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Background
Provision of antiretroviral therapy (ART) for HIV-infected individuals is rapidly expanding in sub-Saharan Africa [1]. HIV itself increases resting energy expenditure independently of viral load, further contributing to HIV-associated weight loss. As HIV infection progresses, it can cause a catabolic state that is compounded by a lack of caloric intake, increasing the severity of preexisting undernutrition [2].

Body mass index (BMI) at ART initiation was defined as BMI below 18.5 kg/m² indicates that a person is underweight, 18.5–24.9 kg/m² is normal weight, and 25.0–29.9 kg/m² is overweight and 30.0 kg/m² or above is obese. HIV compromises the nutritional status of infected individuals and in turn, malnutrition worsens the effects of the infection itself by weakening the immune system consequently accelerating disease progression and death [3].

An improved understanding of the role of nutritional status in HIV disease progression may help in the development of strategies to reduce mortality after ART initiation. To the best of our knowledge, no previous study has examined the effect of pre-ART nutritional status on time to death in the cohort of ART clients enrolled during the specified time in the study area. This study, therefore, intends to examine the associations between nutritional status and its associated mortality among adult patients on ART. Moreover, this study results serve as baseline data for further investigations and provides input for health planners and policy makers.

Methods
Institution based retrospective cohort study was conducted in Fiche Hospital from Jan 01–31/2014. Fiche town has one zonal hospital and two health centers for the catchment area population, which provide ART service for 3937 patients enrolled. Peoples’ living with HIV/AIDS (PLWHA).

Inclusion criteria
HIV positive adults aged 18 years or older who started ART with complete intake form, registers that have been in follow-up from 2006 to 2013.

Exclusion criteria
- Diagnosis is made outside of health institution (transfer in).
- Loss to follow up, transfer out.
- Pregnant and lactating women at the time of ART initiation.

Sample size determination
Sample size was determined using a formula for two population proportions based on the assumption that type I error 5%, power of 90% on exposure (malnourished on pre-ART treatment) and non-exposure (non-malnourished on pre-ART treatment) was taken from previous study [15].

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n_1 = \frac{Z^2 \cdot \sqrt{(1 + \frac{1}{r}) \cdot P(1-P) + Z^2 \cdot P_1(1-P_1) + \left( \frac{P_1(1-P_1)}{r} \right)^2}}{(P_1 - P_2)^2}
\]

α = level of significance, power = 1 − β = 90%, Z_0 = 1.282.
The sample size was 163 for n_1 (exposed group) and 326 for n_2 (non-exposed group). Using proportional allocation to the malnourished and non-malnourished adult patients, a total of 489 samples taken.

Sampling technique
A cohort of antiretroviral patients who were initiated treatment between August 2006 and September 2013 were included in the study and their profiles were evaluated. After thorough evaluation, the number of HIV clients from the list that fulfills the inclusion criteria were 1228. A total of 489 Study participants were selected by using systematic random sampling method by which one random number in the Patient’s ART unique identification numbers as a starting point. The first HIV client was selected by lottery method among the first sampling intervals from the evaluated profiles (Fig. 1).

Data collection methods and instruments
A data collection tool was developed from ART entry and follow-up form being used in the ART clinic. The follow-up documents was evaluated thoroughly about its completeness before data collection takes place. The data was collected by reviewing medical record registers, laboratory requests, and follow-up form of ART. The data was collected from Jan 01–31/2014. Data quality was controlled through continuous supervision and random check-up of the data collection. Three days training was given for data collectors and supervisors. Data quality control during data entry was done by double entry to EPI-info Version 3.5.3 computer software and through multivariate analysis.

Ethical approval was obtained from the Institutional Health Research Ethics Review Committee (IHRERC) of Harar campus, Haramaya University, College of Medicine and Health Sciences. Following the approval by IHRERC, official letter of ethical clearance was written to the concerned bodies by the School of Public Health. As the study was conducted through review of medical records, the individual patients were not subjected to any harm and personal identifiers were not used on data collection forms and confidentiality was maintained.

Data processing and analysis
The data were entered into Epi-Info Version 3.5.3 and then exported to SPSS Version 16.0 and STATA version...
12 statistical packages for data processing and analysis. Actuarial life table analysis was used to estimate cumulative proportion of surviving after initiation of ART. Kaplan–Meier Survival function was used to estimate mortality of HIV patients on ART. The log-rank test was conducted to compare time to death between/among various levels. Before running the Cox regression model, assumption of proportional-hazard was checked by Schoenfeld test and the assumption was not violated. Cox proportional-hazard regression was used to calculate the bivariate and adjusted hazard rate to determine independent determinants (P < 0.05) of time to death.

Results
Socio-demographic characteristics
The study involved a total of 489 adults of people living with HIV/AIDS (PLWHA) on ART; 163 (33.3%) were malnourished (BMI < 18.5 kg/m²) and 326 (66.7%) were non-malnourished adults (BMI ≥ 18.5 kg/m²). Most of the study subjects were females 254 (51.9%) and males 235 (48.1%). The overall mean(±SD) age at ART initiation was 34.36 ± 9.24 years, out of which most of them 201 (41.1%) were in the age range of 18–29 years followed by 149 (30.5%) of 30–39 years (Table 1).

Baseline clinical and laboratory information of the cohort
The baseline mean (±SD) values for BMI of the participants was 19.75 ± 2.96. The median weight at ART initiation was 51 kg [interquartile range (IQR 45–57 kg)]. The median CD4 cell count at ART initiation was 145 cells/μl (IQR 80–222). Three hundred thirty five (68.5%) of the patients had CD4 counts <200 cells/μl. The median hemoglobin level was 12.90 g/dl (IQR 10.9–14.6). Most of the study subjects at ART initiation were 220 (45%) in WHO stage III and 197 (40.3%) in WHO stage II. With regard to functional status, 197 (40.3%) participants were ambulatory at baseline and 27 (5.5%) were bedridden. Out of those who participated, 304 (62.2%) had no previous opportunistic infection, 68 (13.9%) had one previous opportunistic infection and 117 (23.9%) had two and more previous opportunistic infections (Table 2).

Baseline demographic and clinical characteristics and associated mortality of patients on ART
From the study subjects, the proportion of mortality is higher among the age group of 50+ years followed by 40–49 years (20.5 vs. 19%). With regard to educational status, 36 (26.1%) of the participants who had no education died after initiation of ART. The proportion of mortality is higher among males than females (19 vs. 17%) (Table 3).

Survival analysis
A total of 489 HIV infected individuals were enrolled in a retrospective study for a median (IQR) of 22 (14–34) months; 17 (5–34) months among malnourished adults and 23 (17–34) months among non-malnourished adult patients. All the study subjects contributed 1545.4 person year of observation (PYO); 429.35 PYO for those who were
### Table 1  Socio-demographic characteristics of HIV-positive patients at ART initiation in Fiche Hospital, North Shoa, 2006–2013, (N = 489)

| Characteristics | Malnourished (n = 163) | Non malnourished (n = 326) | Total (N = 489) | P value |
|-----------------|------------------------|----------------------------|-----------------|---------|
|                 | Number (%)             | Number (%)                 | Number (%)      |         |
| **Sex**         |                        |                            |                 |         |
| Male            | 95 (58.3)              | 140 (42.9)                 | 235 (48.1)      | 0.002   |
| Female          | 68 (41.7)              | 186 (57.1)                 | 254 (51.9)      |         |
| **Age groups (years)** |              |                            |                 |         |
| 18–29           | 68 (41.7)              | 133 (40.8)                 | 201 (41.1)      | 0.786   |
| 30–39           | 53 (32.5)              | 96 (29.4)                  | 149 (30.5)      |         |
| 40–49           | 31 (19.0)              | 69 (21.2)                  | 100 (20.4)      |         |
| 50+             | 11 (6.7)               | 28 (8.6)                   | 39 (8.0)        |         |
| **Marital status** |                   |                            |                 |         |
| Single          | 24 (14.7)              | 37 (11.3)                  | 61 (12.5)       | 0.139   |
| Married         | 71 (43.6)              | 179 (54.9)                 | 250 (51.1)      |         |
| Separated       | 21 (12.9)              | 43 (13.2)                  | 64 (13.1)       |         |
| Divorced        | 22 (13.5)              | 31 (9.5)                   | 53 (10.8)       |         |
| Widowed         | 25 (15.3)              | 36 (11.0)                  | 61 (12.5)       |         |
| **Educational status** |                 |                            |                 |         |
| No education    | 60 (36.8)              | 78 (23.9)                  | 138 (28.2)      | 0.004   |
| Primary         | 57 (35.0)              | 107 (32.8)                 | 164 (33.5)      |         |
| Secondary       | 36 (22.1)              | 116 (35.6)                 | 152 (31.1)      |         |
| Tertiary        | 10 (6.1)               | 25 (7.7)                   | 35 (7.2)        |         |

P value <0.05 = statistically significant difference

### Table 2  Baseline clinical characteristics of HIV patients in Fiche Hospital (N = 489)

| Characteristics | Malnourished (n = 163) | Non malnourished (n = 326) | Total (N = 489) | P value |
|-----------------|------------------------|----------------------------|-----------------|---------|
|                 | Number (%)             | Number (%)                 | Number (%)      |         |
| **Functional status** |                   |                            |                 |         |
| Working         | 49 (30.1)              | 216 (54.2)                 | 265 (54.2)      | 0.0001  |
| Ambulatory      | 94 (57.7)              | 103 (31.6)                 | 197 (40.3)      |         |
| Bedridden       | 20 (12.3)              | 7 (2.1)                    | 27 (5.5)        |         |
| WHO clinical stage |                    |                            |                 |         |
| Stage I         | 7 (4.3)                | 41 (12.6)                  | 48 (9.8)        | 0.0001  |
| Stage II        | 58 (35.6)              | 139 (42.6)                 | 197 (40.3)      |         |
| Stage III       | 84 (51.5)              | 136 (41.7)                 | 220 (45)        |         |
| Stage IV        | 14 (8.6)               | 10 (3.1)                   | 24 (4.9)        |         |
| **TB history**  |                        |                            |                 |         |
| Yes             | 75 (46)                | 73 (22.4)                  | 148 (30.3)      | 0.0001  |
| No              | 88 (54)                | 253 (77.6)                 | 341 (69.7)      |         |
| **Hemoglobin count (g/dl)** |                  |                            |                 |         |
| <10             | 34 (21.5)              | 30 (9.7)                   | 64 (13.7)       | 0.0001  |
| ≥10             | 124 (78.5)             | 279 (90.3)                 | 403 (86.3)      |         |
| **Previous OIs** |                     |                            |                 |         |
| None            | 86 (52.8)              | 218 (66.9)                 | 304 (62.2)      | 0.0001  |
| One             | 18 (11.0)              | 50 (15.3)                  | 68 (13.9)       |         |
| 2+              | 59 (36.2)              | 58 (17.8)                  | 117 (23.9)      |         |
of 5.63 per 100 person-year observations (87 deaths/1545.4 PYO). Of the 87 deaths, 27 (31%) occurred within the first 3 months of ART initiation and 41 (47.1%) died in the first year of follow-up. The overall estimated survival duration after ART initiation was 48 (95% CI 46.32–50.84) months.

Actuarial life table analysis showed that probability of survival time among malnourished adult ART patients was 79, 91, 93, 94, and 98% at 5, 10, 15, 20, and 30 months respectively. The probability of survival time among non-malnourished adults was 97, 99, 99 and 98% at 5, 10, 15 and 35 months respectively (Fig. 2).

Survival time of adult HIV-positive patients at ART initiation

Kaplan–Meier analysis of patients at ART by socio-demographic characteristics

The overall estimated survival time after ART initiation using Kaplan–Meier survival analysis was 48 months (95% CI 45.32–50.68). The survival experience after initiation of ART estimated by the Kaplan–Meier survival analysis by educational status showed that there was significant difference in median survival time among the groups, no education 44 months (95% CI 40.18–48.82) and secondary education 53 months (95% CI 49.98–56.02), (log rank test X² = 14.321, P = 0.002).

Kaplan–Meier analysis of patients at ART by baseline clinical characteristics

There was significant difference in median survival time among working functional status 54 months (95% CI 52.49–57.51), ambulatory status 41 months (95% CI 36.88–44.22) and bedridden 34 months (95% CI 24.86–43.14) (log rank test X² = 51.976, P = 0.0001).

Predictors of mortality

After adjustment, the following characteristics at the initiation of the ART were the independent significant predictors of mortality: BMI < 18.5 kg/m², baseline functional status (Ambulatory and Bedridden), WHO stage III and IV, CD4 cell count <200 cells/µl and opportunistic infections with two and more. Patients with a BMI <18 kg/m² had a 5.4-fold increased risk of mortality (95% CI 3.03–9.58) as compared to those with ≥18.5 kg/m². The hazard rate for dying is 3.84 times more with baseline functional status of ambulatory compared to patients with functional status of working (AHR = 3.84; 95% CI 2.19–6.74). Similarly, Patients with baseline functional status of bedridden had 4.78 times increased risk of death as compared to patients with stage I and II (AHR 2.21; 95% CI 0.0001).

### Table 3 Baseline demographic and clinical characteristics and associated mortality on ART in Fiche Hospital, Ethiopia

| Characteristics | Total Alive n = 402 Death n = 87 P value |
|-----------------|-----------------------------------------|
| Sex             |                                        |
| Male            | 221 (45.2) 179 (81) 42 (19) 0.604 |
| Female          | 268 (54.8) 223 (83) 45 (17) |
| Age groups (years) |                                        |
| 18–29           | 201 (41.1) 167 (83.1) 34 (16.9) 0.937 |
| 30–39           | 149 (30.5) 123 (82.5) 26 (17.5) |
| 40–49           | 100 (20.4) 81 (81) 19 (19) |
| 50+             | 39 (8.0) 31 (79.5) 8 (20.5) |
| Nutritional status |                                        |
| Malnourished    | 163 (33.3) 122 (74.8) 41 (25.2) 0.004 |
| Non-malnourished| 326 (66.7) 280 (85.9) 46 (14.1) |
| Educational status |                                        |
| No education    | 138 (28.2) 102 (73.9) 36 (26.1) 0.011 |
| Primary         | 164 (33.5) 138 (84.1) 26 (15.9) |
| Secondary       | 152 (31.1) 129 (84.9) 23 (15.1) |
| Tertiary        | 35 (7.2) 33 (94.3) 2 (5.7) |
| Functional status |                                        |
| Working         | 265 (54.2) 257 (96.9) 8 (3.1) 0.0001 |
| Ambulatory      | 197 (40.3) 128 (64.9) 69 (35.1) |
| Bedridden       | 27 (5.5) 17 (62.9) 10 (37.1) |
| WHO clinical stage |                                        |
| Stage I         | 48 (9.8) 47 (97.9) 1 (2.1) 0.0001 |
| Stage II        | 197 (40.3) 192 (97.5) 5 (2.5) |
| Stage III       | 220 (45) 149 (67.7) 71 (32.3) |
| Stage IV        | 24 (4.9) 14 (58.3) 10 (41.7) |
| Previous OIs    |                                        |
| None            | 304 (62.2) 289 (95.1) 15 (4.9) 0.0001 |
| One             | 68 (13.9) 50 (73.5) 18 (26.5) |
| 2+              | 177 (35.9) 63 (58.3) 44 (41.7) |
| Initial ART regimen |                                        |
| d4t(30)-3TC-NVP | 83 (17) 72 (86.7) 11 (13.3) 0.245 |
| d4t(30)-3TC-EFV | 64 (13.1) 51 (79.6) 13 (20.4) |
| AZT-3TC-NVP     | 230 (47) 193 (83.9) 37 (16.1) |
| AZT-3TC-EFV     | 112 (22.9) 86 (76.8) 26 (23.2) |
| HIV related counseling |                                        |
| Yes             | 141 (28.8) 135 (95.7) 6 (4.3) 0.0001 |
| No              | 348 (71.2) 267 (76.7) 81 (23.7) |
| TB history      |                                        |
| Yes             | 148 (30.3) 101 (68.2) 47 (31.8) 0.0001 |
| No              | 341 (69.7) 301 (88.2) 40 (11.8) |

malnourished HIV adult patients and 1116.05 PYO for non-malnourished patients. Out of the study subjects, 87 patients died during the study period giving a mortality rate
and might be due to delayed diagnosis and/or treatment. This study revealed that a low baseline body mass index (BMI) at the start of ART was an independent predictor of early mortality (i.e., in the first 90 days of therapy). This is in line with studies conducted in several sub-Saharan Africa [5, 11, 13–16]. This might be as a result of the aggregate effects of malnutrition-induced immune system dysfunction, a higher burden of opportunistic infections, metabolic derangement and anthropometric variations. Even after the initiation of ART, the side effects of certain antiretroviral drugs (e.g., nausea, insomnia) may prevent adequate intake [17], and malnutrition and low body weight may potentiate drug toxicity [18].

Patients with advanced clinical diseases (WHO stage III or IV) had higher mortality compared to patients with WHO stage I or II. This finding was supported by several other studies [11, 12, 19–22]. This might be due to the fact that patients died mostly because of their late initiation of ART when they had the worst health conditions. In contrast, a study conducted in Western Ethiopia and South Western Uganda reported that WHO clinical stage was not found to be associated with mortality [7, 23].

In this study, patients with two and above opportunistic infections had 2.3 times higher mortality as compared to those who had no starting opportunistic infection. (WHO clinical stage III) at the time of treatment initiation and might be due to delayed diagnosis and/or treatment.

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This study established a similar finding with the studies in sub-Saharan Africa that showed OIs were found to be significant predictors of death among patients under ART [11, 13, 24, 25].

Adult HIV-infected patients who were bedridden at ART initiation had higher risk of mortality compared to the patients with working functional status at treatment initiation. This result is in line with the study done in Eastern Ethiopia and those described elsewhere [6, 21, 23, 26].

Patients starting ART treatment with CD4 cell count ≤200 cells/μl was an independent predictor of mortality in this study. This finding is consistent with studies [4, 6, 12, 20, 25, 27]. Studies have substantiated the fact that low CD4 cell count, a marker of advanced immunodeficiency, was associated with opportunistic infection thereby increasing the likelihood of death [28]. This may partly be explained by the fact that the majority of patients (75.5%) had a CD4 ≤200 cells/μl, which could have made the comparison with higher CD4 counts statistically unstable.

Our study was subjected to several important limitations. Selection bias is possibly introduced due to the fact that patients with incomplete records of variables were excluded. In addition, because we could not ascertain outcomes of patients lost to follow-up, our mortality results might be an underestimation. Anthropometric measurements might not be measured or recorded correctly.

### Table 4 Bivariate and multivariate Cox-regression analysis of socio-demographic and baseline clinical characteristics of the cohort studied in Fiche Hospital, North Shoa during September 2006 to 2013, (N = 489 patients)

| Covariates                  | Number at risk | Number of deaths | Crude HR (95% CI) | Adjusted HR (95% CI) |
|-----------------------------|----------------|------------------|-------------------|----------------------|
| **Educational status**      |                |                  |                   |                      |
| No education                | 138            | 36               | 1.86 (0.73, 4.76) | 1.35 (0.50, 3.6)     |
| Primary                     | 164            | 26               | 1.60 (0.63, 4.10) | 2.05 (0.78, 5.36)    |
| Secondary                   | 152            | 23               | 0.61 (0.22, 1.71) | 0.92 (0.31, 2.74)    |
| Tertiary                    | 35             | 2                | 1                 |                      |
| **Nutritional status**      |                |                  |                   |                      |
| Malnourished                | 163            | 41               | 7.58 (4.63, 12.39) | 5.40 (3.03, 9.58)**  |
| Non-malnourished            | 326            | 46               | 1                 |                      |
| **Functional status**       |                |                  |                   |                      |
| Working                     | 265            | 8                | 1                 |                      |
| Ambulatory                  | 197            | 69               | 4.91 (2.91, 8.26) | 3.84 (2.19, 6.74)**  |
| Bedridden                   | 27             | 10               | 6.86 (3.26, 14.44) | 4.78 (2.14, 10.65)** |
| **WHO clinical stage**      |                |                  |                   |                      |
| Stage I and II              | 245            | 6                | 1                 |                      |
| Stage III                   | 220            | 71               | 3.1 (1.89, 5.07)  | 2.21 (1.16, 4.21)*   |
| Stage IV                    | 24             | 10               | 5.93 (2.89, 12.17)| 4.05 (1.50, 10.97)** |
| **TB history**              |                |                  |                   |                      |
| Yes                         | 148            | 47               | 1.99 (1.31, 3.05) | 0.95 (0.58, 1.55)    |
| No                          | 341            | 40               | 1                 |                      |
| **CD4 count (cells/μl)**    |                |                  |                   |                      |
| ≤200                        | 335            | 260              | 3.44 (1.83, 6.48) | 2.95 (1.48, 5.88)*   |
| >200                        | 154            | 142              | 1                 |                      |
| **Hemoglobin level (n = 467)** |                |                  |                   |                      |
| <10 g/dl                    | 64             | 18               | 1.80 (1.06, 3.04) | 0.82 (0.45, 1.51)    |
| ≥10 g/dl                    | 403            | 62               | 1                 |                      |
| **Previous OIs**            |                |                  |                   |                      |
| None                        | 304            | 15               | 1                 |                      |
| One                         | 68             | 18               | 1.80 (0.99, 3.52) | 1.31 (0.69, 2.5)     |
| 2+                          | 117            | 54               | 3.24 (2.05, 5.13) | 2.30 (1.11, 4.79)*   |
| **HIV related counseling**  |                |                  |                   |                      |
| Yes                         | 141            | 6                | 1                 |                      |
| No                          | 348            | 81               | 3.85 (2.44, 6.08) | 0.57 (0.26, 1.24)    |

1.00 = Reference * P value <0.05, ** P value ≤0.001
Conclusions
Undernutrition at the time of ART initiation was associated with increased risk of death, particularly during the first 3 months after ART initiation. With regard to nutritional status, there was a significant difference in median survival time between malnourished adults 35 months and non-malnourished adults 52 months. Being malnourished, late WHO stage, having low CD4 cell count, ambulatory and bedridden functional status and two and more opportunistic infections were factors independently associated with death. Interventions to promote earlier HIV diagnosis and treatment and nutrition counseling should be integrated at all stages of ART implementation, such as during adherence counseling, regular follow-up sessions, and meetings of PLWHA support groups may improve ART outcomes in this vulnerable population.

Abbreviations
AHR: adjusted hazard rate; AIDS: acquired immunodeficiency syndrome; ART: antiretroviral therapy; BMI: body mass index; IRS: systematic random sampling; CI: confidence interval; Hgb: hemoglobin; HIV: human immunodeficiency virus; HR: hazard rate; IQR: inter quartile range; Kg: kilogram; OI: opportunistic infection; PLWA: people living with HIV/AIDS; PYO: person-year observation; SD: standard deviation; TB: tuberculosis; WHO: World Health Organization.

Authors’ contributions
KT conceived and designed the study, data collection, performed statistical analysis and drafted the initial manuscript. NB and KT performed the statistical analysis and revised the manuscript. HK performed the statistical analysis and drafted the initial manuscript. All authors read and approved the final manuscript.

Author details
1 College of Medicine and Health Sciences, Department of Public Health, Ambo University, PO. Box 21115, Ambo, Ethiopia. 2 School of Public Health, Haramaya University, Harar, Ethiopia.

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Competing interests
The authors declare that they have no competing interests.

Ethical approval and consent to publish
Ethical approval was obtained from the Institutional Health Research Ethics Review Committee (IHREC) of Harar campus, Haramaya University, College of Medicine and Health Sciences. Following the approval by IHREC, official letter of ethical clearance was written to the concerned bodies by the School of Public Health. As the study was conducted through review of medical records, the individual patients were not subjected to any harm and personal identifiers were not used on data collection forms and confidentiality was maintained.

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