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Prevalence, Risk Factors and Residential Variation among HIV/TB co-infected Mortality in Amhara Region, Fenote Selam Hospital: Application of Multilevel Logistic Regression

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Abstract: The purpose of this study was to identify the factors that affect the mortality among adult HIV/TB co-infected patients and to see the nutritional difference among mortality in residence level. Retrospective cohort studies of 417 patients which fulfill our criteria were included. Multilevel logistic regression models were used. MLwiN and SPSS software are used to estimate the parameter. The variance of the random factor in the empty model was significant which indicates that there were residential differences in TB-HIV co-infected mortality and it shows multilevel analysis was an appropriate approach for further analysis. The prevalence of HIV/TB co-infected patients' death was 12.9% in study time. Functional status, age of patients, WHO clinical stages, nutritional status, CD4 counts, regimen, and BMI were found to be significant determinants of HIV/TB co-infected mortality. In our study, patients with the bedridden category of functional status, the fourth stages of WHO clinical stages (stage IV), patients with higher age, patients whose treatments were second-line regimen and low CD4 cell counts were more at risk of death. The study also revealed that; poor nutritional status increased the risk of mortality among HIV/TB co-infected patients and it varies among the residence of the patients (rural area were more at risk).

Keywords: HIV/TB co-infected Mortality, Residential Variations, and Multilevel Logistic Regression.

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1.1.Background of the Study

HIV is the most efficacious factor assignee for the progression of an undercurrent of TB to active and the probability of people living with HIV higher risk to develop TB. HIV/TB co-infection is thus known as double trouble and a public health threat especially for regions where both diseases are endemic [28]. Among the patients of HIV, TB and other infectious diseases increase the rate of HIV replication and this acceleration may result in higher viral replication along with a more rapid progression to AIDS [24]. In another case, HIV-positive patients are 20 to 30 times more likely to develop active TB [21]. In 2017, 1.6 million people died by TB and of which 300,000 deaths was the TB/HIV co-infection death and around 770,000 deaths were HIV/AIDS-related death [27, 28]. According to UNAIDS in 2016, the scaling up of antiretroviral therapy (ART) has been the main contributor to the 45.0% reduction in global deaths among people living with HIV (PLHIV). However, these two diseases have remained raging epidemics, especially in developing countries and TB is the leading cause of death among HIV/AIDS patients. Globally, 1.3 million estimated persons are living with TB and HIV/AIDS co-infection and this burden of TB-HIV co-infection is higher in developing countries [13, 30]. The sub-Saharan Africa bears the brunt of the dual epidemic, accounting for approximately 84% of all death were from HIV- associated TB, in 2018 two out of five TB–HIV patients died within 10 years after ART initiation [7]

Ethiopia is one of the sub-Saharan countries in which the dual burden of TB/HIV co-infection has severely hit. The Ethiopian Federal HIV and AIDS Prevention and Control Office estimated that the single national HIV/AIDS prevalence was 2.4% in 2015, and the country is among the top ten high burden counties with an incidence rate of 341/100,000 of which 31% of TB patients are living with HIV [13]. Malnutrition further weakens the immune system, leading to greater susceptibility to opportunistic infections. In addition, at least one-third of the 36.7 million people living with HIV (PLHIV) worldwide are co-infected with tuberculosis (TB), leading to even greater metabolic stress and risk of malnutrition [26].

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Data and Methodology

We used data from a retrospective cohort of all adult patients of HIV/AIDS under follow-up of ART treatment whose ages were greater than 15 years at Fenote Selam General Hospital from February 2010 to January 2020. In this study, Persons diagnosed with HIV disease that following the ART treatments that's their age were less than 15 years and the patients who does not experience TB at least once in the study time were not included. 417 patients who full filled these criteria were included in this study.

Study Variables

The outcome variable in this study was HIV/TB co-infected mortality. The response variable was dichotomized indicating whether patients of HIV/TB co-infected were dead or alive.

Many explanatory variables were used as predictors of HIV/TB co-infected mortality. These are, age of patients, CD4 counts, sex of the patient, weight, BMI, residence, nutritional status, functional status, WHO clinical stage, and regimen.

Multilevel Logistic Regression Model

We used multilevel modeling approach which we believd that it is appropriate for heirartchical sampling procedure. The main statistical model of multilevel analysis is the hierarchical generalized linear model which is an extension of the generalized linear model that includes nested random coefficients. Hierarchical modeling explicitly accounts for the clustering of the units of analysis, individuals nested within groups. Such data structures are viewed as a multistage sample from a hierarchical population. In this data structure, level-1 is the patient's level and level-2 is the residential level. Within each level-2 unit there are n_j HIV/TB co-infected patients in the j^{th} residence. Let Y_{ij} be the binary response for HIV/TB co-infected patients mortality in j residence and X_{ij} be an explanatory variable at the patients level. We define the probability of the response equal to one $\pi_{ij} = pr(y_{ij} = 1),\ where, \pi_{ij}$ be modeled using a logit link function. The standard assumption is that, Y_{ij} has a Bernoulli distribution. Then, the two level models are given by:

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$$logit(\pi_{ij}) = \log\left[\frac{\pi_{ij}}{1-\pi_{ij}}\right] = \phi_{0j} + \sum_{h=1}^{k}\beta_{hj}x_{hij}, \quad (1)$$

$i = 1,2,...,n_j$, $h = 1,2,...,k$, $j = 1,2...11$, $\phi_{0j} = \beta_0 + U_{0j}$, $\beta_{hj} = \beta_1 + U_{1j},...,\beta_{kj} = \beta_k + U_{kj}$

$$logit(\pi_{ij}) = \log\left[\frac{\pi_{ij}}{1-\pi_{ij}}\right] = \beta_0 + \sum_{h=1}^{k}\beta_{hj}x_{hij} + U_{0j} + \sum_{h=1}^{k}U_{hj}x_{hij}, \quad (2)$$

where,

$X_{ij} = (X_{1ij}, X_{2ij},..., X_{kij})$ represent the first and the second level covariates, for variable k

$\beta = (\beta_0, \beta_1,..., \beta_k)$ are regression parameter coefficient

U_{0j}, $U_{1j},...,U_{kj}$ are the random effect of the model parameter at level two.

We assume that, U_{hj} follows normal distribution with mean zero and variance σ_u^2.

The model decomposes the total variance into residence level and patient's levels, representing the between and within residence variability in the mortality of HIV/TB co-infected patient's. (Hox & Roberts, 2011). The interclass correlation (ICC) measures correlation between observations within cluster as:

$$\frac{\sigma_u^2}{\sigma_{u+}^2\sigma_e^2} \quad (3)$$

Where σ_u^2 is between residence variation and σ_e^2 is within patients variation

Multilevel Analysis of Empty Models

The empty two-level model for a binary response variable refers to a population of groups (level two units) and specify the probability distribution for group dependent probabilities without taking further explanatory variables into account. The logit linear predictor is given as:

$$logit(\pi_{ij}) = \beta_0 + U_{0j} \quad (4)$$

Where $\pi_{ij} = \frac{e^{\beta_0 + U_{0j}}}{1 + e^{\beta_0 + U_{0j}}}$ and the deviation U_{0j} are assumed normal distribution with mean zero and variance σ_0^2.

Multilevel Analysis of Random Intercept Models

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In the random intercept logistic regression model the intercept is the only random effect that the groups (residence) differ with respect to the average value of the response variable. But the relation between explanatory and response variables can differ between groups (residence). We assume that there are variables which potentially explain the observed success and failure. These variables are denoted by X_h, h=1,2,...,k with their values indicated by X_{hij}. Since some or all of those variables could be level one variable, the success probability is not necessarily the same for all individual in a given group. The logit of π_{ij} is a sum of linear function of explanatory variables and given as:

$$\text{Logit}(\pi_{ij}) = \log\left[\frac{\pi_{ij}}{1-\pi_{ij}}\right] = \beta_{0j} + \beta_1 X_{1ij} + \ldots + \beta_k X_{ijk} \quad (5)$$

where the intercept term β_{0j} is assumed to vary randomly and is given by the sum of an average intercept β_0 and group-dependent deviations U_{0j}, that is $\beta_{0j} = \beta_0 + U_{0j}$

$$logit(\pi_{ij}) = \beta_0 + \sum_{h=1}^{k} \beta_{hj} x_{hij} + U_{0j} \quad (6)$$

where $\beta_0 + \sum_{h=1}^{k} \beta_{hj} x_{hij}$ is the fixed part of the model and U_{0j} is the random part. The π_{ij} is given as:

$$\pi_{ij} = \frac{e^{\beta_0 + \sum_{h=1}^{k} \beta_{hj} x_{hij} + U_{0j}}}{1 + e^{\beta_{0j} + \sum_{h=1}^{k} \beta_{hj} x_{hij} + U_{0j}}} \quad (7)$$

Multilevel Analysis of Random Coefficient Models

In logistic regression analysis, linear models are constructed for the log-odds. The multilevel analogue random coefficient logistic regression is based on linear models for the log odds that include random effects for the groups or other higher level units. Consider explanatory variables which are potential explanations for the observed outcomes. The values of X_h (h=1,2,3,...,k) are indicated in the usual way by X_{hij}, since some or all of these variables could be level one variables, the success probability is not necessarily the same for all individuals in a given group(region). Therefore, the success probability depends on the individual as well as the group, and is denoted by π_{ij} . Now consider a model with group specific regression of logit of the success probability logit (π_{ij}) on a single level -one explanatory variables X.

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$$logit(\pi_{ij}) = \log\left[\frac{\pi_{ij}}{1-\pi_{ij}}\right] = \beta_0 + \sum_{h=1}^{k}\beta_h x_{hij} + U_{0j} + \sum_{h=1}^{k}U_{hj}x_{hij} \quad (8)$$

The term $\sum_{h=1}^{k}U_{hj}x_{hij}$ can be regarded as a random interaction between group and the explanatory variables. The deviation U_{hj} are assumed normal distribution with mean zero and variance covariance matrix Ω This model implies that the groups are characterized by two random effects: their intercepts and their slopes. It assumes that, for different groups the pairs of random effects (U_0, U_{hj}, h= 1,2,...,k) are independent and identically distributed. The random intercept variance, $Var(U_{0j}) = \sigma_0^2$, the random slope variance , $Var(U_{1j}) = \sigma_1^2$ and the covariance between the random effects, $Cov(U_{0j}, U_{1j}) = \sigma_{01}^2$ are called variance components (Snijders and Bosker, 1999).

$$logit(\pi_{ij}) = \log\left[\frac{\pi_{ij}}{1-\pi_{ij}}\right] = \beta_{0j} + \sum_{h=1}^{k}\beta_{hj}x_{hij} + U_{0j} + \sum_{h=1}^{k}U_{hj}x_{hij}, \quad (9)$$

$$Where, \pi_{ij} = \frac{e^{\beta_{0j}+\sum_{h=1}^{k}\beta_{hj}x_{hij}+U_{0j}+\sum_{h=1}^{k}U_{hj}x_{hij}}}{1+e^{\beta_{0j}+\sum_{h=1}^{k}\beta_{hj}x_{hij}+U_{0j}+\sum_{h=1}^{k}U_{hj}x_{hij}}} \quad (10)$$

Results

The study included 417 patients with HIV/AIDS who experiences TB at least one time during the study time. As we have seen from the following Table 1, among the total HIV/TB co-infected patients 417, 54 (12.9%) of them are dead in study time. Of the total patients, 56.5 % were female and the rest 43.5% were males. From this result, we have seen that; most of the patients (68.1%) were from an urban area and the rest (31.9%) were from rural parts of our study area. The functional status of the patients was also summarized in this table. Accordingly, out of the total patients of HIV-TB co-infected, 10.3%, 22.7%, and 67% were bedridden, ambulatory, and working respectively. Depending on the WHO stage, most patients were found in the first stage of WHO which was 51.1% and the least percent of the patients were in the fourth stage of WHO which was 6.9%. Among the patients HIV/TB co-infected, most of them (95.9%) were treated by

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using the first-line regimen, and the rest of the patients (4.1%) were treated by the second-line regimen.

Moreover, we have seen from this table that, the mean age of the HIV-TB patients in this area was 35.92 with a standard deviation of 9.43 to be alive and the mean age of HIV/TB co-infected patients to be death were 48.87 years with a standard deviation of 6.96. The mean weight of death in HIV/TB co-infected patients was 44.32 kg with a standard deviation of 8.18 kg. The mean weight for alive of HIV/TB co-infected was 51.93. The mean of the body mass index for dead HIV/TB co-infected patients was 17.58 with a standard deviation of 2.199 were as for alive patients it was 19.34 with a standard deviation of 3.18. The mean of CD4 counts for patients alive and dead for HIV/TB co-infected were 198.78 and 76.66 respectively with their standard deviation of 186.3 and 91.16 respectively.

Table 1: Descriptive Statistics

Variables	Status		chi-square
	alive No(%)	Death No(%)	
Sex			0.315
Female	205(56.5)	30(55.5)	
Male	158(43.5)	24(44.5)	
WHO			0.000
WHO1	179(51.1)	5(9.3)	
WHO2	97(27.7)	8(14.8)	
WHO3	50(14.3)	15(27.8)	
WHO4	24(6.9)	26(48.1)	
Functional status			0.000
Bed driven	39(10.7)	30(55.5)	
Ambulatory	81(22.3)	15(27.8)	
Working	243(67)	9(16.7)	
Nutritional status			0.000
Under nutrition	80(22)	41(75.9)	

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Normal	224(61.7)	11(20.4)	
Over nutrition	59(16.3)	2(3.7)	
Residence			0.000
Urban	246(68.1)	30(55.5)	
Rural	115(31.9)	24(44.5)	
Regimen			
First line	348(95.9)	17(31.5)	
Second line	15(4.1)	37(68.5)	
Age			0.000
Mean+s.deviation	35.92+9.43	48.87+6.96	
BMI			0.017
Mean+s.deviation	19.34+3.18	17.58+2.199	
CD4			0.396
Mean+s.deviation	198.78+186.3	76.66+91.16	
Weight			0.012
Mean+s.deviation	51.93+9.96	44.32+8.18	

The data set has a two-level hierarchical structure, with 417 TB-HIV patients nested within two residences (urban and rural). In this study, we examined determinants of TB-HIV co-infected patient mortality with respect to their residence. From Table 2 below, the result showed that there was a significant variation among the level two's (residence). From the results, the variance of the random factor was significant which indicates that there are residential differences in TB-HIV co-infected mortality. Thus, multilevel analysis was appropriate to approach for further analysis.

Table 2: Multilevel Logistic Regression Empty Model

Model	Estimate	S.E	Z-value	P-value
Fixed Intercept(β_0)	0.135	0.02	6.75	0.000*
Random Intercept $Var(U_{0j})=\sigma^2_{u0}$	0.02	0.007	2.86	0.00222*

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σ_e^2 ICC	0.094 0.175	0.008		

Multilevel Logistic Regression Model Comparison

From Table 3 below, the deviance-based chi-square with their p-values shows the three models (empty model, random intercept, and random slope multilevel model) are significant. From this Table, we have seen also the AIC values for each model. Accordingly, the multilevel random slope model has small (705.9) relative to the other model and shows that, it better fit our data.

Table 3: Deviance χ^2 and AIC for each model

Model		Deviance based χ^2	p-value	AIC
Multilevel Empty model		149.45	0.000*	973.8
Multilevel random intercept		128.3	0.000*	746.5
Multilevel Random slope		197.02	0.00*	705.9

From the result of the random coefficient (slope) multilevel logistic model presented in Table 4 below, the death of adult TB-HIV co-infected who were treated by using the second-line regimen was 7.17 times more likely than that of treated by the first line. From this result, we have seen that the WHO clinical stage was also significantly associated with the death of HIV/TB co-infected. Accordingly, the death of patients for the first and second stages of WHO was 91.2% and 67.7% less likely as compared with that of the fourth WHO stage. The other significant factor of HIV/TB co-infected was their functional status. The odds of ambulatory patients were 0.535. This implies that the death of HIV/TB co-infected patients was 46.5% less likely as compared with the reference category which is bedridden. The death of adult HIV/TB patients for working groups was 59% less likely than that of bedridden. Depending on nutritional status, odds the death for patients of HIV/TB co-infected who's their nutritional status was normal were

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31.1% times less likely than those under nutritional status.

The other significant factors of HIV/TB co-infected death were the age of the patients. For every unit change age, the log odds of death of patients were increased by 0.062. Again, for a one-unit increase in CD4 of the patients, the log odds of being dead were decreased by 0.934. Moreover, the body mass index of the patients was also significantly related to the death of the HIV/TB co-infected patients. This implies that, for a unit increase in BMI of patients, the log odds of death were decreased by 1.04.

From the output again, the random coefficient estimates for intercepts and the slopes vary significantly at a 5% significance level. The residence-wise intercepts and the slope (nutritional status) vary significantly. This shows that there was a significant variation in the effects of these explanatory variables across the residence. The variance of the interaction between the intercept and slopes of the explanatory variables is also significant. The negative sign for the correlation between intercepts and slopes implies that residence with lower intercepts tends to have on average higher slopes on the corresponding predictors. The covariance between the intercept and random slope of nutritional status was -0.0201. This implies that the adult HIV/TB co-infected patients' mortality whose functional status was normal was less than those under nutrition patients at the residence level.

Table 4: Multilevel Logistic Regression of Random Intercept

Fixed Effect	Coefficient	Odds ratio	S.E	Z-value	P-value
Constant					
Sex (ref=male)					
Female	-0.962 -	0.382	0.781	-1.23	0.1097
WHO (ref= WHO4)					
WHO1	-2.43	0.088	0.603	4.03	0.0003
WHO2	-1.13	0.323	0.391	-2.89	0.002
HHO3	1.011	2.75	0.994	1.02	0.1542

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fstatus (ref=bedridden)	-	-	-	-	
Ambulatory	-0.626	0.535	0.072	-8.69	0.000
Working	-0.89	0.41	0.091	-9.78	0.000
Nutrition(ref=under)					
Normal	-0.372	0.689	0.071	-4.6	0.000
Over	0.0735	1.08	0.045	1.63	0.0519
Age	0.062	1.064	0.012	5.17	0.000
Weight	-0.037	0.964	0.0261	-1.42	0.0782
BMI	-1.04	0.353	0.391	-2.66	0.0041
Regimen(ref=reg1)					
reg2	1.97	7.17	0.59	3.34	0.00046
CD4	-0.934	0.393	0.172	-5.43	0.000
Random Effect	**Estimate**		**S.E**	**Z-value**	**p-value**
Var(U_0j)	0.008		0.004	2.0	0.0231
Var(U_5j)	0.010		0.003	3.33	0.00047
Cov(U_0j,U_5j)	-0.0201		0.0041	4.9	0.000
Variance(Residual)	0.0409		0.004	10.23	0.000
Deviance-Based Chi-Square	104.4				0.000

Discussion

This study attempts to see the effect of nutritional status and other factors of HIV/TB co-infected mortality using the multilevel logistic regression analysis. In our study multilevel logistic regression was the best fitted model for our data. From this result we have seen that WHO clinical stages were significantly related to mortality among HIV/TB co-infected patients. Accordingly, the odds of mortality for the first and second WHO clinical stages were lower than that of the reference category (WHO clinical stage four). These results were consistent with the

study done by [5, 8, 15, and 31].

In our study, the Functional status of HIV/TB co-infected patients following ART initiation was a significant predictor of patients' death. According to our results, the odds of death among working patients and ambulatory patients was less than that of bedridden patients. This might be due to the fact that bedridden patients have been long in bed so that their clinical characteristics are deteriorating and the disease progression has been implicated here with low CD4 count. These results were similar to the previous study done by [1, 3, and 19]. This study also showed that patients with low CD4 have a high risk of mortality and as CD4 of patient's increases; the log odds of mortality among HIV/TB co-infection were decreased. These ideas were supported by the study of [5, 9, and 21]. The odds of death among aged patients of HIV/TB co-infected increased and this result is consistent with the study [10, 22]. Similarly, this study showed that; the body mass index (BMI) has significant negative relationships with the mortality among HIV/TB co-infected patients. This implies that, as the BMI increased, the odds of mortality were decreased. This finding was similar to the findings of [4, 17, and 32].

Moreover, HIV/TB co-infected patients who are their treatments were second-line regimen were more likely to die than that of first-line treatment regimen and this result was coinciding with the findings of [12]. From random coefficient multilevel logistic regression, the nutritional status was significantly associated with mortality among HIV/TB co-infected patients. Accordingly, patients were their nutritional status, were normal, and were less likely to die as compared with under nutritional status patients. This result also shows the effect of nutritional status on mortality among HIV/TB patients was significantly different in residential (rural or urban). So, poor nutritional status can contribute to poor adherence to both tuberculosis treatment and HIV antiretroviral therapy (ART). This finding was consistent with the findings of [11, 14, 16, 18, and 20].

Conclusion

The purpose of the study was to identify the determinants of HIV/TB co-infected patient mortality and to assess residential variations of pre-natal mortality in Fenote Selam hospital using multilevel logistic regression analysis. It was found that multilevel random coefficient model is better fits our data as compared to the empty (null) model and random Intercept model. From the result of the multilevel empty model, the variation of patient mortality was among higher levels (residence level) and the multilevel model was appropriate for our data. CD4, age

 doi:10.20944/preprints202201.0165.v1

of patients, BMI, nutritional status, functional status, WHO clinical stages, regimen were significant variables as determinants of HIV/TB co-infected. From our data we have seen that the prevalence of HIV/TB co-infected mortality was 12.9%.

The mortality among patients of HIV/TB co-infected was increased as the age of patients was increased which shows the age and mortality of HIV/TB co-infected were positively related. The mortality of patients was negatively related to CD4 counts and body mass index (BMI) of patients. As CD4 and BMI were increased, the mortality of HIV/TB co-infected was decreased. The odds of mortality for the first and second WHO clinical stages were lower than that of the reference category (WHO clinical stage four). The odds of death among HIV/TB co-infected working patients and ambulatory patients were less than that of bedridden patients. HIV/TB co-patients whose treatments were second-line regimen were more likely died than that of the first-line treatment regimen.

The nutritional status was significantly associated with mortality among HIV/TB co-infected patients. A patient whose nutritional status was normal was less likely to die as compared with under nutritional status patients. The effect of nutritional status on mortality among HIV/TB patients was significantly different in residential (rural or urban). Poor nutritional status can contribute to poor adherence to both tuberculosis treatment and HIV antiretroviral therapy (ART) and in our study, patients from rural areas were experienced poor nutritional status and were more at risk of death than urban.

Abbreviation

AIC Akaike Information Criterion
AIDS Acquired Immune Deficiency Syndrome
ART Anti-retroviral Treatment
HIV Human Immune Deficiency Virus
SPSS Statistical Package for Social Science
TB Tuberculosis
UNAIDS United Nations HIV/AIDS
UNICEF United Nations Children's Fund
WHO World Health Organization.

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Declarations

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Ethics approval and consent to participate
This study has been done by individual and ethical approval and consent to participate is not applicable

Authors' contributions
All activities on this paper were done by Berhanu Bekele.

Availability of data and material
All data supporting the study belongs to Fenote Selam General Hospital. The data is available upon request.

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