HIV viral suppression among adultson antiretroviral therapy at Temeke regional referral hospital care and treatment clinic, Dar es salaam, Tanzania

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HIV VIRAL SUPPRESSION AMONG ADULTS ON ANTIRETROVIRAL THERAPY AT TEMEKE REGIONAL REFERRAL HOSPITAL CARE AND TREATMENT CLINIC,DAR ES SALAAM, TANZANIA

By

Erhad Bilaro

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine (Internal Medicine) of

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October, 2018

CERTIFICATION

The undersigned certify that she has read and hereby recommends for acceptance of dissertation entitled **HIV viral suppression among adults on antiretroviral therapy at Temeke regional referral hospital care and treatment clinic,Dar es salaam, Tanzania**in partial fulfillment of requirements for the degree of Master of Medicine (Internal Medicine) of Muhimbili University of Health and Allied Sciences.

Dr. TumainiJ. Nagu

(Supervisor)

Date

DECLARATION
AND
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I, **Erhad Bilaro**, 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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DEDICATION

I would like to dedicate this dissertation to my father Mr. David Bilaro for his inspiration and motivation throughout my education.

To my mother Jane Bilaro for her encouragement and full support in my life

ABSTRACT

Background: HIV viral load test has been recently rolled out as the standard of care for monitoring patients' response to Antiretroviral Therapy (ART) in Tanzania. Scarce information on HIV viral suppression exists in Tanzania since the adoption of this intervention at public health level.

Objectives: This study aimed at determining HIV viral suppression rate among patients attending at Temeke regional referral hospital care and treatment clinic within twelve months of using antiretroviral therapy.

Methodology: Two study designs were used; a hospital-based retrospective cohort study was conducted among HIV patients initiated on ART between May and November 2016 at Temeke Hospital, Dar es salaam, Tanzania to assess proportion of patients with viral suppression after one year of using ART, and a cross-sectional component was used to assess factors associated with HIV viral suppression. Viral load suppression was defined as HIV-RNA below 50 copies per ml.

Results: A total of 484 patients were retained at Temeke Regional Referral hospital CTC after 12 months of initiation. Among these, 419 (86.6%) patients had HIV viral load measurements within 12 months of ART use. HIV viral suppression was achieved in 318 (75.9%) patients between 6^{th} and 12^{th} month of ART. Factors associated with HIV viral suppression at 12 months were; good adherence to ART; (OR: 11.4; 95% CI 1.1 – 115.5; P = 0.04) and baseline CD4 + T lymphocyte count ≥ 200 cells/µl (OR: 11.2; 95% CI 1.4 – 87.2; P = 0.02).

Conclusion: HIV viral suppression at Temeke HIV CTC is still below the recommended WHO target to end AIDS epidemic by 2030; which requires 90% of patients on ART to have viral suppression to attain the sustainable development goal, SDG (3.3). Earlier initiation of ART among HIV patients would significantly improve HIV viral suppression.

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ABBREVIATIONS

AIDS	-	Acquired Immunodeficiency Syndrome
ART	-	Antiretroviral Therapy
ARV	-	Antiretroviral Drugs
BMI	-	Body Mass Index
DNA	-	Deoxyribonucleic Acid
HIV	-	Human Immunodeficiency Virus
IDU	-	Injection Drug Users
LTF	-	Loss to follow-up
MUHAS	-	Muhimbili University of Health and Allied Sciences
MSM	-	Men having sex with men
RNA	-	Ribonucleic Acid
SD	-	Standard Deviation
SPSS	-	Statistical Package for Social Sciences
STI	-	Sexual Transmitted Infections
TB	-	Tuberculosis
UNAIDS	-	United Nations Program on HIV and AIDS
WHO	-	World Health Organization

DEFINITION OF KEY TERMS

1. Viral suppression is defined as HIV viral RNA load below 50 copies per milliliter in an HIV infected individual on ART (1).

2. Sustained viral suppression in this study isdefined as HIV viral RNA load below 50 copies per milliliter in two consecutiveHIV viral load measurement taken at six and twelve months of antiretroviral therapy (2).

3. Loss to follow-up from CTC care refers to patients who have not returned to the clinic for more than ninety days after missed appointment and with no information on patients whereabouts (3).

4. Good adherence refers to self-reported compliance with more than 95% of the prescribed doses in the previous30 days(4).

CHAPTER ONE

1.1 INTRODUCTION

1.1.1 Background

Human immunodeficiency virus (HIV) is an RNA virus of the retroviridae family, and it is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS)(5). There are two main types of HIV; HIV-1 and HIV-2 which have different genomic organization although they share same basic genetic makeup(5).Each type of the virus has several subtypes and recombinant forms with different geographical distributions, Subtype A, C and AC recombinants arethe most prevalentforms in Tanzania(6,7). HIV is known for its great variability which enables the virus to escape host defenses and antiretroviral drugs. This is attributed to the error-prone nature of reverse transcriptase enzyme, the high rate of replication of the virus and its ability to form recombinant HIV subtypes in an infected individual(5).

1.1.2 Transmission

There are several mechanisms through which an individual can contract HIV infection. These mechanisms mainly depend on geographical location and HIV epidemiology as well as age at HIV infection. Since the introduction of HIV screening of blood and blood products and scale-up of ARV for prevention of mother to child transmission, in areas of generalized HIV epidemic,HIV is transmitted mainly through unprotected heterosexual intercourse, which accounts for approximately 90% of HIV infections acquired in adulthood in Sub-SaharanAfrica(1,8).On the other hand, 90% of new pediatric HIV infections are acquired from HIV infected mother(1).Transfusion of contaminated blood products accounts for 3-5% of new HIV infections globally while 5-10% of new infections arecaused by injection drug users(1). In areas of concentrated epidemics such as Western Europe and North America where HIV infection is mainly among MSM and injection drug users, the main mode of

transmission is same-gender sex and sharing of contaminated needles/syringe system or both(9).

1.1.3 Replication of HIV

HIV replication starts by attachment of the virus to a CD4 molecule through protein gp 120 and one or two of the chemokine co-receptors on the surface of the CD4 molecule.This promotes fusion of the virus and host cell through protein gp 41 and release of viral RNA strands, replication enzymes and accessory proteins into the host cell. These enzymes catalyze the formation of double-stranded DNA and its integration into the host cell chromosomes(5).

The proviral DNA is transcribed into messenger RNA and later it is translated into HIV proteins when the infected cell divides, the formed viral proteins and RNA strands will be assembled and released from the host cell, a process which helps the virus to acquire its external envelope(5).

The newly formed immature virus is cleaved into mature infectious virus by the enzyme protease. The newly formed mature virus will infect other CD4 cells and continues the replication cycle(5).

1.1.4 Natural history of HIV infection

The initialperiod following HIV infection is referred to as early HIV infection, this period is characterized by a high viral load in patient plasma due to uncontrolled viral replication and as a result, patients are highly infectious. Patients may develop acute retroviral syndrome which is characterized byfever, headache, sore throat, myalgia and generalized lymphadenopathy during this period.Prolongation of these symptoms for more than 2 weeks has been shown to be associated with rapid progression to AIDS(10).Patients develop detectable HIV antibodies during this phase of infection, a phenomenon which is referred as seroconversion. The stable viral load after early HIV infection period which is known as the viral set point, and nadir CD4 counts havealso been shown to correlate with the rate of progression of the disease in the absence of ART(10).

The next stage of HIV infection is an asymptomatic phase which is characterized byan asymptomatic progressive decline in CD4+ T lymphocytes in patients without antiretroviral therapy. Varying degrees of viral replication are present and patients are infectious during this period. Many patients present with persistent generalized lymphadenopathy during this period. This may take 10 years in most people living with HIV(10).Progression of HIV infection and decline of immune functions leads to the emergence of opportunistic infections, this is referred to as symptomatic stage, during this stage patient develops symptoms depending on the offending organisms and reactivation from previous exposure to various microbes(1).Severe immunosuppression results into the development of AIDS-defining illnesses in a patient such as cancers and severe disseminated opportunistic infections; this represents the last stage in the natural history of HIV infection(10,11).

1.1.5 Antiretroviral therapy

The use of ART has been shown to prolong life and improves quality of life in people living with HIV by halting occurrence of opportunistic infections and development of AIDS(12).There are six major classes of antiretroviral drugs targeting different stages of viral replication namely entry inhibitors,Nucleoside reverse transcriptase inhibitors, Non-Nucleoside reverse transcriptase inhibitors, nucleotide reverse transcriptase inhibitors,integrase strand transfer inhibitors, and protease inhibitors. Among the mentioned classes, four are locally available currently in Tanzania; these include Nucleoside reverse transcriptase inhibitors, Non-Nucleoside reverse transcriptase inhibitors, nucleotide reverse transcriptase inhibitors and protease inhibitors(1).

The initial two months of taking antiretroviral therapy are characterized by rapid decline in HIV viral load followed by a slower decline to undetectable HIV RNA levels within 6 months of antiretroviral therapy (12). Several clinical and biological parameters may be used in monitoring progression of HIV patients, of these HIV RNA copies has been shown to be the most powerful prognostic indicator of the decline in immune system and risk of development

of HIV drug resistance in people living with HIV. HIV viral load falls at a faster rate than the increment of CD4 lymphocytes in patients who are on ART(1).

WHO recommends viral load monitoring as part of routine care to HIV patients at 6 months in the first year, and every 12 months thereafter or whenever treatment failure is suspected(13).Tanzanian guideline recommends viral load measurements at six months since start of antiretroviral therapy, a second test is recommended after twelve months and then annually for patients with viral load below 1000 copies per ml, Patients with HIV RNA above 1000 copies per ml in the first test are counselled for adherence and a second test is performed after three monthsin areas where viral load monitoring is available (1).

Failure to achieve viral suppression on two consecutive viral load measurements taken within three months with adherence supportin between, in patients who have been taking ART for six months or more is defined as virological failure by World Health Organization (13).Achieving maximal and durable HIV viral suppression for patients on antiretroviral therapy is one of the principal goals of ARTprovision as a higher frequency of drug-resistant mutations has been reported among patients with unsuppressed viral loads(14).

1.1.6 90-90-90 UNAIDS strategy

The Joint United Nations Program on HIV and AIDS (UNAIDS) targets that by the year 2020 ninety percent of HIV-positive people should know their status, ninety percent of those diagnosed should be on continuous treatment and ninety percent of those on treatment should have suppressed HIV viral loads(15).This strategy calls for maximization of preventive effects of HIV treatment for HIV prevention aiming at reducing new HIV infections by 90% in the year 2030(15).

1.1.7 Organization of HIV care and treatment services in Tanzania

HIV care in Tanzania is managed and coordinated by a vertical program, the National HIV and AIDS Control Program (NACP). Services are organized within healthcare facilities through care and treatment clinics throughout the country. There are more than 1300 health facilities

providing care and treatment services in Tanzania, 220 are hospitals and others are primary health facilities (1).

As per UNAIDS data in 2016, it was estimated 1.4 million people are infected with HIV in Tanzania, out of which 63% are on antiretroviral treatment (28). Criteria for start of ART treatment during the time when patients in this study were enrolled included HIV WHO clinical stage 3 or 4 or having a CD4 count of < 350 cells/µl (1). Currently, the country has adopted WHO strategy to treat all HIV infected individuals with antiretroviral treatment as soon as they are diagnosed regardless of CD4 or WHO clinical staging (31).

Temeke hospital is one of the hospitals which provide CTC services in the country, it was chosen as a study site because it's only centre where viral load tests are conducted from all public regional facilities in Dar es Salaam. HIV virological tests samples from other public regional hospitals are sent to Temeke laboratory and the results are sent back to the respective facilities.

Once HIV diagnosis is made, patients undergo thorough in-depth medical history and physical examination including anthropometric measurements. History of prior or recent opportunistic infections such as tuberculosis (TB), fungal infections and skin disease is taken. Clinicians are required exclude or include possibility TB through a set of five screening questions (TB questionnaire) and subject patients to subsequent investigation whenever necessary. It is mandatory to document TB status as well as WHO clinical staging of the patients before they are started on ART. All the information must be documented accurately and completely in CTC2 card which remains at the facility (1). In addition newly diagnosed HIV patients are tested for complete blood count, urinalysis, CD4 + T cell lymphocyte count, liver function tests and renal function tests (31).

Once enrolled into HIV care and treatment facility, patients are monitored for their progress and clinical assessment including their weight, screening for TB symptoms and opportunistic infections.

1.2 LITERATURE REVIEW

1.2.1 HIV situational analysis

Globally HIV poses a serious public health threat, with 36.7 million people being infected with HIV, accounting for a global prevalence of 0.8% in the year 2015. In the same year, 2.1 million new HIV infections were reported and an estimated 1.1 million people died globally due to HIV related illnesses despite the efforts undertaken by several stakeholders in combating the disease. Despite the increase in universal ART coverage, the number of individuals receiving ART globally is still low with only 46% of HIV infected adults receiving ART globally (16).

The epidemics of HIV vary greatly across different geographical locations and within sub-populations in these regions. While Latin America, Middle East, Europe and Asian countries are reported to experience concentrated epidemics; Eastern and Southern African countries are reported to be facing both generalized and concentrated epidemics, with concentrated epidemics reported among key populations such as injection drug users (IDU), men having sex with men (MSM) and commercial sex workers (9).

Reports on magnitude of HIV viral suppression among treatment-naive HIV patients in high-income countries shows that the prevalence of HIV suppressionis 77% in the first year of ART(17). In these studies a viral load cut off of 500 copies per ml was used to define HIV viral suppression.

Systematic reviews from low and middle-income countries on HIV viral suppression after twelve months of antiretroviral therapies using a threshold of 300-500 HIV RNA copies per ml have estimated that proportion of viral suppression to range between 84 - 89% for patients on treatment and proportion of 70.5% for intention to treat population (18,19). However, data on the prevalence of viral suppression among people living with HIV in resource-limited countries is scanty as viral load tests were not routinely conducted in many care and treatment facilities until recently (15). Further, few studies reported were conducted before technological advancement, therefore reported a higher cut off value for viral suppression (20–23).

Sub-Saharan Africa is among the regions highly affected by HIV disease(1).Reports on the proportion of HIV patients with viral suppression in Sub-Saharan Africa vary widely. Systematic reviews of studies conducted to determine the efficacy of antiretroviral drugs in Sub Saharan Africa following the large-scale roll-out of antiretroviral drugs in this region have reported the prevalence of viral suppression to be 78% for patients who have used antiretroviral drugs for six months (24).However, reports from Joint United Nations Program on HIV and AIDS (UNAIDS) estimatesHIV viral suppression to be as low as 32% in Sub Saharan Africa(25).Recent data indicating the prevalence of viral suppression in the first six months of using ART after the introduction of new ART regimes in the management of HIV patients is lacking.

Studies conducted in West Africa to determine the magnitude of HIV viral suppression among people living with HIV twelve months after starting antiretroviral therapy have also reported varying level of suppression;Proportion of HIV patients with HIV viral suppression was reported to be 90% at HIV sentinel sites in Nigeria while it was reported to be 50% in Cote d'Ivoire (26,27).

Similarly,proportion of patients with HIV suppression varies in different parts of East Africa, for example the proportion of HIV viral suppression among people living with HIV in Kenya is reported to be 51% while it is reported to be 60% Uganda(28).A study conducted in Rwanda has reported a prevalence of viral suppression of 86.9% among patients on first year of ART(29).

Tanzania is among the countries hard hit by HIV disease.Reports from the joint United Nations Program on HIV and AIDS in 2016 estimated that 1.4 million people in Tanzania are living with HIV while 63% are on Anti-Retroviral Treatment(28). The incidence of HIV has been decreasing in the past 10 years but the number of people living with HIV is on the rise due to scale up of ART services and HIV related prevention programs. The HIV epidemic in the country is mostly generalized in Tanzania mainland with few concentrated epidemics among injections drug users and commercial sex workers(28).

In Tanzania, the prevalence of HIV infection among adults aged 15 -64 years is reported to be 5.0%(30). Prevalence varies within the different parts of the country, prevalence in Njombe region in the south-western part of the country is 11.4% while other regions of the country like Lindi in southern part, aprevalence of 0.3% has been reported. On the other hand, Zanzibar island experiences concentrated HIV epidemic unlike Tanzania mainland with a reported prevalence of 0.5%(30).

The magnitude of viral suppression among HIV patients in Tanzania has been reported to range between 84 - 91% in different studies conducted in different parts of the country within the first year of ART use to assess clinical and virological response to ART(20,21,23). However, these studies were conducted under clinical trial environment and before the introduction of more efficacious ART regimens with friendly dosages, while other studies were cross-sectional in nature and therefore had some biases as only the patients present at the time of data collection were studied.

Sustainability of viral suppression after initial suppression is an important target of initiating ART regimens. In acohort study conducted on 212 HIV patients in rural Tanzania to determine virological response to antiretroviral therapy using a cut-off of 400 HIV RNA copies per ml for viral suppression, 94.8%, 88%, 75% and 87.5% of HIV patients were found to have viral suppression after 1, 2, 3 and 4 years of treatment respectively (21). This study demonstrated effective sustainability of viral suppression in a rural context in Tanzania, whether similar results can be replicated in urban set up remains to be an important research question.

Temeke CTC follows the national CTC structure and organization. Due to the high burden of patients at the clinic and at patient request, clinicians at Temeke may give longer appointments 2 months to 3 months depending on the clinical status and motivation of the patient.

1.2.2 Factors associated with viral suppression

Adherence to medication soon after starting ART is among the biggest challenge facing HIV care and treatment programs in low and middle-income countries (24). Tanzania is not an exception to this with an estimated 16 – 19% of people living with HIV not adhering to clinic visits in different parts of the country(31-33).Several factors have been listed as contributing to poor adherence and overall poor viral suppression including adverse effects, being away from home, social stigma, lack of disclosure of HIV status and complex treatment regimes(32).

Change to single tablet ART regimens has been adopted into Tanzania and is expected to improve adherence of patients to ART and improve viral suppression as it has been reported by Asian studies(4), studies to assess the level of suppression since the inception of single tablet regimen in our setup are scanty.

Several other factors have also been shown to be associated with poor viral suppression including pre-treatment CD4 levels, WHO clinical stage at the initiation of ART and opportunistic infections(23,32).Among the opportunistic infections,Tuberculosis is leading cause of mortality among people living with HIV and active Mycobacterium tuberculosis has been shown to be associated with poor HIV viral suppression and major resistance mutations to drugs used as first-line antiretroviral therapy(33,34).Recently several strategies have been adopted by the Tanzania Ministry of Health, Community Development, Gender, Elderly and Children to help to tackle the continuing HIV/TB co-infection burden like screening for constitutional symptoms for TB, integrating TB and HIV management, studies to assess viral suppression since the adoption of these strategies are lacking.

Evaluation of HIV viral load after twelve months of initiating ART is recommended by WHO for assessment of effectiveness of ART treatment sites because losses to follow-up and nonadherence to prescribed ART are more likely to occur after initial six months of therapy while HIV viral load measurement after initial 6 months period of using ART are recommended for assessment of initial efficacy of ART regimen(3).

Improved quality of care in CTC facilities has been linked to reduction in morbidity and mortality for patients on ART. CD4 measurement at the commencement of ART, numbers of patients at a health facility, clinician expertise have been shown to affect the level of viral suppression among CTC patients(33,35).

1.3 PROBLEM STATEMENT

There is scarce information on the HIV viral suppression in Sub-Saharan Africa and in particular Tanzaniaduring an era with improved ART drug choices as well as advancing technology in HIV viral detection. Previous studies showed prevalence of virological suppression among HIV patients on ART to be 89%after 12 months of using ART but these studies were either conducted in stringent environment within a clinical trial (23),and/or were conducted before the introduction of more efficacious and better tolerated(21,36), less frequent, ART regimens (1).

Persistence of high loads of HIV viremia and failure to achieve HIV viral suppression despite treatment with antiretroviral drugs (ARV) is associated high risk of HIV transmission as well as development of drug resistance viruses as a result of mutations occurring under drug pressure. The devastating consequence ofthis is an increased potential of transmission of drug-resistant HIV strains to population(14).

Recently, new local and international strategies have started being implemented in managing HIV disease, including UNAIDS 90-90-90 strategy to end AIDS epidemic by 2030 and the local adoption of viral load measurement as monitoring tool for patients on ART by Tanzania National AIDS Control Program (NACP)(15,21,23).Since the inception of these strategies magnitude of viral suppression has not been assessed at the programmatic level of care and treatment clinic/facilities.

National AIDS control Program (NACP) collects virological information from Care and Treatment Clinics throughout the country but additional information on factors which may affect viral load results of patients on ART is not routinely collected at HIV clinics.

Therefore this study was done to determine the proportion of patients with viral suppression within one year of treatment with ART and to describe factors associated with HIV suppression at Temeke regional referral HIV care and treatment clinic in Dar es Salaam.

1.4 RATIONALE

The study aimed at determining the effectiveness of the HIV treatment program at a referral HIV care and treatment clinic. Marking this milestone two years post UN-sustainable goals will track efforts towards the achievement of the targets for goal number 3.3. The study lessons learnt will shed light into ways to expedite the progress towards achieving the WHO benchmarkinending AIDS epidemic.

1.5 RESEARCH QUESTIONS

What is the proportion of HIV patient with viral suppression after six months of starting ART?
What is the proportion of HIV patient with viral suppression after twelve months of starting ART?
What are the factors associated with HIV viral suppression during the first year of ART?

1.6 OBJECTIVES

1.6.1 Broad Objectives

To determine the proportion of HIV viral suppression among HIV infected adultswithin one year of antiretroviral treatment at Temeke hospital HIV Care and Treatment Clinic (CTC).

1.6.2 Specific Objectives

1. To determine the proportion of HIV-infected patients with HIV viral suppression six months after ART initiation.

2. To determine the proportion of HIV-infected patients with HIV viral suppression twelve months after ART initiation.

3. To determine factors associated with viral suppression during the first year of treatment with ART among HIV infected adult at Temeke CTC.

1.7 CONCEPTUAL FRAMEWORK

Viral suppression may be influenced by social demographic factors such as age, marital status of the patient, and clinical factors such as adherence to medication, WHO clinical stage of the patient at the time of diagnosis, opportunistic infections and CD4 - T lymphocyte count at the time of making a diagnosis.

HIV patients with older age, females, those with good adherence and those with higher baseline CD4 + T cell lymphocyte have been shown to have better suppression(20,23,37).

The social and demographic factors such as male sex, stigma, long distance to CTC and failure to disclose HIV status may negatively influence adherence to prescribed medications which may ultimately influence the presence of opportunistic infections and WHO HIV clinical stage of patients(38).

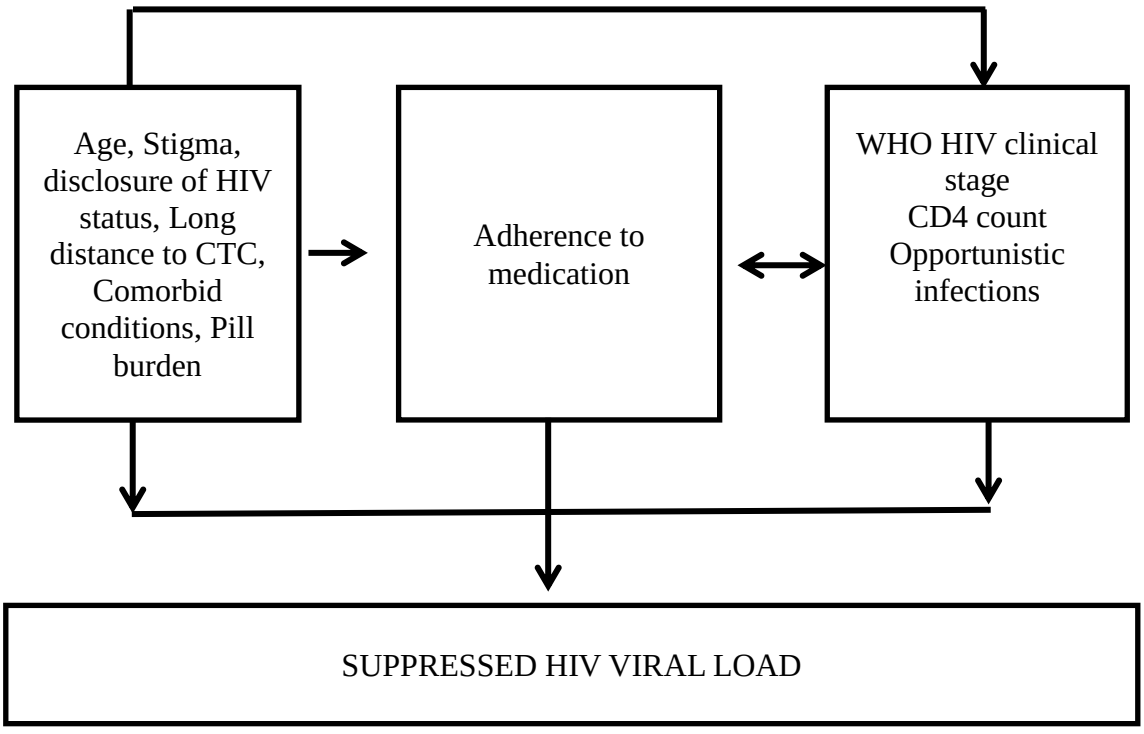

Figure 1: Conceptual framework of factors associated with HIV viral suppression among patients on ART

CHAPTER TWO

METHODOLOGY

2.1.1 STUDY DESIGN

Two designs were used to achieve objectives of the study, a hospital-based retrospective cohort study and a cross - sectional analysis of factors associated with viral suppression.

2.1.2 STUDY AREA

This study was conducted at Temeke Regional ReferralHospital HIV care and treatment clinic in Dar es Salaam, Tanzania. Dar es Salaam city is located at $6^0$48' south and $39^0$17' East on the eastern coast of Africa. It consists of five Municipals namely; Kinondoni, Ilala, Temeke, Ubungo and Kigamboni. The city has three regional referral hospitals namely Temeke, Amana and Mwananyamala.

Temeke Regional Referral Hospital is located within Temeke municipal council, with catchment area of about with an area of 728.71 square kilometers catering for 1,368,881people.HIV prevalence in Temeke region is 8.3% with an estimated 44,000 people living with HIV above fifteen years**(39).** Temeke regional referral hospital HIV Care and Treatment Clinic had registered a total of 22,367 HIV infected adults, of whom 10,433 were still actively attending CTC by October 2017. Temeke CTC receives approximately3-4 new patients perday and 80 – 100patients are seen as follow-up cases daily. Patients are seen at an interval of 1 – 2 months for follow-up care.

Temeke CTC follows the national CTC structure and organization. Due to the high burden of patients at the clinic and at patient request, clinicians at Temeke may give longer appointments 2 month to 3 months depending on the clinical status and motivation of the patient.

2.1.3 STUDY POPULATION

A cohort of HIV patients commencing ART between May – November 2016at Temeke Regional ReferralHospital were recruited and followed retrospectively. We selected patients initiating treatment between May and November 2016 so as to obtain a cohort of HIV infected adults on ART for 12 months at the time of data collection for this study.

2.1.4 INCLUSION CRITERIA

The following were inclusion criteria for this the study:

1. Adult HIV patients aged 18 years or above.
2. Patients initiated on ART from May to November 2016.

2.1.5 EXCLUSION CRITERIA

1. Pregnant women were excluded for logistical reasons.

2.1.6 STUDY PERIOD

Data collection for this study was conducted for 3 months from September 2017 toNovember 2017.

2.1.7 SAMPLE SIZE ESTIMATION

The retrospective component of the study included all patients who started ART between May and November 2016 while sample size for the cross-sectional component was obtained using the Leslie Kish formula

$$N = \frac{Z^2 P (1-P)}{\varepsilon^2}$$

Where N: sample size

Z: critical value 1.96

P: prevalence

ε: Maximum error

Z = 1.96

P = 0.89(23)

ε = 0.05

$N = 1.96^2 \times 0.89 (1 - 0.89)/0.05^2$.

N = 150

Estimated Retention in CTC facilities after 1 year of ART = 78%(40)

$$\text{Sample size} = \frac{150 \times 100}{78} = 193$$

Sample size = A minimum sample of 193 patients was required for the cross-sectional component of the study.

2.1.8 SAMPLING TECHNIQUE

No sampling was done for the retrospective component. All patients fulfilling the inclusion criteria wereincluded in the retrospective study cohort.A subset among the study patients who attended clinic during time of data collection were interviewed for additional variables that are likely to influence HIV viral suppression and were not collected routinely during regular clinic visits for the cross-sectional component of the study. Such information included: adherence to ART, stigma, HIV status disclosure, Alcohol use, number of sexual partners in the past 3 months, monthly income of the family, illicit drug use and payment for sex.

2.1.9 DATA COLLECTION PROCEDURE

The study had two components; Retrospective component and Cross-sectional component.

Retrospective cohort component

Retrospective component included review of files for a cohort of patients who started ART between May and November 2016. For this component, list of all patients eligible patients was extracted from the electronic HIV data based (CTC 2). Primary source of information was from patient's clinical cards (CTC2 Cards). HIV identification number from the electronic database was used to trace all patient files.

Standardized questionnaires were used to collect patient's information such as (demographics, anthropometric, clinical and laboratory variables) as recorded in CTC 2 cards for the visits which were made throughout one year of follow-up for a cohort of patients who started ART between May and November 2016.

Whenever information was missing from the CTC 2 cards, the following were done:

1. Electronic CTC records were retrieved.
2. Laboratory registry whenever viral load was missing.
3. Telephone calls were made to check vital status (death, defaults) or/and whereabouts of those who missed clinics.

Programmatically, not all patients have their viral load determined exactly at 6 months or twelve months due to operational issues, such as frequency of visits, missed appointments and temporary technical faults of viral load machines. Therefore, to overcome this challenge, virological tests conducted between 4^{th} and 8^{th} months of using ART were taken as viral load at 6 months while virological tests conducted between 9^{th} and 15^{th} month of using ART were taken as viral load at 12 months in the analysis of virological results.

Quality of care provided to HIV patients was assessed by using clinical parameters and laboratory parameters. Proportion of patients who had their weights and height measured at the start of ART contributed clinical parameters while proportion of those who had baseline CD4 tests measured and HIV viral load within the first year of ART contributed laboratory parameters.

Cross-sectional component

In addition to retrieval of information from patient cards, we interviewed a subset of the study population who came for their regular clinic at the time of data collection for additional information that is not routinely collected in the patients' CTC 2 cards for the cross-sectional component of the study.

Interviews were conducted by trained nurses using standard prepared questionnaires. Information collected included; adherence to ART, occurrence of opportunistic infections, hospital admissions in the past year and risky behaviors for acquisition of new HIV infection, HIV associated stigma was assessed using AIDS-related internalized stigma scale with a score of five and above representing high stigma and fear of disclosure of HIV status was assessed using two standardized questions. Patients underwent routine care after completion of the interview.

Alcohol and drug use were defined as using alcoholic drinks or using illicit drug in the past one month respectively.

2.1.10 DATA COLLECTION TOOLS

Two structured questionnaires were developed in English. First questionnaire was used for retrospective component of the study to collect patient's information regarding clinical and laboratory and treatment parameters. The second questionnaire was used to obtain for additional information for assessment of factors associated with viral suppression, in the cross-sectional study.

2.1.11 TRAINING OF REASEACH ASSISTANTS AND PRE-TEST

Qualified registered nurse was recruited as a research assistant; one day training on the study objectives and procedures, familiarization with the study questionnaires and ethical issues of the study was conducted. Report on data collection and feedbacks on the problems encountered were discussed daily with the research assistant.

The questionnaire was pre-tested at Temeke regional referral hospital, and corrections were subsequently made to improve clarity before the start of the actual data collection.

2.1.12 STUDY VARIABLES

1. The main variable of interest in this study was viral load suppressiondefined as HIV RNA measurement below 50 copies/ml (as per national HIV treatment guideline (1)
   HIV viral load was detected by nucleic acid amplification polymerase chain reaction method using COBAS®AmpliPrep/COBAS®TaqMan 48 analyzer (Roche Diagnostics, USA) with a detection limit of 20 – 10,000,000 copies/ml.This machine provides accurate quantification with automated dual target assay of HIV RNA copies and has a specificity of 100.00%.
2. Social demographic information included age, sex, marital status and level of education.
3. Clinical information included good adherence which was defined as reporting taking more than 95% of the prescribed doses in the previous 30 days, weight, height, WHO HIV clinical stage, stigma and monthly income.

4. Other laboratory information includedCD4 + T lymphocyte (cells/µl) measured by BD FACS Count™ Flow Cytometer from BD Biosciences (USA) at Temeke regional referral hospital laboratory.

2.1.13 DATA ENTRY AND ANALYSIS

Completed questionnaires were coded and entered into the computer by using Epi infosoftware version 7.Data analysis wasconducted by using statistical package for social sciences (SPSS) version 23.

Categorical variablesweresummarized using proportions and compared with the outcome variable (viral suppression) by using chi-square test. Continuous variables were expressed as means, standard deviation (SD) or median,Interquartile range – (IQR) andcompared by using student'st-test.

Multivariate logistic regression analysis was used to examine factors associated HIV viral suppression. Factors with $p \leq 0.2$ at univariate model were included in the multivariate model. Any association with P value less than 0.05 wasregarded as statistically significant association.

2.1.14 ETHICAL CONSIDERATION

This study was approved by the Muhimbili University of Health and Allied Sciences ethical review board. Permission to conduct the study was sought from Temeke Municipal officer for Health.

Participation into this study was voluntary and participants needed to provide a written consent before participating in this study. Withdraw from the study at any time was a given option to all patients and this did not affect their treatment at the hospital.

Aims and procedure of the study were explained to the participants and written consent was obtained from study participants before conducting the interviews. Patient names were not reported and strict confidentiality was observed throughout all stages of conducting this study.

CHAPTER THREE

RESULTS

A total of seven hundred and forty-seven (747) HIV infected patients aged 18 years and above, started ART at Temeke Hospital between May and November 2016. The mean age of patients was 39 years and 479 (64%) were females. Majority of the patient had advanced immune suppression; almost half (n =319;48.2%) presenting at either WHO HIV clinical stage III or IV and the median baseline CD4+ T lymphocyte count (IQR) was 249 (104 – 421) cells/µl at the time of ART initiation. Table 1 provides more details of the socio-demographic clinical and laboratory characteristics of the patients who started ART between May and November 2016. The 747 patients constituted the initial cohort for the retrospective component of the study.

Out of 484 patients who were assessed for ART use, 476 (98.3%) patients were using Tenofovir (TDF), Lamivudine (3TC) and Efavirenz (EFV), three (0.6%) patients were on Tenofovir, Emtricitabine (FTC) and Efavirenz, three (0.6%) were on Tenofovir, Emtricitabine and Nevirapine (NVP) while one patient (0.2%) was on Atazanavir boosted with ritonavir (ATV/r), Tenofovir and Emtricitabine and another one (0.2%) was on Zidovudine (AZT), Lamivudine and Nevirapine as first line therapies as shown in Table 1.

Patients with missing data were excluded from further analysis of proportion of patients with viral suppression and factors associated with viral suppression.

Table 1: Baseline social demographic, clinical and laboratory characteristics of patients who started ART between May and November 2016 at Temeke Regional Referral Hospital (n =747)

Characteristics	Missing Data (%)	N (%)
Age groups (years)	0	
18 – 29		145 (19.4)
30 – 39		281 (37.6)
40 – 49		208 (27.8)
50+		113 (15.1)
Sex	0	
Male		268 (35.9)
Female		479 (64.1)
Weight (Kg)	70 (9.4)	677 (90.6)
Height (Centimeters)	331 (44.3)	416 (55.7
Baseline CD4 (cells/µl)	512 (68.5)	
≤ 350		160 (68.1)
> 350		75 (31.9)
WHO-HIV stage	85 (11.4)	
I		149 (22.5)
II		194 (29.3)
III		259 (39.1)
IV		60 (9.1)
Type of ART	263 (35.2)	
TDF/3TC/EFV		476 (98.3)
TDF/FTC/EFV		3 (0.6)
TDF/FTC/NVP		3 (0.6)
ATV/r/TDF/FTC		1 (0.2)
AZT/3TC/NVP		1 (0.2)

* TDF – Tenofovir, 3TC – Lamivudine FTC – Emtricitabine,

EFV – Efavirenz, NVP – Nevirapine, AZT – zidovudine,

ATV – Atazanavir boosted with ritonavir

3.1 PATIENTS RETENTION

Figure 2 shows patients' retention at Temeke CTC within the first 12 months of ART. During one year of follow-up, 104 (13.9%) patients were transferred to other CTC within and outside Dar es Salaam.

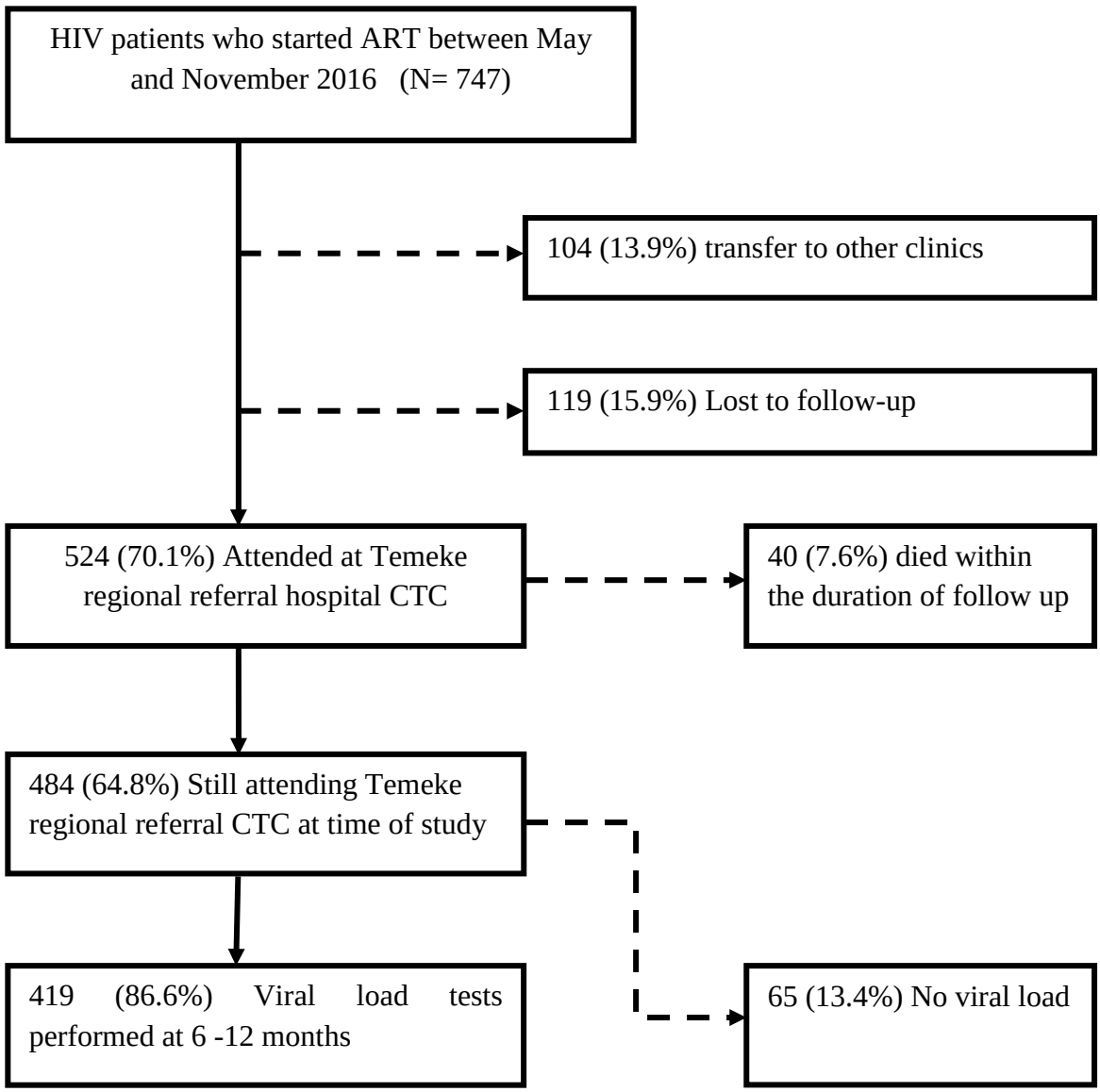

Figure 2: Flowchart showing retention of patients 12 months following commencement of ART (n=747)

A total of 119 (15.9%) patients lost contact with the clinic for more than three consecutive months during follow-up (loss to follow up); were not accessible through their contact address and/or telephone numbers; and never returned for subsequent visits during the 12 months of follow up. Nearly two thirds (80/119, 62%) of these patients disappeared just after initiation of ART and did not return for subsequent visits. Sixty one percent of the patients lost were females (73/119, 61.3%) and almost six out of ten patients aged 40 years (71/119 (59.7%) or younger. Like the overall study cohort (747 patients), these patients had advanced HIV, presenting with a median CD4+ T cell count of 270 cells/µl with a majority(55/87, 63.2%)at HIV WHO clinical stage III or IV at the time of ART initiation. Only eight among the patients lost to follow (8/119) had viral load performed before they were lost.

Meanwhile, 524 (70.1%) patients made some contact with the clinic and were followed up at Temeke regional referral hospital CTC as shown in Figure 2. Among them, 40 (7.6%) patients died, the median time to death was 4.9 months. Of the patients who died, only one (1/40) patients had viral load measurements performed before death occurred. Table 2 summarizes demographic, clinical and laboratory characteristics of patients who either died or were lost to follow-up after they were tested for HIV viral load.

Therefore retention of HIV patients at Temeke CTC at 12 months of treatment with ART was 484/747 (64.8%), for the ART cohort of starting ART between May and November 2016. However, 65 patients among these had no viral load measurement.

Patients who were still attending CTC (484) and those who were not available at 12 months (263) were similar ingender, age,and baseline CD4 + T lymphocyte cell count but those who were still attending were more likely to have early WHO HIV clinical stage (I or II) as compared to those who were not available (76.4% Vs 63.0%).

Table 2: Clinical and laboratory parameters among lost to follow up and dead patients who had virological results (n = 9)

Patient serial numbers	Months of Viral load measurement after ART	Viral load (copies/ml)	Time to death or until LTF (months)	Baseline CD4 (cells/µl	WHO stage
Death					
D1	9.0	485	11.9	3	2
Lost to follow up					
LTFU 1	8.0	0	10.1	*	1
LTFU 2	5.0	0	6.0	*	3
LTFU 3	0.9	0	0.9	110	3
LTFU 4	0.5	0	0.5	22	*
LTFU 5	2.3	0	2.3	*	3
LTFU 6	5.3	0	5.3	261	1
LTFU 7	5.6	62	5.6	*	2
LTFU 8	0.7	20	0.7	*	3

Key

*Results were missing from records

3.2 HIV VIRAL SUPPRESION

Out of 484 patients who were still attending Temeke CTC at 12 months of ART, 419 patients had viral load measurementswhile 65 (13.4%) had no viral load test performed at 6 or 12 month of follow up. The 419 patients who had virological results constituted the study population. Among those with viral load measurement, 137 (28.3%) performed viral load tests at 6 (4 – 8) months and 312 (64.5%) underwent virological tests at 12 (9 – 15) months since the initiation of ART and 30 (6.2%) patients had viral load at both time points (Figure 3).

Patients with viral load results and those without viral load results were similar in gender, baseline CD4 + T cell lymphocyte count andage. However, patient missing viral load were more likely to have HIV WHO Stage IV than those with viral loadmeasurements (13.7% Vs 6%).

3.2.1 Viral suppression at six months

A total of 137 patients hadHIV viral load test results at 6 (4-8) months of ART use. Of these, 108 (78.8%)had attainedHIV viral suppression. The median viral load (IQR)at six months of ART among adults alive and still attending Temeke CTC was 20 (0-40) copies per ml.

3.2.2Viral suppression at twelve months

Out of 312 patients who were tested for HIV viral load at 12 (9 – 15) months,232 (74.4%)had attained HIV viral suppression. The median viral load (IQR) at this time point was 0 (0-52) copies per ml.

3.2.3 Sustained virological suppression

Thirty (30) patients had HIV viral load measurement at both time points;6 and 12 months of ART. The median duration between the two viral load tests was 6.6 months. Among these patients, 20 (66.7%) patients had sustained viral suppression(HIV viral load of less than 50 copies per ml at both time points). In addition, three (3) patients who had initially unsuppressed viral loads at six months were able to achieve viral suppression at twelve months.

Further,two (2)patients who had HIV viral suppression at six months failed to maintain their viral suppression at twelve months; while 5 (16.7%) patients were found to have unsuppressed viral loads on both time pointsas shown in Figure 3. Mean age of patients with sustained viral suppression was 39 years while that of unsuppressed group was 43 years.

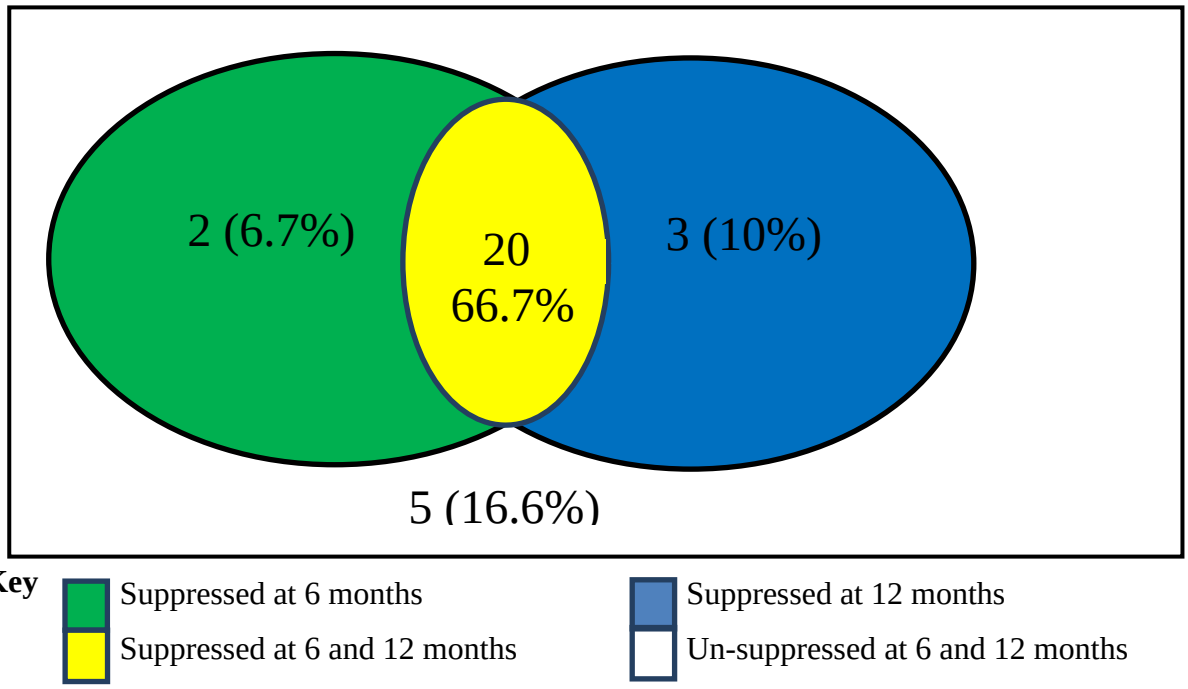

Figure 3: Venn diagram showing HIV viral suppression at different study time points for patients who had viral load results at 6 and 12 monthsof ART (n=30)

3.2.4 Viral suppression at any time during first year of follow up.

Out of 419 patients who had HIV viral load test at any time during the first year of ART, 318 (75.9%, 95% CI (71.6 – 79.7%) were found to have viral suppression. The median (IQR) viral load was found to be 0 (0-44) copies per ml.

Table 3 provides comparison of clinical and socio-demographic parameters of the patients with and without HIV suppression at any time during first 12 months. The proportion of patients with viral suppression was non-significantly to be higher among adults youngerthan 30 years (57, 82.6%) compared to patients older than 50 years (46 (76.7%); p

=.0.26.Furthermore, significantly higher proportion of females had viral suppression as compared to males (79.4% vs. 69.4%); p =.0.02). The gender disparity was much more conspicuous among patients aged more than 50 years where 87.2% of females were virally suppressed as compared to only 57.1% of males (Figure 4).

Meanwhile the proportion of viral suppression was found to be highest among widowed individuals (87.1%) as compared to other marital status categories, however there was no statistical significant association between HIV viral suppression and marital status. (Table 3)

Advanced HIV infection at ART initiation was significantly associated with inability to achieve HIV viral suppression within one year of ART. The proportion of patient with viral suppression was found to be highest among people who started ART while in WHO Clinical HIV stage 1 (86.7%) and lowest at WHO clinical stage IV (54.2%); P trend< 0.01. In addition, higher CD4 + T cell count ≥350 cells/µL was significantly associated with highest viral suppression rate (90%), compared to 200 - 350 cells/µL (81%) and <200 cells/µL (62.5 %) P trend = 0.01. Each increase in 1cell/ µLof baseline CD4+ T cell lymphocyte was significantlyassociated with 0.4% increase in the likelihood to attain HIV viral suppression in the first year of ART. (OR = 1.004, P <0.002).

Likewise, patients who achieved HIV viral suppression within the first year of ART had significantly higher mean BMI compared to those without viral suppression (23.2 kg/m^2 vs 21.4 kg/m^2. P = 0.04).

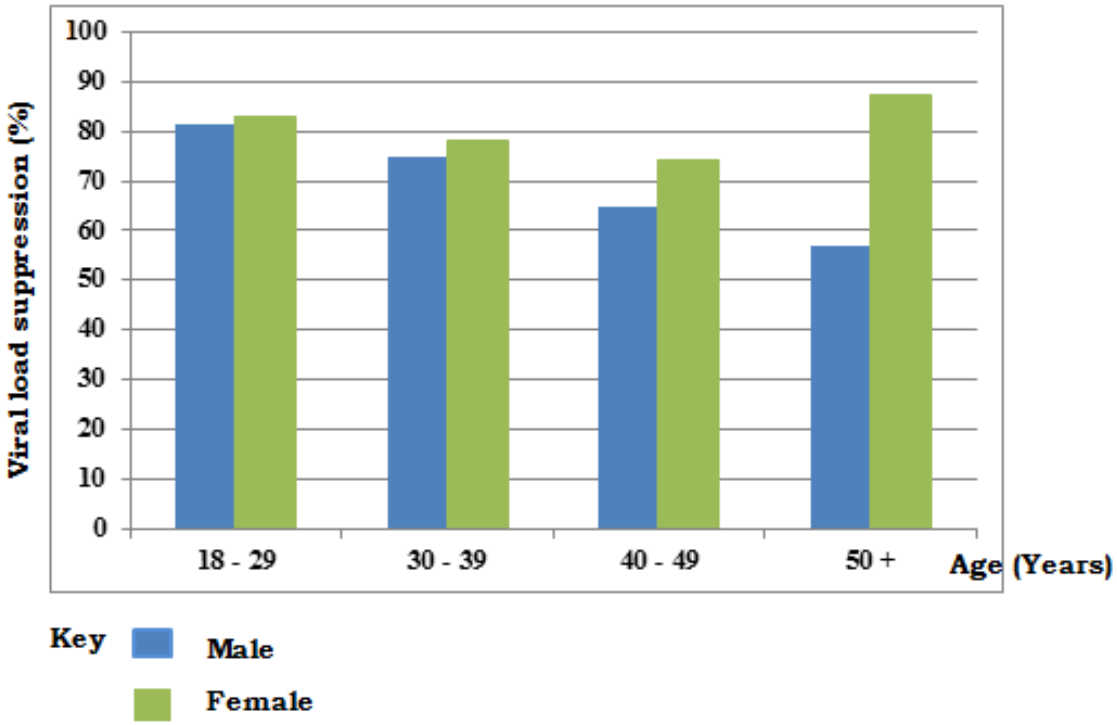

Figure 4: Proportion of patients with HIV viral suppression within 12 months of using ART at Temeke Regional referral hospital by age and sex (n = 419)

Table 3: Comparison of patients with and without HIV viral suppression at 6 – 12 months of ART (n =419)

Characteristics	Missing (%)	Proportion/ Mean with Suppressed HIV viral loads (%) N = 318	Proportion/ Mean with Unsuppressed HIV viral loads (%) N = 101	P value	Total (%) N = 419
Age (Mean) years	0	38.8	40.3	0.18	
Age group (years)	0			0.26	
18 – 29		57 (82.6)	12 (17.4)		69 (16.5)
30 – 39		125 (77.2)	37 (22.8)		162 (38.7)
40 – 49		90 (70.3)	38 (29.7)		128 (30.5)
50+		46 (76.7)	14 (23.3)		60 (14.3)
Gender	0			0.02	
Male		102 (69.4)	45 (30.6)		147 (35.1)
Female		216 (79.4)	56 (20.6)		272 (64.9)
Marital Status	121 (28.9)			0.33	
Single		81 (73)	30 (27.0)		111 (37.2)
Married/Cohabiting		102 (81)	24 (19.0)		126 (42.3)
Divorced/Widowed		48 (78.7)	13 (21.3)		61 (20.5)
Mean BMI (Kg/m^2)	149 (35.6)	23.2	21.5	0.04	
WHO-HIV clinical stage	19 (95.5)			< 0.01	
I		91 (86.7)	14 (13.3)		105 (26.3)
II		95 (76.0)	30 (24.0)		125 (31.3)
III		106 (72.6)	40 (27.4)		146 (36.5)
IV		13 (54.2)	11 (45.8)		24 (6.0)
Baseline CD4 (cells/µl)	283 (67.5)			0.01	
<200		40 (62.5)	24 (37.5)		64 (47.1)
200 – 350		26 (81.3)	6 (18.8)		32 (23.5)
>350		36 (90.0)	4 (10.0)		40 (29.4)
ART type	0			0.68	
Single tablet regimen		317 (76.6)	97 (23.4)		414 (98.8)
Other		5 (100)	0 (0)		5 (1.2)

3.3 FACTORS ASSOCIATED WITH HIV VIRAL SUPPRESSION

Among 419 patients who had HIV viral load measurements, 188(45%) patients were present during data collection (September and November 2017) and were interviewed for additional factorssuch as adherence to ART in the cross-sectional component of the study, inter-current illness during the one year of follow up and stigma which could potentially influence HIV viral suppression. Among the interviewed, 188 patients, 149 (79.3%) achieved viral suppression within one year of follow up.

Multivariate analysis of factors associated with viral suppression among interviewed HIV patients attending Temeke regional referral hospital

Table 4 provides univariate and multivariate factors associated with HIV viral suppression within 12 months of follow up. Baseline CD4 >200 (cells/µl) was significantly associated with viral suppression in univariate analysis of factors associated with viral suppression.

Upon multivariate analysis of factors associated with viral suppression, baseline CD4>200 cells/µL was associated with more than eleven fold increased like hood (OR: 11.2; 95% CI 1.4 – 87.2; P = 0.02) to attain viral suppression during the first year of ART compared to less than 200 cells/µL. In the same note, patients with good adherence to ART were significantly more likely (OR: 11.4; 95% CI 1.1 – 115.5; P = 0.04) to attain viral suppression compared to those with poor adherence independent of age, sex, alcohol intake and WHO HIV clinical stage at initiation of ART as shown in table 4.

Table 4: Univariate and multivariate analysis of factors associated with HIV viral suppression within one year of ART among adults patients attending Temeke Hospital care and treatment clinic (n=188)

Variable	Univariate analysis		Multivariate Analysis	
	OR (95% CI)	P value	OR (95% CI)	P value
Gender		0.78		0.10
Male	Ref		Ref	
Female	1.1 (0.5 – 2.3)		0.2 (0.0 – 1.4)	
Age group		0.46		0.32
18 – 29	2.4 (0.6 – 10.5)		1.6 (0.1 – 132.1)	
30 – 39	1.2(0.4 – 3.2)		1.5 (0.1 – 22.2)	
40 – 49	0.8(0.3 – 2.4)		0.2 (0.0 – 3.1)	
50+	Ref		Ref	
Income (Tanzanian Shillings)		0.49		
<250,000	1.3 (0.6 – 3.0)			
≥250,000	Ref			
Occupation		0.75		
Employed	0.7 (0.2 – 2.4)			
Not employed	Ref			
Current alcohol use		0.14		0.25
Yes	Ref		Ref	
No	2.0 (0.8 – 5.1)		4.2 (0.4 – 49.1)	
Adherenceto ART		0.40		0.04
Good	1.6 (0.5 – 5.1)		11.4 (1.1 – 115.5)	
Poor	Ref		Ref	
History of admission during preceding 12 months		1.0		
Yes	Ref			
No	0.0 (0.0)			
Pulmonary TB		0.44		
Yes	Ref			
No	1.5 (0.5 – 4.6)			

Continuation of Table 4: Univariate and multivariate analysis of factors associated with HIV viral suppression within one year of ART among adults patients attending Temeke Hospital care and treatment clinic (n = 188)

Variable	Univariate analysis		Multivariate Analysis	
	OR (95% CI)	**P value**	**OR (95% CI)**	**P value**
WHO HIV clinical stage		0.13		0.48
1	5.6 (1.4 – 22.8)		4.6 (0.2 – 132.1)	
2	2.8 (0.8 – 10.1)		0.9 (0.0 – 22.8)	
3	2.5 (0.8 – 8.3)		3.2 (0.2 – 62.1)	
4	Ref		Ref	
Baseline CD4 (cells/µl)		0.02		0.02
≤200	Ref		Ref	
>200	4.4 (1.2 – 15.4)		11.2 (1.4 – 87.2)	
Marital status		0.48		
Single	Ref			
Married/Cohabiting	1.7 (0.7 – 3.9)			
Divorced/Widowed	1.5 (0.6 – 3.9)			
Mean BMI (Kg/m^2)	1.03 (1.0 – 1.1)	0.51		
ART type		1.0		
Single-tablet regimen	0.0 (0.0)			
Others	Ref			
Level of education		0.53		
Primary and below	1.4 (0.5 – 3.6)			
Above Primary	Ref			

* Other variables including;HIV disclosure status, unsafe sexual practices, oral sex, anal sex, ART used, HIV status of regular sexual partner, area of residence, Number of sexual partners in the last 3 months and Prior ART exposure were analyzed but were non-significant and they are not included in this table.

3.4 QUALITY OF CARE

Quality of care provided to HIV patients was assessed by using clinical parameters and laboratory parameters among the 747 who were initiated on ART at Temeke CTC. A total of 677 (90.6%) patients had their baseline weights documented while 416 (55.7%) had their heights documented at the initiation of ART. Meanwhile 662 (88.6%) had clinical assessment by WHO HIV clinical staging and results were documented at the initiation of ART. Only 31.5% of the 4had their baseline CD4 measured at the start of ART as shown in Table 5.

Out of 484 patients who were still attending Temeke CTC clinic, 137 (28.3%) performed viral load tests at 6 months and 312 (64.5%) underwent virological tests at 12 months since the initiation of ART. On the other hand, only 30 patients had HIV viral load measurements at both $6^{th}$and 12^{th} month of ART.

Table 5: Baseline clinical and laboratory surrogates of quality of care assessed at the initiation of ART (n =747)

Measurement/Assessment	Patient who had assessment n (%)	Patients who did not have assessment n (%)
Weight	677 (90.6)	70 (9.4)
Height	416 (55.7)	331 (44.3)
CD4 (cells/mm^3)	235 (31.5%)	512 (68.5)
WHO-HIV stage	662 (88.6%)	85 (11.4)

CHAPTER FOUR

DISCUSSION

This study describes the following findings: first, about 7 in 10 adults receiving ART at Temeke CTC attained HIV viral suppression within first year ofART. Second, good adherence to ART and higher baseline CD4 counts (>200 cells per µl) at initiation of ART was significantly associated with better HIV viral suppression rates. Third, we noted low (64.8%)patient retention at 12 months in Temeke CTC. Finally there was sub-optimal quality of care in baseline assessment and monitoring patients.

The level of HIV viral suppression in our study (75.9 %) is low compared to previous studies conducted in northwest, rural and urban Tanzania; which reported HIV viral suppression ranging from 84 to 91% (20,21,23). The differences observed may be attributed to the different cut off values used to define viral suppression.In our study viral suppression was defined as having viral load of less than 50 copies per ml while in the studies mentioned above, viral load cut offs of 400 -1000 HIV RNA copies per ml were used but also the studies mentioned were cross-sectional in nature(20,21,41).Meanwhile one study was conducted under clinical trial environment which had selected patients with relatively well preserved immunity(23).

Indeed,in our study,large proportion of patients started ART at advanced stage of HIV disease as evidenced by nearly half who started at either WHO HIV clinical stage III or IV and more than two thirds who had baseline CD4 count of less than 350 cells per µl. Advance HIV at ART initiationas characterized by either WHO clinical stage III or IV and/or low baseline CD4 count has been shown to affect level of HIV viral suppression in previous published studies(20,41).

On the other hand, virological suppression rate found in our study is similar to the level of suppression reported in meta-analysis of studies in Sub-Saharan Africa(24).In the meta-analysis, 76% of HIV infected patients had suppressed viral loads within 12 months of using ART (24). However, the definition of viral suppression varied among the studies in the meta-analysis with the majority of studies having a more lenient cut off value of HIV RNA (400

copies /ml). Therefore, if our definition was employed there is a possibility that suppression could be lower than in our study (24).

The level of HIV viral suppression in our study is relatively higher as compared to levels reported in other parts of Sub-Saharan-Africa like Cote d'Ivoire where HIV viral suppression has been reported to be as low as 50% (26).The reasons for relatively higher viral suppression may be attributed to continuous capacity building of practitioners by local and international Non-Governmental Organizations and effective electronic data management system in our study sites(20).

Our results show that adherence to ART and higher baseline CD4 + T cell count at the initiation of ART were the independent factors associated with higher level of HIV viral suppression. A finding which is similar to a study done in rural Tanzania, where having CD4 + T cell count greater than 200 cells/µl was significantly associated with viral suppression independent of other factors(20). Similarly, Claudia et al reported in a study conducted in Dar-es-salaam that lower CD4 + T cell count and non-adherence to ART were significant predictors of virological failure(20,23).

Although there was no statistically significant independent association between WHO staging and virological suppression noted in this study, there was a trend towards higher suppression in patients who started therapy at earlier WHO clinical staging, this was comparable to findings from a study conducted in Dar es salaam to assess development of virological failure and drug resistance mutations (23). This finding underscores the benefit of starting ART in the early stages of HIV infection.

In our study we observed, females had higher level of HIV viral suppression as compared to males across all age groups. Gender disparity in HIV care and treatment outcomes is of great interest. Our findings are similar to what was reported in previous published studies to assess gender differences in HIV disease progression in Tanzania by Moshaet al(37). This could be a result of many opportunities and interventions targeting women such as prevention of mother tochild transmission of HIV (PMTCT) and family planning clinics which might foster earlier diagnosis and treatment (42). Other explanation may be a better health seeking behavior of

women; in general women are known to seek health servicesquicker than men (43). This is also evident in our study whereonly 41.6% males started ART at either HIV WHO stage I or II as compared to 57.2% females who started ART at WHO stage I or II.

Patients with higher BMI in our study were more likely to have HIV viralsuppression; however the association was not statistically significant. This finding is similar to the findings by Koethe et al to assess relationship between pre-treatment BMI and immune recovery among HIV patients, in which overweight patients were shown to have optimal immune recovery as compared to other BMI groups(44).In African studies, increasing BMI is associated with better feeding and good education(45).Patients with higher BMI in our study were also found to have higher average monthly incomeas compared to those with lower BMI (315,000 Vs 240,000 Tanzanian shillings) and this may explainbetter nutrition and better education which might favor good adherence to ART.

The quality of care provided to patients is sub-optimal as evidenced by low number of patients with documented baseline clinical and laboratory parameters. These findings are below the recommended practice by Tanzania national HIV guideline which requires baseline documentation of weight, height, TB status, WHO HIV clinical stage and CD4 + T cell lymphocytes to all patients enrolled into CTC (1). Low percent on virological assessment could be explained by the missed appointments of patients on the dates that they were supposed to undergo virological measurements but also some temporary technical machine faults which impair the daily checking of viral loads at study site as well as inconsistent laboratory supply and provider related factors such as number of patients seen by health care provider(46,47).

Retention to CTC services at the end of one year follow-up in our study waslow;this is lower compared to a study done in southwest Tanzania by Layer et al which reported retention of 81% after one year of follow-up(48).Low level of retention in our study could be contributed by shortage of human resource which compromisesquality of care provided by health care personnel(48,49).Improved quality of care and retention has been noted in placeswhere the

WHO advocated task shifting strategy has been adopted to address the human resource shortages. (44).

Nearly one fifth of patients in our study were either lost from follow-up or died within the first year of follow-up. Therefore the level of suppression reported could be an over estimation of true viral suppression rate in this cohort. Indeed, patients who were lost from follow-up were sicker than patients remaining into care, as determined by higher proportion of lost patients being inWHO clinical stage III/IV (63.2%)compared to 48.2% among those retained in the clinic at 12 months. Assuming the worst case scenario, if non-retained (n = 159) patients had no suppressed viral load at 12 months,in this case, the level of suppression could be as low as 55%, and therefore the true viral suppression could be between 55% - 75.9%. This could be a set-back in achieving the WHO sustainable development goal target of ending AIDS epidemic by the year 2030, which requires 90% of patients on ART to have viral suppression by the year 2020(50).

The proportion of patients who were lost from follow – up was similar to a study conducted at Muhimbili National Hospital to assess various strategies on improving adherence to antiretroviral therapy in resource-limited countries, which reported a loss to follow up of 16.4% among patients who were enrolled. (32). Reasons for loss to follow-up among these patients may include silent transfersand unreported deaths (51). It was shown in a study to trace loss to follow-up patients in a care treatment program in western Kenya that46% of the loss to follow up patients had either died or silently transferredto anotherCTC(51).

Nearly two thirds patientsfrom our study were lost from follow-up during the first month of follow-up since the start of ART. This early loss to follow-up is different from findings reported in sentinel treatment sites in limited resource countries where loss to follow-up is noted mainly after the initial 6 months of using ART(3). The discrepancy in retention between our study and the sentinel survey could be explained by the fact that Temeke CTC is located within the Regional referral hospital; therefore some of patients enrolled into ART were still admitted in the wards as in-patients when ART was initiated. These patients upon discharge might find nearby health facilities for CTC services (52).

CHAPTER FIVE

STRENGTH AND LIMITATIONS

5.1Strength of this study

This study was able to retrospectively follow-up a cohort of patients who were started on ART and assessed their viral loads at different course of their treatment including a subset of patients who had virological assessmentat 2 different points in their follow-up. In addition it provides factors associated with HIV viral suppression through the cross-sectional assessment of patients who were present g data collection which has scarcely been reported in Tanzania at programmatic setting. This study is among the first study to report HIV suppression since the adoption of more efficacious Tenofovir based regimens and roll out of HIV viral load as a monitoring tool for HIV patients in programmatic setting.

Conducted in a routine clinical environment, it represents what is actually taking place in our CTCs and therefore in addition to examination of viral load suppression, it provides us with a quick state of quality of care.

Patient who were initiated on ART in our study were similar to national cohorts of patient starting ART, (1)and another study at national hospital in demographic and clinical characteristics. (53)The similarity provides strength to generalize our findings to other similar settings in Tanzania.

5.2 Limitations

The virological suppression rates reported in this study was limited to patients who were still attending care and treatment clinic at 12 months. This is a selection bias as most unselected patients had not measured viral load at the time of censoring (deaths and loss to follow up). Patients with no viral loads were excluded in the analysis which might have resulted into over estimation of HIV viral suppression rate. Patients excluded in the analysis and patients included in the analysis did not differ bytheir age, sex and CD4count at the initiation of ART, butexcluded patients had higher (III/IV) WHO clinical status at initiation of ART as compared to patients included in the analysis which is associated with low suppression rates. Our findings therefore are more likely to over-estimate the suppression rate by selecting slightly well patients.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

In conclusion, the proportion of adults receiving ART at Temeke CTC who attained HIV viral suppression within12 monthsof ART (75.9%) is below the WHO recommended target on trackto end AIDS epidemic by 2030.

6.2 Recommendations

ART should be initiated at an early stage of HIV infection as current recommendation by WHO to improve level of viral suppression,we recommend implementation of strategies to ensure/encourage adherence support to patients on ART through peer educators, lay counsellors and treatment support groupsto improve level of suppression.

Programs should enforce adherence to National guidelines on monitoring of patients at recommended intervals through regular quality assessment and quality improvement activities and HIV drug resistance testing to patients fulfilling virological failure criteria.

REFERENCES

1. United Republic of Tanzania, Ministry of Health and Social Welfare, National guidelines for the management of HIV and AIDS, 5th Ed. National AIDS Control Program (NACP) 2015.
2. Yehia B, Frank I. Battling AIDS in America: an evaluation of the National HIV/AIDS Strategy. American journal of public health. 2011 Sep;101(9):e4-8.
3. Jordan MR, Bennett DE, Bertagnolio S, Gilks CF, Sutherland D. World Health Organization surveys to monitor HIV drug resistance prevention and associated factors in sentinel antiretroviral treatment sites. Antiviral therapy. 2008 Jan 1;13:15.
4. Rangarajan S, Colby DJ, Le Truong Giang DD, Nguyen HH, Tou PB, Danh TT, Tran NB, Nguyen DA, Nguyen BT, Doan VT, Nguyen NQ. Factors associated with HIV viral load suppression on antiretroviral therapy in Vietnam. Journal of virus eradication. 2016 Apr;2(2):94.
5. Fanales-Belasio E, Raimondo M, Suligoi B, Buttò S. HIV virology and pathogenetic mechanisms of infection: a brief overview. Annali dell'Istituto superiore di sanita. 2010 Mar;46(1):5-14.
6. Mosha F, Urassa W, Aboud S, Lyamuya E, Sandstrom E, Bredell H, Williamson C. Prevalence of genotypic resistance to antiretroviral drugs in treatment-naive youths infected with diverse HIV type 1 subtypes and recombinant forms in Dar es Salaam, Tanzania. AIDS research and human retroviruses. 2011 Apr 1;27(4):377-82.
7. Kiwelu IE, Novitsky V, Margolin L, Baca J, Manongi R, Sam N, Shao J, McLane MF, Kapiga SH, Essex M. HIV-1 subtypes and recombinants in Northern Tanzania: distribution of viral quasispecies. PLoS One. 2012 Oct 31;7(10):e47605.
8. Schneider WH, Drucker E. Blood transfusions in the early years of AIDS in sub-Saharan Africa. American journal of public health. 2006 Jun;96(6):984-94.

9. Tanser F, de Oliveira T, Maheu-Giroux M, Bärnighausen T. Concentrated HIV sub-epidemics in generalized epidemic settings. Current Opinion in HIV and AIDS. 2014 Mar;9(2):115.

10. Bartlett JG, Hirsch MS, McGovern BH. The stages and natural history of HIV infection. UpToDate. com. 2010.

11. De Cock KM, Fowler MG, Mercier E, de Vincenzi I, Saba J, Hoff E, Alnwick DJ, Rogers M, Shaffer N. Prevention of mother-to-child HIV transmission in resource-poor countries: translating research into policy and practice. Jama. 2000 Mar 1;283(9):1175-82.

12. Kilaru KR, Kumar A, Sippy N, Carter AO, Roach TC. Immunological and virological responses to highly active antiretroviral therapy in a non-clinical trial setting in a developing Caribbean country. HIV medicine. 2006 Mar 1;7(2):99-104.

13. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. World Health Organization; 2016.

14. Assoumou L, Descamps D, Yerly S, Dos Santos G, Marcelin AG, Delaugerre C, Morand-Joubert L, Ruffault A, Izopet J, Plantier JC, Pakianather S. Prevalence of HIV-1 drug resistance in treated patients with viral load> 50 copies/mL in 2009: a French nationwide study. Journal of Antimicrobial Chemotherapy. 2013 Feb 12;68(6):1400-5.

15. UNAIDS. 90-90-90: an ambitious treatment target to help end the AIDS epidemic. UNAIDS JC2684. Joint United Nations Programme on HIV/AIDS. 2014 Feb 16.

16. Joint United Nations Programme on HIV/AIDS (UNAIDS). Fact sheet, People living with HIV, HIV, antiretroviral therapy, new HIV infections, AIDS, tuberculosis, facts. Fact Sheet. 2016 [cited 2017 Mar 21];(June):1–8.

17. Braitstein P, Brinkhof MW, Dabis F, Schechter M, Boulle A, Miotti P, Wood R, Laurent C, Sprinz E, Seyler C, Bangsberg DR. Mortality of HIV-1-infected patients in the first year of antiretroviral therapy: comparison between low-income and high-income countries. Lancet (London, England). 2006 Mar;367(9513):817-24.

18. Eshleman SH, Wilson EA, Zhang XC, Ou SS, Piwowar-Manning E, Eron JJ, McCauley M, Gamble T, Gallant JE, Hosseinipour MC, Kumarasamy N. Virologic outcomes in early antiretroviral treatment: HPTN 052. HIV clinical trials. 2017 May 4;18(3):100-9.

19. McMahon JH, Elliott JH, Bertagnolio S, Kubiak R, Jordan MR. Viral suppression after 12 months of antiretroviral therapy in low-and middle-income countries: a systematic review. Bulletin of the World Health Organization. 2013;91:377-85.

20. Ntamatungiro AJ, Muri L, Glass TR, Erb S, Battegay M, Furrer H, Hatz C, Tanner M, Felger I, Klimkait T, Letang E. Strengthening HIV therapy and care in rural Tanzania affects rates of viral suppression. Journal of antimicrobial chemotherapy. 2017 Apr 6;72(7):2069-74.

21. Johannessen A, Naman E, Kivuyo SL, Kasubi MJ, Holberg-Petersen M, Matee MI, Gundersen SG, Bruun JN. Virological efficacy and emergence of drug resistance in adults on antiretroviral treatment in rural Tanzania. BMC infectious diseases. 2009 Dec;9(1):108.

22. Johannessen A, Naman E, Ngowi BJ, Sandvik L, Matee MI, Aglen HE, Gundersen SG, Bruun JN. Predictors of mortality in HIV-infected patients starting antiretroviral therapy in a rural hospital in Tanzania. BMC infectious diseases. 2008 Dec;8(1):52.

23. Hawkins C, Ulenga N, Liu E, Aboud S, Mugusi F, Chalamilla G, Sando D, Aris E, Carpenter D, Fawzi W. HIV virological failure and drug resistance in a cohort of Tanzanian HIV-infected adults. Journal of Antimicrobial Chemotherapy. 2016 Apr 13;71(7):1966-74.

24. Barth RE, van der Loeff MF, Schuurman R, Hoepelman AI, Wensing AM. Virological follow-up of adult patients in antiretroviral treatment programmes in sub-Saharan Africa: a systematic review. The Lancet infectious diseases. 2010 Mar 1;10(3):155-66.

25. Joint United Nations Programme on HIV/AIDS (UNAIDS). How AIDS Changed Everything. J Chem Inf Model [Internet]. 2015;53(9):1689–99.

26. Djomand G, Roels T, Ellerbrock T, Hanson D, Diomande F, Monga B, Maurice C, Nkengasong J, Konan-Koko R, Kadio A, Wiktor S. Virologic and immunologic outcomes and programmatic challenges of an antiretroviral treatment pilot project in Abidjan, Cote d'Ivoire. Aids. 2003 Jul 1;17:S5-15.

27. Ugbena R, Aberle-Grasse J, Diallo K, Bassey O, Jelpe T, Rottinghaus E, Azeez A, Akpan R, Muhammad M, Shanmugam V, Singh S. Virological response and HIV drug resistance 12 months after antiretroviral therapy initiation at 2 clinics in Nigeria. Clinical infectious diseases. 2012 May 15;54(suppl_4):S375-80.

28. Avert. Global HIV and AIDS Statistics [Internet]. www.avert.org. 2017. Available from: https://www.avert.org/global-hiv-and-aids-statistics.

29. Ndahimana JD, Riedel DJ, Mwumvaneza M, Sebuhoro D, Uwimbabazi JC, Kubwimana M, Mugabo J, Mulindabigwi A, Kirk C, Kanters S, Forrest JI. Drug resistance mutations after the first 12 months on antiretroviral therapy and determinants of virological failure in Rwanda. Tropical Medicine & International Health. 2016 Jul 1;21(7):928-35.

30. United Republic of Tanzania, Ministry of Health, Community Development, Gender, Elderly and Children. Tanzania HIV Impact Survey (THIS). Dar Es Salaam, Tanzania; 2017.

31. United Republic of Tanzania, Ministry of Health, Community Development, Gender, Elderly and Children. National guidelines for the management of HIV and AIDS, 6th Ed.National AIDS Control Program (NACP) 2017.

32. Mugusi F, Mugusi S, Bakari M, Hejdemann B, Josiah R, Janabi M, Aboud S, Aris E, Swai H, Mhalu F, Biberfeld G. Enhancing adherence to antiretroviral therapy at the HIV clinic in resource constrained countries; the Tanzanian experience. Tropical Medicine & International Health. 2009 Oct 1;14(10):1226-32.

33. Braun A, Sekaggya-Wiltshire C, Scherrer AU, Magambo B, Kambugu A, Fehr J, Castelnuovo B. Early virological failure and HIV drug resistance in Ugandan adults co-infected with tuberculosis. AIDS research and therapy. 2017 Dec;14(1):1.

34. Bello EJ, Correia AF, Marins JR, Merchan-Hamann E, Kanzaki LI. Predictors of virologic failure in HIV/AIDS patients treated with highly active antiretroviral therapy in Brasília, Brazil during 2002–2008. Drug target insights. 2011 Jan;5:DTI-S7527.

35. Geldsetzer P, Ortblad K, Bärnighausen T. The efficiency of chronic disease care in sub-Saharan Africa. BMC medicine. 2016 Dec;14(1):127.

36. Engelhard EA, Smit C, Nieuwkerk PT, Reiss P, Kroon FP, Brinkman K, Geerlings SE. Structure and quality of outpatient care for people living with an HIV infection. AIDS care. 2016 Aug 2;28(8):1062-72.

37. Mosha F, Muchunguzi V, Matee M, Sangeda RZ, Vercauteren J, Nsubuga P, Lyamuya E, Vandamme AM. Gender differences in HIV disease progression and treatment outcomes among HIV patients one year after starting antiretroviral treatment (ART) in Dar es Salaam, Tanzania. BMC public health. 2013 Dec;13(1):38.

38. Ramadhani HO, Thielman NM, Landman KZ, Ndosi EM, Gao F, Kirchherr JL, Shah R, Shao HJ, Morpeth SC, McNeill JD, Shao JF. Predictors of incomplete adherence, virologic failure, and antiviral drug resistance among HIV-infected adults receiving antiretroviral therapy in Tanzania. Clinical infectious diseases. 2007 Dec 1;45(11):1492-8.

39. United Republic of Tanzania. National Bureau of Statistics, Statistics for Development. 2012. Available from: http://www.nbs.go.tz/nbs/takwimu/references/Tanzania_in_figures2012.pdf

40. Fox MP. Retention of adult patients on antiretroviral therapy in low-and middle-income countries: systematic review and meta-analysis 2008–2013. Journal of acquired immune deficiency syndromes (1999). 2015 May 1;69(1):98.

41. Mosha F, Ledwaba J, Ndugulile F, Nsubuga P, Morris L, Kasubi M, Swai A, Vercauteren J, Vandamme AM. Clinical and virological response to antiretroviral drugs among HIV patients on first-line treatment in Dar-es-Salaam, Tanzania. The Journal of Infection in Developing Countries. 2014 Jul 14;8(07):845-52.

42. Mutabazi JC, Zarowsky C, Trottier H. The impact of programs for prevention of mother-to-child transmission of HIV on health care services and systems in sub-Saharan Africa-A review. Public Health Reviews. 2017 Dec;38(1):28.

43. Wang Y, Hunt K, Nazareth I, Freemantle N, Petersen I. Do men consult less than women? An analysis of routinely collected UK general practice data. BMJ open. 2013 Aug 1;3(8):e003320.

44. Koethe JR, Jenkins CA, Shepherd BE, Stinnette SE, Sterling TR. An optimal body mass index range associated with improved immune reconstitution among HIV-infected adults initiating antiretroviral therapy. Clinical infectious diseases. 2011 Nov 1;53(9):952-60.

45. Amoah AG. Sociodemographic variations in obesity among Ghanaian adults. Public health nutrition. 2003 Dec;6(8):751-7.

46. Stevens WS, Marshall TM. Challenges in implenting HIV load testing in South Africa. Journal of Infectious Diseases. 2010 Apr 15;201(Suppl_1):S78-84.

47. Roberts T, Cohn J, Bonner K, Hargreaves S. Scale-up of routine viral load testing in resource-poor settings: current and future implementation challenges. Clinical Infectious Diseases. 2016 Jan 6;62(8):1043-8.

48. Layer EH, Kennedy CE, Beckham SW, Mbwambo JK, Likindikoki S, Davis WW, Kerrigan DL, Brahmbhatt H, LTC Tanzania Collaborative Study Team. Multi-level factors affecting entry into and engagement in the HIV continuum of care in Iringa, Tanzania. PLoS One. 2014 Aug 13;9(8):e104961.

49. Ameyan W, Kamara H, Sesay J, Sheriff M, Dumbuya K, Timbo M, Conteh S, Guillard E. A Participatory Approach to Improving Retention in HIV Treatment and Care for Newly Diagnosed Patients in a Secondary Health Facility in Sierra Leone. J AIDS Clin Res. 2017;8(686):2.

50. World Health Organisation. Sustainable Development Goals - United Nations Sustainable Development,2016. Available from: http://www.who.int/topics/sustainable-development-goals/en/.

51. Rachlis B, Ochieng D, Geng E, Rotich E, Ochieng V, Maritim B, Ndege S, Naanyu V, Martin J, Keter A, Ayuo P. Evaluating outcomes of patients lost to follow-up in a large comprehensive care treatment program in western Kenya. Journal of acquired immune deficiency syndromes (1999). 2015 Apr 1;68(4):e46.

52. Geng EH, Nash D, Kambugu A, Zhang Y, Braitstein P, Christopoulos KA, Muyindike W, Bwana MB, Yiannoutsos CT, Petersen ML, Martin JN. Retention in care among HIV-infected patients in resource-limited settings: emerging insights and new directions. Current HIV/AIDS Reports. 2010 Nov 1;7(4):234-44.

53. Nagu TJ, Bakari M, Matee M. Hepatitis A, B and C viral co-infections among HIV-infected adults presenting for care and treatment at Muhimbili National Hospital in Dar es Salaam, Tanzania. BMC Public Health. 2008 Dec;8(1):416.

APPENDICES

QUESTIONNAIRE

1. Questionnaire number ……..
2. Date of interview ……..(DD/MM/YYYY)
3. Name of interviewer ……..

Section A: Patient particulars

4. CTC card number …….…….
5. Date of birth …….. (DD/MM/YYYY)
6. Date of initiation of ART …….. (DD/MM/YYYY)
7. Date last visited CTC …….. (DD/MM/YYYY)
8. Reason for not attending if not attended for more than 3 months
    i. Death (Date of death on question 10)
    ii. Transfer to another clinic within Dar es salaam
    iii. Transfer to another clinic out of Dar es Salaam
    iv. Transfer to unknown clinic
    v. Loss to follow up
    vi. Unknown reason
9. If dead provide date of death …….. (DD/MM/YYYY)
10. If transferred provide date of transfer …… (DD/MM/YYYY)
11. How many total number of clinic visits has the patients made in the last 12 months? ……..
12. How many unscheduled clinic visits has the patients made in the last 12 months?…….
13. Gender
    i. Male
    ii. Female

14. Age ……..(years)

15. Education level

i. Incomplete primary
ii. Complete primary
iii. Incomplete secondary
iv. Complete secondary
v. College or university

16. Residence (district) ……..

17. Residence (ward) ……..

18. Occupation

i. Employed
ii. Self employed
iii. Student
iv. Housewife
v. Casual labour
vi. Others

19. Current antiretroviral therapy

i. TDF/3TC/EFV
ii. TDF/FTC/EFV
iii. TDF/FTC/NVP
iv. AZT/3TC/EFV
v. AZT/3TC/NVP
vi. ATV/r/TDF/FTC
vii. LPV/r/TDF/FTC
viii. ATV/r/AZT/3TC
ix. LPV/r/AZT/3TC
x. ATV/r/ABC/3TC
xi. LPV/r/ABC/3TC

20. Date of last clinic attendance …….. (DD/MM/YYYY)

21. Initial Status at ART initiation

i. Weight
ii. Height
iii. CD4+ count
iv. WHO stage
v. Prior ARV exposure
   a) None
   b) Prior therapy
   c) PMTCT monotherapy
   d) PMTCT combination therapy
   e) PRE EXPOSURE PROPHYLAXIS (PEP)

22. Marital status

i. Single
ii. Married
iii. Divorced
iv. Widowed
v. Cohabiting

23. Economic status

i. Income per month
ii. Number of meals per month
iii. Expenditure on food per day
iv. How many people eat from the same pot? …….

Section B: Anthropometric measurements

Parameter		Baseline	6 Months of using ART	Current
24.	Weight (Kg)			
25.	Height (Cm)			

Visit no	Visit date	Visit type Scheduled or unscheduled	WHO stage	Cd4	Pregnancy	TB screening	IPT	ARV status	ARV regimen	Reason for change of ARV	Prophylaxis for OI	Adherence	Referred to/ disposal	Hb	Viral load
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
15															

Section C: Clinical Information

26. Single tablet regimen
    i. Yes
    ii. No

27. Other people living in your house hold
    i. Yes
    ii. No

28. Do you have a regular sexual partner?
    i. Yes
    ii. No

29. If YES, What is the HIV status of a regular spouse sexual partner
    i. Negative
    ii. Positive
    iii. Unknown
    iv. Refuse to answer

30. Number of sexual partners in the past 3 months
    i. < 2
    ii. ≥ 2

31. Unprotected intercourse on the last sexual act
    i. Yes
    ii. No

32. Participationin different sexual practices
    i. Vaginal
    ii. Oral
    iii. Anal intercourse

33. Paying or being paid for sex
    i. Yes
    ii. No

34. Alcohol use in the last 30 days
    i. Yes
    ii. No

35. Binge alcohol use in the last 30 days
    i. Yes
    ii. No

36. Ever used illicit drugs
    iii. Yes
    iv. No

37. Did you get any episode of diarrhea illness in the last 12 months
    i. Yes
    ii. No

38. If your answer to question 38 above was yes, can you recall the frequency diarrhea episodes
    i. Almost every day of the week
    ii. Some days of every week
    iii. Less than 14 days every month
    iv. More than 14 months every month

39. Did you get any episode of diarrhoea illness in the last 30 days
    i. Yes
    ii. No

40. If YES,how many diarrhea episodes did you suffer?

    ……..

41. Did you get any episode of diarrhoea illness in the last 7 days

i. Yes

ii. No

42. If YES in question 42, how many episodes?

……..

43. Ever being admitted in the hospital during the last 12 months?

i. Yes

ii. No

44. If YES, What was the cause of admission?

……..

45. Do you have history of any of the following disease/infections in the past 12 months (Yes or No)

iii. Meningitis ☐

iv. Oral candidiasis ☐

v. Pneumonia ☐

vi. Tuberculosis ☐

vii. Kaposi's sarcoma ☐

viii. Anemia ☐

ix. Cancer (mention part affected) _____

x. Other (mention) _____

46. Have you disclosed your HIV status?

i. Yes

ii. No

47. If YES, To whom have you disclosed your HIV status
    i. Spouse
    ii. Trusted friend not spouse
    iii. Mother
    iv. Father
    v. Sibling
    vi. Other (mention) _____

48. I have been treated differently since I disclosed my HIV status to friends and family (discrimination)
    i. Strongly agree
    ii. Agree
    iii. Indifferent
    iv. Disagree
    v. Strongly disagree

49. There are people I have not told that I am HIV positive out of fear of negative consequences patients managed in higher-level clinical (non-disclosure)
    i. Strongly agree
    ii. Agree
    iii. Indifferent
    iv. Disagree
    v. Strongly disagree

50. If I were sick and needed someone to lacking international donor support. However, take me to a doctor, I would have we feel the findings are robust as the vast trouble finding someone (lack of social support)
    i. Completely true
    ii. Somewhat true
    iii. Somewhat false
    iv. Completely false

51. I feel a strong emotional bond with at least one other person (emotional support)
    i. Strongly agree
    ii. Agree
    iii. Indifferent
    iv. Disagree
    v. Strongly disagree

52. I feel that there is no one I can share my most private concerns and fears with (social isolation)
    i. Strongly agree
    ii. Agree
    iii. Indifferent
    iv. Disagree
    v. Strongly disagree

53. There are people I have not told that I am HIV positive out of fear of negative consequences (non-disclosure)
    i. Strongly agree
    ii. Agree
    iii. Indifferent
    iv. Disagree
    v. Strongly disagree

54. How many doses of medication did you miss in the past 7 days

    _____

55. How many doses of medication did you miss in the past 30 days

    _____

INFORMED CONSENT

HIV viral suppression among adults on antiretroviral therapy at Temeke Regional Referral Hospital Care and Treatment Clinic, Dar Es Salaam, Tanzania

Greetings

My name is Dr. Erhad Bilaro, a resident in the internal medicine department at MUHAS, I amconducting a research to assess the magnitude of HIV viral suppression and its associated factors among HIV patients who have been on antiretroviral therapy for a period of twelve months.

What is the purpose of the study?

The study aims at determining HIV patients who have suppressed viral load after twelve months of using antiretroviral therapy. This will help to design strategies to help achieving viral suppression.

Who are the participants?

All HIV patients who have been on antiretroviral therapy treatment for twelve monthsare invited to take part in this study

Confidentiality

Personal information collected during this research will be revealed only to the patient and the attending doctor

Voluntary participation and withdrawal

Participation into this study is strictly voluntary and you will be needed to sign this form if you agree to participate in the studyyou have the right to withdrawal from the study at any time and this will not affect in anyway your right to care

Refusal to participate will in no way affect your treatment at this hospital

What is the recorded information?

Participants will conduct an interview on demographic information, physical examination, current comorbidities and a blood sample will be taken. Participants with high viral load will be treated as per hospital standard of care

For further contact

Dr. Erhad Bilaro 0768283494, Principal investigator
Dr. TumainiNagu
Lecturer and supervisor, MUHAS

For further clarification on your rights as a study participant, please contact:

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IRB chairperson,
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P. O. Box 65001, Dar es Salaam.
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I …… have read/been told of the contents of this form and understood its meaning. I agree to participate in this study.

Signature…… (Participant) Date…….