Factors associated with virological non-suppression after enhanced adherence counselling among people living with hiv on antiretroviral therapy in Kigoma Ujiji municipal

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FACTORS ASSOCIATED WITH VIROLOGICAL NON-SUPPRESSION AFTER ENHANCED ADHERENCE COUNSELLING AMONG PEOPLE LIVING WITH HIV ON ANTIRETROVIRAL THERAPY IN KIGOMA UJIJI MUNICIPAL

By

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A Dissertation Submitted in Partial Fulfillment of the requirement for the degree of Master of Public Health of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that has read and hereby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation titled ***"Factors Associated with Virological Non Suppression after Enhanced Adherence counselling Among People Living with HIV on Antiretroviral Therapy in Kigoma Ujiji Municipal''*** in partial fulfillment of requirements for the degree of Masters of Public Health of Muhimbili University of Health and Allied Sciences

_____

Supervisor; Dr Nathanael Sirili

(Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I **Geofrey Tarimo**, declare that this **dissertation** is my own original work and it has not been presented to any other University for similar or any other degree award.

Signature_____ Date_____

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DEDICATION

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LIST OF ABBREVIATIONS

ART	Antiretroviral Treatment
AIDS	Acquired Immune Deficiency Syndromes
IAC	Enhanced Adherence Counselling
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
HVL	HIV viral load
PLHIV	People Living with HIV
THIS	Tanzania HIV Impact Survey
VLs	Viral Load
WHO	World Health Organization

OPERATIONAL DEFINITION

Viral load suppression	Reducing a person's viral load (HIV RNA) to an undetectable level when a patient is in antiretroviral therapy (ART). Viral suppression does not mean a person is cured; HIV remains in the body, in this case, if ART is discontinued, the person′s viral load will likely return to a detectable level
Anti-retroviral treatment	ART are medications that treat HIV. The drugs do not kill or cure the virus. However, when taken in combination they can prevent the growth of the virus. When the virus is slowed down, so is HIV disease. Antiretroviral drugs are referred to as ARV. Combination ARV therapy (cART) is referred to as highly active ART (HAART).
Adherence	Adherence means "to stick firmly." So for people with HIV, medication adherence means sticking firmly to an HIV regimen—taking HIV medicines every day and exactly as prescribed
CD4 count	The CD4 count is a test that measures how many CD4 cells you have in your blood. These are a type of white blood cell, called T-cells, which move throughout your body to find and destroy bacteria, viruses, and other invading germs
HIV Viral Load	The number of HIV particles in a millilitre (mL) of blood. These particles are also known as "copies." The test assesses the progression of HIV in the body. It's also useful in seeing how well a person's HIV therapy is controlling HIV in their body.
Highly Active Antiretroviral Therapy	This is the type of therapy comprising of three or more drugs for the effective treatment of HIV. Highly active antiretroviral therapy reduces virus multiplication in the body. By so doing the body immune system becomes stronger hence slow down the development of HIV. This also prevent further transmission of HIV to others such as from mother to child during birth

ABSTRACT

Background Introduction.

The UNAIDS 90–90-90 strategy stipulates that 90% of all people on (ART) should have a suppressed viral load after enhanced adherence counselling. However, despite the introduction of enhanced adherence counselling to people living with HIV on ART whose viral load suppression has failed, yet there are some cases where viral load suppression has failed.

Objective

To determine factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on ART in Kigoma Ujiji Municipal Council.

Methods: A cross-sectional study design employing a quantitative approach was done for people living with HIV on ART who had their viral load measured between July and December 2018. The study involved retrospective reviewing of information on the factors associated with virological non-suppression among people living with HIV on Antiretroviral therapy in Kigoma Ujiji. Raw data were entered and cleaned in SPSS version 24. Factors associated with virological non-suppression were determined through multivariable logistic regression. To control for possible confounders factors with p-value<0.2 in the bivariate analysis was further entered into the multivariate analysis. Adjusted odds ratio with 95% confidence interval were used to establish an association between predictor variables and dependent variables.

Results:

The study was composed of 460 patients; of these, 402(87.4%) had suppressed viral load while 58 (12.6%) had an unsuppressed viral load. Virological non-suppression was higher, among patients in 2nd line of ART treatment (AOR: 1.181(0.557-2.503), among patients with more than 4 weeks' time interval from HIV diagnosis to ART initiation (AOR:2.831(1.455-3.963), among patients with 2 years and above on ART treatment (AOR: 1.698(0.899-3.205) and among patients with no previous ARV exposure (AOR: 1.698 (0.899-3.205)

Conclusion

This study found the prevalence of virological non-suppression in Kigoma Ujiji was 12.6%, with From this study, male, history of non-communicable diseases, poor treatment adherence, history of TB Co-infection and incorrect dosing schedule being the factors strongly associated with virological non-suppression.

CHAPTER ONE

INTRODUCTION

1.1. Background introduction

Though there is no curative therapy for Human immunodeficiency virus (HIV), the introduction of highly active antiretroviral therapy (HAART) in the late 1990s has substantially decreased HIV associated morbidity and mortality, and increased patient survival [1–3]. Proper use of these medications have transformed the disease from an inevitably fatal disease to a chronic, treatable condition by suppressing the viral load to undetectable levels and providing a consistent increase in the number of CD4+ T lymphocytes [4,5]

HIV infected individuals on HAART are usually recommended to monitor clinically, immunologically and virologically on a regular manner to ensure successful treatment, identify adherence problems and determine whether HAART regimens should be switched or not[6]. Compared to clinical or immunological monitoring, virological monitoring provides an early and more accurate indication of treatment failure and the need to switch from first-line to second-line drugs and reducing the accumulation of drug resistance mutations and improving clinical outcomes. However, due to the high costs and technical demands of the test, clinical and immunological assessments are usually recommended to start and monitor the efficacy of therapy [6]. As a result, patients may be at risk of unrecognized virological failure and subsequent development of drug resistance.

In 2014, UNAIDS committed to ambitious testing and treatment targets to end the AIDS epidemic. By 2020, 90% of all people living with HIV will know their HIV status. By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy. By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression [7].

Once a person living with HIV achieve and is able to maintain HIV viral load below 1000 copies per ml reduces chances of passing infection to another person to nearly zero, hence if we achieve

viral suppression in 90% of all PLHIV on ART this will definitely reduce new HIV infection to zero eventually we will be able to end the AIDS epidemic. Since 2014 much efforts have been invested by all stakeholder in making sure the three 90s are realized by 2020.

The number of people accessing antiretroviral therapy (ART) has gradually increased in recent years [8]. With the rising numbers of patients accessing ART, it is important to sustain treatment success and limit the development of viral non-suppression.

To allow timely detection of treatment failures, WHO in July 2013 recommended the use of viral load testing as the gold standard to monitor patients' response to ART [9]. Establishment of the virological suppression status among patients enrolled on ART is important for timely detection of treatment failures, identification of patients in need of more enhanced adherence support and minimizes the development of drug resistance and unnecessary switch to expensive and limited ART regimen options [10,11].

As of July 2018, 36.7 million people worldwide are living with HIV/AIDS. Approximately 70% of people living with HIV globally are aware of their HIV status in 2016. The remaining 30% (over 11 million people) still need access to HIV testing services. HIV testing is an essential gateway to HIV prevention, treatment, care and support services. As of June 2017, 20.9 million people living with HIV were accessing antiretroviral therapy (ART) globally, up from 15.8 million in June 2015, 7.5 million in 2010, and less than one million in 2000.1 million people died from AIDS-related illnesses in 2016, bringing the total number of people who have died from AIDS-related illnesses since the start of the epidemic to 35.0 million. [12]

In Tanzania, 52.2% of PLHIV ages 15 to 64 years (55.9% of HIV-positive females and 45.3% of HIV positive males) know their HIV positive status. Among these, 90.9% (92.9% of HIV-positive females and 86.1% of HIV-positive males) self-report current use of ART. Furthermore, out of these PLHIV who self-report current use of ART, 87.7%(89.2% of HIV-positive females and 84% of HIV-positive males) are virally suppressed [13]

The National HIV treatment guidelinerecommend that viral load testing should be done 6 months after initiating ART, then at 12 months and thereafter annually for people who have achieved viral suppression. However, people with viral loads above 1000 copies per ml should undergo enhanced adherence counselling for 3 months followed by confirmatory viral load testing in order to determine if viral suppression has occurred or client is categorized as treatment failure if there is no significant change in viral load suppression (log change<0.5) or viral load went high. Those with treatment failure are switched to second-line ART [14].Previous studies have highlighted several factors that may be associated with virological suppression. Patients with WHO clinical staging 4 are more likely to be non-suppressed while those whose health status is evaluated by physicians on each clinic visit are less likely to experience virological failure [14]. Children and adolescents on ART are more likely to have high viral loads [15]. Suboptimal adherence, poor tolerability, and drug and food interactions, CD4 cell count, treatment history and drug-resistance (primary or transmitted) have also been associated with virological non-suppression. Suboptimal adherence and drug intolerance are the major cause of regimen discontinuations and hence virological failure [16,17,18].

Virological non-suppression may also be caused by several factors such as poor drug adherence, use of sub-optimal drug combinations, previous ARV exposure alcohol or drug abuse, Immunological failure, stage in which the Patient is based on WHO, low CD4 +count, High viral Load, Tb Co-infection, Non communicable diseases, HBV co-infection, time on ART, Time from HIV diagnosis to ART start (weeks), Non Adherence to ARVs, Duration on treatment and Treatment line [19].

Despite the increasing number of HIV+ patients accessing ART, there is limited information about virological non-suppression rates amongst the different groups of people enrolled in many resource-limited settings in general. Also little is done on the factors associated with virological non-suppression in most developed countries and resource-limited settings. The aim of this study will be to identify level and factors associated with virological non-suppression among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council.

1.2 Problem Statement

HIV remains a public health problem in many sub-Saharan African countries including Tanzania. Globally, 36.9% million people were living with HIV at the end of 2017 which caused 940,000 HIV related death worldwide [12]. Estimates shows that there were about 1.5 million people aged 15-49 years living with HIV in Tanzania in 2017 [13]. The National prevalence of HIV among people aged 15-49 years in Tanzania is estimated to be 5.1% which is higher (6.5%) among female and lower (3.5%) among males [13].

Virological failure is a common problem that HIV patient faces after starting treatment. [15]. Current guidelines recommend that once patients start treatment, virological failure should not exceed 10%. [16]. However, studies show that virological failure is much higher than expected and viral replication continues to be a major challenge among patients living with HIV. [17].

Several factors have been identified as predictors of non-suppression, such as poor drug adherence, use of sub-optimal drug combinations, previous ARV exposure alcohol or drug abuse, Immunological failure, stage in which the patient is based on WHO, low CD4 +count, high viral load, TB co-infection, Non communicable diseases, HBV co-infection, time on ART, Time from HIV diagnosis to ART start (weeks), Non Adherence to ARVs, Duration on treatment and Treatment line [22].

Despite the increasing number of HIV+ patients accessing ART, there is limited information about suppression rates amongst the different groups of people enrolled in care in most of developing countries including Tanzania. [18].The aim of this study was to determine the factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council. Enhanced counselling.

1.3 Rationale of the study

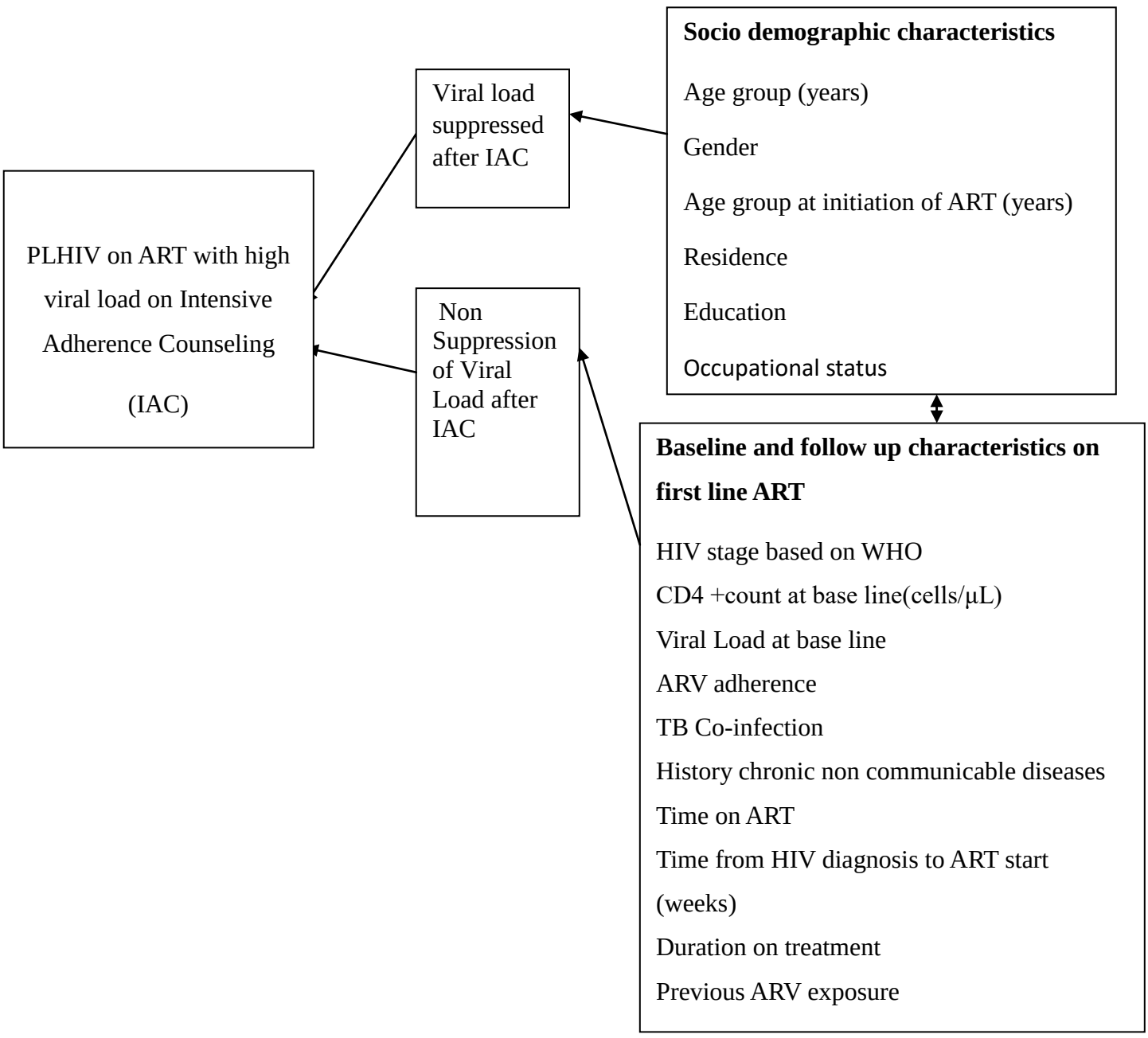
The findings of this study add to the body of knowledge on awareness and understanding of the factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy. The latter is important to health care professionals and all other stakeholders in the HIV/AIDS specifically on the future management of PLHIV with immunologic and/or clinical failure.

1.4 Conceptual Framework.

This is a written or visual presentation that:explains the main variables to be examined under the study and the presumed relationship among them".(Miles and Huberman, 1994, P18)

The conceptual framework below comprises of independent variables on the left side which explains the occurrence of the dependent variable. In this study, the independent variables are demographic characteristics and clinical characteristics of the HIV affected patients attending CTC in Kigoma Ujiji Municipals. The mentioned independent variables will be measured to what extent they contribute to either suppressed or unsuppressed viral load

Figure 1: Conceptual framework



Source: Researcher's construction

1.5. Research Questions

1.5.1 Broad Research Questions

What are the factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council?

1.5.2 Specific Research Questions

1. What is the proportions of PLHIV on ART with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council?
2. What are the socio-demographic factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council?
3. What are the clinical characteristics associated with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council?

1.6. Objectives

1.6.1 Broad Objective

To determine factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council.

1.6.2. Specific Objectives

1. To determine the proportional of PLHIV on ART with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council.
2. To determine the socio-demographic factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council.
3. To determine clinical characteristics associated with virological non-suppression after enhanced adherence counselling among people living with HIV in Kigoma Ujiji Municipal Council.

CHAPTER TWO

LITERATURE REVIEW

2.1. Back Ground Introduction

Human immunodeficiency virus (HIV) is a leading cause of the global burden of disease [21]. In recent years, significant progress has been made in increasing access to antiretroviral therapy for people living with HIV/AIDS [22]. A key goal of ART is to suppress the replication of the virus. Suppressed viral replication facilitates the restoration of the immune function and significantly reduces the risk of onward HIV transmission [23].

Despite the increased access to ART, numerous studies have demonstrated suboptimal levels of viral suppression in different populations in many low-resource settings [24]. In 2014, the UNAIDS launched the 90-90-90 targets with the intention of increasing awareness of HIV status, access to ART, and viral suppression among individuals who were diagnosed with HIV [24].

High rates of viral suppression are attainable at the community and country level and studies have identified numerous individual, interpersonal, and institutional factors that are associated with viral suppression in general population samples [25].

It is known that poor adherence to antiretroviral is associated with failure to suppress HIV. The best indicator of adherence and response to treatment is the virologic response, and more than 90% – 95% adherence is required to achieve viral suppression [26]. Other factors have also been shown to be associated with a delay in or failure to attain viral suppression, were age group less than 15 years, male gender, prior ART exposure and being on tuberculosis treatment [27].

Other factors associated with failure to attain viral suppression, were age group less than 20 years and CD4 count less than 350 cells/μL. In contrast. Another factor associated with a higher incidence of viral failure is a high VL at the initiation.[28]. A high CD4+ cell count and better clinical stage at initiation are, however, associated with earlier viral suppression [29].

Other studies found that longer duration post-cART initiation, less previous antiretroviral drug use before lifelong cART, higher baseline CD4 cell count and lower baseline VL were associated with 10 years of sustained viral suppression status [30].

The World Health Organization (WHO) recommends monitoring viral load (VL) as a preferred approach to immunological and clinical supervision to obtain early and more accurate ART failure indications and switch to second-line therapy.[31] For this purpose, the WHO recommends systematic monitoring of VL after 6 months of ART and at least every 12 months.[31]

The goal of early antiretroviral therapy (ART) for patients with HIV infection is to completely suppress viral replication, thus preventing further damage to the immune system, decreasing AIDS-associated morbidity and mortality, allowing the immune function to return to normal, and reducing the risk of transmitting HIV infection to others [32].

The number of people receiving ART continues to rise in Africa, viral load Suppression among PLHIV in most ART programs continues to be one of the biggest challenges.[33]. Due to the fact that the rate of viral suppression among patients on ART in many resource-poor settings is not known due to routine laboratory monitoring of HIV viral load not being performed in the public treatment programs.
But this has not always been apparent as many of the patients' experience deterioration and develop treatment failure, which can be explained by virological, clinical, or immunological causes or all of these because they do not behave according to expectations. [34].

Virological failure is a common problem that an HIV patient faces after starting treatment. [35]. Current guidelines recommend that once patients start treatment, virological failure should not exceed 10%. [36]. However, studies show that virological failure is much higher than expected and viral replication continues to be a major challenge among patients living with HIV. [37].

Despite the increasing number of HIV+ patients accessing ART, there is limited information about suppression rates amongst the different groups of people enrolled in care in most of developing countries including Tanzania. [38].

This study was focused on determining viral suppression and associated factors after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council in order to provide insights to policymakers about the different public health strategies in the HIV/AIDS programs specifically on the future management of PLHIV with immunologic and/or clinical failure.

CHAPTER THREE

METHODOLOGY

3.1. Study design

The study wasa cross-sectional design. The study design was chosen because of its simplicity in measuring the outcome and the exposures in the study participants at the same time. It is a design which is mostly used for estimating the prevalence in clinic-based studies.

3.2 Study area

The study was conducted in Kigoma Ujiji Municipal. Kigoma Ujiji Municipal is located along Lake Tanganyika in the western part of Tanzania. In the south is located with geographical coordinates 4° 54′ 20″ and east with geographical coordinates 29° 40′ 34 ″. It is composed of 10 wards. The total population for Kigoma Ujiji Municipal is estimated 215,458 people where the female population is estimated to be 111,273 (51.6%) of the population and male population is estimated to be 104,185 (48.4%) of the Population. (Information from Kigoma Ujiji Municipal Council, 2016). Kigoma is selected because it s among the regions with the highest HIV prevalence. Kigoma Municipal has a total of 21 facilities in the distribution of 15 dispensaries, 2 hospitals,3 health care facilities and 1 clinic. Of those 21 facilities,14are government facilities and 7 are private facilities. Of those, 21 health care facilities, only 13 providing care and treatment services among people living with HIV [20].

3.3 Study population

The population for this study were People Living with HIV ages 15 to 64 on antiretroviral therapy whose registered in the facilities providing care and treatment among people living with HIV in Kigoma Ujiji Municipal Council between July 2018 and December 2018.

3.4 Inclusion and Exclusion Criteria

3.4.1. Inclusion Criteria

People Living with HIV who had viral load test results attending for routine CTC visit from July and December 2018.

3:4:2. Exclusion Criteria

- Those not completing 3 sessions of EAC after first high viral load results.
- Participants below the age of 18 years old
- Those living with HIV, not on Antiretroviral therapy

3.5 Sampling and sample size

3.5.1 Sample size

The Sample size was determined using previous prevalence of unsuppressed viral load among HIV-positive adults ages 15 to 64 years in Tanzania, which is 12.3% according to Tanzania HIV Impact Survey (THIS, 2016-2017), with standard normal deviate of 1.96 for 95% confidence interval and 5% margin of error.

The formula for sample size calculation derived from *(*Israel, *et al*, 1992).

Therefore, the minimum sample size was calculated as follows;

For a large population:

$$n = \frac{z^2 p\,(100-p)}{\varepsilon^2} \times Df$$

Where

n= required sample size

Z= Critical value of the standard normal distribution for the 95% confidence interval around the true proportion which is 1.96

P= 12.3%, which is the prevalence of viral load non-suppression is 12.3% among HIV-positive adults ages 15 to 64 years**.**

DF=Degree of freedom to fit the required sample size.

Substituting in the above formula**;**

$$n = \frac{1.96^2\ 12.3\ (100-12.3)}{3^2} \times 1 = 460.4 \approx 460$$

N=460

None response

10%: N=n/(1-0.1)

460/0.9=511

Therefore, the minimum required sample size were 511 participants

3.5.2. Sampling procedure

Multi-stage sampling technique was used for this study for the selection of health care facilities and study participants. Simple random technique was used to select 5 health facilities from a list of 13 facilities providing care and treatment to HIV affected individuals. The serial number of each eligible health facility were written on small pieces of paper and placed in a box. Each health facility was given a unique number representing the name of the facility. From the box containing all 13 facilities, one paper at a time were randomly selected. The paper selected corresponded to the name of the health care facility was listed as a study facility. The box was reshuffled before the next pick until the required number of 5 health facility was obtained. Providing care and treatment was the major criteria for the selection of health care facilities and the inclusion of demographic and health survey hospital database.

The number of HIV affected individuals attending care in the selected health facilities were summed up and the number to be studied in each facility were determined by the proportion each facility contributes to the total. Then the required number from each facility were purposively selected until the required number was obtained.

3.6. Data collection

3.6.1. Data source

Secondary data were collected from CTC 2 database from the selected health care facilities. Data were collected from PLHIV on ART who had their viral load measured between July and December 2018.

3.6.2. Data Collection method and Tool

The socio-demographic data, HIV status, viral load suppression and non-suppression and other parameters associated with non-suppressionof the selected study participants were then retrieved from the CTCs database. Data were collected using a data abstraction form. Principal Investigator in collaboration with care and treatment and DHIS team were involved in data collection.

3.6.3 Data quality

The validity of the data was enhanced by a standardized record-keeping system in the health facility database. These records are normally readily available and regularly updated by the attending clinician and data clerk during each Patient visit. Data recorded from the register in the health facilities were found to be similar to the data in the CTC 2 database at facility and reports submitted to the District Health Team central office, where the data from the clinics were collected and analyze. Therefore, the reliability of the study was ensured by consistently using the same data collection sheet throughout the data collection process.

3.7 Data management and analysis

The collected data were sorted, captured, edited and entered into Microsoft EXCEL software and then imported into SPSS statistical package version 24 for analysis. Descriptive statistical measures like mean and standard deviation were done. Frequencies were produced for categorical variables and differences between proportions were examined using descriptive univariate analysis. The factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy were assessed using odds ratios with respective 95% CI. To control for potential confounders p-value less than 0.2 in the bivariate analysis were included in the multivariate analysis. Variables having a *P*-value less than 0.05 in the multivariate binary logistic regression model were considered statistically significant.

3.8 Ethical considerations

Ethical Clearance for this study was obtained from the Senate Research and Ethics Committee of Muhimbili University of Health and Allied Sciences. Permission letters were obtained from Kigoma Regional administrative secretary and were submitted to Kigoma Ujiji Municipal Director. Permission was also sought from the Council Health Management team under the leadership of Medical officer to collect data from their respective health facilities. Privacy and confidentiality of any information collected and shared were assured. Unique IDs were uses instead of participants

CHAPTER THREE

RESULTS

4.0. Overview

This section presents the findings of the research. The findings are divided into three parts namely demographic characteristics of respondents, clinical characteristics of the respondents and viral load results after three Months of ART initiation and six months of ART initiations.

4.1. Socio-demographic characteristics of respondents

A total of 460 records of patients were recruited to participate in the study. Four participants were excluded due to death before the end of 6 months' follow-up, 19 participants were excluded because of missing viral load results and seven were transferred to other clinics. The mean age of the study participants was 43years old with (SD: ±15). The age maximum and minimum were 88 and 18 respectively

Table 1: Demographic Characteristics of the patients (N=460)

Patients Characteristics	**Variable Responses**
Patients age	Number (%)
18-29 years	74 (16.1%)
30-44 years	155 (33.7%)
45-59 years	179 (38.9%)
60 years and above	542 (11.3%)
Sex of the patients	
Male	146 (31.7%)
Female	314 (68.3%)
Residence of the patients	
Rural	287 (62.4%)
Urban	173 (37.6%)
Education status of the patients	
None	77 (16.7%)
Primary	293 (63.7%)
Secondary	68 (14.8%)
College and above	22 (4.8%)
Employment status	
Employed	104 (22.6%)
Unemployed	110 (23.9%)
Self employed	246 (53.5%)
Marital status	
Married	197 (42.8%)
Never Married	139 (30.2%)
Cohabiting	37 (8%)
Widowed	53 (11.6%)
Divorced	34 (7.4%)

From table 1; Majority of the study participants were females 314(68.3%), married 197(42.8%), Age group 45-49 years, 179(38.9%), with self-employment 246(53.5%) and living in rural area 287 (62.4%). Majority of the study participants had attended school, however, most of them had an education level of primary education 293(63.7%)

4.2. Clinical Characteristics of the patients

Table 2 below shows that, majority of the participants 156(33.9%)were in HIV stage I because many patients delay for HIV test after infection. There must be a campaign to create awareness among people to early check their HIV status as soon as possible so that preventive measure can be initiated for negative and positive tested with HIV as result minimize HIV prevalence of Karagwe and National Again, Majority of the respondents 387(84%) had no history of non-communicable diseases. 227(49.3%) of the patients, their AIDS was defined as Kaposi's sarcoma which is common among HIV patients. Majority of the patients 382(83%) were in the 1st line of treatment and 206 (44.8%) had 0 to 1 weeks' time interval from HIV diagnosis to ART start, this shows, shows early show up of HIV infected patients for HIV screening, diagnosis, care and treatment.

The results showed, 442(96.1%) of the patients had good treatment adherence, due to Enhanced Adherence Counselling provided by Health Care Workers at CTCs. Of 460 participants, 331(72%) were in 0 to one year on ART, this shows the effectiveness of 1st line ARV treatment among patients making more HIV patients being in a very short period on ART dose. Likewise,13(2.8%) of the respondents had a history of TB co-infection, low prevalence of Tuberculosis is due to the inclusion of another program such as IPT which reduce the incidence of Tuberculosis among HIV Infected patients on ART. Majority of the respondents, 305(66.3%) were previously exposed with ARV and 382(83%) were self-reported to correct follow the dosing schedule because of the effectiveness of the Enhanced Adherence Counselling provided in the Care and treatment Centres in Kigoma Health Care Facilities.

Table 2: Clinical Characteristics of the patients (N=460)

Variable	N(Percent)
WHO HIV Stage,	
Stage I	156 (33.9%)
Stage II	68 (14.8%)
Stage III	102 (22.2%)
Stage IV	134 (29.1%)
History non-communicable diseases	
Yes	73 (15.9 %)
No	387 (84.1%)
AIDS-defining Events	
Seborrhoeic dermatitis	115 (25%)
Popular Pruritus eruptions	5 (1.1%)
Kaposi sarcoma	227 (49.3%)
HIV Wasting syndrome	10 (2.2%)
Extra pulmonary tuberculosis	58 (12.6%)
Asymptomatic	6 (1.3%)
Severe weight loss	28 (6.1%)
Moderate weight loss	11 (2.4%)
ARV REGIMES	
1st line	382 (83%)
2nd line	78 (17%)

Table 3: Clinical Characteristics of the patients (N=460)	
Time from HIV diagnosis to ART start (weeks)	
0-4 weeks	370 (80.5%)
4+ weeks	90 (19.5%)
Treatment adherence	
Poor	18 (4%)
Good	442 (96%)
Time on ART	
0-1 Years	331(72%)
2 and above years	129 (28%)
Reason for non-adherence	
Side effect	4 (22.2%)
Forgot	8 (44.4%)
Social problem	4 (22.4%)
Too ill	2 (11%)
TB Co-infection	
Yes	13 (2.8%)
No	447 (97.2%)
Previous ARV exposure	
Yes	305 (63.3%)
No	155 (33.7%)
Self-reported dosing schedule	
Incorrect dosing	78 (17%)
Correct dosing	382 (83%)

4.3. Viral load results after 6 months of ART initiation and enhanced adherence counselling

Table 3 below shows that 402 (87.4%) of the participants had viral load count less than 1000c/ml compared to 58 (12.6%) who had viral load count greater than 1000c/ml.

The overall results showed that after six months of ART initiation and Enhanced Adherence Counsellingthere was a high number of male with unsuppressed viral load 68(14.8%) compared to female 48(10.4%). The reasons for this could be, female tends to more show up on virus testing and counselling than male. The overall unsuppressed viral load after 6 months of ART Initiation and Enhanced Adherence Counselling was 12.6% and Enhanced Adherence Counselling.

Table 4: Viral load status by gender and overall suppression status after 6 months of ART initiation and Enhanced Adherence Counselling

Overall Viral load results after 6 Months of ART initiation and Enhanced Adherence Counselling		
<1000c/ml	402	87.4%
>1000c/ml	58	12.6%
Viral load results after 6 months of ART initiation and Enhanced Adherence Counselling by male gender		
<1000c/ml	392	85.2%
>1000c/ml	68	14.8%
Viral load results after 6 Months of ART initiation and Enhanced Adherence Counselling by female gender		
<1000c/ml	412	89.6%
>1000c/ml	48	10.4%
Overall viral load suppression status after 6 Months of ART Initiation and Enhanced Adherence Counselling		
Suppressed	402	87.4%
Unsuppressed	58	12.6%

4.4: Multivariable characteristic of the demographic characteristics associated with Viral Load Suppression

Table 4 below shows the multivariable logistic regression model for Demographic Characteristics Associated with unsuppressed Viral Load at Maweni hospital, Kigoma. The odds of virological non-suppression increased with increasing age from 18-29 years (AOR: 2.167 (0.042-3.624) to 60 years old and above with (AOR 3.424, CI: 0.241-5.135).

The odds of virological non-suppression decreased among female with (AOR: 0.758 (0.197-0.984) compared to their counterparts male. This association between gender and viral load suppression was statistically significant to establish the direct relationship between sex of the respondents and viral load suppression. Thus female was more likely to have suppressed viral load than male.

Likewise, the odds of virological non-suppression decreased among patients who had primary, secondary and tertiary education with (AOR: 0.890(0.171-20.926), (AOR: 0.075(0.338-27.950), (AOR: 0.056(0.200-21.169) compared to those who had had no education at all. The association between education status and virological non-suppression were not statistically significant due to P-value being greater than 0.05.

Likewise, the odds of virological non-suppression decreased among unemployed and self-employed
(AOR: 0.684(CI: 0.583-2.830) and (AOR: 0.708(CI: 0.487-2.519) compared to employed participants. Though the association was statistical, not significant.

The odds of virological non-suppression decreased among never married, widowed and divorced patients (AOR: 0.922(0.234-3.635), (AOR: 0.447(0.073-2.750), (AOR:0.594(0.115-3.077) compared to marriage and cohabiting participants. The association between marital status and non-suppression status was not statistically significant because of the P-Value being greater than 0.05.

Table 5: Multivariable characteristics of the demographic characteristics

Independent Variable	Crude Odds Ratio with 95 Confidence Interval	Adjusted Odds Ratio with 95% Confidence Interval	p-value
18-29 years (1)	1	1	
30-44 years (2)	2.964 (0.074-3.964)	3.152 (0.363-4.367)	0.997
45-59 years (3)	5.342 (0.245-13.352)	6.245 (0.568-18.876)	0.997
60 years above (4)	2.563 (0.624 - 4.187)	3.424 (0.241 - 5.135)	0.997
Male (1)	0.454(0.204-0.873)	0.758(0.197-0.984)	0.013
Rural (1)	1.071(0.604-1.898)	1.285(0.610-2.706)	0.814
None	1	1	
Primary (1)	0.458(0.161-13.180)	0.890(0.171-20.926)	0.737
Secondary (2)	0.810(0.500-29.044)	0.075(0.338-27.950)	0.197
College and above (3)	0.410(0.280-20.754)	0.056(0.200-21.169)	0.423
Employed	1	1	
Unemployed (1)	0.169(0.602-2.271)	0.684(0.583-2.830)	0.645
Self employed (2)	0.849(0.418-1.724)	0.708(0.487-2.519)	0.651
Married	1	1	
Never married(1)	0.991(0.320-3.070)	0.922(0.234-3.635)	0.988
Cohabiting (2)	1.487(0.478-4.627)	1.142(0.290-4.496)	0.493
Widowed (3)	0.662(0.137-3.198)	0.447(0.073-2.750)	0.608
Divorced (4)	0.781(0.94-3.142)	0.594(0.115-3.077)	0.728

Reference Category= First

Dependent Variable Encoding; Original Value is suppressed encoded by internal value 0 and the original Value is Unsuppressed encoded by internal value 1

4.5 Multivariable characteristic of the clinical factors associated with viral load suppression

The odds of virological non-suppression increased among Patients in WHO HIV stage III (AOR: 1.290 (0.232-7.164) and stage IV (AOR: 1.986(0.523-9.9134) respectively. The association between HIV stage and viral load suppression is not statistically significant.

The odds of virological non-suppression decreased among patients with no history of non-communicable (AOR: 0.422(0.310-0.767). The association between history of non-communicable diseases and virological non-suppression were statistically significant due to the p-value is less than 0.05.

The odds of virological non-suppression decreased among patients with Popular Pruritus eruptions (AOR: 0.250 (0.034-1.834), HIV Wasting syndrome (AOR: 0.495(0.076-3.227), Asymptomatic (AOR: 0.397 (0.051-3.080), and Severe weight loss (AOR: 0.936 (0.116-7.577) while increased among patients with Seborrhoeic dermatitis, Kaposi sarcoma and extra pulmonary tuberculosis AIDS defining events, though the association is not statistically significant.

The odds of virological non-suppression decreased among patients with good treatment adherence (AOR: 0.589 (0.062-0.612), with statistically significant association due to probability value being less than 0.05, thus those who adhere with treatment are more likely to have suppressed viral load compared to those with poor treatment adherence.

The odds of virological non-suppression decreased among patients with no history of TB Co-infection (AOR: 0.472(0.321-0.767), with statistically significant association due to probability value being less than 0.05, thus those with no history of TB Co-infection are more likely to have suppressed viral load than those with poor treatment adherence.

On the other hand, the odds of virological non-suppression decreased among patients with correct dosing schedule (AOR: 0.733(0.369-0.978),with statistically significant association due

to probability value being less than 0.05, thus those with correct dosing schedule are more likely to have suppressed viral load than those with incorrect dosing schedule. and vice versa.

Table 6: Multivariable characteristic of the clinical factors associated with viral load suppression

Independent Variable	Crude Odds Ratio with 95 (CI)	Adjusted Odds Ratio with 95% (CI)	P-Value
WHO clinical stage I	1	1	
WHO clinical stage II (1)	0.632(0.122-3.268)	0.630(0.118-3.371)	0.158
WHO clinical stage III (2)	1.333(0.245-7.248)	1.290(0.232-7.164)	0.589
WHO clinical stage IV (3)	1.678(0.675-8.435)	1.986(0.523-9.134)	0.539
Non history of NCD (1)	0.357(0.125-0.963)	0.422(0.310-0.767)	0.050
Seborrhoeic dermatitis	1	1	
Popular Pruritis eruptions(1)	0.292(0.053-1.616)	0.250(0.034-1.834)	0.158
Karposi sarcoma (2)	1.125(0.078-16.307)	3.432(0.146-80.584)	0.931
HIV wasting syndrome (3)	0.738(0.153-3.575)	0.495(0.076-3.227)	0.706
Extra Pulmonary tuberculosis(4)	1.125(0.127-9.943)	2.090(0.154-28.365)	0.916
Asymptomatic(5)	0.519(0.090-2.987)	0.397(0.051-3.080)	0.463
Severe weight loss(6)	0.900(0.064-12.583)	3.246(0.146-72.134)	0.938
Moderate weight loss (7)	1.500(0.259-8.673)	0.936(0.116-7.577)	0.651
ARV 2nd line(1)	0.668(0.341-1.307)	1.181(0.557-2.503)	0.239
Time interval of 4+ weeks (1)	3.731(1.455-4.914)	2.831(1.455-3.963)	0.150
Good adherence (1)	0.334(0.275-0.538)	0.589(0.062-0.612)	0.034
2 and above years on ART(1)	0.931(0.508-1.707)	1.698(0.899-3.205)	0.818
No history of TB infection (1)	0.363(0.237-0.903)	0.472(0.321-0.767)	0.042
No history of ARV exposure(1)	1.698(0.899-3.205)	1.698(0.899-3.205)	0.102
Correct Dosing Schedule(1)	0.640(0.279-0.768)	0.733(0.369-0.978)	0.029

Reference Category= First

Dependent Variable Encoding; Original Value is suppressed encoded by internal value 0
Original Value is Unsuppressed encoded by internal value 1

CHAPTER FIVE

DISCUSSION

5.1. The key findings

The finding from this study, revealed that among 460 patients who were initiated with 1st line ART and Viral Load test done, 12.6% had unsuppressed Viral load (VL ≥1000 copies/mL). The finding from this study is greater than 12%, reported by the previous study done in Papua New Guinea [39]. The finding from this study is less than 14.9%, reported by the study done in Tanzania [40,41]

5.2. Demographic factors associated with viral load suppression

The finding from this study showed that older age group is associated with unsuppressed viral load compared lower age group, though the association is not statistically significant. The results of this study contradict with the other studies done which concluded that the older age group (> 40 years) is associated with better viral load suppression among patients on ART [42,43]

The finding from this study showed that, male were more likely to have unsuppressed viral load compared to their counterparts to female. The results from this study contradict with other studies done in the USA and Canada which revealed that failure of viral load suppression was observed mostly among women compared to male.[44,45].

5.3. Clinical factors associated with viral load suppression

Patients who were in WHO HIV stage IV were more likely to have unsuppressed viral load compared to those in HIV stage II. The finding from this study is similar with the previous study which revealed that WHO clinical staging 4 patients are more likely to be non-suppressed while those whose health status is evaluated by physicians on each clinic visit are less likely to experience virological failure [46]. The finding also contradicts with other studies done in Canada which revealed that there is no relationship between the WHO HIV clinical staging of patients and their viral load suppression [47].

The findings from this study showed that Patients with no history of non-communicable were less likely to have unsuppressed viral load compared to those with a history of non-communicable diseases. This is because. This is because non-communicable diseases increase the risk for other diseases infection due to increased compromised immunity as results unsuppressed viral load also increases.

Also, patients in the 1st line of ART treatment were more likely to have unsuppressed viral load compared to those in 2nd line of ART treatment. The first line of treatment is linked to treatment failure as a result of the unsuppressed viral load. The finding from this study is similar to the one reported previously which reported that being on third-line treatment decreased the odds of unsuppressed viral load.[48].

Patients with more than 4 weeks' time interval from HIV diagnosis to ART initiation were more likely to have unsuppressed viral compared to those with less than 4 weeks' time interval from HIV diagnosis to ART initiation

Poor drug adherence was among the risk factors associated with unsuppressed viral load. This study reported 18(4%) of poor adherence. Adherence is important in the management of HIV patients because good treatment adherence patients are less likely to have unsuppressed viral load compared to those with poor treatment adherence. The proportions of poor adherence reported from this study are less than 14% of the study reported in china [49]. Good adherence can promise the suppression of HIV and utilise the optimum effectiveness of ART therapy [50]. The finding from this study on adherence is similar to other study previous done which showed that poor ART adherence leading to failure of viral load suppression [51]

Patients who had good treatment adherence were less likely to have unsuppressed viral load compared to those who had poor treatment adherence. The association between treatment adherence and viral load suppression is statistically significant, thus those who adhere with treatment are more likely to have suppressed viral load compared to those with poor treatment adherence. The results of this study are similar to the previous study done which revealed that adherence to treatment was associated with unsuppressed viral load. The findings from this study

are consistent with those of studies conducted in Mozambique, France, and Guangxi, China, where poor medication adherence was the main risk factor for virological failure. [52,53,54]

Patients with 2 years and above on ART treatment were associated with unsuppressed viral load compared to those with less than 2 years. The reasons for this could be due to the development of drug resistance in those stayed long on ART. The results of this study are similar to other previous study which reported that patients on ART treatment for more than one year are more likely to have virological failure and resistance mutations.[55]. The possible reason might be that as the duration of ART increased, the likelihood of developing poor adherence and drug interruption, as well as drug side effects, also increased [56].

Patients with no history of TB Co-infection were less likely to have unsuppressed viral load compared to those with a history of TB Co-infection. The finding from this study is similar to the study done in Malawi which concluded that active TB increased the odds of unsuppressed viral load. [57].

Patients with no previous ARV exposure were more likely to have unsuppressed viral load compared to those with previous ARV exposure. But the association is not statistically significant.

The results of this study contrasting with the study which showed, prior exposure to ART were reported to be associated with unsuppressed viral load. [58].

Patients with correct dosing schedule were less likely to have unsuppressed viral load compared to those with the incorrect dosing schedule. The finding from this study is supported by the previous studies which revealed that individuals missing 3 doses of ART per month are associated with an increased risk of drug resistance and reduced immunity [59].

5.4 Limitation

This study presented quite a number of limitations.

1. One of the major limitations is being a cross-sectional study design, no causal inference was made between HIV incidence and population viral load.
2. This study also used secondary data which was entered into the database through a multiple clerk single entries and this may have resulted in erroneous data which can lead to misinterpretation of the data collected as results overestimation or underestimation of the research data.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1. Conclusion

The low prevalence of 12.6% of unsuppressed viral load six months after ART initiation demonstrated in this study was possibly linked to the generally high self-reported level of adherence to medication. There was a relationship between unsuppressed viral load and poor treatment adherence. However, among the patients who did not achieve viral load suppression, there was a significantly higher percentage of female compared to male patients, and a significantly higher percentage of single compared to other marital status categories. Also, unsuppressed viral load were statistically associated with a history of non-communicable diseases, Poor treatment adherence, history of TB coinfection and incorrect dosing schedule. The observed high rates of viral load suppression of 87.4% were superior to the WHO target for viral suppression of 70% after at least1year of first line ART and reached the 90% viral suppression goal set by UNAIDS for 2020.

6.2 Recommendations

1. Due to promising results found in this study of increased suppressed viral load from 354(77%) to 402(87.4%) and decreased in clients with decreased unsuppressed viral load from 106(23%) to 58 (12.6%), from 3months of ART initiation to 6months of ART initiation and Enhanced Adherence Counselling, the ART program of this kind should be scaled up to other Regions in order to provide effective care and treatment among PLHIV in Tanzania at large. of 87.4%. The future management of PLHIV with immunologic and/or clinical failure should focus on the key factors identified by this study causing unsuppressed viral load among PLHIV in Kigoma and other parts of Tanzania.

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APPENDICES

APPENDIX I: DATA ABSTRACTION FORM

SECTION ONE (INTRODUCTION)

Form ID Number | | | |

Broad objective of the Study

The broad objective of this study is to determine factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council.

Introduction:

I'm Master of Public Health Student from Muhimbili University of Health and Allied Sciences, I'm in study and currently undertaking my research titled; **″ Factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council**.″ with the long term goal of increasing viral load suppression hence reducing HIV/AIDS prevalence and related death.

SECTION A: GEOGRAPHICAL INFORMATION

1. Name of the Health facility……...
2. Name of District …….....
3. Name of Region.....
4. Date of data Collection .....
5. Place of Residence …….....

PLEASE PUT THE APPROPRIATE NUMBER OF RESPONSE IN A GIVEN BOX

Put a tick (√) for each of the response of your choice

SECTION B; SOCIO DEMOGRAPHIC CHARACTERISTICS OF HIV INFECTED INDIVIDUALS ON ART WHO HAD HIGH VL FROM JULY TO DECEMBER 2018			
1	**Age group (years)**	a) 18-29 years b) 30-39 years c) 40-65 years	( )
2	**Gender**	a) Male b) Female	( )
3.	**Age at initiation of ART (years)**	a) 10-19 years b) 20-29 years c) 30-39 years d) 40-49 years e) 50-65 years	( )
4	**Residence**	a) Rural b) Urban	( )
5	**Education**	a) No formal education b) Primary c) Secondary d) Tertiary	( )
6	**Occupational status**	a) Government employed b) Self employed c) Private employed d) Farmer e) Unemployed	( )
7	**Marital status**	a) Married b) Single	( )
8	**Use of alcohol/ drug abuse**	a) Yes b) No	( )

9	**SECTION C: CLINICAL CHARACTERISTICS OF THE PATIENTS AFTER 3 MONTHS AND 6 MONTHS OF ART INITIATIONS**		
10	**Immunological failure**	a) Yes b) No	( )
11	**WHO Stage**	**a)** Stages 1-2 **b)** Stages 3-4	( )
12	**Reason for non-adherence**	a) Side effects b) Forgot/Social problem c) Too ill	( )
13	**Route of transmission**	a) Mother to child b) Heterosexual c) Blood transfusion	( )
14	**Viral Load after 3months**	**a)** VL<1000 **b)** VL>1000	( )
15	**Viral Load after 6 months**	**a)** VL<1000 **b)** VL>1000	( )
16	**TB Co-infection**	a) Yes b) No	( )
17	**History chronic non communicable diseases**	a) Yes b) No	( )
18	**History of HBV co-infection**	a) Yes b) No	( )
19	**Time on ART**	a) 0 b) 1 c) 2 Years and above	( )

20	**Time from HIV diagnosis to ART start (weeks)**	a) 0 b) 2 – 4 c) 4+	( )
21	**Self-reported dosing schedule**	a) Incorrect dosing b) Correct dosing	( )
22	**Duration on treatment**	a) 0-2 Years b) 3-5 Years c) 6-10 years d) > 10 Years	( )
23	**Indication for treatment initiation**	a) TB infection b) Child under 15 c) PMTCT/Option B+ d) CD4 < 500 e) Others	( )
24	**Report ARV adherence**	a) Poor < 95% b) Good >95%	( )
25	**Treatment line**	a) First line b) Second line c) Third line	( )
26	**Pregnant**	a) Yes b) No	( )
27	**Breast feeding**	a) Yes b) No	( )
28	**Reason for testing**	a) Routine testing b) Suspected treatment failure c) Repeat testers after suspected failure	( )
30	Previous ARV exposure	a) Yes b) No	( )

APPENDIX II:CONSENT FORM (ENGLISH VERSION)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

INFORMED CONSENT FORM

ID-NO ☐☐☐

Consent to participate in interview

Greetings! My name is **Geofrey Tarimo.** I am a student from Muhimbili University of Health and Allied Sciences Pursuing Master degree of Public Health.

I'm requesting your permission to do data collection that will help me to conduct my study titled: ***Factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council.***

Purpose of the Study

This study is intended to collect information on the factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council. The information collected will help the principal investigator to write a dissertation which is a partial fulfillment of MSc of Public Health.

What Participation Involves

If you agree to participate in the study, you will be required to answer questions and to provide necessary information regarding factors associated with virological non-suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Council.

Confidentiality

Privacy and confidentiality will be highly maintained by avoiding unauthorized persons from accessing study information. Anonymity will be maintained by using questionnaire ID. No name will be recorded in the questionnaire.

Risks

We do not expect any harm to happen to the hospital environment and study participants.

Rights to Withdraw and Alternatives

Participation in this study is completely voluntarily. You can stop participating in this study at any time, even if you have already given your consent. You have also got right to refuse to participate or withdrawal from the study and there will be no penalty or loss of any benefits to which you are otherwise entitled.

Benefits

The information provided will be helpful in providing necessary information in order to address the knowledge gap on the current virological non-suppression status after enhanced adherence counselling among people living with HIV on Antiretroviral therapy Kigoma Ujiji Municipal Council. It is hoped that, the results of this study will be utilized by health care professionals and key stakeholders when designing interventions focused on increasing virological suppression after enhanced adherence counselling among people living with HIV on Antiretroviral therapy in Kigoma Ujiji Municipal Hospital and other Areas in Tanzania, with a longer term goal of reducing HIV rate in Tanzania.

In Case of Injury

We do not anticipate any harm to occur in hospital environment, however if any physical injury occurs during data collection, we will provide necessary medical treatment.

Whom to Contact

In case of any questions about this study please don't hesitate to contact **Principle Investigator** Dr **Geofrey Tarimo of** Muhimbili University of Health and Allied Sciences (MUHAS), P.O. Box 65001, Dar es Salaam (Tel. No. +255763125782). And any questions about right to conduct this study, you may call **Chairman of University Research and Publication Committee, Dr Bruno Sunguya** P. O. Box 65001, Dar es Salaam Tel, 2150302-6, **and Dr Nathanael Sirili** who is the supervisor of this study(Tel. No. +).

Signature…….

Do you agree? Participant agrees…… Participant does not agree ……

I _____have read/listened the contents in this form.

My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of research assistant _____

Date of signed consent _____

APPENDIX III: FOMU YA RIDHAA.

CHUO CHA SAYANSI ZA TIBA MUHIMBILI

KURUGENZI YA UTAFITI NA MACHAPISHO

NAMBARI YA SIRI YA FOMU: ☐☐☐

RIDHAA YA USHIRIKI KATIKA UTAFITI

Habari! Jina langu ni: **Dr Geofrey Tarimo,** ni mwanafunzi wa shahada ya pili ya uzamili katika Chuo Kikuu cha Sayansi za Afya Muhimbili. Ninafanya utafiti kama sehemu ya masomo yangu, kuhusu **"Sababu zinazohusiana na kutokandamizwa kwa virusi baada ya kufuatwa kwa ushauri nasaha miongoni mwa watu wanaoishi na VVU na tiba za kurefusha maisha katika mkoa wa Kigoma.**

Umuhimu wa utafiti huu

Matokeo ya utafiti huu yatasaidia kuelewa kiwango cha tatizo hili na kujua sababu zinazosababisha tatizo hili katika vituo vya kutolea huduma katika Manispaa ya Kigoma Ujiji ili kuifahamisha jamii na serikali kwa ujumla ukubwa wa tatizo hili ili kuweza kutafuta mbinu za kulitatua.

Ushiriki unahusisha nini

Ushiriki unahusisha kukubali kujiunga na utafiti huu kwa hiari na kujibu maswali kama yalivyo katika dodoso la utafiti huu ili kuwezesha utafiti huu kufanyika

Usiri

Taarifa zote utakazo jaza katika dodoso ni siri na wala jina lako halitaingizwa katika kompyuta isipokua namba ya dodoso tu.

Uwezekano wa kutokea jambo la hatari

Sitarajii kama kuna jambo lolote baya linaweza kutokea kwa kushiriki katika utafiti huu.

Haki ya kujitoa na mambo mbadala

Ushiriki wako katika utafiti huu ni wa hiari. Hivyo unayo haki ya kujibu au kutojibu swali lolote katika dodoso. Kukataa kujibu swali lolote hakuna adhabu yoyote wala haupotezi haki zako kama mshiriki na katika kupata huduma za kishule kama wanafunzi wengine.

Faida kwa Mshiriki

Endapo utakubali kushiriki katika utafiti huu unaweza ukapata faida ya moja kwa moja au isiyo ya moja kwa moja. Faida isiyo ya moja kwa moja, ni kwamba majibu yako yatakuwa mchango mkubwa katika matokeo ya jumla ya utafiti huu kwanza kwa kujua ukubwa wa tatizo hili; pili, ambayo yanatarajiwa kuleta mapendekezo kwa serikali na nyombo vingine yatakayosaidia kupunguza tatizo hili katika Hospitali ya mkoa waKigoma na nchi nzima kwa ujumla.

Mawasiliano

Endapo utakuwa na swali lolote kuhusu utafiti huu tafadhali wasiliana na msimamizi wa utafiti huu **(Supervisor)**(Tel. No. +).au mtafiti mkuu Dr Geofrey Tarimo, **Chuo Kikuu Kishiriki cha Sayansi za Afya, P.O.Box 65015, Dar es Salaam.**

Endapo una swali lolote kuhusu haki zako kama mshiriki katika utafiti huu, wasiliana na **Mwenyekiti wa Utafiti na Machapishi, Dr Bruno Sunguya, SLB 65001, Dar es Salaam. Simu: 2150302-6.**

Sahihi.....

Je unakubali kushiriki? Ninakubali kushiriki ☐ Sikubali kushiriki ☐

Mimi _____ nimesoma/nimesomewa na kuyaelewa vyema maelezo yaliyomo katika fomu hii. Maswali yangu yamejibiwa. Ninakubali kushiriki katika utafiti huu.

Sahihi ya Mshiriki _____

Sahihi ya Mtafiti _____

Tarehe ya kusaini _____

APPENDIX IV: 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/

16th August, 2019

Mr. Geofrey Tarimo
MPH-Distance Learning.
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "FACTORS ASSOCIATED WITH VIROLOGICAL NON SUPPRESSION AFTER ENHANCED ADHERENCE COUNSELING AMONG PEOPLE LIVING WITH HIV ON ANTIRETROVIRAL THERAPY IN KIGOMA UJIJI MUNICIPAL.

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 **15th August, 2019 to 14th August, 2020.** In case you do not complete data analysis and dissertation report writing by **14th August, 2020,** you will have to apply for renewal of ethical clearance prior to the expiry date.

Dr. Bruno Sunguya
Ag: DIRECTOR OF POSTGRADUATE STUDIES

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