambulatory and bed ridden, CD4 count at outcome, weight at baseline, and CD4 count at outcome were factors for risk of dying. Other studies also revealed similar results. A systematic review in Ethiopia revealed that non-working functional status (bedridden and ambulatory), low baseline CD4 count,

lower baseline weight were identified as predictors of deaths in HIV patients (Ayalew 2017). While the study in Cameroon revealed that only sex, baseline performance scale, bodyweight, and WHO clinical stage were independent significant determinants of mortality and the major independent determinants of mortality among adult HIV-infected patients on ART were male sex, and low baseline bodyweight in Nepal (Laxmi 2013). In contrary with the above mentioned study and incongruent with the current study socio-demographic variables like being male and educational status of lower and primary level have revealed significant association with predictors of survival of HIV patient who undergo ART (Tadesse 2014; Abebe et al. 2016).

Age and sex is not a determinants of survival in this study. This is not consistent with other similar studies. Older age (Ayalew 2017); and (Ren 2017), baseline age >35 (Hailemariam 2016) were predictors of survival. Similarly, in other studies, sex of patients (Sieleunou 2009); being male (Laxmi 2013) was predictor for survival. Body weight below the baseline was found as a factor of risk of dying in this study, which is consistent with other studies; (Ayalew 2017), (Laxmi 2013); and (Hailemariam 2016). Functional status was found to be a factor of dying in this study, which is similar to being non-working (bed ridden and ambulatory) (Ayalew 2017); and (Abebe 2016) and baseline functional status (Hailemariam 2016) as predictors of dying. Another study also revealed that predictor of mortality using the real case assumption model was functional status (ambulatory and bed ridden) (Abebe et al. 2016; Dinberu 2011). Moreover, as other studies, lower CD4 count at outcome was found to be a predictor of survival for patients under ART (Ayalew 2017; Sieleunou 2009; Amanzi 2016 and Ren 2017). The large number of patients and events analyzed was an important strength of this study. The study includes 31 potential hospitals across the regions in Ethiopia and reviewed the entire patient's chart in the hospitals since they started ART service. We have included most of the recommended information we got from the patient chart that are relevant for this analysis. However, it has some limitations. Because the study used secondary data from patient files in a context of routine care rather long observation period and hence it may suffer from incompleteness and illegible writing. It is limited in that it didn't take in to account some predictors of HIV patients' survival including life styles, nutritional status, WHO clinical stage of the disease, hemoglobin level and presence of TB co-infection, as the presence of these variables could have given a good insight about the determinants of HIV patients' survival.

## Conclusions and Recommendation

In this study, the overall survival rate of the ART and Pre ART clients was high. Higher hazard of death was predicted by sex, region, CD4 count at ART initiation, functional status, and CD4 count at outcome, weight and age. Although survival time is good, reinforcing the existing treatment program (early initiation of ART) is needed to take advantage of the preventive potential of ART.

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