Factors associated with viral load suppression among hiv clients on antiretroviral therapy Inititaed enhanced adherence counselling in Mbeya, Tanzania

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FACTORS ASSOCIATED WITH VIRAL LOAD SUPPRESSION AMONG HIV CLIENTS ON ANTIRETROVIRAL THERAPY INITITAED ENHANCED ADHERENCE COUNSELLING IN MBEYA, TANZANIA

By

Sia Robert Temu

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Science (Epidemiology and Laboratory Management) of

Muhimbili University of Health and Allied Sciences
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CERTIFICATION

The undersigned certify that they have read and hereby recommend for the acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **''Factors associated with viral load suppression among HIV clients on antiretroviral therapy initiated enhanced adherence counselling in Mbeya, Tanzania'',** in (partial) fulfillment of the requirements for the degree of Master of Science (Epidemiology and Laboratory management) of Muhimbili University of Health and Allied Sciences.

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(Supervisor)

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DECLARATION AND COPYRIGHT

I, **Sia Robert Temu**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature…… **Date**……

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Lastly, special thanks go to my fellow cohort ten residents for their valuable comments and suggestions which helped me to improve more and more in my research.

DEDICATION

This study is dedicated to my late beloved father who had been a source of my inspiration in my life, my family for their love and support and to my husband for his love, care and patience throughout this dissertation despite my absence.

I also dedicate this dissertation to my MUHAS and FELTP supervisors for their continuous support.

ABSTRACT

Background: HIV clients with viral load above 1000 copies/ml are recommended for enhanced adherence counseling (EAC) to overcome possible barriers to adherence and facilitate viral load suppression (VLS). There is limited information on viral load suppression after EAC and its associated factors in Tanzania.

Objective: The aim of this study was to determine the proportion of VLS after EAC among HIV clients on ART for ≥ six months and associated factors.

Methods: This was a cross-sectional study design conducted in six health facilities among HIV clients on ART with a viral load above 1000 copies/ml and initiated EAC in Mbeya Region. Data abstraction tool was used to collect information on socio-demographic, clinical, behavioral, and counseling sessions. Data analysis was done using STATA software version 13. Chi-square test was used to compare categorical variables. All predictors with P-value ≤ 0.25 in the bivariate level were entered into multivariate analysis with 95% CI (0.05) to identify independent predictors for VLS while controlling for potential confounders.

Results: Of 287 HIV clients enrolled into EAC, the overall VLS was 52.3% (95% CI: 46.6-58.0). Mean time on ART was 5.6 years (SD 2.8). Factors independently associated with VLS on multivariate level were; age above 45 years (aOR=3.6, 95% CI: 1.5-8.6), viral load count below 10000 copies/ml (aOR=5.4, 95% CI: 2.4-12.3), clients at hospital level (aOR=2.7, 95% CI: 1.2-5.7) and ≥ 95% ARV pill count (aOR=3.0, 95% CI: 1.3-6.8).

Conclusion: This study reported low proportion of viral load suppression after EAC among HIV clients on antiretroviral therapy. The study shows older age, ARV pill count more than 95%, initial viral load below 10000 copies/ml and clients at hospital level were associated with VLS. These findings confirm the importance of routine viral load testing, EAC and repeat viral load testing before deciding to switch regimen. The study recommends focusing adherence intervention to younger age, mentorship program between health facilities, creating a lasting solution to help quickly identify at the triage clients who have come for EAC and further studies on possible explanation for facility characteristics influencing VLS.

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LIST OF ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
aPR	Adjusted prevalence ratio
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Zidovudine
CI	Confidence interval
cPR	Crude prevalence ratio
CTC	Care and treatment center
EAC	Enhanced adherence counseling
EDTA	Ethylene diamine tetra-acetic acid
EFV	Efavirenz
FELTP	Field Epidemiology and Laboratory Management Training Programme
FTC	Emtricitabine
HF	Health facility
HIV	Human immunodeficiency virus
IQC	Internal quality control
IQR	Interquartile range
Mls	milliliter
MOHCDGEC	Ministry of health community development gender and children
MUHAS	Muhimbili University of Health and Allied Sciences
NACP	National AIDS control program

NVP	Nevirapine
PLHIV	People living with HIV
PPS	Probability proportional to size
Rpm	Rotation per minute
SRS	Systematic random sampling
TDF	Tenofovir
THIS	Tanzania HIV impact survey
UNAIDS	United Nations program on HIV and AIDS
VLS	Viral load suppression
WHO	World health organization
3TC	Lamivudine

DEFINITION OF TERMS

Enhanced adherence counseling

This is the counseling given to HIV clients with a viral load above 1000 copies/ml to assess possible barriers to adherence and help the client constructs an adherence plan with concrete objectives by reviewing knowledge of HIV and antiretroviral therapy, psychological, client's motivation for taking medication, emotional and socio-economic factors that may contribute to poor adherence.

Viral load suppression

This is defined as viral load less than 1000 copies/ml during second testing after enhanced adherence counseling in HIV clients on antiretroviral therapy for more than six months.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Globally, more than 20 million people living with HIV (PLHIV) were taking antiretroviral therapy (ART) as the end of 2017 (1) . Development of ART has dramatically reduced morbidity and mortality (2,3). An ambitious target was set by the Joint United Nations Program on HIV and AIDS (UNAIDS) that by 2020, 90% of all people diagnosed with HIV infection should receive ART and 90% of people living with HIV receiving ART should achieve viral load suppression (4). Achieving 90, 90, 90 will enable the world to end the AIDS epidemic by 2030 and reduce the risk of HIV transmission (4).

Despite the major achievement in taking ART, almost 2 million new infections continue to occur each year living many countries primarily in sub-Saharan Africa with an overwhelming epidemic (1). In Tanzania, the annual incidence of HIV among adults ages 15 to 64 years was 0.29 percent which corresponds to approximately 81,000 new cases of HIV annually (5). The increase in viral load level increases the risk of HIV transmission and lowers the possibility of ending AIDS epidemic. The HPTN052 clinical trial has shown that viral suppression due to ART can reduce HIV transmission by up to 96% (6).

At the end of 2017, 52.6% of HIV clients had an unsuppressed viral load globally (1). In Tanzania, the prevalence of unsuppressed viral load was estimated to be 48% among adults ages 15 to 64 years (5). This increases the danger of HIV drug resistance and threatens the efforts of ending acquired immune deficiency syndrome (AIDS) epidemic by 2030.

In 2013, World Health Organization (WHO) recommended viral load testing as the preferred monitoring approach to diagnose and confirm treatment failure (7); identify adherence problems and determine the switch of the regimen whenever required (8–11). Viral load testing determines how many viral copies a patient has per milliliter of blood (12). It is also a critical indicator of HIV treatment quality and tracking of progress towards national and global indicators (13). Implementation of routine viral load for patients on ART has been the main focus in most resource-limited countries (14).

In resource-limited settings, where genotypic drug resistance testing is rarely performed and poor adherence is the most common reason for treatment failure, programmatic approaches to handling treatment failure are essential (15). Various methods have been evaluated in sub-Saharan Africa to improve adherence to ART (16) among them being adherence counseling. Emphasis on counseling to improve adherence in most of the national ART program is expected to contribute towards lower proportions of virological failure (17). Attainment of viral load suppression among PLHIV has been the ultimate goal of the HIV care continuum (3).

Viral load suppression (VLS) was defined by WHO as below 1000 copies/ml (8) and viral load failure as a persistently detectable viral load exceeding 1000 copies/ml after at least 6 months of starting a new ART regimen and can be an indication of either antiretroviral (ARV) resistance and/or treatment non-adherence (8). Various countries have defined viral load suppression cutoffs in their HIV guidelines (3). In Tanzania, viral load suppression has been defined as below 1000 copies/ml (18). HIV clients who achieve early virological suppression remain on the first-line ART regimen longer, have a lower risk of developing opportunistic infections and face lower mortality rate (14). When viremia is identified, re-suppression can be achieved especially when adherence interventions are implemented (19).

In Tanzania, enhanced adherence counseling (EAC) intervention is provided to overcome factors contributing to treatment failure (20). The goal of EAC is to assess possible barriers to adherence in a non-judgmental way and help the client construct an adherence plan with concrete objectives by reviewing knowledge of HIV and ART, psychological, client's motivation for taking medication, emotional and socio-economic factors that may contribute to poor adherence (20). It has been suggested that patients' knowledge of their viral load values might help improve adherence to therapy (21).

EAC is usually conducted in three sessions within twelve weeks and after the third session, another viral load test is done in order to differentiate poor adherence from treatment failure (18). Additional EAC is done whenever the possible barriers to adherence are still not removed and ARV resistance and/or treatment non-adherence conditions can be differentiated after receiving adherence counseling support followed by retesting three to

six months later (18). The intervention helps keep patients longer on first-line ART regimen which is cheaper, safer and also preserves the more toxic and expensive second-line ART regimen for as long as possible in a resource-limited setting (22)

The EAC sessions are done on the one-monthly interval for a period of three months and another viral load is tested thereafter (18). Viral load below 1000 copies/ml after EAC is regarded as adherent and the client continues with the same regimen (8,20). Poor adherence to ART is the most common reason for high viral load (18,23) while other common reasons may include drug resistance, malabsorption, drug-drug interactions and drug-associated side effects (18,23). Although the EAC program has been implemented in various health facilities in Tanzania, there is still limited information on viral load suppression after EAC and its associated factors.

1.2 Problem statement

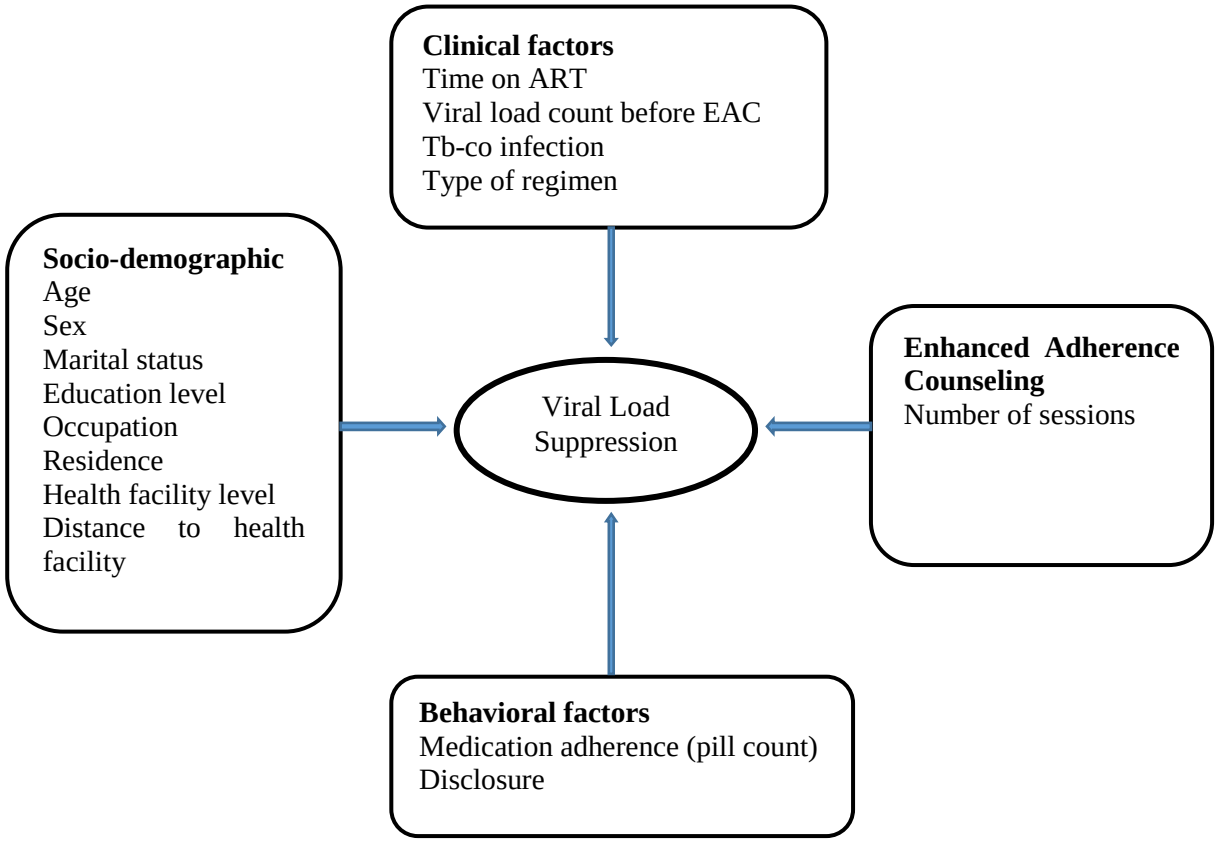
The national guideline for the management of HIV in Tanzania has adopted the WHO guidelines and recommends EAC to clients with a viral load above 1000 copies/ml as a programmatic approach to handling treatment failure since genotypic drug resistance testing is rarely performed and poor adherence is the most common reason for treatment failure.

Tanzania HIV impact survey (THIS) conducted in 2016/2017 reported about 48% of adult's HIV clients ages between 15 to 64 years had viral load above 1000 copies/ml which increases the danger of HIV drug resistance, increases HIV transmission, threatens the efforts of the country to reach UNAIDS last 90 target and ending AIDS epidemic by 2030. Findings from different studies have shown that EAC supports HIV clients to achieve significant viral load suppression and prevents a switch in ART regimen however, the proportion of viral load suppression varied across studies.

Mbeya region was reported as one among the regions with a high HIV prevalence of 9.3 percent with 42.6 percent clients having a viral load of more than 1000 copies/ml. To date, viral load suppression after EAC and associated factors in Mbeya is not well documented. Therefore, this study intended to determine the proportion of viral load suppression after EAC and its associated factors among HIV clients on ART.

1.3 Conceptual framework

This conceptual framework was developed based on previous study literature on viral load suppression. The framework describes some of the factors that may associate with viral load suppression among clients on antiretroviral therapy. On socio-demographic factors, younger age, being female, not having a partner, uneducated, unemployed, residing in a rural and shorter distance to health facility were reported to be less likely to achieve viral load suppression. Clinical factors such as being longer on ART, higher initial viral load level, Tb-coinfection, being on the first line versus the second line were less likely to have viral load suppression. Behavioral factors such as having lower treatment pill count and non-disclosing status were less likely to achieve viral load suppression while attending EAC sessions may facilitate viral load suppression.



Source: Developed based on published study literatures (23–26)

Figure 1: Illustrating factors associated with VLS among HIV clients on ART.

1.4 Rationale

The study findings help inform the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) and National Aids Control Programme (NACP) on the progress of EAC towards viral load suppression and implementation of the national guideline at health facilities and guide decisions on interventions to improve EAC programme so as facilitate retention of HIV clients on treatment. The findings also help health care workers (counselors, clinicians) to understand the gaps in the EAC program and identify groups that need more focusing during EAC at the health facility level.

1.5 Research Questions

1. What is the proportion of viral load suppression after EAC?
2. What are the factors that associate with viral load suppression after enhanced adherence counseling among HIV clients on ART?

1.6 Objectives

1.6.1 Broad objective

- To determine the viral load suppression after EAC and factors associated among HIV clients on antiretroviral therapy.

1.6.2 Specific objectives

1. To determine the proportion of viral load suppression after EAC among HIV clients on ART in Mbeya.
2. To identify factors associated with viral load suppression after EAC among HIV clients on ART in Mbeya.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Viral load suppression among HIV clients on antiretroviral therapy after EAC

Viral load testing after 6 months of ART is a good predictive of future virological failure, HIV disease progression, and mortality (2,8). Studies reported up to 70% of the people with elevated viral load can re-suppress with improved adherence to treatment (27). In a systematic review on viral load monitoring tool to reinforce adherence, five (5) countries reported viral load suppression between 54.2% and 89.1% and showed a subsequent reduction in viral load levels (22). When viral load monitoring is used as a tool to identify clients in need of adherence interventions, the majority achieve viral load suppression and are able to continue with their current treatment regimen (22).

In a study done in Swaziland among children, adolescents, and adults, 54% had viral load suppression after EAC (26) and reported that viral load monitoring has the potential to improve ART treatment support. The same study suggested efforts should be made to exclude ongoing adherence barriers before considering a change in the regimen (26). Improving client's treatment literacy by communicating and explaining their viral load results can motivate clients to adhere to ART and invest in their own health outcomes (26,27).

In Lesotho, southern Africa study showed that 31% re-suppressed (11) and achieving viral suppression was associated with EAC while a study was done in three countries (Kenya, Malawi, and Zimbabwe) on viral load suppression after EAC, the suppression was 31.4% and an additional 7.4% had a greater or equal to 0.5 log drop (28). The same study confirms the importance of viral load testing, adherence counseling and repeats viral load before deciding to switch to second-line ART (28). In Haiti and Zimbabwe, 25% and 31.2% achieved virological suppression (23,25). The role of EAC in achieving viral load suppression in programmatic conditions appears to be limited (23).

EAC is also recommended for HIV clients on second-line treatment and studies done in Johannesburg and Khayelitsha showed about 64 percent and 67 percent of clients on second-line ART showed significant viral load suppression after counseling respectively (15,29). Adherence to treatment is the major barrier to unsuppressed viral load and targeted adherence support is important to reduce the need for third-line treatment. EAC supports the majority of the clients to achieve substantial proportions of viral load suppression however, the proportions vary across studies. The variation between studies may be contributed by the development of drug resistance even before the adherence intervention as clients may have stayed longer on ART. A study in Burkina Faso and Mali reported more than 60% had been on ART and already developed drug resistance when viral load testing started (30).

Despite having several studies on EAC and viral load suppression, there is still limited information on the proportion of viral load suppression after EAC in Tanzania. Therefore, there was a need to determine the proportion of viral load suppression so as to help target interventions and improve the EAC program.

2.2 Socio-demographic factors associated with viral load suppression

Several studies done on the association between age and viral load suppression in clients initiated ART showed viral load suppression improved with increasing age (24,31–33). Patients' age should be taken into accounts when interpreting viral load results (26). Older age may predict viral suppression and might be related to the increasing treatment experience (24,31–33). Age above 40 years and 20 years were reported to be associated with viral load suppression in India and Swaziland respectively (17,26) while 15-20 years was reported in three countries (28). However, other studies reported age was not associated with viral load suppression (23).

The association between gender and viral load suppression has been examined by many studies and contradicting findings have been reported. Some suggest females have worse viral load suppression than males (34–36) while others found gender was not associated with viral load suppression (23,26,28). However, research from resource-limited settings suggests female have good viral load suppression than the male because females have higher health-seeking behaviors and better adherence to treatment (37,38). Being married

or in a committed relationship showed higher proportions of viral suppression while education below university and unemployed had a lower probability of viral load suppression (39,40). Clients who reside in rural areas have a lower probability of viral load suppression compared to urban (41).

Clients can achieve good adherence and clinical outcomes despite a long travel distance (42). A study in Uganda found that there was no difference in the distance traveled to health facilities between those with suppressed and unsuppressed viral load (43). Facilities with a higher volume of clients were more likely to achieve viral load suppression compared to facilities with a lower volume of clients (44). Studies reported lower volume facilities may be less likely to provide onsite related medical care of services or health care workers may be less likely to adhere to HIV related care recommendations (44). The availability of qualified health care workers and training has been reported to promote clients' adherence to treatment, viral load suppression, and retention in care at the health facilities (25,27,44).

2.3 Behavioral factors associated with viral load suppression

Poor adherence leads to ongoing viral replication and HIV drug resistance which then undermines the ability of ARV drugs to fully suppress viral replication (45). The link between inadequate adherence to treatment regimens and lack of viral load suppression has been shown in literature where inadequate adherence negatively influenced viral load suppression, resulting in poor patient clinical outcomes (46). Adherence of more than 95% pill count has been associated with viral load suppression (17). In Tanzania, at least 95% ARV pill count is regarded as adherent (20,47).

Disclosure has been found to be the first step in gaining support from families and significant others (48). However, lack of family support has been reported to have a negative association with viral load suppression (48). Studies done in Zimbabwe and Swaziland reported EAC was not independently associated with viral load suppression when comparing counseling and non-counseling groups (23,26).

2.4 Clinical factors associated with viral load suppression

The study in Zimbabwe reported initial viral load between 1000-5000 copies/ml were more likely to suppress compared to above 5000 copies/ml (23). Higher adherence levels to treatment are good predictors of viral load suppression. Non-tenofovir containing regimens was reported to be associated with a lower probability of achieving viral load suppression while Tb co-infections were not independently associated with achieving viral load suppression (17). A study done in Tanzania reported that viral load suppression among clients was good up to four (4) years after initiating antiretroviral therapy (43). Therefore, there was a need to study and identify the factors associated with viral load suppression among HIV clients on ART. The findings from this study will help to guide health care workers especially clinicians and counselors to focus EAC to groups that need close follow-up and attention at the health facilities.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study area

The study was conducted in the Mbeya region. Mbeya is one of the 31 administrative regions in Tanzania. It is located in the country's southwest. The regional capital is the city of Mbeya. According to the 2012 national census, the region had a population of 2,707,410. The region is administratively divided into seven districts, Busekelo, Chunya, Kyela, Mbarali, Mbeya City/urban, Mbeya rural and Rungwe. The region has a total of 312 health facilities and among them, 231 are public and 81 are private. The study was conducted in two Districts and six health facilities. Four health facilities (Mbeya Zonal Referral Hospital, Mbeya Regional Referral Hospital, Ruanda health center, Kiwanja Mpaka health center) and two health facilities (Kyela District Hospital, and Ipinda health center) from Kyela district (Figure 2).

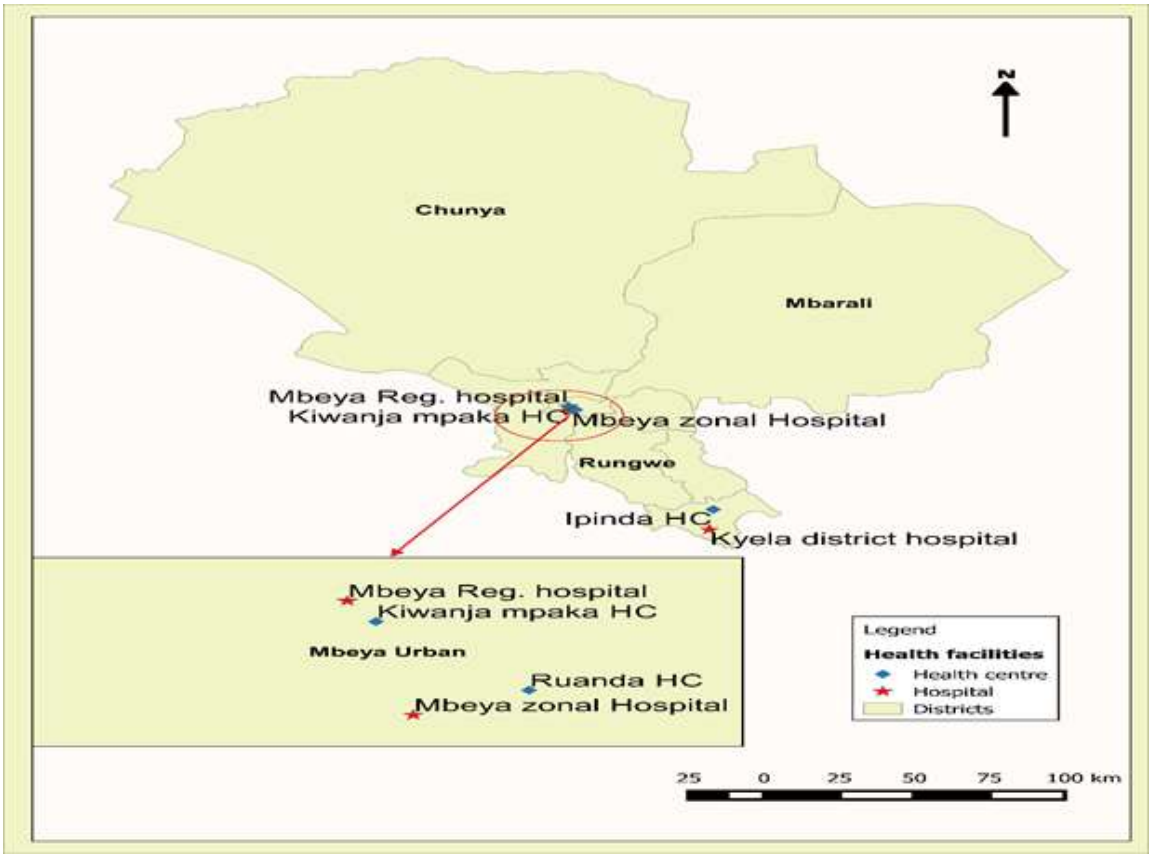


Figure 2: Geographical distribution of health facilities studied in Mbeya

3.2 Study Design

The study was a cross-sectional study that involved a review of client's records on socio-demographic, clinical, behavioral and counseling sessions at the health facilities.

3.3 Study period

The study was conducted for a period of three months starting from February 2019 to April 2019 reviewing data of HIV clients initiated EAC from January 2018 to December 2018.

3.4 Study Population

The study population involved HIV clients on ART for more than 6 months with viral load more than 1000 copies/ml who initiated EAC at care and treatment center (CTC) in Mbeya Urban and Kyela district.

3.4 Inclusion and Exclusion criteria

3.4.1 Inclusion criteria

- HIV clients on ART for more than 6 months with a viral load of more than 1000 copies/ml and initiated EAC.

3.4.2 Exclusion criteria

- The age group below 15 years of age
- Breastfeeding and pregnant women

3.5 Sample Size

The study sample size was estimated using the formula below described in Kelsey et. al.

$$n_1 = \frac{(Z_{\alpha/2} + Z_{1-\beta})^2 \, \bar{p}\bar{q}(r+1)}{r(p_1-p_2)2}$$

whereby;

$$\bar{p} = \frac{p1+rp2}{r+1}$$

$$\bar{q} = 1-p$$

and $n_2 = rn_1$

Key:

$\mathbf{n_1}$ = number of HIV clients exposed

$\mathbf{n_2}$ = number of HIV clients unexposed

$\boldsymbol{Z_{\alpha/2}}$ = 1.96 standard normal deviate for two-tailed test based on alpha level (relates to the 95% confidence interval level)

$Z_{1-\beta}$= standard normal deviate for one-tailed test based on beta level (relates to the power level) = 80%

r = ratio of unexposed to exposed = 1:1

$\mathbf{p_1}$ = proportion of exposed with viral load suppression = 66.0 (26)

$\mathbf{p_2}$ = proportion of unexposed with viral load suppression = 49.0 (26)

$$n_1 = \frac{(1.96+0.8)^2\,(0.575 \times 0.425)\,(2)}{0.0289} = 129$$

n_2= 1 x 129

Sample size=129x2 = 258

To accounted for 10% non-response rate during the study period

$$\text{Non response rate} = \frac{n}{(1-0.1)}$$

$$\frac{258}{(1-0.1)} = 287$$

The total number of study participants included in the study was 287.

3.6 Sampling Technique

The two districts which were Kyela and Mbeya urban were selected using a purposive sampling technique based on the number of clients with a viral load above 1000 copies/ml. Then six health facilities; two from Kyela district and four from Mbeya urban were also selected based on the number of HIV clients with a viral load above 1000 copies/ml using purposive sampling technique. The number of HIV clients with a viral load above 1000 copies/ml per each health facility was obtained and thereafter, excluding age group below 15 years, pregnant and breastfeeding women. After the exclusion, the total number of clients from the six health facilities was obtained and used as the denominator for calculation of sample size to be drawn per each health facility using probability

proportional to sample size (PPS) technique. The sampling frame of all HIV clients meeting the inclusion criteria was obtained from EAC registers at the health facilities selected and systematic random sampling (SRS) technique with an interval of 3 was used to enroll clients into the study at each health facility.

3.7 Variables

3.7.1 Dependent variable

Viral load suppression after EAC.

3.7.2 Independent variables

The independent variables used in the study were; Socio-demographic factors (age, sex, marital status, education level, occupation, residence), Clinical factors (time on ART, viral load count before EAC, Tb co-infection, type of ARV regimen), behavioral factors (medication adherence (pill count), disclosure, level of health facility, distance to the health facility and number of EAC sessions).

3.8 Data Collection Methods

3.8.1 Data collection tool

A data abstraction tool was used to collect data on the variables at the health facilities selected.

3.8.2 Data collection procedure

A data abstraction tool was used to collect information on the selected independent variables of interest from the source documents (EAC registers, EAC counseling forms, patient's files) at the six health facilities. This was piloted and done by research assistants who were trained on data collection and supervised by the principal investigator. A list of clients with a viral load above 1000 copies/ml was extracted from the higher viral load register (EAC) at the health facilities. Clients meeting the inclusion criteria were selected. The first client was selected using simple random sampling and thereafter the SRS technique with an interval of 3 was used to enroll the rest of the clients. After selection, the client's unique CTC identification number was obtained from the EAC register and used it to retrieve the client's individual file, client counseling records, and viral load results. We reviewed the source documents to get information on socio-demographic, clinical,

behavioral, counseling sessions and laboratory viral load results. Individual client's EAC forms were reviewed at the health facilities to obtain information on reasons for poor adherence to treatment.

3.8.3 Recruitment and training of research assistants

During the data collection, two research assistants were selected and trained for one day on research data collection tools.

3.8.4 Pre-testing of the tools

Data collection tools were pre-tested at Mbeya Regional Referral Hospital and revised to ensure clarity before carrying out the study.

3.8.5 Validity and reliability

Validity-means the extent to which the concept is accurately measured. Research assistants were trained on data collection tools prior to the start of study implementation. The data collected were reviewed for completeness and corrections prior to the transfer of data to the electronic questionnaire by the principal investigator. Probability sampling was used to select study participants to be enrolled.

Reliability- means the consistency of measuring. The pre-testing of the tool was done before data collection and standardized to ensure the data collection tool collects what is intended to collect.

3.8.6 Recruitment and selection of study participants

To avoid selection bias during the study, a list of clients with viral load above 1000 copies/ml from the EAC register was obtained and clients were selected and enrolled in the study using a systematic random sampling technique with an interval of 3 at the health facilities.

3.9 Data management and analysis

3.9.1 Data Quality

The data collection tools were cross-checked for completeness by the principal investigator and corrections were made whenever there were discrepancies. Information that was not recorded or not traced in any of the patient records during the review of the patient records was regarded as missing.

3.9.2 Data analysis

Data extracted from the client's files were transferred into the data abstraction tool and later entered into an electronic questionnaire form created in Epi info 7 software (version 7.2.2.2). Data entered in Epi info was cross-checked with the information on the data collection tool and corrections were made whenever there were discrepancies. Data were analyzed using STATA software version 13. Descriptive analysis was done using frequency and proportion for categorical variables. The continuous variable was summarized using mean and standard deviation or median and interquartile range (IQR) per respective continuous variable. A chi-square test was used to compare categorical variables. All predictors with P-value $\leq$ 0.25 in the bivariate level were entered into multivariable binomial logistic regression (Poisson regression) models with 95% CI (0.05) to obtain the prevalence odds ratio and adjusted prevalence ratio while controlling for potential confounders.

3.10 Ethical consideration

Ethical clearance for conducting this study was obtained from the ethical review board of Muhimbili University of Health and Allied Sciences. Permission to conduct the study in the Mbeya region was obtained from Mbeya Medical Research and Ethics Review Committee, Regional Administrative office, Regional Medical offices, District executive directors at Mbeya city and Kyela District, District Medical offices at Kyela district and Mbeya city and Management of health facilities involved. Confidentiality of the participant's information was maintained whereby research assistants and the principal investigator had only access to the participant's information. The information was secured at the facility CTC.

CHAPTER FOUR

4.0 RESULTS

4.1 Socio-demographic characteristics of the study participants

A total of 287 HIV clients were enrolled in the study. Their median age was 42 (IQR: 34-49) years. The majority of the participants 115 (40.1%) were aged between 35 – 44 years and 176 (61.3%) were female. Almost 152 (52.9%) were married, 204 (71.1%) had primary education, 140 (48.8%) were peasants and 148 (51.6%) were residing in urban areas (Table 1).

Table 1: Socio-demographic characteristics of the study participants (n=287)

Variable	frequency/Median	Percentage
Median age	42 (IQR: 34-49)	
Age group (years)		
<25	26	9.1
25-34	48	16.7
35-44	115	40.1
≥45	98	34.2
Sex		
Male	111	38.7
Female	176	61.3
Marital status		
Single	54	18.8
Married	152	52.9
Separated/widowed/divorced	81	28.2
Education level		
Non formal	17	5.9
Primary level	204	71.1
Post-primary	66	23.0
Occupation		
Unemployed	25	8.7
Salary-employed	21	7.3
Self-employed/Business	101	35.2
Peasants	140	48.8
Residence		
Urban	148	51.6
Rural	139	48.4
Distance to HF		
<5 km	99	34.5
≥5 km	188	65.5
Level of facility		
Health Centre	75	26.1
Hospital	212	73.9

4.2 Clinical characteristics of the study participants

Most participants 217 (75.6%) were on first-line ART (AZT+3TC+EFV, AZT+3TC+NVP, TDF+3TC+EFV, TDF+FTC+EFV) **f**or an average time of 5.6 (SD 2.8) years. Their median viral load count before EAC was 1.5 X 10^4 (IQR: 3768-68362). None of the participants had TB co-infection (Table 2).

Table 2: Clinical characteristics of the study participants

Variable	frequency/Mean/Median	Percentage
Time on ART (years)		
Mean time on ART (years)	5.6(SD 2.8)	-
<3	46	16.0
3-5	101	35.2
≥6	140	48.8
Viral load (copies/ml)		
Median VL(copies/ml)	$1.5X10^4$ (IQR: 3768-68362)	-
$1.0x10^3$ - $<1.0x10^4$	122	42.5
$1.0x10^4$ - $<1.0x10^5$	106	36.9
$\geq 1.0x10^5$	59	20.6
ART regimen level		
First-line	264	91.9
Second line	23	8.1
ART regimen type		
Tenofovir containing first line	204	71.1
Zidovudine containing first line	60	20.9
Second line	23	8.0

4.3 Behavioral characteristics of the study participants

Two hundred and forty-six participants (85.7%) reported having disclosed their HIV status to at least one family member. Majority 209(72.8%) had an overall ARV pill count of more than 95% and 222 (77.0%) had attended three enhanced adherence-counseling sessions (Table 3).

Table 3: Behavioral characteristics of the study participants

Variable	Number	Percent
Overall ARV pill count		
≥ 95%	209	79.5
< 95%	54	20.5
Disclosure		
Yes	246	92.5
No	20	7.5
EAC sessions		
1	21	7.3
2	45	15.7
Completed 3	221	77.0

A low level of ARV pill count was observed during the first session and increased by 6.9% from the first session to the third session (Figure 3).

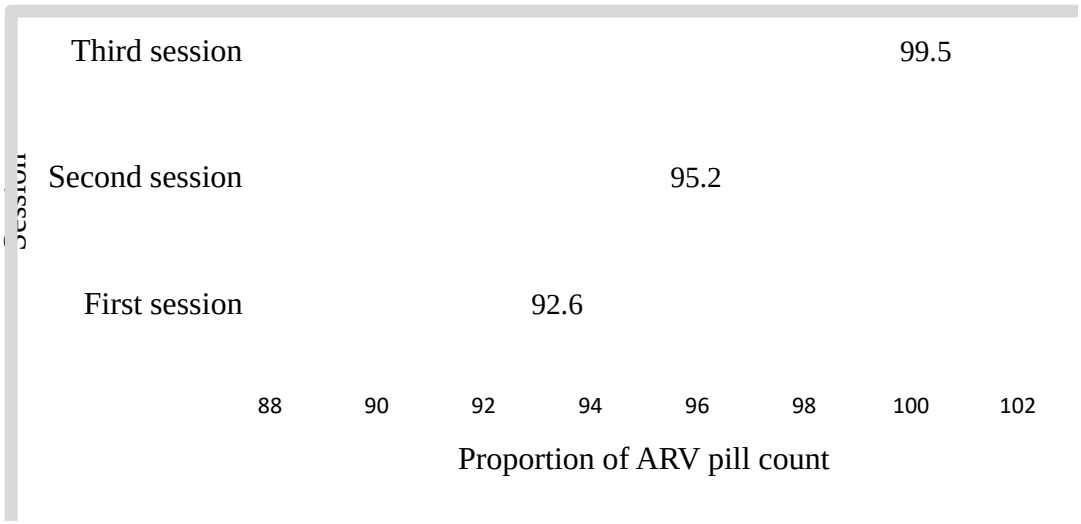


Figure 3: The status of ARV pill count during adherence counseling in Mbeya

4.3.1 Reasons for poor adherence to treatment

Reasons for poor adherence to treatment were reported during counseling. Most 165 (59.1%) of the reasons reported were due to forgetting to take medication because of work-related activities and traveling frequently followed by the use of alcohol 41(14.7%) (Figure 4).

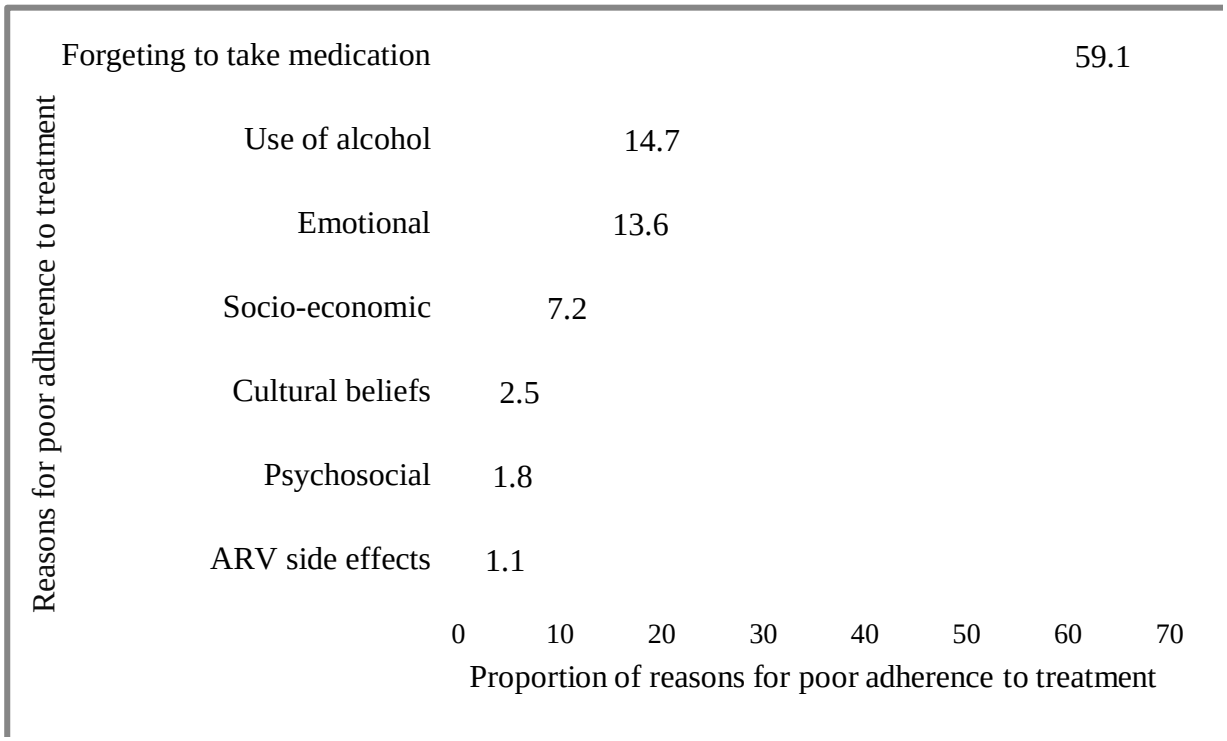


Figure 4: Reasons for poor adherence to treatment among clients on ART

4.4 Viral load suppression in relation to socio-demographic characteristics

Among 287 HIV clients, 150 (52.3%, 95% CI: 46.6-58.0) had significant viral load suppression after EAC. Sixty-three (64.3%, 95% CI: 53.9-73.7) clients with age above 45 years and 93 (52.8% 95% CI: 45.2-60.4) of females had significant viral load suppression. More than half of the clients (60.4%, 95% CI: 53.5-67.0) re-suppressed at the hospital level (Table 4)

Table 4: Viral load suppression in relation to socio-demographic characteristics

		Viral load suppression		
Variable	**Total**	**Yes (n)**	**Proportion**	**95% CI**
Overall suppression	287	150	52.3	46.6-58.0
Age group (years)				
<25	26	14	53.9	33.4-73.4
25-34	48	16	33.3	20.4-48.4
35-44	115	57	49.6	40.1-59.0
≥45	98	63	64.3	53.9-73.7
Sex				
Male	111	57	51.4	41.7-60.9
Female	176	93	52.8	45.2-60.4
Marital status				
Single	54	23	42.6	29.2-56.8
Married	152	84	55.3	46.9-63.3
Separated/widowed/divorced	81	43	53.1	41.7-64.3
Education level				
Non formal	17	8	47.1	22.9-72.2
Primary level	204	111	54.4	47.3-61.4
Higher level	66	31	46.9	34.6-59.7
Occupation				
Unemployed	25	14	56.0	34.9-75.6
Salary-employed	21	10	47.6	25.7-70.2
Self-employed/business	101	53	52.5	42.3-62.5
Peasants	140	73	52.1	43.5-60.7
Residence				
Rural	139	73	52.5	43.9-61.1
Urban	148	77	52.0	43.7-60.3
Distance to HF				
<5 km	99	47	47.5	37.3-57.8
≥5 km	188	103	54.8	47.4-62.0
Level of facility				
Hospital	212	128	60.4	53.5-67.0
Health Centre	75	22	29.3	19.4-40.9

4.5 Viral load suppression in relation to clinical and behavioral characteristics

High suppression of viral load was observed in clients on treatment for 3-5 years (58.4%, 95% CI: 48.2-68.1), on first-line ART (53.3%, 95% CI: 44.9-58.9) and ARV pill count above 95% (61.7%, 95% CI: 54.8-68.3). More than half (56.1%, 95% CI: 49.3-62.8) who received three EAC sessions achieved viral load suppression (Table 5).

Table 5: Viral load suppression in relation to clinical and behavioral characteristics

		Viral load suppression		
Variable	**Total**	**Yes n (%)**	**Proportion**	**95% CI**
Time on ART (years)				
<3	46	22	47.8	32.9-63.1
3-5	101	59	58.4	48.2-68.1
≥6	140	71	49.3	40.7-57.9
Viral load (copies/ml)				
$1.0x10^3$ - $<1.0x10^4$	122	88	72.1	63.3-79.9
$1.0x10^4$ - $<1.0x10^5$	106	45	42.5	32.9-52.4
$\geq 1.0x10^5$	59	17	28.8	17.8-42.1
ART regimen level				
First line	264	138	53.3	44.9-58.9
Second line	23	12	52.2	30.6-73.2
ART regimen type				
Tenofovir containing first line	204	106	51.9	44.9-58.9
Zidovudine containing first line	60	32	53.3	39.9-66.3
Second line	23	12	52.2	30.6-73.2
Overall ARV pill count				
≥ 95%	209	129	61.7	54.8-68.3
< 95%	54	14	25.9	14.9-39.7
Disclosure				
Yes	246	139	56.5	50.1-62.8
No	20	06	30.0	11.9-54.3
EAC sessions				
1	21	04	19.1	5.5-41.9
2	45	22	48.9	33.7-64.2
Completed 3	221	124	56.1	49.3-62.8

4.5 Bivariate analysis of socio-demographic factors associated with VLS

On bivariate analysis, clients aged above 45 years had 3.6 times the odds of having viral load suppression compared to those aged between 25-34 years (cPR= 3.6, 95% CI: 1.7-7.5). On the other hand, clients who obtained their EAC sessions at the hospital level had 3.7 times higher odds of viral load suppression compared to those obtained EAC in health centres (cPR=3.7 95% CI: 2.1-6.5) (Table 6)

Table 6: Bivariate analysis of socio-demographic factors associated with VLS

	Viral load suppression			
Variable	**Yes n (%)**	**No n (%)**	**cPR* (95% CI)**	**P-value**
Age group (years)				
25-34	16(33.3)	32(66.7)	**1**	
<25	14(53.9)	12(46.2)	2.3(0.9-6.2)	0.089
35-44	57(49.6)	58(50.4)	1.9(0.9-3.9)	0.059
≥45	63(64.3)	35(35.7)	3.6(1.7-7.5)	0.001
Sex				
Male	57(51.4)	54(48.7)	**1**	
Female	93(52.8)	83(47.2)	1.1(0.7-1.7)	0.806
Marital status				0.273
Separated/widowed/divorced	23(42.6)	31(57.4)	**1**	
Single	84(55.3)	68(44.7)	1.7(0.9-3.1)	0.111
Married	43(53.1)	38(46.9)	1.5(0.8-3.1)	0.233
Education level				
Higher level	31(46.9)	35(53.0)	**1**	
No formal	08(47.1)	09(52.9)	1.0(0.3-2.9)	0.995
Primary level	111(54.4)	93(45.6)	1.3(0.8-2.4)	0.293
Occupation				
Salary-employed	10(47.6)	11(52.4)	**1**	
Unemployed	14(56.0)	11(44.0)	1.4(0.4-4.5)	0.571
Self-employed	53(52.5)	48(47.5)	1.2(0.5-3.1)	0.686
Peasants	73(52.1)	67(47.9)	1.2(0.5-3.0)	0.699
Residence				
Urban	35(50.0)	35(50.0)	**1**	
Rural	115(53.0)	102(47.0)	1.0(0.6-1.6)	0.934
Distance to HF				
<5 km	47(47.5)	52(52.5)	**1**	
≥5 km	103(54.8)	85(45.2)	1.3(0.8-2.2)	0.239
Level of facility				
Health Centre	22(29.3)	53(70.7)	**1**	
Hospital	128(60.4)	84(39.6)	3.7(2.1-6.5)	<0.001

*cPR- crude prevalence ratio

4.6 Bivariate analysis of clinical and behavioral factors associated with VLS

HIV clients who disclosed their HIV status to a family member had 3.1 times odds of viral load suppression compared to those who did not (cPR=3.1, 95% CI: 1.1-8.2), while those with ARV pill count above 95% during the sessions had 4.6 times odds of viral load suppression (cPR=4.6, 95% CI: 2.4-8.9). Clients who attended three EAC sessions had 5.4 times the odds of viral load suppression compared to those who attended one session (cPR=5.4, 95% CI: 1.8-16.7) (Table 7)

Table 7: Bivariate analysis of clinical and behavioral factors associated with VLS

Variable	Viral load suppression		cPR (95% CI)	P-value
	Yes n (%)	No n (%)		
Time on ART (years)				
<3	22(47.8)	24(52.2)	**1**	
3-5	59(58.4)	42(41.6)	1.5(0.8-3.1)	0.233
>6	69(49.3)	71(50.7)	1.1(0.5-2.1)	0.864
Viral load (copies/ml)				
$\geq 1.0x10^5$	17(28.8)	42(71.2)	**1**	
$1.0x10^3$ - $<1.0x10^4$	88(72.1)	34(27.9)	6.4(3.2-12.7)	<0.001
$1.0x10^4$ - $<1.0x10^5$	45(42.5)	61(57.6)	1.8(0.9-3.6)	0.085
ART regimen level				
Second line	35(50.0)	35(50.0)	**1**	
First line	115(53.0)	102(47.0)	1.1(0.7-1.9)	0.993
ART regimen type				
Tenofovir containing first line	105(51.9)	97(48.0)	**1**	
Zidovudine containing first line	32(53.3)	28(46.7)	1.1(0.6-1.9)	0.852
Second line	13(52.0)	12(48.0)	1.0(0.4-2.3)	0.985
Overall ARV pill count				
< 95%	14(25.9)	40(74.1)	**1**	
≥ 95%	129(61.7)	80(38.3)	4.6(2.4-8.9)	<0.001
Disclosure				
No	06(30.0)	14(70.0)	1	
Yes	139(56.5)	107(43.5)	3.1(1.1-8.2)	<0.05
EAC sessions				
1	04(19.1)	17(80.9)	**1**	
2	22(48.9)	23(51.1)	4.1(1.2-13.9)	0.026
Completed 3	124(56.1)	97(43.9)	5.4(1.8-16.7)	0.003

4.7 Multivariate Poisson regression analysis of factors associated with viral load suppression

Factors with p-value ≤0.25 on bivariate analysis were included in multivariate Poisson regression level analysis. On multivariate Poisson regression analysis after adjusting for possible confounders, factors that were independently associated with viral load suppression were aged above 45 years (aPR= 1.7, 95% CI: 1.1-2.5), viral load count less than 10000 copies/ml before EAC (aPR=1.9, 95% CI: 1.3-2.9), hospital-level (aPR= 1.7 95% CI:1.2-2.4) and above 95% ARV pill count (aPR=1.8, 95% CI: 1.2-2.7) (Table 8).

Table 8: Multivariate analysis of factors associated with viral load suppression.

	Viral load suppression				
Variable	**Yes n (%)**	**No n (%)**	**cPR* (95% CI)**	**aPR**(95%CI)**	**P-value**
Age group (years)					
25-34	16(33.3)	32(66.7)	**1**	**1**	
<25	14(53.9)	12(46.2)	2.3(0.9-6.2)	1.7(1.0-2.8)	0.038
35-44	57(49.6)	58(50.4)	1.9(0.9-3.9)	1.3(0.9-1.9)	0.171
≥45	63(64.3)	35(35.7)	3.6(1.7-7.5)	1.7(1.1-2.5)	0.012
Viral load (copies/ml)					
$\geq 1.0x10^5$	17(28.8)	42(71.2)	**1**	**1**	
$1.0x10^3$ - $<1.0x10^4$	88(72.1)	34(27.9)	6.4(3.2-12.7)	1.9(1.3-2.9)	0.001
$1.0x10^4$ - $<1.0x10^5$	45(42.5)	61(57.6)	1.8(0.9-3.6)	1.2(0.8-1.87)	0.347
Overall ARV pill count					
< 95%	14(25.9)	40(74.1)	**1**	**1**	
≥ 95%	129(61.7)	80(38.3)	4.6(2.4-8.9)	1.8(1.2-2.7)	0.008
Disclosure					
No	06(30.0)	14(70.0)	**1**	**1**	
Yes	139(56.5)	107(43.5)	3.1(1.1-8.2)	2.2(0.6-7.5)	0.229
EAC sessions					
1	04(19.1)	17(80.9)	**1**	**1**	
2	22(48.9)	23(51.1)	4.1(1.2-13.9)	1.8(0.7-4.8)	0.209
Completed 3	124(56.1)	97(43.9)	5.4(1.8-16.7)	2.0(0.8-5.4)	0.164
Level of facility					
Health Centre	22(29.3)	53(70.7)	**1**	**1**	
Hospital	128(60.4)	84(39.6)	3.7(2.1-6.5)	1.7(1.2-2.4)	0.005
Distance					
<5 km	47(47.5)	52(52.5)	**1**	**1**	
≥5 km	103(54.8)	85(45.2)	3.7(2.1-6.5)	0.9(0.7-1.2)	0.869

*cPR – crude prevalence ratio **aPR- adjusted prevalence ratio

CHAPTER FIVE

5.0 DISCUSSION

This study was done to determine the viral load suppression after enhanced adherence counseling among HIV clients on ART in Mbeya Region. The study reported 52.3% of HIV clients achieved viral load suppression after EAC. The proportion observed in this study is lower than what was reported in a systematic review done across five countries (India, Swaziland, Thailand and South Africa) (22). Similar findings have been reported in studies done in Haiti, Lesotho, Zimbabwe, and Swaziland (11,23,25,26,28). The lower reduction of viral load in this study may be linked to the high proportion of clients being on ART for a longer time as demonstrated in the study that the majority of the clients have been on ARV for more than six years. Staying longer on ART increases the likelihood of developing drug resistance (22,49) and studies have shown more than 60 percent of clients had been treated with ARV and drug resistance had already developed when viral load testing started (30). On the other hand, the study shows approximately 23 percent of clients did not complete all the recommended number of EAC sessions and yet they were tested for the second viral load. This may have also underestimated the proportion of viral load suppression since the majority of those clients who did not complete all the sessions had failed to achieve viral load suppression. Follow-up of clients to ensure completion of all recommended number of sessions is very important in facilitating viral load suppression and retention of HIV clients in care.

Apart from determining the proportion of viral load suppression, this study also demonstrated the factors that were associated with viral load suppression which were age, viral load count, ARV pill count, and health facility level.

The study reported age above 45 years was more likely to achieve viral load suppression. This may be due to adherence to treatment among the older age as it has been reported that treatment adherence increases with age (24,31–33). Similar findings have been reported in a study done in India (17). Focusing EAC and knowledge on the importance of treatment adherence to younger age may improve viral load suppression.

Achieving and maintaining viral load suppression requires good adherence to ART supported by retention in care at the facility and individual-level characteristics and type of clinical setting has been shown to influence adherence to treatment (44). The study reported clients receiving EAC at hospital level were more likely to achieve viral load suppression compared to health centers. This is consistent with the study done in Uganda which reported hospitals had better performance in viral load suppression compared to health centers (24). This might be due to differences in training, health care worker's qualifications, supervision or properly following the national guideline in the provision of services in the health facilities. Studies have reported a high level of adherence to guidelines in the provision of HIV services in higher-level facilities compared to lower levels (50) and that services provided by trained health care workers were associated with viral load suppression (51). Furthermore, another study showed facilities with lower patient volume were less likely to provide adherence support and retention of HIV clients in care (44). The findings from this study provide a useful target for intervention to improve EAC program. Further studies are needed to establish the possible explanation for facility characteristics influencing viral load suppression.

Poor adherence to ART has implications for both HIV clients and public health (52). Clients must achieve at least 95 percent of ARV pill count to avoid treatment failure and the risk of developing drug resistance (18). This study reveals clients with ARV pill count above 95 percent were more likely to achieve viral load suppression. A close relationship between pill count and viral load suppression is observed in this study and is consistent with other studies reported (17,53). This may be explained by the high level of the client's awareness of the importance of adhering to treatment during counseling (52). The current study shows that clients reported to have an ARV pill count less than 95 percent during the first session and most of the reasons for not adhering to treatment for most of the clients were due to forgetting to take medication because of work-related activities and frequently traveling. This was also reported in a systematic review of adherence to treatment done in sub-Saharan Africa which showed forgetting to take medication was one of the main reasons for not adhering to treatment (54). The findings from the current study also demonstrated a significant increase in ARV pill count between the first session and third

session. Therefore, this study shows that adherence to treatment increases with counseling and that EAC is very important in assessing the reasons for poor adherence to treatment.

Studies have reported higher adherence levels of ART are good predictors of viral load suppression (23). The study reported clients with an initial viral load below 10000 copies/ml were more likely to achieve viral load suppression compared to above. This may be due to the higher ARV pill count observed among the counseling group in this study which facilitated the suppression. The other reasons might be due to higher level of CD4 count among the counseling group which facilitated the viral load suppression which could not be studied in this current study. However, different findings were reported in another similar study done in Zimbabwe (23) where clients with an initial viral load below 5000 copies/ml were more likely to re-suppress. The difference with the current study may be contributed by children in their study as they are reported to be less likely to adhere to treatment (55). Hence, this may have explained the reason for re-suppression in that level of viral load count.

Clients are recommended to attend a minimum of three sessions during EAC so as to adequately evaluate adherence barriers (18). The study reported not all clients attended the recommended number of sessions and there was no statistically significant in viral load suppression between those who completed sessions versus those who did not. This may be due to the client's awareness of the implications of elevated viral load and decided to manage on their own or the possibility that clients had already developed drug resistance. The act of telling clients they have elevated viral load and poorly adhere to treatment may be a powerful motivation to improve adherence as 3-month counseling (26,56)**.** However, different findings have been reported in other similar studies on EAC (23,26) which found no differences in viral load suppression between counseling and non-counseling groups. We attribute this difference to the two comparison groups (counseling and non-counseling) included in their study compared to one group (counseling group) which was studied in the current study. Further studies are needed to establish possible explanations for this.

The study reported no differences in viral load suppression between females and males even though females accounted for the majority in the study. Similar findings were reported in other studies (23,26). Findings from other studies reported men were less likely

to achieve viral load suppression as most men are vulnerable to treatment and extend beyond adherence (37,38).

Regarding marital status, education level and occupation, this study found no association with viral load suppression. Consistency with other reported findings (48). However, other studies have reported being married or in a committed relationship showed higher proportions of viral suppression while education below university and unemployment were associated with lower probability of viral load suppression (39,40).

Distance to health facilities in this study was not associated with viral load suppression. Possibly this may be because clients can achieve good adherence and clinical outcomes despite long travel distance (42). The finding is consistent with other studies done on distance and viral load suppression (43). The study also reported no difference in viral suppression between those living in rural or urban areas. However, other studies reported clients who reside in rural areas to have a lower probability of viral load suppression compared to urban (41)

Disclosing HIV status is identified as the first step in gaining support from family and significant others (48). Disclosure is an important component of HIV management and clients should be encouraged to disclose their status (18). Fear of disclosing status has been reported to be associated with fear of stigma and family emotions which poses as a major barrier to treatment adherence (52). In this study, disclosure was not independently associated with viral load suppression even though the majority had disclosed their HIV status, of which approximately 57 percent achieved viral load suppression. Similar findings have been reported in other studies (47,56). Failure of viral load suppression among those disclosed their status may not be due to lack of disclosing status (48).

Duration on ART is a significant factor for viral load suppression and the likelihood of developing poor adherence, drug interaction and side effects increases with time spent on ART (49). The present study reported time on ART was not associated with viral load suppression. This may be explained by the high proportion of clients being on ART for more than 6 years and the likelihood of viral suppression decreases as clients stay longer on ART and fail to adhere to treatment. Drug resistance cannot be excluded in this study

despite a higher level of ART adherence observed. This finding is consistent with a similar study reported in Zimbabwe (23).

Being on the first line or second line and type of regimen clients were taking was not associated with viral load suppression in this study. Consistency with other studies reported (23,26). The presence of drug resistance may have attributed to this finding. Other studies have reported being on the second line and non-tenofovir users were more likely to achieve viral load suppression (17)

5.1 Study Limitations

This study involved the use of routinely collected data at the health facilities and therefore missing information to some of the variables such as ARV pill count could not be avoided as they were not recorded at the health facilities. This could not be mitigated since the information depends on the health care worker's documentation at the health facilities and hence difficult to retrieve and recall. Therefore, this may have overestimated or underestimated the ARV pill count in this study.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The study reports a low proportion of viral load suppression after EAC among HIV clients on antiretroviral therapy. This study also shows older age, ARV pill count more than 95%, initial viral load below 10000 copies/ml and clients receiving EAC at hospital level was associated with viral load suppression. The findings confirm the importance of routine viral load testing, EAC and repeat viral load testing before deciding to switch to a second-line or third-line ART regimen.

6.2 Recommendations

The study recommends the following to improve EAC;

- Focusing adherence intervention to younger age is important to facilitate viral load suppression and prevent treatment failure.
- Establishing of a mentorship program between health facilities to improve health centers on the provision of EAC.
- To create a lasting solution that will help quickly identify at the triage clients who have come for EAC to facilitate proper follow-up, retention of the client in care and completion of sessions.
- Further studies are needed to establish the possible explanation for facility characteristics influencing viral load suppression.
- A follow-up study should be done to establish the effect of EAC on viral load suppression between the counseling and non-counseling groups and confirming the drug resistance through viral genotyping.

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APPENDICES

Appendix 1: Data collection tool (abstraction)

Study Title: Viral load suppression after enhanced adherence counseling among HIV clients on antiretroviral therapy in Mbeya, Tanzania

No._____ Date_____

PART A: General information

1. Name of the District
    a) Mbeya city Centre
    b) Kyela District
2. Name of the Facility
    a) Mbeya Regional Referral Hospital
    b) Mbeya Zonal Referral Hospital
    c) Kyela District Hospital
    d) Kiwanja Mpaka Health Centre
    e) Ruanda Health Centre
    f) Ipinda Health Centre
3. The Facility Client's CTC number…….
4. Client's residence (*ward/district)*

    ……..…… …….

5. Clients contact (Phone) number/relative

    …… ……

PART B: Socio-demographic information

6. Sex of the client
    a) Male
    b) Female
7. Date of birth (DOB) Day……month ……. year ……
8. Age (in years) ……
9. The Highest Level of education attended.
    a) No formal education.
    b) Primary education

c) O level education
d) A level education
e) College
f) University
g) Others(specify)……

10. Marital status
    a) Single
    b) Married
    c) Separated
    d) Widow/widower
    e) Co-habiting
11. Occupation status.
    a) Unemployed
    b) Employed
    c) Businessman/woman
    d) Farmer/peasant
    e) Livestock keeper
    f) Housewife
    g) Fisherman
    h) Miner
    i) Student
    j) Others (specify)……
12. The Residence of the client
    a) Rural
    b) Urban

PART C: Structural factors information

13. The level of the Health Facility the clients is attending for EAC.
    a) Hospital
    b) Health Centre
14. What is the distance taken by the client to reach the health facility?.....km.

15. What is the time taken by the client to reach the health facility?.....

PART D: Clinical and enhanced adherence counseling information

16. Is the client currently been treated for TB?
    a) Yes
    b) No
17. If yes to Qn. 16, What type of Tb medication is he/she taking?

    .....

    .....

(Qn. 18 and Qn. 19 are for the clients who already completed the TB medication)

18. When was the client completed the TB medication? (in weeks)

    ……

19. What were the TB medication that the client was taking/prescribed?

    .....

    .....

20. When was the client started taking ARV? Day……Month…….....…. Year……...
21. When did the client perform viral load test before EAC?

    Day……Month…….....…. Year……...
22. When did the results return? Day……Month…….....…. Year……...
23. What was the first viral load count result before starting EAC? (cp/ml)

    …… Log value 1……
24. What is the recent/last client's CD4 count result? (cells/µl)

    …….
25. What type of ARV medication the client is taking/prescribed?

    ……

    ……
26. Did the client attend EAC?
    a) Yes
    b) No

27. If Yes, how many EAC sessions did the client attend?
    a) One
    b) Two
    c) Three
    d) Others(specify)…….

28. What were the dates for the EAC sessions attended by the client?
    i. First session: Day……Month…….....…. Year……...
    ii. Second session: Day……Month…….....…. Year……...
    iii. Third session: Day……Month…….....…. Year……...
    iv. Fourth session: Day…… Month……Year……
    v. Others: Day……. Month……Year…….

29. Was the client tested for second viral load after EAC?
    a) Yes
    b) No

30. If yes to Qn. 28, When was the second viral load test taken?
    Day……Month…….....…. Year……...

31. When was the second viral load result received?
    Day……Month…….....…. Year……...

32. What was the second viral load result? (cp/ml) ..... Log value 2……

33. What is the significant log drop in viral load, if the client did not have below 1000cp/ml after a second viral load test?
    a) Above (>) 0.5 log drop
    b) Below (<) 0.5 log drop

PART E: Behavioral information

34. What was the ARV medication adherence during the sessions? *(e.g. 90%)*
    i. First session……...……...
    ii. Second session…….……...….
    iii. Third session……...……
    iv. Others(specify)…….……

35. What is the client's overall ARV medication adherence?
    a) Above 95%
    b) Below 95%

36. What are the main reasons for ARV non-adherence (*if below 95%)?*

Reasons	1st Session	2nd Session	3rd Session	Additional sessions
Food insecurity	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Fear of disclosing the status	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Travels frequently and forget to take ARV	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Drinking alcohol frequently	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Don't have a reminder or someone to remind me	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Depression	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Mental illness	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
ARV side effects	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Pill burden	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Stigma and discrimination	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Feeling better	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Instructions from HCW on pills intake	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Antiretroviral drugs are not available	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Forgetfulness	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Change in daily routine	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Religious reasons	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Taking traditional medications	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Taking ARV timely and as prescribed	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*
Others(specify)……	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*

37. Did the client Disclose his/her HIV status?

a) Yes

b) No

38. If Yes, to whom did he/she disclose?

a) Spouse

b) Family

c) Friends

d) Other (specify)……...

39. What is the client ARV medication status after EAC?

a) Remain on the current regimen

b) Switched to second line regimen

40. What was the outcome of the client after starting EAC?

a) Viral load suppression

b) Unsuppressed viral load

c) Others……

Appendix 2: Introduction Letter

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

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Ref. No. HD/MUH/T.354/2017

18th December, 2018

Regional Administrative Secretary
Mbeya Region
P.O. Box 754
MBEYA.

Re: INTRODUCTION LETTER

The bearer of this letter Ms. Sia Robert Temu is a student at Muhimbili University of Health and Allied Sciences (MUHAS) who is pursuingMSc. Epidemiology and Laboratory Management.

As part of her studies she intends to do a study titled:"***Viral load suppression rate after enhanced adherence counseling among HIV clients on antiretroviral therapy in Mbeya, Tanzania ".***

The research has been approved by the Chairman of University Senate.

Kindly provide her the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Sharifa Kamby
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School of Public Health and Social Sciences
cc: Ms. Sia Robert Temu

Appendix 3: Approval For Ethical Clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

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Ref. No. DA.287/298/01A/

12th December, 2018

Ms. Sia Robert Temu
MSc. Epidemiology and Laboratory Management
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "VIRAL LOAD SUPPRESSION RATE AFTER ENHANCED ADHERENCE COUNSELING AMONG HIV CLIENTS ON ANTIRETROVIRAL THERAPY IN MBEYA, TANZANIA"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 10th December, 2018 to 9th December, 2019. In case you do not complete data analysis and dissertation report writing by 9th December 2019, you will have to apply for renewal of ethical clearance prior to the expiry date.

Dr. Emmanuel Balandya
ACTING: DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publications
cc: Dean, School of Public Health and Social Sciences

UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

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MBEYA

Ref No. SZEC-2439/R.A/V.1/03a

11th February 2019

Sia Robert Temu,
Registration Number: HD/MUH/T.354/2017
Department of Epidemiology and Biostatistics,
Muhimbili University of Health and Allied Sciences (MUHAS),
Dar es salaam - Tanzania.

RE: **Request for Ethical Clearance for Protocol "Viral Load suppression rate after Enhanced Adherence Counselling among HIV clients on Antiretroviral Therapy in Mbeya, Tanzania"**

The above mentioned subject is concerned.

I would like to inform you that, the Mbeya Medical Research and Ethics Committee received your response to review comments for the aforementioned protocol. The Committee has granted Ethical Clearance of the above mentioned study for the period of one year, from **11th February 2019** to **10th February 2020.**

This Ethical Clearance approval bears the following specifications;

1. To comply with approved study protocol procedures, and at all times you are responsible for ethical conducts of your research;
2. You must notify the Mbeya Medical Research and Ethics Committee in writing regarding any alteration or deviation to the protocol;
3. To submit progress reports to the Committee every six months;
4. If the research has been completed, abandoned, discontinued or not completed for any reason you are required to submit a final report to the Committee;
5. The approval is given for one year from 11th February 2019 to 10th February 2020, and if you are unable to complete your research within the one year validation period you will be required to write to Mbeya Medical Research and Ethics Committee to request for an extension;
6. You must notify immediately the Mbeya Medical Research and Ethics Committee of any adverse event and/or unforeseen events that might affect continued ethical acceptability of the research.

Sincerely,

Executive Director
Mbeya Zonal Consultant Hospital
P.O. Box 419
Mbeya, Tanzania

Dr. Godlove F. Mbwanji
Chairman
Mbeya Medical Research and Ethics Review Committee.

Dr. Ruby D. Mcharo
Secretary

cc: The Chairman; National Health Research Ethics Review Committee; P.O.Box 9653, Dar es Salaam.
cc: RMO - Mbeya.