

Level of Cardiovascular Disease Risk and Associated Factors among Clients on Highly Active Antiretroviral Therapy in Vihiga County, Kenya

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Received May 18, 2024, accepted July 4, 2024, published October 1, 2024.

ABSTRACT

Context: HIV/AIDS is still a public health concern globally, especially in sub-Saharan Africa and Kenya. HIV-positive clients are initiated on highly active antiretroviral therapy (HAART) to reduce the multiplication of HIV and improve their immunity. These clients are at an increased cardiovascular disease risk due to a complex interplay of factors, including traditional cardiovascular risk factors such as smoking cigarettes, obesity due to inactivity, and diabetes.

Aim: This study sought to determine the level of cardiovascular disease (CVD) risk factors among people living with HIV (PLHIV) on highly active antiretroviral therapy (HAART) in Vihiga County, Kenya.

Methods: The study employed a cross-sectional survey design to report baseline survey data for an interventional study on the level of CVD risk factors. The study involved a systematic sample of 211 patients on HAART in six health facilities purposively selected from Vihiga County. Data was collected using the WHO STEPWISE questionnaire from six comprehensive care clinics in Vihiga County from March to July 2022. The World Health Organization-International Society of Hypertension (WHO-ISH) tool AFRI E CHART was used to estimate the cardiovascular risk.

Results: The majority (96.68%) of PLWHIV on HAART in Vihiga county had low overall cardiovascular risk as predicted WHO/ISH score. Age (OR = 1.199, 95% CI [1.031, 1.394], p = 0.018) and smoking status (OR = 0.115, 95% CI [0.024, 0.558], p = 0.007) exhibited a significant association with the level of cardiovascular risk.

Conclusion: The majority of PLHIV have a low estimated CVD risk. There is a need to prioritize weight management in HIV care, integrating healthy lifestyle behaviors and nutritional support while conducting regular cardiovascular risk assessments, focusing on modifiable factors like smoking. Age-specific interventions can also help mitigate the risk across the different age groups.

Keywords: Cardiovascular risk, HAART

Citation: Amugitsi, I. L., Mbuthia, G. W., & Ochanda D. A (2024). Level of cardiovascular disease risk and associated factors among clients on highly active antiretroviral therapy in Vihiga County, Kenya. *Evidence-Based Nursing Research*, 6(4), 21-30. <http://doi.org/10.47104/ebnrojs3.v6i4.351>.

1. Introduction

HIV/AIDS is still a public health concern globally, especially in sub-Saharan Africa, Kenya included (*HIV and AIDS Epidemic Global Statistics, 2023; Moyo et al., 2014*). According to *UNAIDS (2022)*, approximately 1.7 million individuals globally were newly infected by HIV, and about 37.9 million people were living with HIV/AIDS (*UNAIDS, 2022*). About seven hundred and seventy thousand people died of HIV and AIDs related illnesses (*UNAIDS, 2022*). Individuals who are HIV positive, following HIV testing and counseling, are usually initiated on highly active antiretroviral therapy (HAART) to reduce the multiplication of HIV and improve their immunity (*Eggleton & Nagalli, 2023; Kemnic & Gulick, 2024*).

Highly Active Antiretroviral Therapy (HAART) is the main treatment expected to prolong survival and improve

quality of life in HIV-infected patients (*Eggleton & Nagalli, 2023*) and is generally a combination of at least three classes of antiretroviral drugs namely protease inhibitors (PIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), and nucleoside reverse transcriptase inhibitors (NRTIs), one of which is a PI or an NNRTI or a combination of NRTI (*Eggleton & Nagalli, 2023; Pau & George, 2014*). Recent studies have found cardiovascular disease (CVD) to be a significant cause of increased morbidity among persons living with the human immunodeficiency virus (*Appiah et al., 2019; Fragkou et al., 2023; Ntsekhe & Baker, 2023*).

By 2030, the epidemic caused by HIV and CVD is expected to overtake infectious diseases alone as the primary cause of death in Sub-Saharan Africa (*Appiah et al., 2019*). Studies around the globe have been done to determine the level of cardiovascular risk among people living with HIV. Generally, a low prevalence of cardiovascular disease has been found among the studies.

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This low prevalence is shown in studies that were conducted in South Africa (*Mashinya et al., 2015*), Brazil (*Nery et al., 2013*), and Nairobi, Kenya (*Vusirikala et al., 2019*). The risk is slightly lower than that of a study conducted in Malaysia and Cambodia (*Otgontuya et al., 2013*).

Despite previous studies indicating a low risk of cardiovascular disease among patients on HAART, there has generally been an increase in risk over the years, raising concerns about the well-being of people living with HIV/AIDS (*Ekun et al., 2021; Nsagha et al., 2015*). The factors that have exacerbated this risk include the female gender (*Gebremariam et al., 2022; Njelekela et al., 2009; Xing et al., 2020; Zhang et al., 2020*) as a result of several factors related to females such as including hormonal differences (*Appannah et al., 2015; Hulsegge et al., 2017*), genetic predispositions (*Guevara-Cruz et al., 2019; Jeon et al., 2019; Telles et al., 2018*) and socio-cultural influences (*Bhowmik et al., 2019; Robinson et al., 2021*).

Others include duration of antiretroviral therapy (ART) (*Nsagha et al., 2015*), systolic and diastolic blood pressure (*Enriquez et al., 2022; GBD 2021 Sickle Cell Disease Collaborator (2023)*), and higher age (*Muhammad et al., 2013*). Studies have confirmed that indeed HIV positive clients on HAART are at an increased risk of CVD (*Feinstein et al., 2016; Ruamtawee et al., 2023*) owing to a range of risk factors, including smoking (*Peprah et al., 2021*), diabetes mellitus (*Duguma et al., 2020*), hypertension (*Mbuthia et al., 2021*) and obesity and overweight (*Guehi et al., 2016*), there is still a gap in assessing the level of this risk among patients specifically among counties in Western Kenya which have a high prevalence of HIV. Vihiga County is one of the counties most affected by HIV (*Mworia, 2023*).

2. Significance of the study

Cardiovascular disease (CVD) is a significant cause of increased morbidity among persons living with the human immunodeficiency virus (*Appiah et al., 2019*). Sub-Saharan Africa is experiencing a high burden of HIV and limited domestic resources; for this reason, innovative and alternative treatment delivery for PLWHIV has been realized lately (*Grand et al., 2020*). The focus is on achieving “stable” (virally suppressed) ART patients who require less medical attention than those commencing treatment or failing therapy with complications such as cardiovascular diseases.

In Vihiga County, as of November 2019, 8,242 clients on highly active antiretroviral therapy were recorded compared to November 2018, which had a total of 7801. This trend was a tremendous increase, implying the burden likely to be experienced due to HIV infection. Statistics from previous studies indicate that 7.9% of incidences of cardiovascular diseases can be directly linked to HAART use (*Aminde et al., 2017*). In Kenya, a study by *Juma et al. (2019)* on cardiovascular risk factors among people living with HIV in rural Kenya reported a significant prevalence of undiagnosed hypertension (13.3%). The study sought to find the level of cardiovascular disease risk among patients on HAART in Vihiga County. The findings will

inform academia and lead to policies tailored towards interventions to reduce the risk of cardiovascular disease by controlling for the associated risk factors.

3. Aim of the study

This study sought to determine the level of cardiovascular disease (CVD) risk factors among people living with HIV (PLHIV) on highly active antiretroviral therapy (HAART) in Vihiga County, Kenya.

3.1. Research questions

Two research questions guided the study:

- What is the level of cardiovascular risk among clients on HAART receiving care at Vihiga County?
- What are the determinants of the level of cardiovascular disease risk among HIV-positive clients on HAART receiving care at Vihiga County?

4. Subjects & Methods

4.1. Research Design

The study was an interventional study, but baseline data was used for the current study. This study was a baseline study for an interventional study with the prospect of conducting a quasi-experimental design to investigate the effect of nurse-led differentiated care intervention on reducing cardiovascular risk among patients on HAART. The study employed a cross-sectional survey design to report baseline survey data for the interventional study on the level of CVD risk factors.

4.2. Study setting

Vihiga County is in western Kenya. Twenty-six facilities offer comprehensive care to HIV clients in Vihiga County, and a total of eight thousand two hundred and forty-two patients on HAART as of 2019 (*Health Information System office Vihiga County, 2019*). The health care facilities offer various services, including, but not limited to, inpatients, outpatient, comprehensive care, maternal and child health, radiological examinations, and laboratory. Six of the 26 health facilities in Vihiga County were randomly selected, including Comprehensive Care Clinic (CCC) facilities. These were Emuhaya Sub-County Hospital, Jumuia Hospital, Sabatia Sub-County Hospital, Serem Health Centre, Vihiga County Referral Hospital, and Vihiga Health Centre.

4.3. Subjects

The study population included all patients on HAART care in Vihiga County. It comprised persons above 18 but not older than 60 who had been on HAART for more than six months, were permanent residents of Vihiga County, and consented to participate in the study.

Sample size determination

Since the study was a baseline study for an interventional study and with the prospect of conducting a quasi-experimental design to investigate the effect of nurse-led differentiated care intervention on the reduction of cardiovascular risk among patients on HAART, the study employed a two-sample population formula to

obtain the study participants for the baseline study, out of whom half would then be assigned to the intervention group and the other half to the control group.

Two-sample population formula

$$N = n_1 + n_2 = \frac{4(z_{1-\alpha/2} + z_{1-\beta})^2 \left[\left(\frac{P_1 + P_2}{2} \right) \left(1 - \frac{P_1 + P_2}{2} \right) \right]}{(d = P_1 - P_2)^2}$$

Where,

n= desired sample size

r=control to case ratio (1 for the same number of subjects in both groups)

p=proportion of population

p1=60%= 0.60,

p2=40%=0.40

Z_{1-β} at 80% power =0.84

Z_{1-α} at 95% C.I =1.96

$$N = \frac{4(1.96 + 0.84)^2 \left[\frac{0.6+0.4}{2} \right] \left(1 - \frac{0.4+0.6}{2} \right)}{(0.6 - 0.4)^2}$$

N= 196

Adding an attrition rate of 7.5, we have

N= 196x1.075=211 participants

A sample of 211 participants was selected for the study.

Sampling technique

Six health facilities were selected randomly from the health facilities in Vihiga County that deal with HIV care. Convenience sampling was used to identify Vihiga County. Systematic sampling was used to select the study participants at each study site; since there is a variable number of clients in each health facility, the kth person will differ, as shown in the table below. Two hundred eleven participants were selected to ensure that all had an equal chance of participating in the study. The 211 were identified by proportionate sampling: The number of clients in each study site is known from the clinic data, and the first person on the list was used as the first person from were counting to get the kth person counted.

Table (1): Sampling method.

Emuhaya Sub-County Hospital	Jumuia Hospital	Sabatia-sub County Hospital	Serem Health Centre	Vihiga County referral hospital	Vihiga Health Centre
535	680	891	597	1886	480
36	36	36	36	36	36
535/36 =15 th	680/36 =19 th	891/36 =25 th	597/36 =17 th	1886/36 =52 nd	480/36 =13 th

4.4. Tools of data collection

4.4.1. World Health Organization/International Society of Hypertension (WHO/ISH) Risk Prediction Charts

The level of cardiovascular risk among patients on HAART was collected using the WHO/ISH-questionnaire. Here, the prevalence of clients with obesity, those who smoke cigarettes and consume alcohol, those who do not engage in physical activity, those who lead sedentary lifestyles, and those with diabetes and hypertension were collected, and the prevalence was determined. In addition, the sociodemographic characteristics of these patients were also collected. Additionally, height, weight, waist circumference and hip

circumference were used to identify the BMI of patients. Both systolic and diastolic blood pressure measurements were collected from the patients and recorded in the patient's data tool. The combination of drug regimen, medication adherence, duration of HIV, viral loads, and CD4 count were also recorded.

The WHO/ISH Stepwise questionnaire was used to collect data; WHO/ISH, specifically AFRI E, figure 4, which allows risk assessment of clients in low-income areas where lipid profiles are unavailable, was used to assess the level of cardiovascular risk. Here, the presence or absence of diabetes mellitus was assessed, along with gender, whether the client smokes a cigarette, their age, and their systolic BP. The color codes are used to grade the levels of cardiovascular risk: Green color for less than ten percent, yellow for 10 to less than 20%, Orange means 20 to less than 30%, red for 30 to 40% risk, and deep red for more than 40% cardiovascular risk. In addition, the sociodemographic characteristics of these patients were also collected (WHO/ISH, 2007).

4.5. Procedures

Ethical consideration: Permission to conduct the study was granted upon reviewing the proposal by the Masinde Muliro University of Science and Technology Ethics and Research Committee and the National Commission for Science, Technology, and Innovation (NACOSTI) No.120458/132219. Participants signed, voluntary informed consent before participation and were briefed on their rights and the expected benefits of the study. Questionnaires were serialized to ensure anonymity. No other form of identification was required from participants. Data collected from the participants was accessed only by the researcher. They were stored under lock, key, and research information in computers under passwords. The principle of beneficence and non-maleficence was ensured by informing participants of the potential benefits of the study and the risks before participating.

Instrument validity and reliability: Validity is the degree to which an instrument measures what it is supposed to measure (Ahmed & Ishtiaq, 2021). The WHO/STEPWISE questionnaire has been approved and validated. Although the validity of the WHO cardiovascular risk assessment tools has been tested in different studies where they have been used, they were also submitted to the experts to assess face, content, and construct validity. Regarding reliability, the WHO cardiovascular risk assessment tools have been used in other studies, and their reliability has been ascertained. In the studies where they have been used, their Cronbach α test ranges between 0.70–0.98 (Al-Mawali et al., 2023; Amoghashree et al., 2020; Thulani et al., 2021).

A pretest of the semi-structured questionnaire was conducted in Iguhu Sub County Hospital in Kakamega County, a site different from where the actual study was conducted, to ensure its reliability. The pretest results were used to refine the data collection tools before the actual study.

Data was collected from six comprehensive care clinics in Vihiga County from March to July 2022.

4.6. Data analysis

Descriptive data was analyzed using measures of central tendency (means) and measures of dispersion (standard deviation) for all demographic variables. Frequency tables were used to indicate the level of cardiovascular risk among patients on HAART. A logistic regression model was used to identify the predictors of cardiovascular risk, with factors with a p-value equal to or less than 0.05 considered significant. Similarly, using the multivariate analysis helped to control for confounding variables.

5. Results

Table 2 indicates that data was collected from a sample of 211 participants and indicates their sociodemographic characteristics. Most of the participants were females (70.14%). Approximately half had attained primary education as their highest level of education (54.03%) and were married (55.45%).

Table 3 The results indicate that most of the clients had a low risk of cardiovascular disease as indicated by most of them (96.68%) falling in the green category.

Table 4 shows the bivariate analysis. It explored the relationship between cardiovascular risk and various sociodemographic factors. Among the sociodemographic factors examined, only age showed a statistically significant association with the level of cardiovascular risk category. For each unit increase in age, there was a 1.199 increase in the odds of having an increased risk of cardiovascular disease according to the WHO/ISH categorization (OR = 1.199, 95% CI [1.031, 1.394], p = 0.018).

Table 5 shows the relationship between lifestyle characteristics and level of cardiovascular risk. Smoking status exhibited a significant association with the level of cardiovascular risk, with individuals who did not smoke showing significantly lower odds of having an increased risk of cardiovascular disease according to the WHO/ISH categorization compared to those who did smoke (OR = 0.115, 95% CI [0.024, 0.558], p = 0.007). Other factors, including history of alcohol use, alcohol intake in the past year, engagement in exercise, and regular blood sugar checks, did not demonstrate significant associations with the level of cardiovascular risk.

Table 6 There was no relationship between HIV-related factors, including regimen combination, medication adherence, duration of HIV, Viral load, and CD4 cell count.

Table (2): Frequency and percentage distribution of sociodemographic characteristics of the participants on HAART (n=211).

Characteristics	Frequency	Percent
Gender		
Female	148	70.14
Male	63	29.86
Education Level		
Never Been to School	5	2.37
Primary	114	54.03
Secondary	80	37.91
University/College	12	5.69
Race		
African	211	100
Marital Status		
Divorced	1	0.47
Married	117	55.45
Separated	20	9.48
Single	25	11.85
Widowed	48	22.75
Work Status (Past 12 months)		
Government Employee	5	2.37
Homemaker	21	9.95
Non-Government Employee	25	11.85
Non-paid	6	2.84
Retired	3	1.42
Self-Employed	90	42.65
Student	3	1.42
Unemployed (Able to work)	55	26.07
Unemployed (Unable to work)	3	1.42
Age (Mean±SD)		45.5 ±9.1

Table (3): Level of cardiovascular risk among the study the participants on HAART (n=211).

Level of cardiovascular risk	Frequency	Percent
<10% (Green)	204	96.68
10% to <20% (Yellow)	3	1.42
20% to <30% (Orange)	1	0.47
30% to <40% (Red)	2	0.95
>40% (Deep red)	1	0.47

Table (4): Socioeconomic determinants of level of cardiovascular risk among the study the participants on HAART (n=211).

Variables	Bivariate analysis		
	OR	95% CI	p-value
Gender			
Female	REF		
Male	1.752	[0.381,8.061]	0.471
Education Level			
Primary	REF		
None	0.000	[0,0]	0.994
Secondary	1.438	[0.283,7.311]	0.662
University/College	3.499	[0.335,36.567]	0.295
Marital Status			
Married	REF		
Divorced	1.000	-	0.999
Separated	1.519	[0.161,14.334]	0.715
Single	1.000	-	0.994
Widowed	1.212	[0.215,6.84]	0.828
Work Status (Past 12 months)			
Employed	REF		
Homemaker	1.000	-	0.996
Non-paid	1.000	-	0.998
Retired	1.000	-	0.998
Self-Employed	1.000	-	0.469
Student	1.000	-	0.998
Age (Mean±SD)	1.199	[1.031,1.394]	0.018
Income per year (Mean±SD)	1.000	[1,1]	0.810

Table (5): Relationship between lifestyle factors and level of cardiovascular risk among the study the participants on HAART (n=211).

Variables	Bivariate analysis		
	OR	95% CI	p-value
Smokes tobacco			
Yes	REF		
No	0.115	[0.024,0.558]	0.007
History of alcohol use			
Yes	REF		
No	0.860	[0.099,7.433]	0.891
Taken alcohol in the past year			
Yes	REF		
No	0.747	[0.086,6.482]	0.791
Engages in exercise			
Yes	REF		
No	3.189	[0.585,17.387]	0.180
Regularly checks blood sugar			
Yes	REF		
No	1.000	-	0.992

Table (3): Relationship between HIV-related factors and level of cardiovascular risk among the study the participants on HAART (n=211).

Variables	Bivariate analysis		
	OR	95% CI	p-value
Regimen Combination			
TDF/3TC/DTG	REF		
ABC/3TC/DTG	1.000	-	0.997
AFZE	1.000	-	0.994
AZT/3TC/ATU	1.000	-	0.998
TDF/3TC/ATR	1.000	-	0.997
TLD	1.377	[0.299,6.33]	0.681
Adherence to medication			
High	REF		
Moderate	3.713	[0.402,34.269]	0.247
Low	1.000	-	0.994
Duration with HIV (Mean±SD)	1.112	[0.949,1.303]	0.189
Viral Load (Mean±SD)	1.000	[0.998,1.001]	0.808
CD4 cell count (Mean±SD)	1.000	[0.997,1.003]	0.847

6. Discussion

Cardiovascular risk prediction is important to make treatment decisions especially in primary prevention of CVDs based on a total risk approach (Thulani *et al.*, 2021). The WHO/ISH, specifically AFRI E, which allows risk assessment of clients in low-income areas where lipid profiles are unavailable was used to assess the level of cardiovascular risk. The presence or absence of diabetes mellitus was assessed, gender, whether the client smokes cigarette, their age, and the systolic BP. The color codes are used to grade the levels of cardiovascular risk, green color for less than ten percent, Yellow for 10 to less than 20%, Orange means 20 to less than 30 %, Red for 30 to 40% risk, and Deep red for more than 40% cardiovascular risk. The results indicate that most clients had a low risk of cardiovascular disease as indicated by most of them (96.68%) falling in the green category.

This study sought to determine the level of cardiovascular disease (CVD) risk factors among people living with HIV (PLHIV) on highly active antiretroviral therapy (HAART) in Vihiga County, Kenya. It was found that most of the clients on HAART had a low risk of cardiovascular disease, less than 10%. This result may suggest that HAART, while effectively managing HIV, does not significantly increase CVD risk for most patients. These findings are similar to those of Lu *et al.* (2021) conducted in Taiwan, which indicated that treatment-experienced participants had a lower risk of cardiovascular disease than treatment naïve participants.

The bivariate analysis conducted in the study aimed to identify determinants of cardiovascular risk among HIV clients on HAART in Vihiga County, Kenya, according to WHO/ISH categorization. The results indicate that age and smoking status were significantly associated with the level of cardiovascular risk.

Regarding sociodemographic factors, only age showed a statistically significant association with the cardiovascular risk category. Specifically, for each unit increase in age, there was an increase in the odds of having an increased risk of cardiovascular disease according to WHO/ISH

categorization. The association between increasing age and higher cardiovascular risk may be attributed to physiological changes, cumulative exposure to risk factors, and age-related comorbidities. This finding is consistent with well-established epidemiological trends, as age is a known non-modifiable risk factor for cardiovascular disease. The findings are similar to studies by Bress *et al.* (2017), Mohammadnezhad *et al.* (2016), Rezaianzadeh *et al.* (2023), Tian *et al.* (2023) Wang *et al.* (2021).

In terms of lifestyle characteristics, smoking status emerged as a significant determinant of cardiovascular risk. Individuals who did not smoke showed significantly lower odds of having an increased risk of cardiovascular disease compared to smokers. This finding aligns with extensive evidence linking smoking to a heightened risk of cardiovascular morbidity and mortality (Bedimo *et al.*, 2010; Jeong *et al.*, 2021; Mehta *et al.*, 2015). Smoking increases plaque formation in blood vessels, and heart muscles are narrowed by plaque or blocked by clots. Chemicals in cigarette smoke cause the blood to thicken and form clots inside veins and arteries. Blockage from a clot can lead to a heart attack (Gallucci *et al.*, 2020). Smoking cessation is known to lead to significant reductions in cardiovascular risk, highlighting the importance of tobacco control efforts in cardiovascular disease prevention (Gallucci *et al.*, 2020).

Regarding medication regimens, individuals on the "TLD" regimen were more likely to be in a higher BMI category compared to those on the reference regimen. TLD typically consists of Tenofovir, Lamivudine, and Dolutegravir, while TDF/3TC/DTG comprises Tenofovir Disoproxil Fumarate, Lamivudine, and Dolutegravir. While both regimens contain the same antiretroviral agent, Dolutegravir, they differ in their other components. Tenofovir Disoproxil Fumarate (TDF) in the TDF/3TC/DTG regimen is associated with potential renal and bone toxicity. In contrast, Tenofovir in the TLD regimen is the newer Tenofovir Alafenamide (TAF), which is believed to have fewer side effects on renal and bone health (Mtisi *et al.*, 2019; Turner *et al.*, 2019).

Therefore, the observed difference in BMI categories between the two regimens could be attributed to the differential side effect profiles of the components.

Dolutegravir-based regimens, including TLD, are generally favored for their potency, high barrier to resistance, and favorable tolerability compared to other antiretroviral agents (Semengue et al., 2022). Therefore, individuals on the TLD regimen may experience better virologic control and overall health status, which could indirectly influence weight gain. In addition, differences in treatment adherence or duration on specific regimens could also contribute to variations in weight status among individuals. The findings indicated that the clients on the TLD regimen had better drug adherence, positively impacting their weight status.

Dolutegravir-based regimen is associated with weight gain (Maartens et al., 2023). The high adherence to TLD, coupled with its propensity to lead to weight gain (Hirigo et al., 2023), is a possible reason for the observed difference in the regimen. The findings contrast that of a study done in Botswana by Tshikuka et al. (2020), which found no association between the regimen type and overweight and obesity. However, adherence levels and other clinical variables like duration with HIV, viral load, and CD4 cell count did not show significant associations with the BMI category. This finding is likely due to an overwhelming majority of the individuals showing medication adherence and thus was not significantly associated with BMI.

7. Conclusion

Age and smoking status emerged as significant determinants of cardiovascular risk, highlighting the importance of addressing modifiable risk factors such as smoking cessation to reduce cardiovascular morbidity and mortality among HIV patients on HAART.

8. Recommendations

The study findings indicate a generally low cardiovascular disease risk among HIV-positive clients on HAART. However, these clients need to be educated on ways to remain free of cardiovascular disease risk by maintaining optimum body weight, exercising adequately, cigarette smoke cessation, and frequent checkups for diabetes and hypertension. There is a need to develop strategies to assess, prevent, and detect cardiovascular risk effectively in PLWHIV. Those who are at low risk of developing cardiovascular disorders are assisted in preventing the occurrence of cardiovascular disorders using cost-effective means of assessment, detection, prevention, and management.

9. Acknowledgements

The researcher acknowledges all research assistants and clients who participated in the study.

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