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Defaulting from antiretroviral therapy and associated factors among HIV/AIDS patients in public hospitals of Eastern Zone, Tigray, Ethiopia, 2020: a cross-sectional study

Tsegu H. Gebru, Haftea H. Mekonen

Adigrat University, Adigrat, Ethiopia

Abstract

Introduction: Globally, over 76 million people have been infected with human immunodeficiency virus (HIV), and the infection has contributed to more than 35 million deaths since its emergence. Studies revealed that in developing countries, defaulting patients were outnumbering patients who were known to have died. The burden of defaulting and associated factors among adults receiving antiretroviral therapy (ART) is lacking in this particular study area. Therefore, this study aimed to assess the prevalence of defaulting and associated factors among adult HIV/AIDS patients receiving antiretroviral therapy in Eastern Zone, Tigray, Ethiopia.

Material and methods: A structured questionnaire was employed to collect data from 501 study participants through an interview. The required sample size was determined with a single population proportion formula. Participants were selected using a systematic random sampling method. Data were entered and analyzed with Statistical Package for Social Science (SPSS) version 22. Multivariable logistic regression analysis was used to obtain factors, with p-value < 0.05.

Results: The mean age of participants was 40.97 (± 9.35) years. The prevalence of defaulting was 25% (95% CI: 21.2-29.1%). Side effects of ART, mental instability, poor adherence to ART, and high pill burden were independently associated with defaulting from ART.

Conclusions: The results of the study indicated that defaulting was high. Furthermore, participants with high pill burden, drug toxicity, mental instability, and poor ART adherence were more likely to default from the treatment. Healthcare providers should advise HIV patients to improve adherence to treatment, and highlight its importance as a priority issue.

Introduction

The human immunodeficiency virus (HIV) pandemic is among the greatest health crises ever faced by humanity [1]. HIV infection has contributed to more than 35 million deaths since its emergence. By the end of 2018, about 76 million people were living with HIV globally. Sub-Saharan Africa remains among the hardest hit regions by the pandemic, with nearly one in every 25 adults (4.2%) [2]. In the Ethiopian Demographic Health Survey (EDHS) in 2016, the overall pre-

Address for correspondence: Tsegu H. Gebru,
Adigrat University, Adigrat, Ethiopia,
e-mail: tsegshhailu16@gmail.com

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valence of HIV was found to be 0.9%. Regionally, in Gambella Regional State, Addis Ababa and few parts of Tigray were mapped with significantly high clusters of people living with HIV [3].

Antiretroviral therapy (ART) is considered the breakthrough in care and treatment of people living with HIV. With access to ART treatment, human immune deficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) has transformed into a chronic treatable condition for a significant proportion of people living with HIV (PLWHA). ART is now considered an integral part of comprehensive response to HIV prevention, care, and support. An increasingly widespread use of potent combination of ART since 1996 has substantially improved the prognosis of PLWHA in both developing and developed countries [4, 5].

The rapid expansion of treatment in resource-limited settings results in live-savings, quality of life improvement, and contribution to rejuvenation of households, communities, and the entire society [6, 7]. Nowadays, with the development of safe and effective ART drugs, HIV-positive people have longer and healthier lives [8]. Since currently available drugs do not cure HIV infection and only prevent its development into AIDS, PLWHA need to take ART drugs continuously for life-time [8, 9]. ART lowers viral load only when PLWHA fully adhere to the treatment regimen permanently. The process of initiating ART involves assessing patients, willingness to start treatment, readiness to commence therapy, and understanding of its implication (lifelong therapy, adherence, and toxicity) [10]. Furthermore, defaulting from ART may lead to sub-optimal therapy, and ultimately to treatment failure [11]. In resource-constrained settings where healthcare services are not well-developed, poor adherence to treatment and defaulting from treatment are the two major challenges for ART programs [12]. In developing countries, defaulting patients were outnumbering patients who were known to have died. Studies form South Africa and Malawi indicated that defaulting from ART resulted in 50% of all deaths [13, 14].

Previous studies on ART-linked database with 15 ART programs in Asia and South America showed that 16% of patients had defaulted from treatment [15]. The magnitude of defaulting in Africa, including Ethiopia, ranges from 13.6% to 36.0% [16-18]. Spiritual or religious (Holly water) healing, loss of interest in program, moving to hometown of origin, address change, untraceable home, drug side effects, high-cost of transportation to clinic, relatives' persuasion to stop ART, lack of public transport to hospital, fear of swallowing tablets in front of family, improved or deteriorating health, stigma, social problems, loss of hope in medication effectiveness, self-referral to other ART centers, lack of sufficient food, mental illnesses, khat chewing, alcohol drinking, and smoking are the predictors of defaulting. In addition, being bed ridden, high pill burden, poor ART adherence, having HIV-negative or unknown HIV status partner, low baseline CD4+ count, age, transfer to another ART program, co-infection at baseline, and higher World Health Organization (WHO) clinical stage, have been iden-

tified as the main factors associated with defaulting [15-17, 19-23]. However, the above-mentioned factors differ across the studies.

Even though different studies have been conducted on defaulting from treatment among people living with HIV in Ethiopia, majority of these studies used only patients' clinical records to collect data. Hence, important factors for defaulting, such as adherence to ART, substance use (smoking, khat chewing, and alcohol consumption) were not investigated [24-26]. In order to fill this gap, the current study used both medical records and interviewer-administered tools.

The Federal Democratic Republic of Ethiopia has committed to reducing new adult HIV infections by 50% by 2020, and to ending AIDS as a public health threat by 2030. This is clearly reflected in the Country's Health Sector Transformation Plan II 2015-2020, where one of the major indicators is the reduction of HIV incidence rate from 0.03% to 0.01%. The country has observed remarkable progress over the past two decades in reducing HIV prevalence rate from 3.3% in 2000 to 0.9% in 2017, and AIDS-related deaths from 83,000 in 2000 to 15,600 in 2017, thus being on the right track to deliver its commitments. However, the improvements made so far seem to be challenged by defaulting from ART and complacency regarding primary HIV prevention [27].

The distribution of HIV prevalence is highly skewed. It is therefore indispensable to revitalize and increase defaulting prevention interventions on the basis of population priorities and involving all the relevant stakeholders [28]. Identifying defaulting in combination with the implementation of evidence-based prevention strategies will have the ability to reduce HIV transmissions substantially and achieve significant epidemic control [29].

For evaluation and management of ART programs, especially to prevent the development of drug resistance, it is important to effectively track defaulting and address the pressing question of why patients do not adhere to treatment and what conditions are needed to retain them. Moreover, appropriate identification of the prevalence and factors of defaulting from ART is essential to conduct programs, planning, and organizing care for PLWHA on ART. Despite this fact, there is a limited number of studies, which indicated the burden of defaulting and associated factors among HIV-infected patients in Tigray Region, particularly in Eastern Zone. Therefore, in order to fill the gap, this study aimed to assess the prevalence of defaulting and associated factors among adult HIV/AIDS patients in Eastern Zone of Tigray, northern Ethiopia.

The results of the study will provide a good figure on the magnitude of defaulting among HIV/AIDS patients and associating factors. The study could be of great practical relevance for healthcare providers, as it presents patients' characteristics, which need to be targeted in educational interventions aiming at preventing defaulting and promote adherence to treatment.

Material and methods

Study design, area, and period

A hospital-based, cross-sectional study was conducted among HIV/AIDS patients attending three selected hospitals of Eastern Zone, Tigray, Ethiopia. Eastern Zone Tigray is one of the seven administrative zones of Tigray Regional State. It is bordered on the east by Afar, on the south by Southern Eastern Zone, on the west by Central Zone, and on the north by Eritrea. The study hospitals were Adigrat General Hospital, Wukro General Hospital, and Freweini Primary Hospital. These hospitals were selected randomly for representativeness. The research study was conducted for two consecutive months, from March to April, 2020.

Population

Study population included people living with HIV/AIDS who have been enrolled in ART follow-up service, aged greater than or equal to 18 years, and currently receiving ART treatment. Seriously ill or unconscious patients were excluded.

Sample size determination

The required sample size was determined using single population proportion formula as follows:

$n = (Z \alpha/2)^2 p(1 - p)/d^2$,

where n is the sample size, Z is the standard error from the mean corresponding to 95% confidence level = 1.96, d is the margin of error taken as 3%, and p is the estimated prevalence defaulting (13.6%) taken from a previous study [17]. The sample size calculated with the above formula was $n = (Z \alpha/2)^2 p(1 - p)/d^2$, $n = (1.96)^2 (0.136) (1 - 0.136)/(0.03)^2$ ($n = 501$ participants).

To select the required sample size, the total sample size was proportionally allocated to three public hospitals. Accordingly, a list of patients was taken from follow-up unit of the three public hospitals, and sampling frame was developed. Then, the first study subject was randomly selected from the sampling frame by using a lottery method, and participants were selected using a systematic sampling technique.

Data collection tools and procedure

Data were collected using an interviewer-assisted structured questionnaire and medical chart review. The questionnaire consisted of six parts. Part 1: Questions assessing socio-demographic characteristics, such as age, marital and living status, educational level, occupation, ethnicity, religion, and residence. Part 2: Behavioral/lifestyle characteristics, such as alcohol, khat, and smoking status. Part 3: ART medication adherence. Part 4: Knowledge on ART, alternative therapy utilization (traditional healer), defaulting, and reasons for defaulting, ART side effects, disclosure and partner HIV status, mental status, and number of pills per day. Part 5: Stigma towards own self by evaluation of stigma index using a 5-point Likert scale from 1 ("very strongly disagree") to 7 ("very strongly agree"). Part 6: Medical chart review was used to extract information, such as clinical profiles (i.e., baseline WHO clinical staging, viral load, and CD4+ level). To maintain consistency, the questionnaire was first prepared in English then translated to the local language (Tigrigna), and was back-translated to English by professional translators.

The study was conducted during patients' ART clinic visits (outpatient). Three nurses with Bachelor of Science degrees (BSc) from a recognized university were recruited as data collectors. Another BSc holder nurse with experience in data collection was assigned as a supervisor to check for daily activity, consistency, and completeness of the questionnaire.

Data processing and analysis

Data were coded, entered, checked, cleaned, and analyzed using Statistical Package for Social Science (SPSS) version 22 statistical program. Descriptive statistics were computed using the frequency table and numerical summary measures. Binary logistic regression was done to determine the direction, magnitude, and strength of association between a set of independent variables and outcome variable. Variables with p-value < 0.25 significance level in bivariate logistic regression was taken to multivariable logistic regression. Finally, variables with p-value < 0.05 in multivariable logistic regression analysis were considered as significantly associated variables. Significance was considered using adjusted odds ratios, with 95% confidence interval (CI). Text and tables were applied to describe the results.

Data quality control

The collected data were reviewed and checked for completeness before data entry. Cleaning process was done by running a simple frequency after data entry for its consistency. Not consistent data were verified by referring to hard copy questionnaire. Two weeks before the actual data collection period, a pre-test was performed on 10% of sample size in the Adwa General Hospital. Depending on the result of pre-test, correction and modification of the questionnaire were performed and applied on the study population. One-day training was given by the principal investigator to data collectors and supervisor on how to take informed consent, approach participants, and ensure ethical procedures by the principal investigator. The questionnaire was prepared in English then translated to the local language (Tigrigna), and back-translated to English for consistency.

Study variables

Independent variables: 1. Socio-demographic variables, such as age, sex, marital status, religion, educational status,

place of residence, occupational status, and social or family support. 2. Patients' and social factors, including knowledge on ART, adherence to ART, disclosure and partners HIV status, stigma and discrimination, lack of sufficient food, substance use status, source of food, and alternative therapy utilization.

Clinical factors: Baseline CD4+ count, WHO clinical stage, other chronic disease and co-infection, drug side effects, and pill burden.

Dependent variable: Defaulting from ART.

Operational definition: 1. Defaulter: An individual who missed two or more clinical appointments (i.e., was not seen in ART clinic for the last 2 months) [16]. 2. Knowledge: Each respondent's level of knowledge was determined by a scoring system. Eight questions on ART knowledge were scored, with each right answer gaining one point. Patients who scored 0 to 3 points were classified as having poor knowledge, between 4 to 5 points were classified as having fair knowledge, and those who scored 6 to 8 points were classified as having good knowledge [30]. 3. Medication adherence: Morisky medication adherence scale-8 (MMAS-8) was used (eight questions; yes = 1 point and no = 0 point), with score 7-8 points meaning good adherence and score ≤ 6 points meaning poor adherence [31]. 4. Stigma: Respondents were classified as having high stigma if their score of the evaluation of stigma index was above the mean value, and as having low stigma if their score of the evaluation of stigma index was below the mean value [32].

Results

Socio-demographic characteristics of the participants

A total of 501 HIV/AIDS-infected patients were included, out of which, 326 (65.1%) were females. The mean age (± SD) of the respondents was 40.97 (± 9.35) years. Regarding marital status, 152 (30.3%) patients were divorced. On the other hand, 174 (34.7%) individuals were unable to read and write (Table 1).

Behavioral and clinical characteristics of the respondents

In substance use, about 455 (90.8%) patients had no history of khat chewing, and 121 (24.2%) had no habit of alcohol consumption. More than half (61.9%) of the respondents developed side effects of ART. In medication adherence, about 195 (38.9%) of the participants had poor adherence to ART medication. Clinical condition of the participants at ART initiation indicated that most patients started ART with advanced disease. For instance, 216 (43.1%) of the study participants had baseline WHO clinical stage III. On the other hand, 119 (23.8%) of the respondents presented with high stigma towards own selves (Table 2).

Table 1. Socio-demographic characteristics of HIV-infected patients in Eastern Zone, Tigray, Ethiopia, 2020

Variable/Category	n (%)
Gender	
Male	175 (34.9)
Female	326 (65.1)
Age in years	
18-30	62 (12.4)
31-50	382 (76.2)
> 50	57 (11.4)
Marital status	
Married	233 (46.5)
Single	51 (10.2)
Divorced	152 (30.3)
Widowed	65 (13.0)
Level of education	
Can not read and write	174 (34.7)
Can read and write	77 (15.4)
Primary school	143 (28.5)
Secondary school	78 (15.6)
Diploma and above	29 (5.8)
Occupation	
Farmer	101 (20.2)
Housewife	92 (18.4)
Governmental employee	54 (10.8)
Not working	62 (12.4)
Daily worker	115 (23.0)
Merchant	55 (11.0)
Other	22 (4.4)
Religion	
Orthodox Christian	480 (95.8)
Muslim	11 (2.2)
Catholic	10 (2.0)
Residence	
Rural	165 (32.9)
Urban	336 (67.1)

Bivariate and multivariable logistic regression models for factors associated with defaulting from ART among HIV/AIDS patients

In this study, both bivariate and multivariable logistic regression analyses were assessed. In the bivariate model, gender, marital status, educational level, khat chewing, smoking, alcohol consumption, alternative treatments utilization, ART side effects, mental instability, ART adherence, WHO clinical stage, knowledge on ART, stigma, and pill

Table 2. Behavioral and clinical characteristics of HIV-infected patients in Eastern Zone, Tigray, Ethiopia, 2020

Variable/Category	n (%)
Khat chewing	
Yes	46 (9.2)
No	455 (90.8)
Smoking	
Yes	39 (7.8)
No	462 (92.2)
Alcohol consumption	
Yes	121 (24.2)
No	380 (75.8)
Any support	
Yes	310 (61.9)
No	191 (38.1)
Source of food	
Independent	430 (85.8)
Dependent	71 (14.2)
Disclosure status	
Yes	456 (91.0)
No	45 (9.0)
Partner's HIV status	
HIV-positive	276 (55.1)
HIV-negative	53 (10.6)
Unknown	172 (34.3)
Side effect of ART	
Yes	310 (61.9)
No	191 (38.1)
Defaulter	
No	376 (75.0)
Yes	125 (25.0)
Medication adherence	
Poor	195 (38.9)
Good	306 (61.1)
Mental status	
Unstable	55 (11.0)
Stable	446 (89.0)
Knowledge on ART	
Poor	34 (6.8)
Fair	42 (8.4)
Good	425 (84.8)
Pill burden	
No	382 (76.2)
Yes	119 (23.8)
Stigma	
Low	382 (76.2)
High	119 (23.8)

Table 2. Cont.

Variable/Category	n (%)
Alternative medication	
Yes	202 (40.3)
No	299 (59.7)
CD4+ count (cells/µl)	
< 200	243 (48.5)
200-350	138 (27.5)
351-500	62 (12.4)
> 500	58 (11.6)
WHO clinical stage	
Stage I	71 (14.2)
Stage II	164 (32.7)
Stage III	216 (43.1)
Stage IV	50 (10.0)

ART – antiretroviral therapy

burden, were found associated with defaulting. However, in the multivariable logistic regression analysis, ART side effects (AOR = 2.26; 95% CI: 1.25-4.09%), mental instability (AOR = 3.32; 95% CI: 1.40-7.85%), poor adherence to ART (AOR = 10.30; 95% CI: 5.51-19.20%), and high pill burden (AOR = 2.10; 95% CI: 1.11-3.90%) were more likely to influence defaulting (Table 3).

Discussion

The current study focused on assessing the prevalence of defaulting from ART and associated factors among HIV-infected patients. The overall prevalence of defaulting was 25% (95% CI: 21.2-29.1%). This result is consistent with other institutional-based study conducted in Nekemte Hospital (21.7%) [16], but differs from studies conducted in southwest Ethiopia (13.6%) [17] and Nigeria (36%) [18]. This discrepancy might be due to the difference in sample size, study design, and selection of respondents.

Based on the response from defaulters who participated, the main reasons for defaulting from ART program were loss of hope in medication effectiveness (18%), presence of opportunistic infections (20%), financial problems (19.2%), ART side effects (16.8%), religious reasons (6.4%), lack of balanced diet (8.8%), fear of stigma (4%), and others (6.4%). The reasons given by defaulters as the causes for defaulting from ART programs were almost consistently similar throughout the studies conducted on this subject [17, 18, 33, 34].

This study identified important factors of ART treatment defaulting. Side effect/toxicity of ART was a strong associated factor for defaulting, indicating that patients who were suffering from repeated side effects of ART medication were more likely to default from treatment (AOR = 2.26;

Table 3. Bivariate and multivariable analyzes of factors associated with defaulting in Eastern Zone, Tigray, Ethiopia, 2020

Variable	Defaulter		COR (95% CI)	AOR (95% CI)
	No, n (%)	Yes, n (%)		
Gender				
Male	119 (31.6)	56 (44.8)	1.75 (1.16-2.65%)	1.11 (0.588-2.10%)
Female	257 (68.4)	69 (55.2)	1	1
Marital status				
Married	170 (45.2)	63 (50.4)	1	1
Single	33 (8.8)	18 (14.4)	1.47 (0.77-2.80%)	1.67 (0.71-3.97%)
Divorced	121 (32.2)	31 (24.8)	0.69 (0.42-1.13%)	1.62 (0.82-3.19%)
Widowed	52 (13.8)	13 (10.4)	0.67 (0.34-1.32%)	1.06 (0.42-2.64%)
Educational level				
Cannot read and write	142 (37.8)	32 (25.6)	0.86 (0.33-2.29%)	1.47 (0.42-5.20%)
Can read and write	45 (12.0)	32 (25.6)	2.73 (0.99-7.46%)	3.07 (0.87-10.75%)
Primary school	104 (27.7)	39 (31.2)	1.44 (0.54-3.79%)	1.81 (0.53-6.18%)
Secondary school	62 (16.5)	16 (12.8)	0.98 (0.35-2.84%)	1.60 (0.44-5.85%)
Diploma and above	23 (6.1)	6 (4.8)	1	1
Chat chewing				
Yes	20 (5.3)	26 (20.8)	4.67 (2.51-8.73%)	1.24 (0.47-3.27%)
No	356 (94.7)	99 (79.2)	1	1
Smoking				
Yes	18 (4.8)	21 (16.8)	4.02 (2.01-7.82%)	1.21 (0.43-3.35%)
No	358 (95.2)	104 (83.2)	1	1
Alcohol intake				
Yes	70 (18.6)	51 (40.8)	3.01 (1.94-4.68%)	0.95 (0.49-1.82%)
No	306 (81.4)	74 (59.2)	1	1
Alternative medication use				
Yes	139 (37.0)	63 (50.4)	1.73 (1.15-2.61%)	0.96 (0.55-1.68%)
No	237 (63.0)	62 (49.6)	1	1
Side effects of ART				
Yes	100 (26.6)	80 (64.0)		2.26 (1.25-4.09%)*
No	276 (73.4)	45 (36.0)	1	1
Mental status				
Unstable	28 (7.4)	27 (21.6)	4.91 (3.19-7.55%)	3.32 (1.40-7.85%)*
Stable	348 (92.6)	98 (78.4)	1	1
WHO clinical stage				
Stage I	57 (15.2)	14 (11.2)	1	1
Stage II	138 (36.7)	26 (20.8)	0.77 (0.37-1.58%)	0.45 (0.18-1.12%)
Stage III	147 (39.1)	69 (55.2)	1.91 (0.99-3.66%)	1.1 (0.46-2.46%)
Stage IV	34 (9.0)	16 (12.8)	1.91 (0.83-4.41%)	0.75 (0.26-2.17%)
ART adherence				
Poor	94 (25.0)	101 (80.8)	12.6 (7.64-20.87%)	10.3 (5.51-19.2%)*
Good	282 (75.0)	24 (19.2)	1	1
Knowledge on ART				
Poor	14 (3.7)	20 (16.0)	5.47 (2.66-11.26%)	2.29 (0.89-5.9%)
Fair	25 (6.6)	17 (13.6)	2.60 (1.35-5.04%)	1.79 (0.70-4.57%)
Good	337 (89.6)	88 (70.4)	1	1

Table 3. Cont.

Variable	Defaulter		COR (95% CI)	AOR (95% CI)
	No, *n* (%)	Yes, *n* (%)		
Pill burden				
No	301 (80.1)	81 (64.8)		1
Yes	75 (19.9)	44 (35.2)		2.1 (1.11-3.90%)*
Stigma				
Low	294 (78.2)	88 (70.4)	1	1
High	82 (21.8)	37 (29.6)	1.51 (0.96-2.38%)	0.82 (0.41-1.66%)

Statistically associated variable in multivariable logistic regression at p < 0.05.
AOR – adjusted odds ratio, ART – antiretroviral therapy, COR – crude odds ratio.

95% CI: 1.25-4.09%), which is in line with a previous study from the US [22]. This might be due to patients' repeated intoxication from their medication, which can lead to loss of hope in effectiveness of medication and stop taking ART. On the other hand, patients mental status was significantly associated with ART treatment defaulting. Respondents with mental instability status were found to have 3.32 times higher risk of defaulting (AOR = 3.32; 95% CI: 1.40-7.85%). This is supported by studies done in Ethiopia and Nigeria [16, 18], and could be due to depression and negative emotions associated with HIV infection, leading to defaulting from ART [18].

Moreover, adherence to ART showed a significant association with defaulting. The present study indicated that participants with poor adherence to ART were found 10.3 times more likely to default from treatment compared with those who had good adherence to ART (AOR = 10.3; 95% CI: 5.51-19.2%), which is consistent with previous studies [22, 24]. This similarity might be due to the fact that adherence to ART difficulty can reduce the effect of ART on viral load suppression, which in turn results in decreasing of CD4+ cell count. Therefore, the patient is losing hope in effectiveness of the drug, and may explore different options [35]. On the other hand, respondents with high pill burden per day were strongly associated with defaulting. Patients taken more drugs per day were found having 2.1 times of higher risk for defaulting compared with patients who were taken one pill per day only (AOR = 2.1; 95% CI: 1.11-3.90%). This is also comparable with another study, showing similar result [22]. This might be because patients with additional management of different drugs and regular ART treatment have worse side effects, such as loss of appetite and poor nutritional status, which compromise drugs' resistance with the disease, and can be considered as reason for defaulting from ART.

Limitation of the study

The limitation of this study is related to its cross-sectional nature that could not accurately show the cause-and-effect relationship between factors and defaulting. Similarly, there may be re-called bias and social desirability bias, since some of the variables, such as medication adherence and substance use (alcohol and smoking status) of the study participants were based on self-reports. Another limitation is that this study focused on quantitative methods only, which cannot triangulate with qualitative approaches.

Conclusions

The results of this study indicated that the prevalence of defaulting was high. Furthermore, PLWHA with high pill burden, drug toxicity, mental instability, and poor ART adherence were more likely to default from the treatment. Healthcare providers should advise their patients to improve adherence to treatment, and efforts should be made to reduce stigma. Addressing stigma on individual and community levels should be considered. Increasing counseling of patients before starting and during treatment is important, so that PLWHA can adjust both psychologically and emotionally to the disease. Additionally, further studies are recommended, especially triangulate with qualitative methods, to evaluate reasons for non-adherence to ART.

Disclosures

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