ORIGINAL RESEARCH

Level of Attrition from Antiretroviral Therapy Among Human Immune Deficiency Virus-Infected Children: The Cases of Sidama Zone, Southern Ethiopia

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Background: Human immune deficiency virus (HIV) remains one of the leading causes of infectious disease mortality and morbidity in Sub-Saharan Africa. Although remarkable progress has been made in prevention and treatment of HIV, there is a higher rate of loss to follow-up in HIV-infected children than in adults, once they enter care.

Objective: To determine the incidence and identify predictors of loss to follow-up among HIV-infected children on anti-retroviral treatment in Sidama Zone, Ethiopia.

Methods: A retrospective cohort study was done among children that were enrolled in ART care in Sidama Zone from September 2014 to August 2018. A total of 143 eligible children were included in this study. A structured checklist was used to extract data from patients' medical records such as patient intake forms, electronic database, and registers. Data were entered, cleaned, coded, and analyzed by STATA version 12. Cox proportional hazards models were fitted to investigate predictors of loss to follow-up.

Results: Of the 143 participants, 76 (53.15%) were female children with a median age of 7 years and interquartile range of 4–9. The incidence rate was 5 per 100 person-years and the cumulative incidence 12.59%. The median follow-up time was 2.46 years and the total time at risk was 356.06 person-years. Furthermore, 55.56% and 72.22% of those lost to follow-up were within the first and the second years of follow-up, respectively. In multivariable Cox proportional model, only the TB status of the children was significantly associated with loss to follow-up with hazard ratio 3.348 [1.174831, 9.543494] and *p*-value of 0.024.

Conclusion: In this study, TB status of children was the significant determinant of loss to follow-up. However, the overall retention was 87.4% and a substantially higher proportion of loss was observed within the first and second years of follow-up.

Keywords: lost to follow-up, attrition, HIV-infected children, ART, Sidama zone

Introduction

The Human Immune Deficiency Virus (HIV) remains one of the leading causes of infectious disease morbidity in the world. While investments in HIV response have achieved promising results, by the end of 2020, 37.6 million people were living with HIV, of which 1.6 million were newly infected.[1] Additionally, 1.7 million children were living with HIV around the world in 2020.[2] The majority of these cases are in Africa, where acquired immune deficiency syndrome (AIDS) remains the leading cause of death among adolescents.[1]

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The Joint United Nations Program on HIV and AIDS (UNAIDS) 90-90-90 target called on countries to reach the following goals, 90% of people living with HIV diagnosed, 90% of diagnosed people on antiretroviral treatment, 90% of people on treatment with a fully suppressed viral load by 2020.[2,32] With the ambition of ending the HIV epidemic, this fast-track approach sets these targets at 95-95-95 by the year 2030.[2] However, as of 2019, only 67% of the people that knew their HIV status (81%) were on anti-retroviral treatment (ART).[2] These outcomes were even lower in HIV-infected children in all three categories. In 2019, less than fifty percent of HIV-infected children that were younger than 15 years were receiving ART.[2,3] The UNAIDS targets cannot be met if children are not retained in care. Thus, it is crucial to understand the determinants and risks of "lost to follow-up" (LTFU) in ART-receiving children. Preventative measures should also be taken accordingly since treatment interruption results in significant increase of viral load as well as ART drug resistance.[2–4,32]

LTFU is particularly a problem for developing countries. Previous studies have shown that, even though both children and adults on ART are LTFU, it is more common in children.[1–7,9] In Asia and Africa it has been shown that at 18 months after initiation of ART, 12.3% are LTFU.[26] Seventy percent of people living with HIV reside in Sub-Saharan Africa where HIV remains the leading cause of death among adults, women of child-bearing age, and children.[2,4,9,13] Ethiopia is a country with a low generalized HIV epidemic with significant heterogeneity among regions and population groups. In Ethiopia there is a declining national HIV prevalence of 1.1% and 0.33/1000 incidence.[2,9,18] Moreover, the urban population is more affected than rural areas while females are twice as affected as the male population.[2,18] ART care and treatment have been expanded at regional, zonal, woreda, and kebele levels through targeted social mobilization and active community participation to prevent and control the spread of the epidemic. Despite this remarkable progress, several adults and children discontinue ART at different time points.

In Ethiopia, HIV-infected children stop coming back for ART for different reasons. Studies conducted in Adama and Northern Ethiopia demonstrated that rates of LTFU in ART-receiving children were 18% and 9.81%, respectively.[10,15,30] According to these studies, CD4 count, or level of disease advancement was a factor that can contribute to LTFU of children on ART care.[15]

To achieve the 95-95-95 targets for children, HIV-infected children must be identified, linked to care, initiated on ART,

retained in care, and finally achieve sustained virologic suppression.[14,32] High levels of adherence to ART and retention in treatment programs are required for successful virologic suppression and treatment outcomes.[32] Accordingly, our study explored the possible predictors of LTFU in HIV-infected children in Sidama zone, which will be important in order to apply a retention mechanism and optimal outcomes among HIV-infected children.

Conceptual Framework

This conceptual framework was adapted from previous similar literature.[8–12,15,16,17,20,29] Thus, the relationship between dependent and independent variables can be conceptualized as shown in Figure 1.

Objective

To determine the incidence and predictors of LTFU among HIV-infected children that were receiving ART care in Sidama Zone from September 2014 to August 2018.

Methods and Materials
### Study Site and Period

This study was conducted in Sidama Zone Government Hospital from September 2014 to August 2018. Sidama Zone is located in Southern Ethiopia. HIV prevalence for the region is 0.9% while the national prevalence is 1.5%.[2,18] Sidama Zone is the largest zone in the region covering 6972.1 square kilometers with a total population of 3,019,442. The zone has 21 woredas (districts). The capital of the zone is Hawassa city, and it is located 275 kilometers to the south of Addis Ababa (the capital city of the Ethiopia). In the zone, there are four governmental hospitals and 107 public health centers.[19]

Study Design

Retrospective cohort study design was used by reviewing children's intake, follow-up, and routine data forms from both paper-based and electronic database system. CD4 count ≤ 350 (cells/mm3) was considered as exposed group and CD4 count >350 (cells/mm3) non-exposed group based on a similar study conducted in Adama.[15]

Study Population

The study population was HIV-infected children (age <15 years) registered for antiretroviral therapy from September 2014 to August 2018.
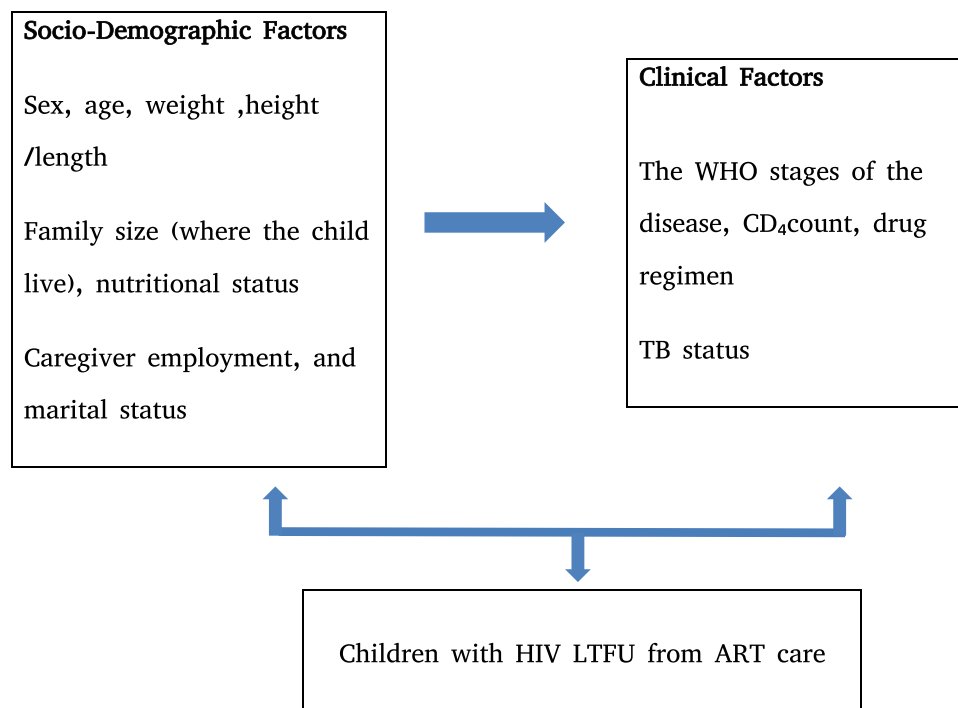
Figure 1 A conceptual framework for determinants of LTFU among HIV-infected children in ART care in Sidama Zone from September 2014 to August 2018.

Eligibility Criteria

Children that registered for ART care between September 2014 to August 2018 were eligible for this study. However, those who did not have at least one follow-up visit after the initiation of ART or those who had incomplete baseline data due to transferring to treatment centers or lost records were not included.

Study Variables

In this study, the dependent variable was time to lost to follow-up (LTFU) and LTFU is defined as not seen since ≥ 1 month based on the national ART treatment guideline and WHO patient monitoring guideline for HIV care and ART.[20,21]

The explanatory variables were socio-demographic variables including the children's age, sex, family size as well as caregivers' marital status, religion, and employment status. Moreover, clinical variables such as the children's baseline TB status, CD4 count, and clinical stage were considered as explanatory variables.

Sample Size Calculation

143 children (age <15) that were enrolled for ART treatment in Sidama Zone from September 2014 to August 2018 were included in this study.
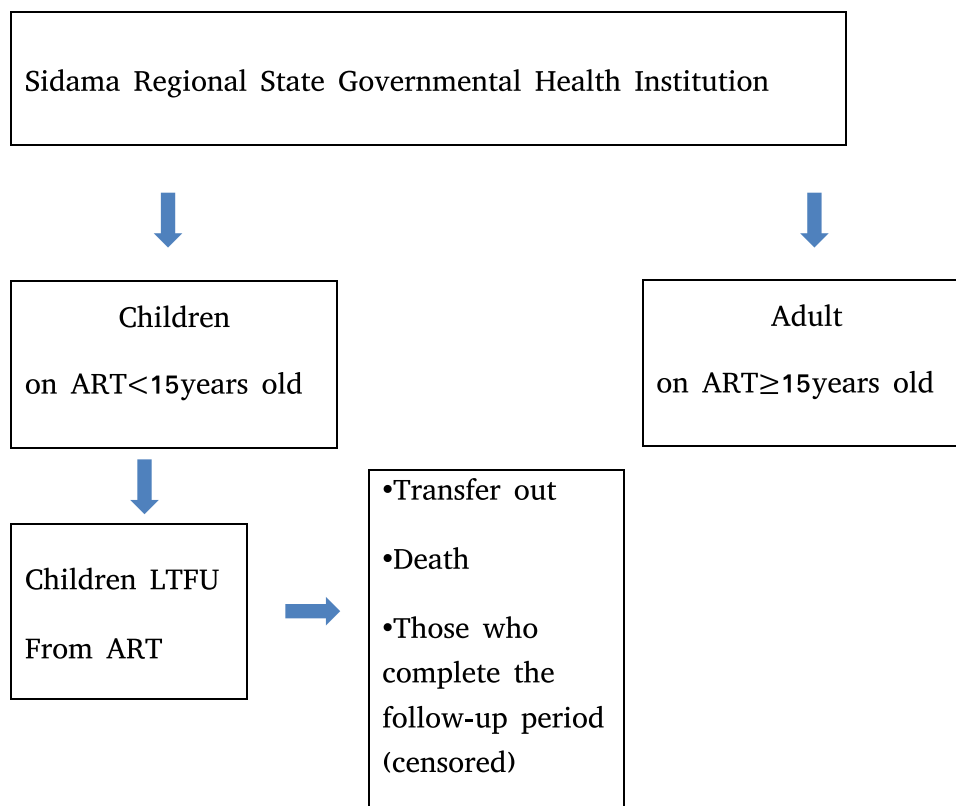
Sampling Procedure

In this study the study population and the sample size were equal (Figure 2).

Data Collection Tools and Techniques

Structured data extraction checklist was used to capture relevant variables for the study. The tool was developed by consulting the standardized HIV/AIDS care intake forms, individual patient records, and other relevant literature.[8–11,20,21] Seven nurses working at ART clinics were recruited for data collection. The principal investigators provided two-day training for data collectors on the objective of the study and the data collection tool. The data collection was closely supervised, and accuracy of the data was cross-checked and managed accordingly daily by two supervisors and the principal investigators.

Data Quality Control

The collection of data was closely supervised by principal investigators. The data quality was maintained through selection and training of data collectors. Both the electronic database and patient intake forms were used as a source of data and inconsistencies were checked and only the appropriate patient intake form was considered for this study.

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Children
on ART<15years old

Adult
on ART≥15years old

Children LTFU
From ART

• Transfer out

• Death

• Those who complete the follow-up period (censored)

Figure 2 Study participant selection procedure for determinants of LTFU in children followed-up on ART care in Sidama regional state from September 2014 to August 30 2018.

Data Management

The data were entered, cleaned, and coded by STATA version 12 software package and it was used for all statistical analysis. Event was LTFU and it was coded as 1 and censorship was considered for death, transfer out and follow-up period completion and was coded as 0. Time to event was calculated by subtracting the date of ART started (t_o) from the date the event occurred (t_e) and some of the continuous variables like age and CD4 count were categorized depending on need for interpretation.

Data Analysis

Descriptive statistics such as frequency and percentages were calculated for categorical variables and survival analysis was carried out to calculate the incidence of LTFU. Kaplan-Meier retention estimates and the Log rank test were used to estimate retention across the levels of categorical variables. However, univariate Cox-proportional hazard regression was fitted for the continuous variables. Based on Hosmer & Lemeshow recommendation, significant variables (at $p_1 \leq 0.25$) during

univariate analysis were identified and selected for multivariable regression, then, by using Collett model selection method, four step process was used.[22] Backward selection to eliminate non-significant variables at the level of $p_2=0.10$ was used as the first (1) step, then, those variables that were non-significant from step (1) were considered using forward selection, with significance level $p_3 =0.10$. Finally, any that were significant at p_3 would be added, then stepwise regression with significance level $p_4 =0.05$ was used. Multivariable Cox proportional hazards model was fitted to investigate predictors of LTFU. Proportionality assumptions were checked by using -log-log plot graphically and fitting the model with time-varying covariates and global tests (using Schoenfeld residuals) were used to test for validity of the proportional hazard assumption. Then, multi-collinearity test was done by using variance inflation factor (VIF) and tolerance. The interactions between predictor variables were also checked. The goodness of fit for the model was checked by using Cox-Snell residuals and both the Akaike and Bayesian information criteria (AIC/BIC)

were used to assess model parsimony. For detecting the outlier and influential case, deviance residual and delta-beta estimates were used. The statistical significance was tested using Wald statistics, with results $p<0.05$ considered statistically significant. The strength of association was measured and presented as hazard ratio (HR) with 95% confidence intervals (95% CIs).

Results

Table 1 shows the baseline socio-demographic characteristics of the HIV-infected children and their caregivers included in this study. 76 (53.15%) of the participants were female children with a median age of 7 years and interquartile range of 4 −9. The median number of family members where the children resided was 4, as 96.5% of the children were living in a family size of 4. 77% of the children's caregivers were married, while 15% were widowed. Additionally, the majority of the caregivers were protestants (86.7%) (Table 1).

Baseline Clinical Characteristics of Children

Based on the WHO clinical staging system for HIV/AIDS, 56.64% of the children were stage I while 27.97% of them were stage II (Table 2). At baseline, the median CD4 count was 701 cells/ mm^3. Stage III and IV are considered as the

advanced stages of the disease, and they accounted for 15.39% of our participants (Table 2).

Incidence of Lost to Follow-Up

The incidence rate was 5 per 100 person-years and the cumulative incidence rate was 12.59%. The median follow-up time was 2.46 years while the total time at risk was 356.06 person-years. Furthermore, 55.56% and 72.22% of those lost were within the first and the second years, respectively, of follow-up (Table 3).

Comparison Groups

Test of equality across strata to explore whether or not to include the predictor in the model was checked by Log rank test (Chi-squared test). If the predictor test had a $p \leq 0.25$ it was considered for model building (Table 4). The Kaplan-Meier retention estimate graphically showed the retention difference between groups and if the difference was significant, the graphs were separated as this indicated an insight to consider the variable in the model and if there was no difference between groups the graphs were close to each other and crossing (Figure 3).

Predictors of Lost to Follow-Up

In the univariate analysis, for variables with fewer cases we merged them based on their relationships and we rerun

Table 1 Baseline Socio-Demographic Characteristics of Children That Were Enrolled in ART Care in Sidama Zone from September 2014 to August 2018

Characteristics	Number (%)	
Sex	Male	67(46.85)
	Female	76(53.15)
Age	≤7	95(66.43)
	>7	48(33.57)
Number of family members where the child lives	Family size <4	5(3.5)
	Family size > 4	138(96.5)
Caregivers' related variables		
Employment Status	Employed	30(20.98)
	Not employed	113(79.02)
Marital Status	Never married	5(3.50)
	Married	111(77.62)
	Divorced/separated	5(3.50)
	Widowed	22(15.38)
Religion	Orthodox	16(11.19)
	Muslim	4(2.8)
	Protestant	123(86.01)

Table 2 Baseline Clinical Characteristics of Children That Were Enrolled in ART Care in Sidama Zone from September 2014 to August 2018

Characteristics		Number (%)
WHO clinical stage	I	81(56.64)
	II	40(27.97)
	III	20(13.99)
	IV	2(1.40)
CD4 count (cells/mm^3)	≤701	124(86.71)
	>701	19(13.29)
TB Status	TB positive	19(13.29)
	TB negative	124(86.71)
Functional Status	Walking	96(67.13)
	Ambulating	43(30.07)
	Bedridden	4(2.80)

the data with these merged variables. For instance, according to the WHO clinical staging system for HIV/AIDS, stage I and stage II can be considered as early stages of the disease (121 cases after merging) and WHO clinical stage III and stage IV can be considered as advanced stages of the disease (22 cases after merging). However, even after merging, the clinical stages were not candidate variables for multiple Cox regression model.

TB status, sex, and functional status of the HIV-infected children were candidate variables for multivariable Cox proportional hazard model. However, in the multivariable Cox proportional model, we found that only TB status of the child was significantly associated with lost to follow-up (Table 5) with hazard ratio of 3.348 [1.174831, 9.543494] and *p*-value of 0.024.

Discussion

Several studies have demonstrated that LTFU poses a major threat to the success of ART programs throughout the world. A discontinuation of ART care, in children and adults, is associated with a rapid increase in viral load, in development and transmission of the drug resistant virus variants as well as compromised immune function that puts the patients at risk of other opportunistic

Table 3 Incidence of Lost to Follow-Up Time Interval for Children That Were Enrolled in ART Care in Sidama Zone from September 2014 to August 2018

Interval	Total	Lost to Follow-Up	Censored	Retention Probability	Error	[95% Conf. Int.]
0–1	143	10	31	0.9216	0.0238	[0.8591 0.9570]
1–2	102	3	17	0.8920	0.0285	[0.8206 0.9361]
2—3	82	2	19	0.8674	0.0326	[0.7876 0.9187]
3–4	61	1	16	0.8510	0.0359	[0.7640 0.9079]
4–5	44	1	37	0.8177	0.0475	[0.7015 0.8920]
5	6	1	5	0.5840	0.2003	[0.1530 0.8572]

Table 4 Log Rank Test for Equality of Lost to Follow-Up Between Different Groups of Children Followed-Up in Sidama Zone from September 2014 to August 2018

Variable	Log Rank Test (Chi^{2}Test)	Degrees of Freedom (DF)	p-value
Age Dummy	0.90	1	0.3431
Sex	1.97	1	0.1601
WHO clinical stage	1.18	3	0.7589
CD4 count Dummy	0.82	1	0.3665
Functional status	9.51	2	0.0086
TB status	1.97	1	0.1602
Marital status	3.45	3	0.3267

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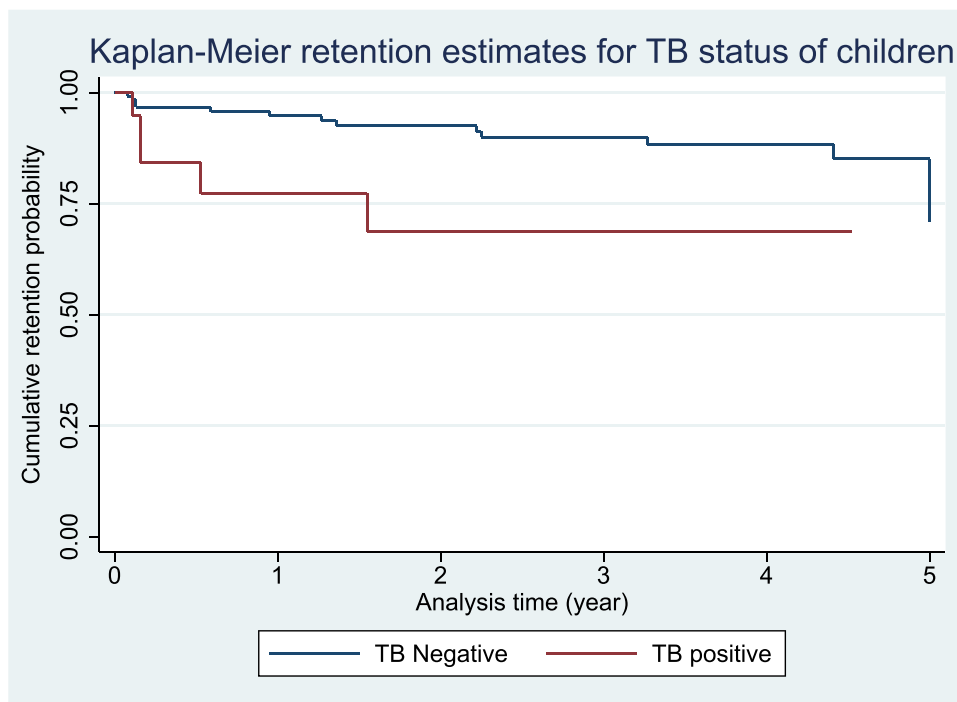
Figure 3 Kaplan-Meier retention estimates for the variable TB status of children followed-up in ART care in Sidama Zone from September 2014 to August 2018.

infections.[3,7,23,24,32] Thus, understanding the predictors associated with LTFU is crucial for the development of targeted interventions to improve patient retention.[27,28] Accordingly, our study sought to determine the incidence rate and predictors of LTFU among HIV-infected children in Sidama zone, Ethiopia. In this study, the incidence rate was estimated to be 5 per 100 person-years and the cumulative incidence, 12.59%. The median follow-up time was 2.46 years and the total time at risk was 356.06 person-years.

The attrition rate we calculated is higher than that of similar studies conducted in Gondar (6.2%), Addis Ababa (8.3%), Asia (4.1%), and South Africa (9.0%).[4,26,30,31] This is in contrast to reports from Adama (18%), East Africa (14%), and West Africa (21.8%).[15,25,26] Regardless of the lower cumulative incidence rate compared to these previous studies, our study shows that a significant number of children were still LTFU from care.

Other studies have also indicated that LTFU is associated with TB/HIV co-infection in both adults and children. Consistently, our findings showed that TB/HIV co-infected children were more likely to be lost compared to those who had no TB/HIV co-infection with hazard ratio of 3.348 [1.174831 9.543494] and p-value of 0.024.[30,31,33,34] In addition, we found that 55.56% and 72.22% were lost within the first and the second years of follow-up, respectively.

Table 5 Univarate and Multivariable Analysis of Predictors of LTFU for Children Followed-Up in Sidama Zone from September 2014 to August 2018

Characteristics		Multivariable HR and 95% CI	p-value
TB status	TB Postive TB Negative	3.348 [1.174831 9.543494]	0.024
Sex	Male Female	[0.1865302 1.350691]	0.172
Functional status	Walking Ambulating Bedridden	0.391 [0.1191284 1.285411]	0.172

Correspondingly, other studies in different parts of the world have shown that the highest proportion of LTFU is, indeed, observed within the first (14%) and second (28%) years of ART care.[15,25,25]

Our study explored the characteristics of HIV-infected children and their care givers in an attempt to identify predictors of LTFU in the Sidama zone. However, we also had several limitations as the method we used was a retrospective cohort study. As a result, some important variables such as the children's nutritional status were not included. Since the patient intake form did not specify whether the children had edema or if their height was measured in standing or recumbent position, we were not able to assess the children's nutritional status in relation to LTFU.

Conclusion

In this study, we found that TB status of the HIV-infected children was a significant determinant of LTFU in the Sidama zone. Also, higher proportions of loss were observed within the first and second years of follow-up. Our finding is further supported by similar studies conducted in other parts of Ethiopia such as Adama, Tigray, and Benishangulgumz, which showed TB status of HIV-infected children and adults is a significant predictor of LTFU.[15,30,31,33,34] Thus, our study calls for a new policy supporting different retention mechanism for children and adults in ART with and without TB infection, especially during the first and second years of ART care follow-up.

Abbreviations

AIDS, Acquired Immune Deficiency Virus; ART, Anti-Retroviral Treatment; ARV, Antiretroviral; BIC, Bayesian Information Criteria; CD4, Cluster of differentiation 4; CI, confidence interval; CPT, Cotrimoxazole Prophylaxis; EDHS, Ethiopian Demographic Health Survey; GOE, The Government of Ethiopia; Hgb, Hemoglobin; HIV, Human Immune Deficiency Virus; HR, hazard ratio; INH, Isoniazid; IQR, interquartile range; LTFU, Lost To Follow-up; NGO, Non-Governmental Organization; NTD, Neglected Tropical Disease; PCP, Pneumocystis Carinii Pneumonia; PLHIV, People Living with Human Immune Deficiency Virus; PMTCT, Prevention of Mother to Child Transmission of HIV; SD, standard deviation; SDG, Sustainable Development Goal; TB, Tuberculosis; UNAIDS, Joint United Nations program on HIV and AIDS and WHO, World Health Organization.

Data Sharing Statement

The datasets used are available from the corresponding author and thus, it will be provided based on reasonable request.

Ethical Consideration of the Study

Ethical approval was obtained from the Institutional Review Board of Hawassa college of Health Science with ref number H/H/S/C/05/15/272/1 and also a support letter sought from Sidama Zone office to all ART treatment centers with ref number H/1/1514/1. Confidentiality of patients' data was ensured by using non-personal identifiers such as patients' medical registration number and the unique ART number to distinguish study subjects during data collection. Written consent was not feasible for records' review in our setting. However, this study was done in accordance with the Declaration of Helsinki.

Author Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

Disclosure

The authors declare that they have no conflicts of interest for this work.

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