Rate and predictors of first line antiretroviral treatment failure among adults living with HIV/aids in Dar es salaam, Tanzania

Florence George

ABSTRACT

Background: HIV/AIDS is a major public health problem in Tanzania, where 1.4 million people are living with HIV in 2017. Of these 66%, are on ART and 48% are virally suppressed. In order to respond to the HIV epidemic, UNAIDS set a 90 90 90 global target. In Tanzania, several studies have been done prior availability and implementation of routine viral load testing. Therefore, this study shall be the first to assess the treatment failure since the initiation of the routine viral testing and implementation of the **test and treat** policy.

Objectives: To determine the rate and predictors of first line antiretroviral treatment failure among adults living with HIV/AIDS in Dar es salaam, Tanzania.

Methods: A retrospective cohort study including all clients on first line antiretroviral therapy for at least six months aged 18 years and above was conducted in all five municipals in Dar as Salaam in 2019. Using probability proportional to size (PPS) sampling methods, eligible clients from high volume CTC clinics were recruited. Kaplan-**M**eier curve and Log -Rank test was used to assess the median time to failure. Bivariate

and multivariate Cox-regression modelling were used to determine predictors of treatment failure.

Results: A total of 340 participants with a median age was 37years were recruited and two third of them (67.9%) were female. The overall treatment failure rate was 5.24 (95% CI =3.72-7.27) per 100 person years at risk with a **median time to failure** of 18 months. Independent predictors of treatment failure were being on treatment for less than two years (**Adjusted Hazard Ratio**=12.48, 95%CI 3.64-42.71), being male (AHR=2.78,95%CI 1.16-6.63) and self-employed (AHR=5.58, 95%CI 1.43-21.82).

Conclusion and Recommendation: The rate of treatment failure was unacceptably high in this population and occurs early during the treatment. Self-employed male clients who have been on treatment for less than 2 years were at higher risk of failure to continue with fist line treatment.CTC should provide special counseling and follow up mechanism for self-employed male including reinforced routine viral load monitoring and this should be intensified very early on during treatment initiation.

MD

MSc (Applied Epidemiology) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2019

Muhimbili University of Health and Allied Sciences

Department of Epidemiology and Biostatistics

RATE AND PREDICTORS OF FIRST LINE ANTIRETROVIRAL TREATMENT FAILURE AMONG ADULTS LIVING WITH HIV/AIDS IN DAR ES SALAAM, TANZANIA

By

Florence George Samizi

A Dissertation Submitted in (Partial) Fulfilment of the Requirements for the Degree of Master of Science (Applied Epidemiology) of

Muhimbili University of Health and Allied Sciences
October, 2019

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled: **"Rate and predictors of first line antiretroviral treatment failure among adults living with HIV/AIDS in Dar es salaam Region, Tanzania'',** in (partial) fulfillment of the requirement for the degree of Master of Science (Applied Epidemiology) of the Muhimbili University of Health and Allied Sciences.

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Prof. Elia John Mmbaga

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Date

DECLARATION AND COPYRIGHT

I, **Florence George Samizi**, hereby declare that this **dissertation** is my original work and that has not been presented and will not be presented to any other university for similar or any other degree award.

Signature……. **Date**…….

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ACKNOWLEDGEMENT

I would like to convey my sincere appreciation for the commitment, encouragement support and constructive contribution of the following

My supervisor Prof. Elia John Mmbaga for his supervision, motivation, and encouragements he gave me during the whole process from proposal preparation, data collection, data analysis and report writing.

Ms. Senga Sembuche Malugu for her supervision, guidance and support she gave me in the completion of my dissertation and throughout my journey as a TFELTP resident.

TFELTP and MOHCDGEC; under the MOHCDGEC, for fully funding my dissertation

MoHSW-NACP staff; for all the support in the development of the proposal and provision of necessary literature for referencing.

TFELTP staffs and Fellow residents; for their technical support in various areas during the whole process of preparing my dissertation.

Dar es Salaam Regional administrative officer, Regional medical officer and District Executive Directors (DED), District Medical officers for Dar es salaam municipals for granting me the permission to conduct the research in their respective councils

Medical officers incharge for Temeke Hospital, Mbagala Health center, Tandale HC, Vingunguti HC, Makurumla HC, Buguruni Hospital, Sinza HC, Magomeni, Vijibweni Hospital for their cooperation and for granting me permission to collect data in their respective health facilities.

MDH project Regional manager and his team for their cooperation and for granting me permission to use the site Data quality officers to collect data in Dar es salaam region.

Research Assistants for their cooperation and tireless efforts in collecting the study data which is the backbone of the whole research project.

Study participants for their willingness and participation in the study.

Special thanks to my support system, my family and friends for their understanding, support, and endless prayers that led to the successful completion of this dissertation.

Finally, I would like to thank the Almighty for granting me good health and strength to complete my MSc course.

DEDICATION

I would like to dedicate this dissertation to my husband, who instilled in me the virtues of perseverance and commitment and relentlessly encouraged me to strive for excellence.

ABSTRACT

Background: HIV/AIDS is a major public health problem in Tanzania, where 1.4 million people are living with HIV in 2017. Of these 66%, are on ART and 48% are virally suppressed. In order to respond to the HIV epidemic, UNAIDS set a 90 90 90 global target. In Tanzania, several studies have been done prior availability and implementation of routine viral load testing. Therefore, this study shall be the first to assess the treatment failure since the initiation of the routine viral testing and implementation of the **test and treat** policy.

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Results: A total of 340 participants with a median age was 37years were recruited and two third of them (67.9%) were female. The overall treatment failure rate was 5.24 (95% CI =3.72-7.27) per 100 person years at risk with a **median time to failure** of 18 months. Independent predictors of treatment failure were being on treatment for less than two years (**Adjusted Hazard Ratio**=12.48, 95%CI 3.64-42.71), being male (AHR=2.78,95%CI 1.16-6.63) and self-employed (AHR=5.58, 95%CI 1.43-21.82).

Conclusion and Recommendation: The rate of treatment failure was unacceptably high in this population and occurs early during the treatment. Self-employed male clients who have been on treatment for less than 2 years were at higher risk of failure to continue with fist line treatment.CTC should provide special counseling and follow up mechanism for self-employed male including reinforced routine viral load monitoring and this should be intensified very early on during treatment initiation.

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LIST OF ABBREVIATION

AHR	Adjusted Hazard Ratio
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CDC	Centre for Disease Control and Prevention
CTC	Care and Treatment Clinic
DACC	District AIDS Control Coordinator
DBS	Dried blood spot
DMO	District Medical Officer District
DRCHCo	District and Child Health Coordinator
DTLC	District Tuberculosis and Leprosy Coordinator
HIV	Human Immunodeficiency Virus
HIVDR	Human Immunodeficiency Virus Drug Resistance
HMIS	Health Management Information System
MC	Municipal council
M&E	Monitoring and Evaluation
MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MTCT	Mother to Child Transmission
NACP	National AIDS Control Program
NHL-	National Health Laboratory for Quality Assurance and Training Centre

NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside/Nucleotide Reverse Transcriptase Inhibitor
PCR	Polymerase Chain Reaction
PLHIV	People Living with HIV
RMO	Reginal Medical Officer
RNA	Ribonucleic acid
RRCHCo	Regional Reproductive and Child Health Coordinator
RTLC	Regional Tuberculosis and Leprosy Coordinators
TACAIDS	Tanzania Commission for AIDS
TB	Tuberculosis
THIS	Tanzania HIV Impact Survey
THMI	Tanzania HIV and Malaria Indicator Survey
UNAI	Joint United Nations Program on HIV/AIDS
VF	Viral Failure
WHO	World Health Organization

DEFINITION OF TERMS

First line Regime: Non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors.

High volume sites: Facilities with more than 500 clients on antiretroviral therapy.

Treatment failure: Two conservative high viral load results >1000cp/ml with adherence support, after being on treatment for at least six months.

Viral load suppressed: Viral load <1000 cp /ml after six months of ART initiation

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Human immunodeficiency viruses (HIV) remains a public health problem worldwide. In 2017, approximately36.9million people were living with HIV worldwide and less than one (1) million people died due to AIDS related conditions. In the same year Eastern and southern Africa remains the region most affected by the HIV epidemic, accounting for 45% of the world's HIV infections and 53% of people living with HIV globally(1).An estimated 1.8 million people acquired HIV new infection globally in 2017, of these Sub-Saharan Africa account for 66% of the global HIV new infection(1).According to UNAIDS 2017, Tanzania had approximately 1.5 million people **who** were living with HIV, of these 32 thousands people die due to AIDS related complication and an estimated 65000 (4.3%) people contributed HIV new infection of these infection (1).

Since 2013 UNAIDS set 90-90-90 HIV Global targets in responding to HIV epidemic. This calls by 2020, 90% of all people living with HIV know their status,90% of those diagnosed as HIV-infected receive sustained antiretroviral therapy, and 90% of people receiving antiretroviral therapy **were** have viral suppression (2).Implementation of UNAIDS target, has attained significance level since launched in 2014. The number of people on antiviral treatment has been increasing worldwide from 19.4 million people since end of 2016 to 21.7 million people in 2017.Among 19.6 million people living with HIV in eastern and southern Africa at the end of 2017, 81% were aware of their HIV status, an increase from 77% in 2016 whereas about 12.9 (66%) million people in the region were accessing antiretroviral therapy and an estimated percentage of people living with HIV who achieved viral suppression increased from 48% in 2016 to 52% in 2017 (1). In 2017, Tanzania had reported, 52.2% known their HIV status,66% were on antiretroviral treatment and 48 were virally suppressed (1,3).

In order to attain global target, the Tanzanian government adopted the universal test and treat approach with the aim of reducing transmission and reducing the number of new HIV infections(4). In this new approach all PLHIV are eligible to start treatment regardless of their CD4 count or WHO staging so all PLHIV are supposed to start treatment.

In 2001, the united national general assembly (UNGASSA) on HIV/AIDS recommended that antiretroviral drugs should be made available in resources limited countries to address the disparity between rich and poor countries regarding access to antiretroviral (7). First line antiretroviral therapy in Tanzania are regimen that are less toxic and more convenient as fixed dose combination. Once daily regimens comprising a non -thymidine NRTI backbone and one NNRT are maintained as preferred choice in adults, adolescents and children older than three years. For children younger than three years, a Protease Inhibitor-based regimen is preferred (5).

There was a significant regional variation in the current number of clients receiving HIV care services. The Dares Salaam region has higher number110664clients on ART compared to other regions in Tanzania Mainland.

In 2013 WHO recommended use of consolidated guidelines on the use of antiretroviral drugs for treating HIV infected clients based on viral load testing as the preferred monitoring tool for diagnosing and confirming the failure of antiretroviral therapy. The guidelines recommend that, the viral loads of individuals receiving ART be measured every six months or three months after enhanced counselling (6).

The HIV Viral Load testing determines how many viral copies a patient has per milliliter of blood, a direct measure of HIV RNA replication. It is done using a Reverse Transcriptase Polymerase Chain Reaction (PCR) machine using whole blood, plasma, or Dried Blood Spot (DBS) samples. So HIV viral load tests is vital test in monitoring all HIV clients who are on ART for better earlier detection of virological failure to allow targeted adherence interventions and better preservation of the efficacy of second line regimens (7).

Viral load should be used to monitor ART, VL monitoring was conducted at 6 and 12 months after initiation of treatment, and yearly if the patient is virologically suppressed. All adults and adolescent with VL measurement of greater than 1000/ml copies should be managed as possible treatment failure(8). The recent survey conducted by National AIDS program and other stakeholders in Tanzania has shown significant variation of Viral load suppression prevalence across geographical region whereby Dar es Salaam region reported low prevalence rate (44.7%) of viral load suppression among aged 15 years and above.

1.2 Problem Statement

In 2013, World health Organization recommended use of Virological routine monitoring to measure antiretroviral treatment failure rather than immunological and clinical criterion. The study done in India by Anita and other co-workers has shown 10.7 rate of antiretroviral treatment failure per 100-person years, among adults' clients on first-line ART (9). Several studies conducted in African Countries including Uganda, South Africa and Tanzania, have reported 11%, 15%and 14.9% respectively, rate of treatment failure among adults' clients on first line ART(10–12).Recent surveys conducted in Tanzania had reported 55.3% unsuppressed viral load in Dar es salaam region. Despite having high number of people using ART compared to other regions (3).Hence, the study reported in Tanzania were done prior availability and implementation of routine viral load testing. Therefore, this is the first study to assess the treatment failure since the initiation of the routine viral testing and implementation of the test and treat policy.

1.3 Justification

This study is designed to assess treatment failure of first line users among adults in Dar es Salaam, Tanzania where scanty data are available. The results will help to identify risk group/factors for treatment failure among patient on first line ART and bring about the development of intervention to address the problem. The results will also help to inform timely management to prevent further damage to immune system, decreasing AIDS associated morbidity and mortality, allowing immune system to return normal, reduce the risk of HIV transmission to others and early decision to switch to second line regime.

1.4 Conceptual framework

The conceptual framework shows how various factors can interact and determine the level of viral load as a dependent variable. In this study, independent variables were medication adherence, which has direct linkage with dependent variable, other independent variable with indirect linkage, includes social demographic factors, nutritional factors, distance, WHO clinical stage, low CD4, regime and transportation. On socio demographic factors, studies have shown that younger age, being male, are less likely to suppress viral load and also education level, marital status, occupation, distance, TB co- infection, nutritional factors and place of residence may contribute to achieving of failing viral load suppression. On Behavioral factors, medication adherence and non-disclosure also may associate in failure to suppress viral load

Some of the independent variable interacts with each other such as social demographic factors i.e. age can interact with medication likewise adherence factors like type of drugs or pill burden and transportation factors like distance from home to health facility can have an interaction with medication adherence factors like dose frequency and missed appointments hence leading to treatment failure.

Some of the factors that may be associated with treatment failure have been portrayed in the problem tree diagram below in figure in figure 1

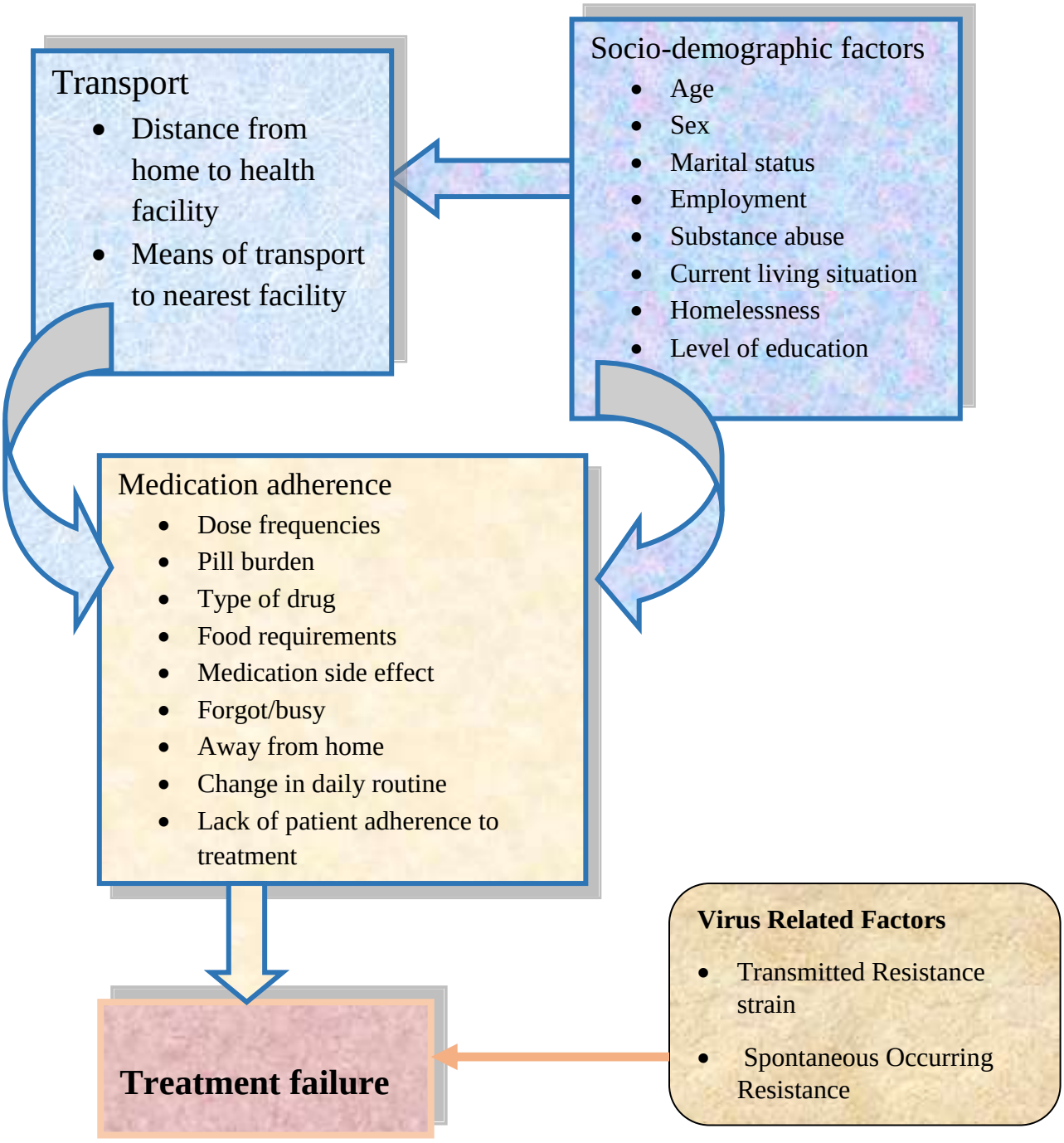

Figure 1: Conceptual framework illustrating factors associated with treatment failure among HIV clients on first line ART

1.5 Research Hypothesis

1.5.1 Null Hypothesis

1. The rate of first line ART failure among PLHIV is high in Dar es Salaam.
2. Treatment failure occurs early (within first year of treatment) among PLHIV on first line ART.

1.5.2 Research Questions

1. What is the rate of treatment failure among PLHIV on first line ART in Dar es salaam Region, Tanzania?
2. What is the median time to failure among PLHIV on first line ART in Dar es Salaam Region, Tanzania?
3. What are the predictors of treatment failure among PLHIV on first line ART in Dar es Salaam Region, Tanzania?

1.6 Research Objectives

1.6.1 Broad objective

To determine rate of, time to and predictors of treatment failure among adults living with HIV on first line Antiretroviral therapy in Dar es Salaam region, Tanzania.

1.6.2 Specific Objectives

1. To determine rate of treatment failure among adults living with HIV on first line antiretroviral therapy.
2. To determine median time to failure among adults living with HIV on antiretroviral therapy.
3. To determine predictors of treatment failure among adults living with HIV on first line antiretroviral therapy.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Rate and time for Treatment failure among adults' patients on first line ART

The rapid scale-up of antiretroviral therapy (ART) for human immunodeficiency virus (HIV) in resource-limited countries is an international priority (13). Several studies have shown high rates of antiretroviral treatment among individual on first-line ART. The previous study done in India among individual on first-line antiretroviral treatment reported 10.7 rate of antiretroviral failure per 100 person's year with the commutative incidence of 13.2% at 1 year and 16.5% over two years while Sivadasan et al. reported 39.6% incidence of treatment failure for individual on first line antiretroviral therapy (9,14).In China the study has reported 28% of antiretroviral failure among adult's clients on ART. Also the definite virological failure found in 10%,14% and 18% for participant receiving ART for 6-12 months, 12-23 months and above 24 months respectively (15). Another study conducted in Gabon has found that 41.3% rate of antiretroviral therapy among adults clients on first line antiretroviral therapy while (16). According to UNAIDS 2017, Eastern and Southern Africa has reported 48% of unsuppressed viral load among clients on ART whereas in Western and Central Africa about 69% of client on ART were not virally suppressed (1). In low- and middle-income countries including Africa antiretroviral failure rate have been reported for instance study done in South Africa demonstrated 4.5 rate of antiretroviral failure per 100 person years among clients on ART with cumulative incidence of 9.9% while Davey et al. recorded 15% of antiretroviral therapy among adults clients on first line treatment (11,17). Previous studies done in East Africa including Uganda has demonstrated 11% overall proportion of antiretroviral therapy among adults clients on use of first line antiretroviral treatment (10). Since 2016, Tanzania has implemented viral load as routine monitoring for antiretroviral treatment failure. The study conducted in Tanzania by Claudia et al recorded 14.9 rate of virological failure among adults on first line treatment (18).The recent survey conducted in Tanzania by National AIDS Control program and other stakeholders among age 15 to 64 years have found that 52% viral load suppression. However, viral load varies geographically across Tanzania, ranging from 66.0 percent in Kagera and 66.8percent in Kilimanjaro to 44.7percentage in Dar es Salaam

2.2 Predictor of treatment failure among adults' clients on first line treatment

Antiretroviral therapy has been shown to reduce HIV related morbidity and mortality among those living with HIV and reduced transmission of virus to those who are yet to be infected(19). However, this outcome maximum ART adherence and HIV programs around the back effort to ensure optimum adherence (20). The previous studies have demonstrated the predictors of virological treatment failure varied considerably across population and setting with respect to demographic, psychological, behavioral and economic factors. In China several studies have reported that being patients less than 40 were more significantly more likely to experience virological failure than those aged above 40 years, whereas other predictors including sex, educational level, place of residence, body mass index (BMI), co-infection with tuberculosis, low adherence, baseline CD4 counts and choice of NNRI were not associated to failure (9,14). Similarly, patients with advanced HIV infection were more likely to develop antiretroviral treatment failure compared with early stage of HIV infection (14). In china the research found that the high rates of antiretroviral failure seen in missing pills for in the last 7 days, among those with short treatment duration and being age less than 40 years and male were associated with antiretroviral treatment failure (15).The types of regime used like didadosine-based regime consistently demonstrated (15). However, other studies have shown regime containing (21,22)Zidovudine and Lamivudine were superior to those containing didanosine and stavudine. Several studies have been done in African Countries including Ethiopia, Gabon and South Africa have demonstrated that age at start ART, current age, TB status, gender, lack of social support, active drug alcohol use, serostatus disclosure, Low adherence, low duration on ART, CD4 baseline, pregnancy and prior ART exposure were predictors of antiretroviral first line treatment failure (11,16,23). A qualitative analysis data obtained from 51 people living with HIV (PLWH) identified 18 barriers affecting retention and ART adherence. The barriers were as follows eleven factors were common to both behaviors (mental illness, substance abuse, stigma, insurance, social support, housing, reminder strategies, competing life activities, symptoms, co-location of services and provider factors (24). Three were specific to retention (appointment scheduling, clinic experiences, transportation), and four were specific to adherence (pharmacy services, medication

characteristics, health beliefs, health literacy). Other studies focusing on underserved populations (women, low income) have identified similar factors affecting retention such as patient/provider relationships, social support, transportation, and stigma (25–27)**.** These findings indicate that multiple factors, ranging from the patient to the external environment can impact both retention and adherence. Easter African Countries including Uganda and Tanzania previous studies showed young age, poor adherence, having active tuberculosis, low CD4 counts, body mass index (BMI), hemoglobin, higher WHO clinical stage, low level of education, gender, stigma, inadequate referral system and poor access to treatment center and were associated with antiretroviral treatment failure among adults clients on first line treatment (10,12,18)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study area

The study was conducted in Dar es Salaam region. Dar es Salaam is one of the 26 Regions in Tanzania Mainland. Dar es Salaam is located on a massive natural harbor on the Eastern Indian Ocean coast of Africa. Situated close to the equator and the warm Indian Ocean, the city of Dar es Salaam experiences a tropical climate, typified by hot and humid weather throughout much of the year. Administratively the region has five (5) municipal. This include Ilala, Kinondoni, Temeke, Ubungo and Kigamboni. According to 2018, population projection the Dar Es Salaam region has an estimated 5.4 million people.

The region has a total of 116 care and treatment Center. Ilala, Temeke, Kinondoni, Ubungo and Kigamboni with 34, 25,25, 19 and 13 number of CTC sites respectively. Dar es Salaam was chosen because of its high HIV prevalence (4.7%) and low rate (44.7%) of viral load suppression.

The Regional Health Management Team RHMT is responsible for all health services in the region, including HIV/AIDS services which are coordinated by Regional AIDS Control Coordinator (RACC). The RACC is also responsible for monitoring and evaluation M&E function related to HIV and AIDS. The RACC works closely with Regional Reproductive and Child Health Services Coordinator (RRCHCo), the Regional Tuberculosis and Leprosy Coordinator RTLC and the Regional Health Management Information System HMIS focal person. The District AIDS Control Coordinator (DACC) works closely with the District Reproductive and Child Services Coordinator (DRCHCo), the District Tuberculosis and Leprosy Coordinator (DTLC) and the Council Health Management Information Systems (CHMIS) focal person. In lower level HIV Care and Treatment Clinic CTC Coordinator or the Home based care HBC coordinator, coordinates all the activities at facility level, and available staff provide any and all services at different times and location of the facility.

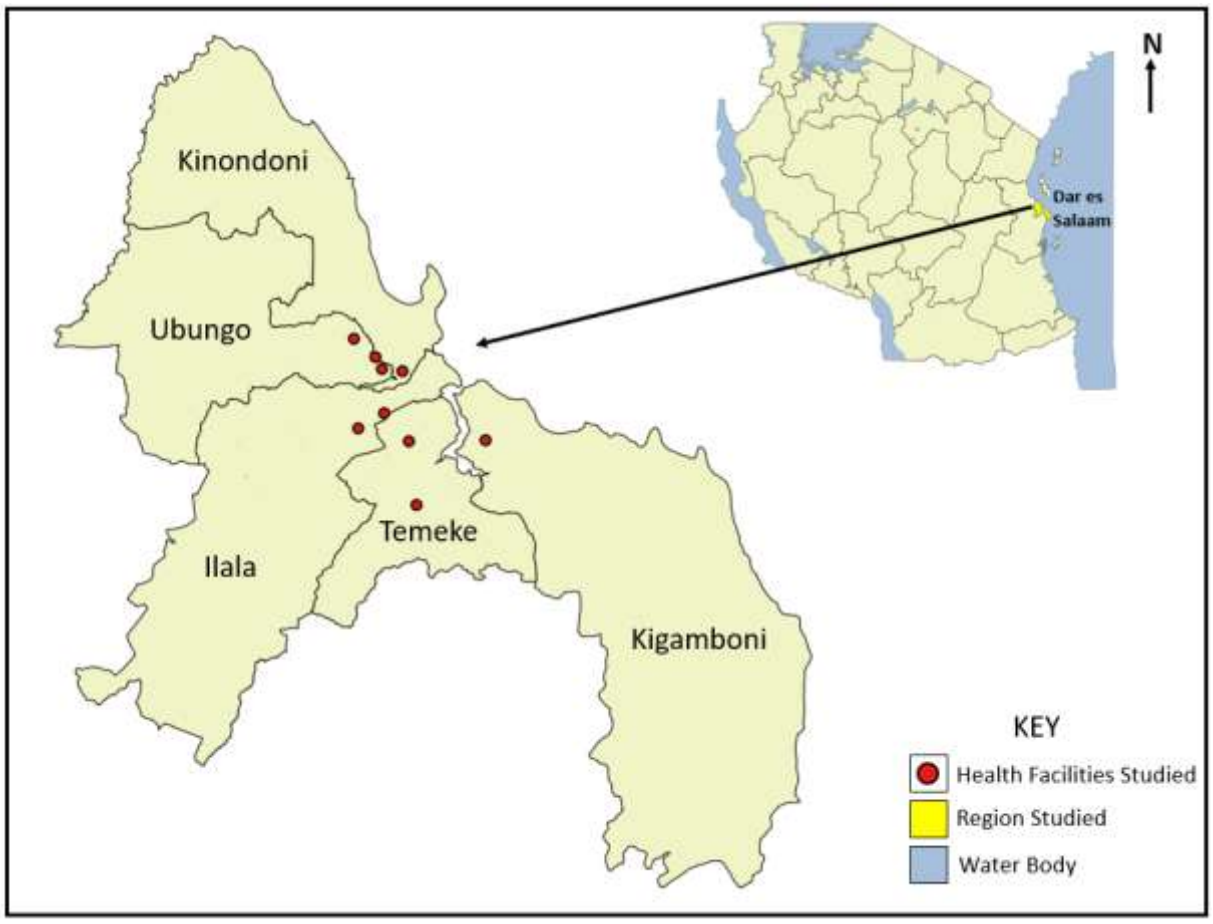

Figure 2: Map of Dar es Salaam showing the study sites.

3.2 Study design

A Retrospective cohort study was used where HIV infected individual on first line ART was recruited. The design addressed my research questions by giving an opportunity to calculate rates, estimate time to failure and analyze predictors of treatment failure. Baseline and follow up clinical laboratory data was collected from each study participant's medical records using checklist. In addition, socio demographic characteristics, clinical and laboratory data (viral load) were also collected from each study participants. A structured questionnaire was administered to participant to assess additional predictors of treatment failure.

3.3 Study population

All adults people living with HIV/AIDS who are on first line antiretroviral therapy (ART)for at least six months attending Care and Treatment Clinics in the region were eligible to participate. Currently the regions had a total of 110664 clients on ART. Of these 97.1% clients are on first line treatment.

3.4 Criteria for selection of study participants

3.4.1 Inclusion criteria

1. Aged between 15 and 64
2. Having viral load test results
3. Must have been recruited on ART for a least 6 months
4. Resident of Dar es Salaam region (having an address in the city and having lived in the city for the past 1 year
5. Provide consent for interview

3.4.2 Exclusion criteria

1. Too sick to be interviewed
2. Person with impaired speech

3.5 Sample size calculation

The outcome of interest for this study was treatment failure after initiation of ART. The study population included individuals who are already on ART for at least 6 months or more. It has been reported that patients might be on ART for up to 12 months and still have elevated viral load. In the African regions this is estimated to be over 25% of patients on ART (28). In many settings in Tanzania criterion for initiation of ART based on test and treat if you found HIV positive they initiate ART. Poor adherence secondary to pill burden of anti TB was selected exposure where proportion of patient with poor adherence due to TB infection having high viral load were 30% and those without TB infection with high viral load were 15% (29). Therefore, unexposed group was the clients with good adherence and exposed group was the clients with poor adherence.

3.6 Sample Size

The study sample size was estimated using the formula below described in Kelsey et. al. (28).

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

whereby;

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

$\bar{q} = 1-p$

And

$n_2 = rn_1$

Key:

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

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

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

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

r = ratio of unexposed to exposed = 1:1

p_1 = proportion of unexposed (good adherence) who developed treatment failure = 15 (ref. 29)

p_2 = proportion of exposed (poor adherence) who developed treatment failure = 30 (ref. 29)

$n_1 = \frac{(1.96+0.8)^2 \, (0.225 \times 0.775) \, (2)}{(0.3-0.15)^2 \times 0.7 \times 0.3 \times (1+1)} = 156$

$n_2 = 1 \times 156$

sample size=156x2 = 312

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

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

$\frac{312}{(1-0.1)} = 340$

The minimum sample size was estimated at 312 individuals. A non-response rate was approximated at 10% hence the sample size was adjusted to 340.Both exposed and non-exposed group.

Therefore, the required sample size was 340 participants.

3.7 Sampling technique

The sampling procedure was two stage sampling. The first stage was the selection of all five municipal councils in Dar es Salaam. The list of high-volume care and treatment center was obtained for each municipal. Ten (10) care and treatment Centre sites was selected randomly (two CTC for each municipal). The total clients for each selected CTC was obtained from CTC2 data base. The probability proportion to size was used to allocate the calculated sample size for each Care and Treatment Center. Then Simple random sampling was used to obtain study participants through computer generated random number. The data was extracted retrospectively from 2016 to 2018. All CTC 2 cards of the selected random numbers was identified, and data was extracted accordingly. There after all clients selected was traced and consented for the structured questionnaire interview. All clients who are on ART for at least six months with viral load result was having equal chance to be recruited for the study.

3.8 Variables

3.8.1 Dependent variable

Treatment failure. Two consecutive high viral load results >1000cp/ml with adherence support, after being on treatment for at least six months was the proxy of treatment failure

3.8.2 Independents variables

In this study independent variables were Socio-demographic characteristics such as age, sex, marital status, place of residence, duration of living, educational level, occupation, had history of travelled in the last three months, Behavioral factors such as the adherence and alcohol use. Health system factors such, privacy, health education on side effect of drugs and distance from the health facility, means of transport. etc. Clinical factors like number of viral load, WHO

clinical stage, number of CD4 count, co infection and regime used. Psychosocial factors like stigma, non –disclosure and social support.

3.9 Data collection tools

A data extraction tool was designed to extract data from CTC2 database to collect data on baseline investigations, clinical information, nutritional and follow up laboratory results (viral load and CD4). A standardized structured questionnaire was used to collect information about socio demographic data and other predictors of treatment failure from the HIV/AIDS clients who are on ART. The questionnaire was developed in English and it was translated by translator into Kiswahili and backward into English.

3.10 Recruitment and Training of Research Assistants

A total of 10 research assistants who are registered counselors working in selected health facilities conversant in HIV issues were recruited and trained for two days on research methodologies, data collection tools and interviewing techniques. Their role was retrospective review of routinely recorded data and administer of structured questionnaire All of them should be fluent in Swahili language as a data collection language.

3.11 Pretesting of the tools

Data collection tools were pretested in one health facilities point (that was not be included in the study) in selected District and then revised to ensure clarity before carrying out the study.

3.12 Data processing and analysis

Data were entered, cleaned and analyzed using EPI Info 7 software.

Categorical variables were summarized using frequency distributions while continuous variables were summarised using mean and standard deviation (SD) or median and interquartile range (IQR)

Survival analysis was employed in this analysis where Kaplan Meier method to estimate time to failure. Differences in failure time between different groups were examine using Log -Rank test. Cox-regression modelling was used to determine predictors of treatment failure.

All predictors with p-value ≤ 0.2 in bivariate level was entered Multivariable Cox- regression models to identify the independent predictors for treatment failure while controlling for potential confounders. The best parsimonious model was based on the lowest Akaike Information Criterion. All analysis was two-tailed, and significance level was set at 5%.

2.13 Ethical consideration

Ethical clearance for conducting this research was obtained from the Ethical Review Board of Muhimbili University of health and Allied Science. Permissions to conduct this study in Dar es Salaam region were obtained from the Regional Administrative Office, District Medical Officer and Health Facilities In-charges. Participant's names and Identifiers were not included in the data collections tools. Participant's names were not included in the data collection tool in order to maintain confidentiality, but CTC number was used to identify the participants and viral load information from their records. Written informed consent was obtained from all participants before enrollment to the study. Participants were assured that their participation in this study was voluntary and they are free to withdraw any time without any negative impact in their treatment at the clinic.

CHAPTER FOUR

4.0 RESULTS

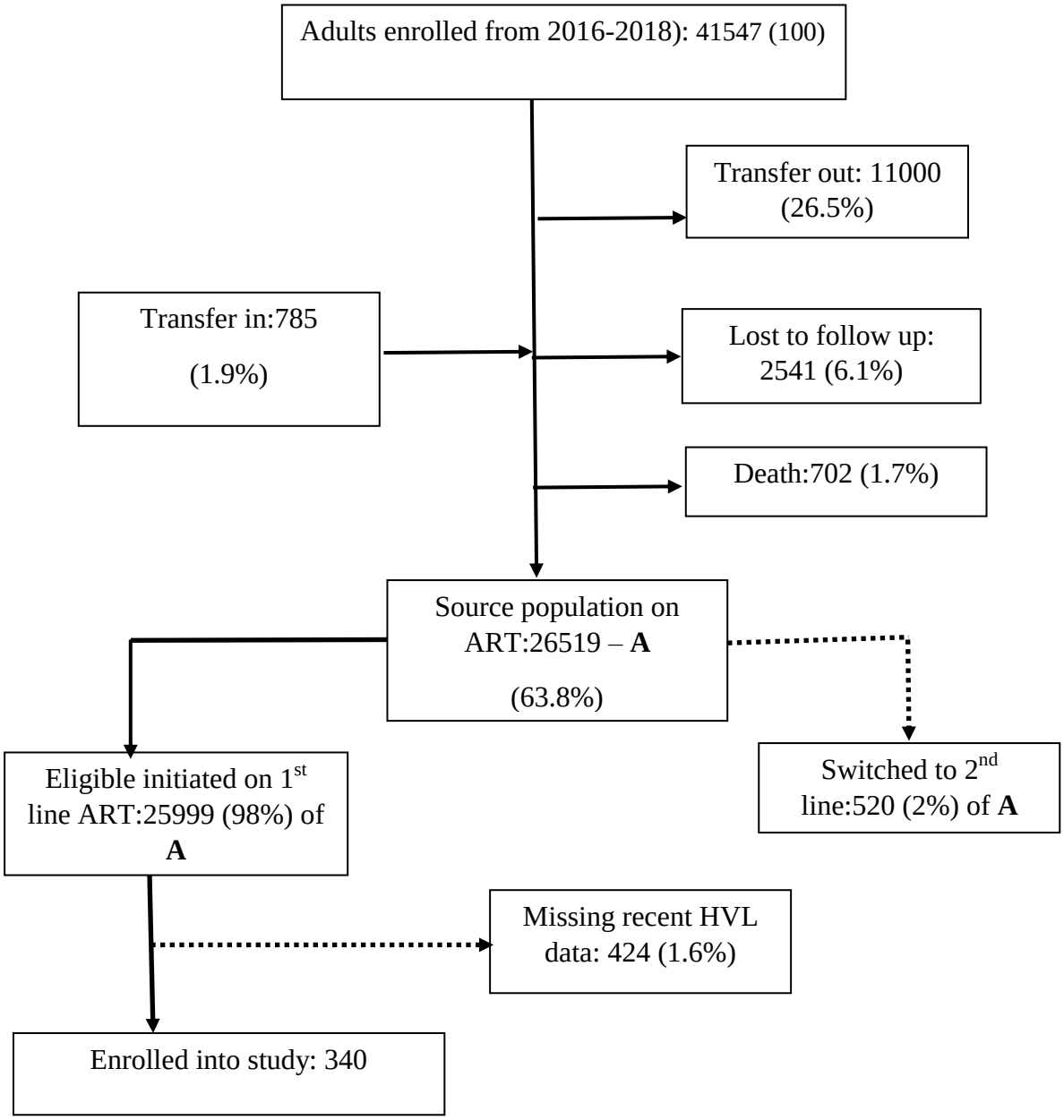

Figure 3: Flow Patterns of Study Participants

4.1 Socio-demographic characteristics of the study participants

A total of 340 eligible participants with mean age of 37 (Standard deviation 10) were enrolled into the study. Two third of the participants (67.9%, n=23) were female, (42.9%) were aged above 40 with half (52.1%) reporting to have not attended school. Moreover, half (50.0%) of the participants were married or cohabiting and 37% reported business to be their main occupation. Nearly two third (65%) were living within 5 km from the CTC (Tables 1).

Table 1: Socio-demographic factors of the study participants

Variables	Number	Percentage
Age (mean age= 37.0, SD= 10.0)		
18-24	34	10.0
25-30	59	17.4
31-39	101	29.7
Above 40	146	42.9
Sex		
Male	109	32.1
Female	231	67.9
Education		
None/Primary	192	56.5
Secondary/college/University	148	43.5
Marital status		
Married/cohabiting	170	50.0
Single	129	37.9
Widowed/ separated	41	12.1
Residence		
Kinondoni MC	99	29.1
Ubungo MC	73	21.5
Ilala MC	57	16.8
Temeke MC	86	25.3
Kigamboni MC	25	7.3
Occupation		
Employed	50	14.7
Unemployed	85	25.0
Business	129	37.9
Self employed	49	14.5
peasant	27	7.9
Distance to health facility (in km)		
<5	221	65.0
≥ 5km	119	35.0

4.2 Clinical characteristics of the study participants

About half of the participants 190(55.9%) were on ART for more than two years with mean treatment time of 2.3 years (SD 1 years). The median CD4 count was 351/ ml (IQR 285-1402) a total of 175 (51.5%) participants were in WHO clinical stage 3 and majority (96.5%) on TDF/3TC/EFV combination. TB co-infection rate in this population was 7.1%. Distribution of Clinical characteristics of study participants are presented in (Table 2).

Table 2: Distribution of Clinical characteristics of study participants

Variables	Number	Percentage
Years on ART		
0-2 years	150	44.1
More than two years	190	55.9
Initial CD4		
Less 350	136	49.8
350_{+}	137	50.2
WHO stage		
Stage 1	60	17.6
Stage 2	92	27.1
Stage 3	175	51.5
Stage 4	13	3.8
ART regime used		
TDF/3TC/EFV	328	96.5
AZT/3TC/NVP/EFV/DTG/ETC	12	3.5
TB co-infection		
Yes	24	7.1
No	316	92.9

4.3 Rate of treatment failure among adults living with HIV on first line antiretroviral therapy by socio-demographic, clinical and facility factors

The overall treatment failure among adults on first line ART was 5.24 (95% CI =3.72-7.27) per 100 personal years. The median failure time among participant on first line ART was 18 months (Figure 3) the treatment failure was higher among male, single, with less than 350 CD4 count and those who were on ART for less than 2years. Treatment failure was higher among those with poor adherence and TB co infection (Table 3).

Table 3: Rate of treatment failure among adults living with HIV on first line antiretroviral therapy by socio-demographic, clinical and facility characteristics

Variable	ART treatment failure			
	Follow up time (months)	Cases	Rate per100	95%CI
Age				
18-24	250.97	13	5.18	3.01-8.92
25-30	187.167	10	5.34	2.88-9.92
31-40	113.5	6	5.29	2.37-11.77
Above 40	134	7	5.19	2.48-10.89
Sex				
Male	230.733	14	6.06	3.59-10.24
Female	455.67	22	4.83	3.18-7.33
Education				
None/Primary	436.53	21	4.81	3.14-7.38
Secondary /College/ university	249.87	15	6.00	3.62-9.96
Marital status				
Married/cohabiting	226.2	11	4.86	2.69-8.78
Single	418.77	23	5.49	3.65-8.27
Widowed/ separated	41.43	2	4.82	1.21-19.30
Residence				
Kinondoni MC	60.1	3	4.94	1.59-15.32
Ubungo MC	163.13	9	5.52	2.87-10.60
Ilala MC	159.3	9	5.69	2.94-10.86
Temeke MC	233.1	11	4.72	2.61-8.86
Kigamboni MC	70.17	4	5.70	2.14-15.19

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Occupation				
Employed	51.3	3	5.85	1.87-18.13
Unemployed	194.27	10	5.15	2.77-9.57
Business	366.5	18	4.91	3.09-7.78
Self employed	59.23	4	6.75	2.53-17.99
Peasant	15.1	1	6.62	0.93-47.01
Means of transport				
Public	616.43	32	5.19	3.67-7.34
Private	21.5	1	4.65	0.65-33.02
Walking	48.47	3	6.19	1.90-19.19
Years on ART				
2 years	141.47	11	7.78	4.31-14.04
More than two years	544.933	25	4.59	3.09-6.79
Distance to health facility in km				
<5	395.2	22	5.57	3.67-8.45
≥5km	291.2	14	4.81	2.85-8.11
Adherence				
Good	41.33	2	4.84	1.21-19.35
Medium	244.17	12	4.92	2.79-8.65
Poor	400.9	22	5.49	3.61-8.33
Initial CD4				
Less 350	350.7	19	5.42	3.46-8.49
350_{+}	228.83	11	4.81	2.66-8.56
Do you take alcohol				
Yes	227.77	12	5.27	2.99-9.28
No	458.63	24	5.23	3.50-7.80
WHO stage				
Stage 1	93.33	5	5.36	2.23-12.87
Stage 2	28.33	2	7.06	1.7-28.22
Stage 3	513.87	27	5.25	3.60-7.66
Stage 4	50.87	2	3.93	0.98-15.72
TB co-infection				
Yes	168.53	11	6.53	3.61-11.79
No	517.87	25	4.83	3.26-7.14
ART regime used				
TDF/3TC/EFV	636.73	33	5.18	3.38-7.29
AZT/3TC/NVP/EFV/DTG/ETC	49.67	3	**6.04**	1.94-18.73

4.4 Median time to failure among clients on first line ART by number of years

Generally, majority of clients on first line antiretroviral treatment failed at median time of 18 months. The probability of antiretroviral treatment failure was higher among adult's clients on first line ART for less than two years compared to those who were on ART for more than two years (log rank test, p<0.0001) Figure 3.

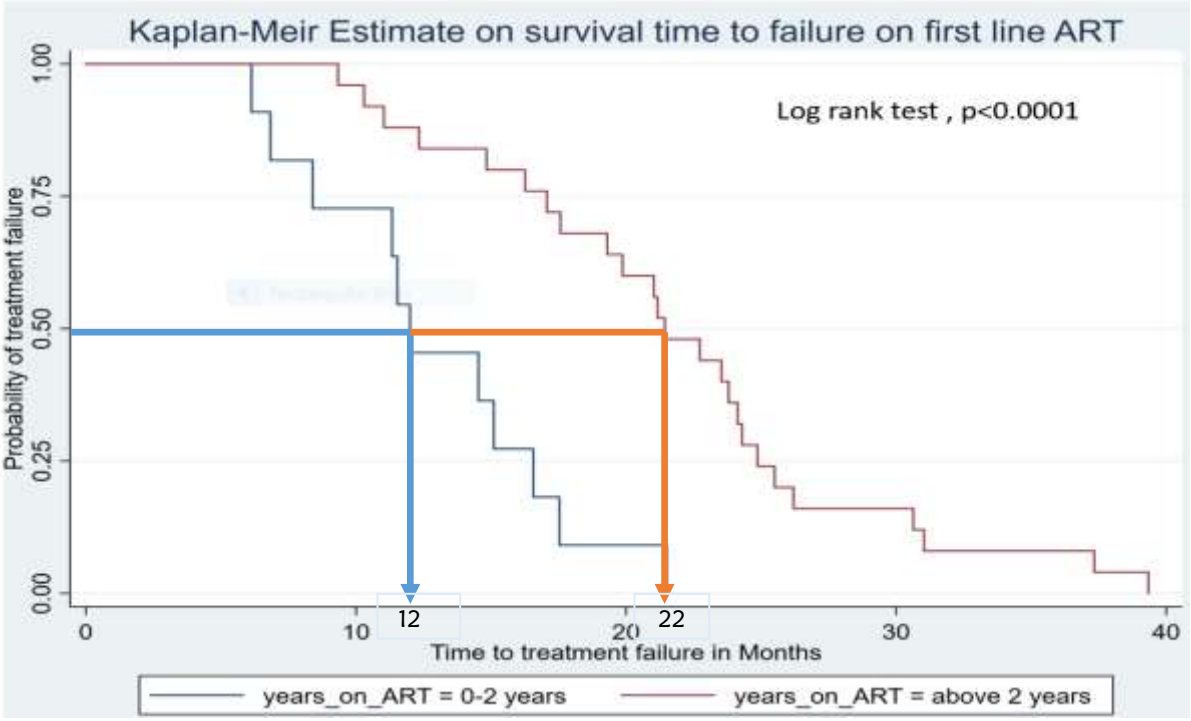

Figure 4: Median time to failure among adults living with HIV/AIDS on first line antiretroviral therapy by numbers of years on ART.

4.5 Predictors of first line ART treatment failure among adults living with HIV/AIDS

Bivariate analysis of predictors of first line ART treatment failure among adults living with HIV/AIDS is presented in (Table 4 &5). The incidence of developing treatment failure was 4.89 (HR=4.89, 95%CI=2.09-11.44) times higher among clients on ART for less than two years compared to those who were on ART for more than two years. Moreover, participants who had TB co-infection has two times higher risk (HR, 1.93, 95%CI: 0.92-4.06) of failure as compared to those who did not have the co-infection. However, this estimate had a borderline significance at 5% level.

Table 4: Cox regression of Predictors of first line ART treatment failure among adults living with HIV/AIDS by sociodemographic factors

Variable	Treatment failure		Crude Hazard Ratio	95%C1	p-value
	Follow up months	Cases			
Age group					
18-24	250.97	13	1.15	0.45-2.94	0.78
25-30	187.16	10	1.03	0.38-2.79	0.95
31-40	113.5	6	1.27	0.41-3.93	0.68
Above 40	134.76	7	Ref.		
Sex					
Male	230.73	14	1.77	0.88-3.59	0.11
Female	455.67	22	Ref.		
Education					
None/Primary	436.53	21	0.58	0.29-1.18	0.13
Secondary/college	249.87	15	Ref.		
Marital status					
Married/cohabiting	226.2	11	ref		
Single	418.77	23	1.33	0.63-2.82	0.45
Widowed/ separated	41.43	2	1.07	0.23-4.99	0.93
Residence					
Kinondoni MC	60.7	3	Ref.		
Ubungo MC	163.13	9	1.76	0.45-6.81	0.41
Ilala MC	159.3	9	1.95	0.51-7.51	0.33
Temeke MC	233.1	11	0.94	0.25-3.51	0.93
Kigamboni MC	70.17	4	1.72	0.37-8.03	0.49
Occupation					
Employed	51.3	3	1.69	0.45-6.33	0.43
Unemployed	194.26	10	Ref.		
Business	366.5	18	0.86	0.39-1.90	0.71
Self Employed	59.23	4	2.22	0.68-7.30	0.18
Peasant	15.1	1	2.61	0.31-21.73	0.37
Distance to health facility in km					
1-5	395.2	22	Ref.		
6 & above	291.2	14	0.76	0.38-1.49	0.4

Table 5: Cox regression of Predictors of first line ART treatment failure among adults living with HIV/AIDS by clinical/behavioral factors

Variable	Treatment failure		Crude Hazard Ratio	95%C1	p-value
	Follow up months	Cases			
WHO stage					
Stage 1	93.33	5	Ref		
Stage 2	128.33	2	1.50	0.29-0.78	0.62
Stage 3	513.87	27	0.82	0.31-2.17	0.69
Stage 4	50.87	2	0.21	0.02-1.92	0.17
ART regime used					
TDF/3TC/EFV	636.73	33	Ref.		
AZT/3TC/NVP/EFV/D TG/ETC	49.67	3	1.89	0.55-6.43	0.31
TB co-infection					
Yes	168.53	11	1.93	0.92-4.06	0.08
No	517.87	25	Ref.		
Initial CD4					
Less than 350	350.7	19	1.24	0.57-2.69	0.59
350+	228.833	11	Ref.		
Adherence					
Good	41.33	2	Ref.		
Medium	244.17	12	1.35	0.29-6.21	0.69
Poor	400.9	22	1.57	0.35-6.98	0.55
Years on ART					
0-2 years	141.47	11	4.89	2.09-11.44	<0.001
Above 2 years	544.93	25	Ref.		
Frequency of food per day					
Twice	29.63	2	2.79	0.61-12.61	0.18
Thrice/fourth/fifth	656.77	34	Ref.		
Means of transport					
Public	616.43	32	1.03	0.13-7.68	0.98
Private	21.5	1	Ref		
Walking	48.47	3	1.69	0.17-16.39	0.65

4.6 Independent predictors of ART treatment failure among the clients on first line ART

Independent predictors of treatment failure were estimated using adjusted Cox regression modeling Being on treatment for less than two years was associated with 12 times higher rates of treatment failure (AHR, 12.48 (HR=12.48, 95%CI 3.64-42.71) as compared to those who were on first line ART for more than two years. The hazard rate of treatment failure was three times (AHR, 2.78 (HR=2.78,95%CI 1.16-6.63) higher among male than that of female in this population. Additionally, the incidence of treatment failure was 5.58(HR=5.58, 95%CI 1.43-21.82) higher among those reported to be self-employed compared to unemployed clients (Table 6).

Table 6: Adjusted Cox regression modeling of Independent predictors of ART treatment failure among the clients on first line ART

Variable	Crude Hazard ratio (95%CI)	Adjusted Hazard ratio (95%CI)	p-value
Sex			
Male	1.77	2.78(1.16-6.63)	0.02
Female	Ref.	Ref.	
WHO clinical stage			
Stage 1	Ref	4.69(0.46-47.37)	0.19
Stage 2	1.50	1.62(0.10-25.30)	0.73
Stage 3	0.82	3.54(0.43-29.08)	0.24
Stage 4	0.21	Ref	
Occupation			
Employed	1.69	0.44(0.95-2.04)	0.96
Unemployed	Ref.	Ref	
Business	0.86	1.37(0.54-3.48)	0.50
Self employed	2.22	5.58(1.43-21.82)	0.01
Peasant	2.61	0.77(0.02-20.62)	0.88
Years on ART			
0-2 years	4.89	12.48(3.64-42.71)	0.00
Above 2 years	Ref.	Ref.	
twice	2.79	0.93(0.91-9.65)	0.96
Thrice/fourth/fifth	Ref.	Ref.	

CHAPTER FIVE

5.0 DISCUSSIONS

The identification and management of first line ART failure is a key challenge for HIV/AIDS programs in resources limited settings. Tanzania and WHO guideline suggest a programmatic approach to defining virological treatment failure, which **relie**s on confirmation of viremia after attempts to optimize enhanced adherence counseling. Persistence viral load of >1000 copies/ml after enhanced counseling confirms treatment failure. Therefore, this study aimed to determine the rate, median time of first line ART treatment failure and associated predictors.

The overall virological failure among patient initiated ART during this study was 5.24 per 100 personal years at risk which is closer to previous study done in low- and middle-income countries including South Africa and Ethiopia demonstrated 4.5 and 4.1 rate of antiretroviral failure per 100 person years among clients on ART (29,30). This has been below study done in Tanzania which showed 7% treatment failure which might be due use of immunological criteria to assess treatment failure compared to virological criteria which is recommended earliest marker for assessing treatment failure (31,32). High rate of treatment failure (10.7) has been documented in India among the clients on first line ART compared to our study and other study done in Myanmar which reported 3.2 rate per 100 personal year follow up (9,33). This discrepancy could be explained by use of secondary data. Similar study done in India showed (16.5% at 2 years of ART) and a systematic review of 89 studies from sub-Saharan Africa reported a 33% failure rate at 3 years of ART (14). High failure rate during the early period of treatment initiation might be due to treatment related factors, which includes side effects, use of unfavorable taste brand, and missing opportunity for counselling due to shortage of staffs. On the other hands, the median failure time in this study estimates was relatively lower than that of studies in Cameroon and Northern Ethiopia study which showed median failure times of 23 and 28, respectively (34,35)

The study found that the majority of the clients on first line ART failed at the median time of 18 months. High probability of ART treatment failure was reported among clients on ART for two years and less. This findings was consistence with the study done in South Africa, Haiti

and which showed ART median time to failure of 12 and 16 months respectively (17,33), this might be due to treatment related factors which includes side effects, use of unfavorable taste brand, and missing opportunity for counselling due to shortage of staffs. But it has been below the study done in Cameroon and Northern Ethiopia and Senegal study which shows 23, 24 and 28 respectively (35,36,15). A recent analysis of patients from seven countries in Africa and Asia indicates a modest rate of 11% at 12 months and 12% at 24 months of ART, although these numbers may be an underestimate as deaths, missing patients and those switched to second line were not included in the denominator (16).

Studies have indicated that demographic and clinical parameters may impact treatment failure for ART patients (27, 29–32). An evaluation study done in South Africa and Tennessee also revealed that males' gender, years on ART and occupation predicted virologic failure. These result are consistent with findings in this study and that of others suggesting that male faces multiple social, psychological and adherence challenges increasing their vulnerability to treatment failure (27–29). Similar studies in done in Tanzania, Uganda and Haiti corroborated the findings of gender independent association between male gender and virologic failure (10,12,33,36).

Self-employed clients were found to have higher failure rate in this study, supporting findings from another study done in Tanzania which showed that the self-employed clients are very busy with their work, travelling making them missing medication refill ,appointments or follow up, and meals which contribute to poor adherence leading to ART treatment failure (37).

Implementation of routine VL monitoring for patients on ART has been the main focus in most resource-limited countries since the publication of the WHO 2013 consolidated ARV guideline (38). The Ministry of Health of Tanzania adopted the WHO recommendations in 2013. However, until 2016, implementation of routine VL monitoring in Tanzania though National Aids Control Program has been hampered by the lack of high throughput VL testing platforms and limited human resources. This study is the first study to assess treatment failure since initiation of the routine viral load testing monitoring and test and treat policy for patients on ART. The results of this study will guide the ongoing implementation and scale up of

routine VL monitoring at the national level. The challenges and factors associated with treatment failure identified in this study will inform the expansion of routine VL testing efforts aimed at achieving the third of UNAIDS' 90-90-90 goal leading to epidemic control (39)

5.1 Study limitations

The study limitation was missing information, loss to follow up, desirability bias. Selection of appropriate study population, maintaining good rapport and probing was employed to minimize social desirability. The limitation of this study was use of secondary data, which restrict the number of variables that would be studied such as psycho social factors (Depression, stigma), Body Mass Index and differences in quality of care and service in each hospital.

CHAPTER SIX

6.1 Conclusions

We conclude from this study that the first-line ART failure rate was 5.24 per 100 personal years among adults on first line ART. The treatment failure was higher among male, single, less than 350 CD4 count, self-employed and those who were on ART for less than 2years. Treatment failure was higher among those with poor adherence and TB co infection. majority of study participants had 50% probability of treatment failure at median time of 18 months.

6.2 Recommendation

The rate of treatment failure was unacceptably high in this population and occurs early during the treatment. Self-employed male clients who have been on treatment for less than 2 years were at higher risk of failure to continue with fist line treatment. CTC should provide special counseling and follow up mechanism for self-employed male including reinforced routine viral load monitoring and this should be intensified very early on during treatment initiation. Strengthening HIV drug resistance surveillance and monitoring strategy to all clients on first line ART who were unsuppressed HIV virus after six months enhanced adherence counselling session.

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APPENDICES

Appendix 1: Informed Consent

Muhimbili University of Health and Allied Sciences - Directorate of Research & Publications.

ID-NO: …… /……/…….

Consent to participate in this study

Greetings, my name is ……. from Muhimbili University of Health and Allied Sciences, Dar es Salaam. At the moment, we are carrying out a study to assess the rate, time for failure and predictors of treatment failure among PLHIV on first line antiretroviral therapy in Dar es Salaam, Tanzania.

Purpose of the study

This study aims to collect information on rate, time for failure and predictors for treatment failure among PLHIV on first line antiretroviral therapy in Dar es Salaam, Tanzania. You are being asked to participate in this study as a stake holder and a resident from the study site. We believe you have knowledge that is important in this study.

What participation involves

If you agree to participate in this study the following was occur

You was sit with trained interviewer and you was required to answer question that have been prepared for the study through a guided questionnaire in order to obtain the intended information to inform policy maker on how best to achieve viral load suppression.

Confidentiality

I assure you that all the information collected from you was kept confidential. Only people working in this research study was have an access to the information. We were ensured that any information included in your report does not identify you as respondent as we were not put your name or other identifying information on the records of the information you provide.

Risks

No risk is foreseen in this study. But at any moment if the question makes you feel uncomfortable you may refuse to answer any particular question and you may stop the interview at any time.

Rights to withdraw and alternatives

Your participation in this study is voluntary. If you choose not to participate in the study or if you decide to stop participating in the study no harm was come to you. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdraw from the study was not involve loss of any benefit to which you are otherwise entitled.

Benefits

The information you provide to us is extremely important and valuable. It was help policy makers and other health officials at every level to improve or otherwise rectify logistics and circumstances in favor of service users. There is no direct benefit however; individual benefit was obtained through intervention programs which can be conducted in this particular area.

In case of injury

We are not anticipating that any harm was occur as the result of your participation in this study.

Compensation

There was no compensation of time spent during the interview; however, your participation is highly appreciated.

Who to contact?

Dr. Bruno Sunguya the Acting Director of Research and Publication**,** Muhimbili University of Health and Allied Science (MUHAS), P. O. Box 65001, Dar es Salaam, Tel. no 2150302-6. OR

Dr. Florence George Samizi –MUHAS phone number 0683300056

Dr. Elia Mmbaga - MUHAS phone number 0785900101

Consent

I have read the content in this form, my questions have been answered, I agree to participate in this study.

Signature of Participant/thumb print ….……

Signature of Research assistant……...……..…

Date of signed consent……...…….

Appendix 2: Fomu ya Ruhusa

Chuo Kikuu cha Sayansi za Afya na tiba Muhimbili - Kurugenzi ya Utafiti na Machapisho

Namba ya Utambulisho……. /……./…….

Ridhaa ya kushiriki katika utafiti huu

Habari, Jina langu naitwa……natoka Chuo Kikuu cha Sayansi za Afya Muhimbili, Dar es salaam. Nafanya tathmini ya kuangalia idadi ya wagonjwa ambao mstari wa kwanza wa matibabu ya kupunguza makali ya ukimwi imeshindwa kufanya kazi kwa wateja wanaoishi na maambukizi ya ukimwi katika mkoa wa Dar es Salaam.

Malengo ya utafiti

Utafiti huu una lengo la kukusanya taarifa zitakazoelezea sababu zinazopelekea kufanikishwa kwa matibabu ya mstari wa kwanza wa dawa za kupunguza makali ya ukimwi na changamoto zanizokabali kushindwa kufanya kazi kwa dawa hizo za mstari wa kwanza kwa wagonjwa wanaoishi na maambukizo ya VVU Katika mkoa wa Dar es Salaam ili kusaidia uboreshaji wa huduma hii. Hivyo unaombwa kushiriki katika utafiti huu ukiwa miongoni mwa jamii husika/ mdau wa huduma hii.

Ushiriki unahusisha nini?

Ukikubali kushiriki katika utafiti huu yafuatayo yatatokea2.

1. Tutaomba taarifa zako za utambulisho jina, kadi ya matibabu ili tueweze kupata taarifa zako za matibabu zitachukuliwa kwa kipindi cha miaka minne nyuma ili kufuatilia mlolongo wa matibabu kwa kipindi hicho.
2. Utakaa na msaili/mtafiti aliyepewa mafunzo ya jinsi ya kuhoji na kujibu maswali yahusuyo vichocheo na changamoto zinazoikabili huduma ya wale wanaotumia mstari wa kwanza wa dawa za kupunguza makali ya VVU katika mkoa wa Dar es Salaam.

Usiri

Nakuakikishia kwamba taarifa zote zitakazokusanywa kutoka kwako zitakuwa ni siri, ni watu wanaofanya kazi katika utafiti huu tu ndio wanaweza kuziona taarifa hizi.Tunakuakikishia ya kwamba taarifa zitakazojumuishwa kwenye ripoti yetu hazitakuwa zinatoa utambulisho wako. Hatutaweka jina lako au taarifa yoyote ya utambulisho kwenye kumbukumbu ya taarifa utakazo tupatia.

Madhara

Hamna madhara yeyote yanayotegemewa kutokana na kujumuika kwako katika utafiti huu.Baadhi ya maswali yanaweza kukufanya usijisikie vizuri hivyo unaweza kukataa kujibu swali lolote na unaweza kusimamisha usaili wakati wowote.

Haki ya kujitoa na mbadala wowote

Ushiriki wako katika utafiti huu ni wa hiari. Kama utachagua kutoshiriki au utaamua kusimamisha ushiriki wako hautapata madhara yoyote. Unaweza kusimamisha ushiriki katika muda wowote hata kama ulisharidhia kushiriki. Kukataa kushiriki au kujitoa katika utafiti hakukufanyi upoteze stahili yoyote unayotakiwa kupata.

Faida

Taarifa utakayotupatia ni muhimu sana na yenye thamani kwa kuwa itasaadia kuandaa mpango na mikakati ya kuboresha huduma ya wagonjwa wanaoishi na maambukizo ya VVU wanaotumia mstari wa kwanza wa dawa za kupunguza makali ya maambukizo ya virusi vya UKIMWI.

Endapo utaumia

Hatutegemei madhara yoyote kutokea kwa kushiriki kwako katika utafiti huu

Fidia ya muda

Hakutakuwa na fidia ya muda uliotumika wakati wa kufanya mahojiano au majadiliano katika utafiti huu, ijapokuwa ushiriki wako katika utafiti huu utashukuriwa na kutathiminiwa.

Watu wa kuwasiliana nao

Kama kuna swali kuhusianan na utafiti huu itakubidi kuwasiliana na

Mkurugenzi wa Utafiti na UchapishajiDrJoyce Masalu - Chuo Kikuu cha Afya na Sayansi ya Tiba Muhimbili, S.L.P. 65001 DSM. Simu namba 2150302-6. Kama una maswali zaidi unaweza kuwasiliana na

Dr. Florence Samizi –MUHAS namba ya simu 0683300056
Dr. Elia Mmbaga - MUHAS namba ya simu 0785900101

RIDHAA.

Nimesoma maelezo ya fomu hii, maswali yangu yamejibiwa na nimeridhika. Nakubali kushiriki katika utafiti huu.

Sahihi ya Mshiriki/Dole gumba……..

Sahihi ya Mtafiti msaidizi……..

Tarehe ya kutia sahihi ya kushiriki…….....

Appendix 3: Clients Tracing Form

A copy of this is given to the client with referral form to CTC

1. Unique identification number given at CTC ……
2. Study identification number…….
3. Name of the health facility/HTC site where the patient attending for services--------
4. Date of diagnosis----------
5. Full name of the patient
   First name----------
   Middle name----------
   Last name----------
6. What is your popular name in your catchment area?.....
7. Residence
   Districts----------
   Wards----------
   Street----------
8. What is the name of famous building nearby your homeplace? ……
9. What is the name of your ten-cell leader…….?
10. Phone number of the client on ART ----------
11. Name of the next of kin; ----------
12. Phone number of next of kin----------

Appendix 4: Fomuya Kumfuatilia Mteja

1. Namba ya kumtambua mteja aliyopewa CTC…….
2. Namba ya kutambua mteja wa tafiti……..
3. Jina la kituo mteja anachotibiwa ……...
4. Tareheya kuanza dawa …….
5. Jinakamili la mteja

   Jina la kwanza……...

   Jina la Kati …….

   Jina la ukoo ……...
6. Jina gani maarufu lilo zoeleka /unalolitumia katika eneo unaloishi?

   …….
7. Mahali anapoishi mteja

   Wilaya …….

   Kata …….

   Mtaa ……
8. Jina la jingo marrufu karibu na nyumbani kwako……
9. Jina la mzee wako wa nyumba kumi ……
10. Nambayasimuyamteja …….
11. Jina la mwenza/ mtu wakaribu

    …….
12. Namba ya simu ya mwenza / mtu wakaribu

    …….

DATA EXTRACTION TOOL

S.N0	Participant ID	Age	Sex	Marital status	Date started ART	Initial CD4	Recent CD4	Regime used	Initial VL	Recen tVL	WHO Clinica stage	EAC	TB Status	Date of treatment failure

Appendix 5: Structure questionnaire (English version)

Introduction

Thank you for accepting to be interviewed. The interview should not take more than half (½) hour. However, you can stop the interview at any time. You are also not obliged to answer all the questions. I'll start by asking you some general questions about yourself. Let me assure you that this information was treated with utmost confidentiality.

SECTION A: IDENTIFIER INFORMATION

Questionnaire number …….. Date of Interview……. /……/……

Patient name/ID……phone

number…….

Region……, District…….

Ward……..., Village/Street……, Name of health facility…….

SECTION 2: SOCIO-DEMOGRAPHICS INFORMATION

1. How old are you (age in complete years) …….?
2. Sex of the study participant
    a) Male
    b) Female
3. What is your highest Level of education you attended?
    a) None
    b) Primary Education
    c) Secondary Education
    d) Higher Education (college, university, technical school)
4. What is your occupation status?
    a) Employed
    b) Self-employed
    c) Unemployed
    d) Student
    e) Peasant
    f) Others specify…….

5. What is your marital status?

a) Married
b) Single
c) Divorced
d) Widowed
e) Cohabiting

6. In the last six months, did you travel and sleep away from home?

a) Yes
b) No
c) Don't know

7. What is the maximum duration you were away from home in the last 6 months ------ days?

SECTION B: DISTANCE

8. What is the distance from where you live to the referred CTC where you receive ART?

a) 0-1 km
b) 2-5 kms
c) 6- 10 kms
d) Other specify……

9. What is the distance from home to CTC?

a) 0-1 km
b) 2-5 kms
c) 6- 10 kms
d) 10kms and above

10. Others ……. Which means of transport was you use to reach CTC?

a) Walking
b) public transport
c) Private transport

11. What is the transport cost (in Tsh) from home to CTC?

a) 400 - 600 Tshs
b) 650 - 1000 Tshs
c) > 1000 Tsh

12. Have ever been away for more than one month?

a. Yes
b. No

SECTION C: MORISKY 8 ITEM MEDICTION ADHERENCE

QUESTIONAIRE

13. Do you sometimes forget to take your medicine? Yes/No

14. People sometimes miss taking their medicine for reasons other than forgetting, thinking over the past 2 weeks, were there any days when you did take your medicine?Yes/No

15. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it? Yes/No

16. When you travel or leave home, do you sometimes forget to bring along your medicine Yes/No

17. Did you take all your medicine yesterday? Yes/No

18. When you feel like your symptoms are under control, do you sometimes stop taking your medicine? Yes/No

19. Taking medicine every feel hassled about sticking to your treatment plan? Yes/No

20. How often do your difficulty remembering to take your medicine?

A-Never/rarely
B-Once in a while
C-Sometimes
D-Usually A=O
E-All the time B-E=1

Total score

Score :>2= Low adherence

1 or 2 =medium adherence

0=high adherence

SECTION D: FACILITY FACTORS THAT MAY INFLUENCE ADHERENCE.

a) Do the health care providers listen to you carefully? **Yes/No**

b) Do you feel respected by health care providers at CTC? **Yes/No**

c) Do the health providers answer your questions in a kindly manner? **Yes/No**

d) Is the waiting time at the CTC too long? **Yes/No**

e) Were you told about side effects of drugs? **Yes/No**

f) Are you satisfied with answers given by health care providers? **Yes/No**

g) Do they provide care in privacy manner? **Yes/No**

h) Do you receive your laboratory results timely**?** **Yes /No**

i) Are you satisfied with their confidentiality? **Yes/No**

j) In general, are you satisfied with the care of people get at the CTC? **Yes/**

Appendix 6 : Dodoso la Kiswahili

Dodoso la Kiswahili

kwa wagonjwa walioko kwenye dawa za kufumbuza makali.

SWAHILI VERSION

Utangulizi

Asante kwa kukubali mahojiano.Dodoso hili litatumia si zaidi ya nusu saa, hata hivyo yanaweza kumalizika wakati wowote.Si lazima ujibu maswali yote.Nakuhakikishia kuwa taarifa zako zitatunzwa kwa usiri wa hali ya juu

SEHEMU A: TAARIFA BINAFSI

Weka alama ya tiki katika kiboksi

1. Jinsia

   Mume ☐ Mke ☐

2. Tarehe/Mwaka wa kuzaliwa …….

3. Hali ya ndoa

a) Si mwanandoa ☐ b) Mwanandoa ☐

c) Mmetengana/kuachana/Mjane ☐ d) Mnaishi hamjafunga ndoa ☐

4. Kiwango cha elimu

   a) Hakuna ☐
   b) Shule ya msingi ☐
   c) Shule ya sekondari ☐
   d) Chuo/chuo kikuu ☐

5. Kazi

   a) Mkulima ☐
   b) Nimeajiriwa ☐
   c) Sikuajiriwa ☐
   d) Mfanyabiashara ☐
   e) Ajira binafsi ☐

6. Makazi

a) Temeke ☐
b) Ilala ☐
c) Kinondoni ☐
d) Ubungo ☐
e) Kigamboni ☐

7. Ndani ya miezi sita iliyopita ulisafiri nje ya nyumbani kwako?

a) Ndio
b) Hapana
c) Sikimbuki

8.Ndani ya miezi sita iliyopita umekuwa nje ya nyumbani kwako kwa siku ngapi…..?

SEHEMU YA B: UMBALI KUFIKA KITUO CHA KUCHUKULIA DAWA

9. Kuna umbali gani toka sehemu unayoishi mpaka CTC uliyoelekezwa?

a) 0-1 km ☐
b) 2-5 km ☐
c) 6- 10 km ☐
d) 10km na zaidi ☐

10. Njia gani ya usafiri utakayotumia kufika CTC?

a) Unatembea ☐
b) Usafiri wa umma ☐
C) Usafiri binafsi ☐

11.Unatumia gharama gan kutoka nyumbani kwako hadi hospitali unayochukulia dawa?

a)400 - 600 Tshs
b)650 - 1000 Tshs
c)> 1000 Tsh

SECTION C: MORISKY 8 ITEM MEDICTION ADHERENCE QUESTIONAIRE

12. Kuna wakati unasahau kunywa dawa zako za kupunguza makali ya VVU?Ndio/Hapana

13. Wengine hupitiwa kunywa dawa zao kwa sababu mbalimbali na kujisahau ndani ya wiki mbili zilizopita kuna siku hukunywa dawa zako za ARV?Ndiyo/Hapana

14. Je kuna siku uliacha kunywa dawa bila kumshirikisha mtoa huduma wako vile zilikuletea madhara mwilini?Ndiyo/Hapana

15. Kwa siku ya jana ulikunywa dawazako zote za ARV?Ndiyo/Hapana

16. Wakati unajisikia hujambo huwa unaacha kunyw dawa zako?Ndiyo/Hapana

17.Pale unaposafiri au kuwa nje ya nyumbani huwa unasafiri ns dawa zako au wakati mwingine unazisahu nyumbani?Ndiyo/Hapana

18. Inaeleweka kuwa kunywa dawa kila siku inaweza kuwa ngumu kwa watu wengine? Je wewe hujisikia kuchoshwa na ratiba ya unywaji dawa kila siku?Ndiyo/Hapana

19. Mara ngapi unapata ugumu kukumbuka kunywa dawa zako?

a) Haijawahi/mara chache
b) mara moja moja
c) wakati mwingine
d) mara kwa mara
e) mara nyingi

SEHEMU D.Uridhishwaji wa Ubora wa huduma katika CTC

a) Je, watoa huduma za afya wanasikiliza kwa umakini? Ndio/Hapana
b) Je, Unahisi kuheshimiwa na watoa huduma za afya katika CTC? Ndio/Hapana
c) Je, watoa huduma za afya hujibu maswali yako kwa namna nzuri? Ndio/Hapana
d) Je, mnasubiri kwa muda mrefu sana wakati wa kupata huduma CTC? Ndio/Hapana
e) Je, Umeambiwa kuhusu madhara ya dawa? Ndio/Hapana
f) Je, unaridhishwa na majibu yaliyotolewa na watoa huduma za afya? Ndio/Hapana

g) Je, Hutoa huduma kwa njia ya faragha? Ndio/Hapana
h) Je, Unapokea matokeo yako ya maabara kwa wakati? Ndio/Hapana
i) Je, unaridhishwa na usiri wao? Ndio/Hapana
j) Kwa ujumla, unaridhishwa na huduma zinazotolewa kwa watu kutoka CTC? Ndio/Hapana

20.Je wewe unakunywa pombe/bia? Ndiyo/Hapana

21.Je unakunywa bia ngapi kwa siku? ……..

kwa wagonjwa walioko kwenye dawa za kufumbuza makali.

Appendix 7: Approval of ethical clearance

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

P.O. Box 65001
DAR ES SALAAM
TANZANIA
Web: www.muhas.ac.tz

Tel G/Line: +255-22-2150302/6 Ext. 1015
Direct Line: +255-22-2151378
Telefax: +255-22-2150465
E-mail: dpgs@muhas.ac.tz

Ref. No. DA.287/298/01.D/84

24th January, 2018

Florence George Samizi,
MSc. Applied Epidemiology
MUHAS.

RE: "RATE AND PREDICTORS OF FIRST LINE ANTIRETROVIRAL TREATMENT FAILURE AMONG ADULTS LIVING WITH HIV/AIDS IN DAR ES SALAAM, TANZANIA".

Reference is made to the above heading.

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

The ethical clearance is valid for one year only, from 24th January, 2019 to 24th January, 2020. In case you do not complete data analysis and dissertation report writing by 24th January, 2020, you will have to apply for renewal of ethical clearance prior to the expiry date.

Dr. E. Balandya,
ACTING: DIRECTOR OF POSTGRADUATE STUDIES

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

Appendix 8: Research Permit

THE UNITED REPUBLIC OF TANZANIA
President's Office
REGIONAL ADMINISTRATION AND LOCAL GOVERNMENT

DAR ES SALAAM REGION
Phone Number: 2203158
Fax number: 2203158
email: ras@dsm.go.tz
website: www.dsm.go.tz

REGIONAL COMMISSIONER'S OFFICE
3 RASHID KAWAWA ROAD,
P.O. BOX 5429,
12880 DAR ES SALAAM

In reply please quote:
Ref. No. .....

30/01/ 2019

District Administrative Secretary,
ILALA
P. O. Box .....,
DAR ES SALAAM.

RE: RESEARCH PERMIT

Prof/Dr/Mrs./Ms/Miss Fiona George Samia is student/Research from MUHAS has been permitted to undertake research on Rate and predictors of first line Antiretrovirals treatment failure among Adults living with HIV/AIDS in Dar-es-Salaam, Tanzania From 24/5 January 2019 to 24/5 January 2020 2019.

I Kindly request your good assistance to enable her/his research.

For; REGIONAL ADMINISTRATION SECRERTARY
DAR ES SALAAM

Copy: Municipal Director,
ILALA
DAR ES SALAAM.

Principal/Vice Chancellor
Dr. E. Balandya

UBUNGO MUNICIPAL COUNCIL

ALL CORRESPONDENCES TO BE ADDRESSED TO THE MUNICIPAL DIRECTOR

Tel: 0222-926341
Fax: 0222-926342

In reply please quote:

MUNICIPAL DIRECTOR UBUNGO
MUNICIPAL COUNCIL ,
P. O. BOX 55068
DAR ES SALAAM.

DATE: 12/02/2019

Ref. AB.27/333/01

Florence George Samizi,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65015,
DAR ES SALAAM.

RE: **RESEARCH ATTACHMENT**

Refer to the above heading.

I am pleased to inform you that your above request has been considered by the Municipal Director, and has offered you a place to research attachment from **24 January, 2019** to **January, 2020.**

Upon receipt of this letter, please report to the, **Ward Executive Officers Sinza – Makurumla** for commencement of your research.

During the period of research you are required to obey the rules and regulations of the institution.

Yours Sincerely.

E. F. Kisenha
For: **THE MUNICIPAL DIRECTOR**
UBUNGO

Copy: Principal /Vice Chancellor,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65015,
DAR ES SALAAM.