SCHOOL OF PUBLIC HEALTH

GLOBAL AND INTERNATIONAL HEALTH

UNIVERSITY FOR DEVELOPMENT STUDIES, TAMALE

DETERMINANTS OF VIROLOGICAL FAILURE IN HIV PATIENTS ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART) IN THE UPPER EAST REGION OF GHANA, 2022

BY

MUTAKA, M. AWELL OLIVES

(UDS/MPH/0035/20)

THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY FOR DEVELOPMENT STUDIES, TAMALE IN PARTIAL FULFILLMENT FOR THE REQUIREMENT OF THE AWARD OF MASTER OF PUBLIC HEALTH DEGREE.

SEPTEMBER

DECLARATION

I, Mutaka, M. Awell Olives, the author of this research, herewith declare that this research is independently my own except the references made and acknowledge from other people's work. I declare further that no part or whole of this research has been submitted elsewhere.

…….. 13TH SEPTEMBER 2022

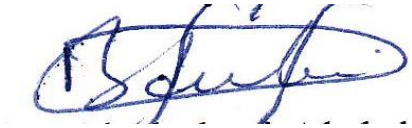
…….

MUTAKA, M. AWELL OLIVES (UDS/MPH/0035/20)

DATE

CERTIFICATION

I hereby certify that this research work was supervised in accordance with the research procedures of the University for Development Studies (UDS), Tamale.



11/04/2023

…….. ……

PROF. ABDULAI ABUBAKARI DATE

BA; MPH; PHD: PROF

(SUPERVISOR)

11/04/2023

…….. ……

MR. HABIB ISSAH DATE

BA; MA/M.SC; MPH; EUROPUBHEALTH

(CO-SUPERVISOR)

ACKNOWLEDGEMENT

I give glory to God Almighty for my health and strength in everyday life. I thank my supervisors; Professor Abdulai Abubakari and Mr. Habib Issah (Co-supervisor) for their direction, assistance and guidance. I appreciate my colleague ART Data Managers (GHS) in the Upper East Region for their great support in data collection. I further acknowledge Ms. Rosina Darcha of the University for Development Studies for her counseling and support.

DEDICATION

This thesis is dedicated to my mothers and my late father (his soul rest in peace) and siblings for their prayers and care. I further dedicate it to my outstanding wife Ayisibea Joycelyn Nyampong and my children; Raed, Zia and Zain for their great love and care in my life.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retroviral Therapy
BMI	Body Mass Index
CD4	Cluster of differentiation 4
CHAG	Christian Health association of Ghana
CHPS	Community-Based Health Planning Services
DSD	Differentiated Service Delivery
EAC	Enhanced Adherence Counseling
FSW	Female Sex Workers
GAC	Ghana AIDS Commission
GHS	Ghana Health Service
HAART	Highly Active Antiretroviral Therapy
HCs	Health Centers
HIV	Human Immunodeficiency Virus
KP	Key Population
MSM	Men Having Sex with other Men
NACP	National AIDS Control Programme

PK	Pharmacokinetic
PLHIV	People Living with HIV
SDG	Sustainable Development Goal
SPSS	Statistical Package for Social Sciences
SQ	Survey Questionnaire
SSA	Sub-Saharan Africa
TPB	Theory of Planned Behavior
TB	Tuberculosis
UER	Upper East Region
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
US	United States
VF	Virological Failure
VL	Viral Load
VLF	Viral Load Failure
VS	Viral Suppression

ABSTRACT

Background: The UNAIDS target for the 3rd 90% stipulated that; 90% of HIV patients on ART attained VS by end of 2020 (Ansah, et al., 2021; Marsh et al., 2019). The WHO recommended intensified adherence counseling to increase VS rate (WHO, 2015). This research determined VLF in HIV patients and recommended strategic interventions to achieve the new third 95% VS rate by 2025 (UNAIDS, 2016). The GHS identified the UER as a hotspot with increased HIV prevalence and VLF. In 2019, the UER recorded an increase in HIV from 2.8% in 2018 to 3.6% leading to high VF (GHS, 2019). The Theory of Planned behavior was adapted to provide effective behavior change interventions to improve adherence and undetectable VL (Abraham C., 2009). **Methods:** A retrospective cross-sectional study with Consecutive sampling technique was conducted on the 366 participants aged ≥15 years, on ART for ≥6 months with VL results in 2020 (Dissertation L. , 2012). A random sampling method (MS, 2016) was used to select the 8 HCs and 4 piloted sites. Patients' folders and VL registers were reviewed. Kobo Collect tool (version v2021.2.4) with designed structured questionnaire (KoBo, 2017) was used to collect face-to-face data. Microsoft Excel (version 10) was used to clean the data and SPSS (version 26) used for data analysis. Logistic regression analysis was conducted with 95% C.I. and p-value ≤ 0.05 (Gunarto, 2019). **Results**: 73.2% of the respondents were female and 37.2% were within the age group 25-34. The prevalence of VLF was 47% and ART Adherence was 62.6%. The predictors of VF were non-formal education (OR=8.873, 95% C.I.=2.578 - 30.541), basic education (OR=7.283, 95% C.I. =2.020 - 26.259), SHS/Voc/Tech education (OR=5.111, 95% C.I.=1.400 - 18.654). 61% earned monthly income <GH₵375.00 (OR=8.134, 95% C.I.=1.697 - 38.995), alcohol intake (OR=0.425, 95% C.I.=0.197 - 0.915) and ART duration

<1 year (OR=0.293, 95% C.I.=0.094 - 0.192). Other predictor factors were ART regimen (high Tenofovir+Lamivudine+Efavirenz) (OR=4.883, 95% C.I.=1.172 - 20.346), 2-4 times missed medication per month (OR=0.023, 95% C.I.=0.008 – 0.064) and ≥5 missed medication per month (OR=0.113, 95% C.I.=0.036 - 0.351). **Conclusion**: This study determined factors that were associated with VF in HIV patients in the UER and found that VF was about half percent.

CHAPTER ONE

1.1. Background of the study

The first reported event of acquired Immunodeficiency Virus (HIV) globally was in 1981 in the United States of America (USA) (UNAIDS. et al., 2003). For the past two decades, there has been a lack of consensus among scholars, policymakers, and health practitioners regarding the cause(s), effect(s), and answers to the occurrence of HIV infection including opportunistic illnesses as well as deaths (Abuogi et al., 2016). HIV/AIDS is a part of the leading causes of global disease burden. By the end of the year 2020, over 37.7 million people globally lived with the virus, new infections of HIV were 1.5 million people, while patients who died from HIV related diseases were 680,000 people. About 6.1 million people had no knowledge that they had been infected with HIV (World Health Organization, 2020). The United Nations Programme on HIV/AIDS (UNAIDS) together with the World Health Organization (WHO) encouraged nations and partners globally to transform evidence-based benefits of Antiretroviral therapy's from investigation routine-based work practice through a chain of ambitious strategic target setting initiatives (Ansah, Kumah, Bawontuo, Agyei-baffour, et al., 2021; Marsh et al., 2019).

The UNAIDS with a vision to end the HIV/AIDS epidemic in 2030 launched a global-wide target of 90-90-90 in 2014. The 90-90-90 target implied that, by the end of the year 2020, 90% of persons living with HIV should be aware of their status, 90% of all HIV confirmed cases should be put on sustained antiretroviral treatment, and 90% of all patients on treatment should attain viral suppression (<1000 copies/ml) (Ansah, Kumah,

Bawontuo, Agyei-baffour, et al., 2021; Marsh et al., 2019). According to statistical models, increasing resource concentration from 90–90–90 to the new 95-95-95 and scaling-up to specific measures of prevention would decrease new infections and deaths related to HIV/AIDS by 90% globally from 2010 to 2030 (Marsh et al., 2019). Globally, out of the UNAIDS 90-90-90 target for 2020, 84% (67%-98%) became aware of their HIV positive status, 73% (56%-88%) accessed antiretroviral treatment, and 66% (53%-79%) had viral suppression at the end of 2020 (World Health Organization, 2020).

Reports have shown that only ten (10) countries in the Sub-Saharan Africa (SSA) contributed 67% out of the total of 37.7 million people infected with HIV worldwide (Rahman, 2019). A greater percentage of HIV infected patients are found in the Low- and Middle-Income Countries (LMICs). The daily prevalence of HIV infection in the Sub-Saharan Africa (SSA) was 67% out of the 4,500 daily new contractions worldwide. The most HIV infected regions across the world in 2019 include East and Southern Africa with about 20.7 million people and new infections of 730,000 (Averting HIV and AIDS, 2020; World Health Organization, 2020).

There has been a considerable political and financial commitment to fighting the epidemic in East and Southern Africa. Some African nations including Kenya and South Africa made great efforts to scale up their prevention, treatment, and care services (Mushi, 2017). The implication of the 90-90-90 set target meant that by 2020, 73% of HIV patients will be virological suppressed. In the Sub-Saharan Africa (SSA), approximately 51% adults infected with HIV became aware of their status, 43% received antiretroviral therapy, and 32% adults had viral suppression in 2014 (UNAIDS,

2016). By the end of 2019, countries that attained the 73% viral suppression target were fourteen (14) including Eswatini, Rwanda, Uganda, Boswana, Zimbabwe etc. in Africa. Eswatini was the first country to make a significant viral suppression achievement over the UNAIDS 95% target of 2030 (Marsh et al., 2019).

Ghana recorded its first event of Human Immunodeficiency Virus (HIV) in 1986 (Ghana AIDS Commission, 2019c). The prevalence of HIV epidemic in Ghana is at a low level. However, the prevalence rate among the key-populations (KPs) including men having sex with men (MSM) and female sex worker (FSW) was extremely high. These groups accounted for 28% of all new infections (UNAIDS, 2014). The prevalence rate of HIV/AIDS in Ghana steadily declined before a sharp increase in 2015 (National AIDS Control Programme (NACP), 2017). The median prevalence rate of HIV dropped from 2.4% to 2.1% in 2016 and 2017 respectively. However, in 2018, the prevalence reverted to 2.4%. It thus, constituted 14.3% rise from 2017 to 2018 and 50% rise from 2014 to 2018. The national incidence rate from 2015 to 2019 has, on the other hand, remained constant by 0.11% and it is anticipated to fall further in 2020 to 0.09% (Ghana AIDS Commission (GAC), 2019). Adobea, (2020) (as cited in NACP, 2017) indicated that out of approximately 30.8 million Ghanaians population, 1.12% (346,120) were HIV positive with new infection of 18,928 in 2020. Adult (aged 25 years and above) constituted 53% (9,796), young people (age 15-24) constituted 28% (5,211), and children (age 0-14) constituted 19% (2,961) of HIV infection (Adobea Y Owusu, 2020). The report revealed that females recorded the highest of 83% infection as against 17% for males. The high rate occurred due to how susceptible women are to contracting HIV

due to the nature of their reproductive organs. The Ghana AIDS Commission reported that Ghana recorded 12,758 deaths form HIV/AIDS related diseases due to infected persons not taking the prescribed antiretroviral drugs, reporting to herbal treatment, and others living under the superstition of being healed spiritually (GAC, 2020).

As a country that wants to achieve a 95-95-95 fast-track target by 2030, factors such as non-adherence to medication, shortage of ARVs, poor testing coverage etc. that led to the failure of Ghana to achieve the UNAIDS 90-90-90 in 2020 are quite worrying. Ghana achieved 58-77-68 of the 90-90-90 at the end of 2020 (GAC, 2019). Strategically, the Ghana Government seeks to accelerate progress to eradicate the HIV/AIDS epidemic in 2030 to reduce new HIV infection by 85% and increase viral suppression to 95% in the general population, key population, adolescent girls, and young women, and eliminate mother-to-child transmission (Ghana AIDS Commission, 2020).

The Upper East Region is one of the five Regions of the North in Ghana that is affected by HIV epidemic. It has a prevalence of 5,776, with new infections at 339, and a death rate of 230 (GAC, 2020). Adult prevalence is 0.77% with 4,487 adults on antiretroviral treatment and total coverage of 77.7% in 2020 (GAC, 2020). A study revealed that early ART initiation, treatment adherence, and treatment monitoring should be encouraged to promote HIV disclosure to increase viral suppression in HIV patients. However, the study did not find any association between HIV disclosure and treatment adherence, treatment monitoring and viral load failure (Atugba T. A., 2022). The Upper East

Region performed about 51% at the end of 2020 below the UNAID 90% viral suppression target (Ghana AIDS Commission, 2019a). Some studies have shown that various factors including gender, marital status, age, educational level, adherence, and multiple sexual partners were associated with virological failure in HIV patients (Bulage et al., 2017; Hicham et al., 2019). The above studies did not produce enough evidence on the determinants of virological failure among people living with HIV on HAART in the Upper East Region (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021). Identifying and managing these factors in HIV patients can lead to increased success of HIV treatment for undetectable levels of viral load in the Region (Hicham et al., 2019).

This study seeks to build on existing studies to determine the associated factors of virological failure in HIV patients on antiretroviral therapy (ART) in the Upper East Region of Ghana and produce findings for informed policy and decision making to attain the 95-95-95 in 2025 to end the HIV epidemic in 2030 (GAC, 2019).

1.2. Problem statement

The suppression of viral load is when viral load plasma is less than 1000 copies/ml.

On the other hand, virological failure is an initial response failure to antiretroviral therapy or viral rebound after suppressed viral load is reached in HIV patients. If the viral load of the repeated plasma is more than 200 copies/ml after the patients is on therapy for 6 months, then there is a viral failure (WHO, 2015).

The major approach implemented by the United Nations (UN) to eliminate the HIV/AIDS epidemic was to improve patients access to antiretroviral therapy across the across the globe towards attaining the UNAIDS 95-95-95 in 2030. The study showed that, globally, less than 50% of HIV patients on antiretroviral therapy achieved viral suppression (UNAIDS, 2018a; WHO, 2018). In 2016, the Ghana government adopted the Joint United Nations Programme on HIV/AIDS (UNAIDS) "treat all" policy and the 90 – 90 – 90 target to eradicate the HIV/AIDS epidemic in 2030 (Rahman, 2019; UNAIDS, 2014). According to the Ghana AIDS Commission (GAC), in 2019, Ghana achieved 58%-77%-68% of the 90-90-90 at the end of 2020 (Ghana AIDS Commission, 2019a). The Upper East Region attained the first two 90s but performed about 51% on the third 90 below the UNAIDS 90% at the end of 2020. According to Poku, F. N. (2019), though Ghana, as well as the Upper East Region, could not fully meet the 90-90-90 target in 2020, "the hope is that we know the barriers and we have the roadmap as a country to meet the target in the years ahead, maybe beyond 2020" to achieve the new UNAIDS 95-95-95 by 2030 (Ghana AIDS Commission, 2019b).

In a study by Ansah et al. (2021), they discovered 23.6% virological failure and viral load suppression rate of 76.4% in HIV patients on ART in the Kumasi Metropolis. Though the result (76.4%) was less than the UNAIDS third 90% target for viral suppression of patients in ART, there was an increased proportion of virological failure (23.6%) compared to 34% national achievement (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021). Another study in the Ho Municipality, Volta Region revealed that 31.3% virological failure was reported among HIV patients (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021) and 69% of patients with viral suppression. The 69% suppression rate was comparable to the

64.3% reported by the Ghana statistics though >34% in Sierra Leone and >41% in Senegal. However, the suppression rate was lower than reports from Bostwana and Eswatini with 81% and 74% respectively (Lokpo et al., 2020). Comparing the findings from Ansah et al. in 2021 and Lokpo et al. in 2020, there is some possible variations in the prevalence of HIV patients having a virological failure in a different part of the country (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021). Implies, several different factors would have accounted for the virological failure in people living with HIV on antiretroviral in the different regions.

Ansah et al, (2021) found that viral load non-suppression among HIV patients on treatment was significantly associated with age, gender, marital status, education, ART duration and comorbidity. The analysis showed that amongst men, viral load failure was 1.3 times more likely compared to female patients (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021). Similar studies showed that age, gender, marital status, housing, employment status, and income were significantly associated with viral load failure in HIV patients on ART (Chawana et al., 2014).

Earlier studies have emphasized that several factors are linked to viral suppression in patients with HIV on antiretroviral including treatment adherence, ART regimen, gender, and duration on ART (Bulage et al., 2014; World Health Organisation., 2013; Yayehirad et al, 2013). Other significant findings showed that virological failure was statistically significant with educational status, being male, young age and unsatisfactory adherence (Yishak et al., 2020). A longitudinal research by Owusu et al. in 2017 found that there was 5.4% (1.4% – 20.9%) increased odds of virological failure among children whose parents were not employed than patients whose parents were employed. A recent retrospective study

in Ho Municipality, Volta Region reported timely ART refill and patients on treatment for more than 3 years were significant with viral load suppression (Lokpo et al., 2020).

Upper East Region like many other regions in Ghana strived in the direction of achieving the UNAIDS 90-90-90 target by 2020 (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021). A literature by Jobanputra et al. (2015) revealed that the proportion HIV patients in the Upper East Region with viral load suppression of about 2,168 (51%) by end of 2020 was moderate, but fell short of the global target of 90% suppression rate. Implies, the viral load failure rate of about 49% was quite high among limited population with HIV in the region. Upper East Region faces increased HIV/AIDS transmission rate including mother-to-child transmission, opportunistic infections, increased mortality and decreased life span compared to other regions in Ghana (Jobanputra et al., 2015). Also, Limited evidence exists on the factors associated with viral load failure in patients on antiretroviral therapy in resource limited regions, particularly Upper East Region (Afrane et al., 2021). Therefore identifying and managing these factors causing viral load failure in HIV patients is important in attaining significant treatment achievement. This will ensure an improved quality of life of HIV/AIDS patients in the Upper East Region (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021).

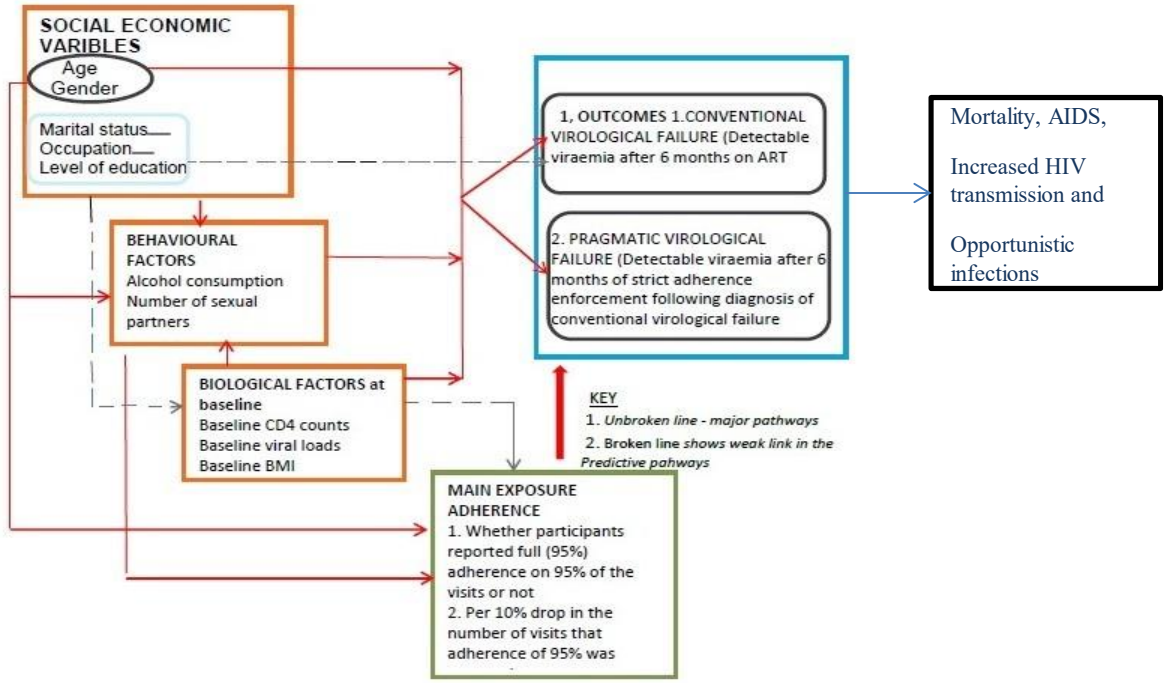
Though substantial advancement is made in reaching out to people on antiretroviral therapy, it is important to divert attention to the determinants of viral load failure and community-led services within differentiated care approaches (Yusuff Adebayo et al., 2021) and enhance effective disease surveillance systems to evaluate the viral suppression rate in HIV patients (Lokpo et al., 2020) to provide an exclusive path to enable the Upper East Region to

organize for the breakthrough of the new target 95-95-95 (Yusuff Adebayo et al., 2021). The Upper East Region was identified as a hotspot region with increased cases HIV leading to high viral load failure. GHS, (2019), reported that the Upper East region recorded an increase in HIV cases from 2.8% in 2018 to 3.6% (GHS, 2019).

Thus, this study is determined to evaluate significant factors related to Virological Failure among patients on highly active antiretroviral therapy (HAART) in the Upper East Region.

1.3. Conceptual framework

The researcher modified this framework from Kazooba et al., (2018) to provide conceptual factors that are significant with virological failure in patients on HAART in the Upper East Region.



Source: Modified from (Kazooba et al, 2018)

Figure 1.1: Conceptual framework for associated factors with virological failure

Kazooba et al., 2018 (as cited in Victoria et al., 1997) revealed that adherence to antiretroviral therapy was statistically significant with unsuppressed viral load. Additional confounding risk factors comprised socio-demographic characteristics such as age, occupation, marital status and educational level. Behavioral characteristics include many sexual partners and alcohol intake, as well as biological factors such as baseline viral load, CD4 counts and body mass index (BMI). Considering confounders like age and gender, the relationship with antiretroviral therapy adherence was found insignificant, while alcohol consumption was considered to approximate. The study found that biological factors such as low CD4 counts, low body mass index, poor antiretroviral adherence, and patients' poor health status were significantly associated with high baseline viral load in patients on ART. It is further presumed high viral load baseline to be related to probable drug resistance and causing virological failure (Kazooba et al., 2018). However, the CD4 count and Body Mass Index (BMI) are no more necessity for initiating patients on antiretroviral or testing for viral load (WHO, 2015) and therefore were not part in the analysis and discussion in this study.

Conventional/Pragmatic Virological Failure

Conventional/pragmatic viral load failure defined a single viral load result ≥1000 copies/ml or successive two (2) viral loads >400 copies/ml taken when a client was ≥6 months on antiretroviral for at least six (6) months apart. The clients were provided intensified adherence counseling to continue first line antiretroviral treatment for 6 months. Patients with persistent viral loads failure (≥1000 copies/ml) were then considered as exact or pragmatic failures. These patients could then be moved to a second line antiretroviral regimen. The outcome of these failures could be AIDS, further transmission and sexually transmitted infections (STIs), or death.

Exposure

Adherence to Antiretroviral therapy was the key exposure which was evaluated during monthly refill of ARVs using patients self-report and pill-count. Kazooba et al. (2018) defined ART adherence as follows; ≥95% adherence (means good adherence if clients missed no doses since the last ART refill visit or in the previous 4 days) and <95% adherence (means poor adherence if clients missed doses in the last refill visit of in the previous 4 days) (Kazooba et al. 2018).

1.4. Justification

The main reason to take antiretroviral therapy is to achieve viral suppression to help HIV patients live healthy and longer, and to further decrease the likelihoods of HIV transmission ("US Dept of Health and Human Services," 2017). Nevertheless, the failure of patients in attaining viral suppression was associated with some socio-democratic factors such as age, male gender, unsteady accommodation, low level of education, and joblessness (Plymoth et al., 2020a) and behavioral characteristics including alcoholism and multiple sexual partners (Kazooba et al., 2018). For Do and Meekers (2009), men probably have many sex partners compared to women and therefore exposed more to virological failure than women (Do & Meekers, 2009). These require the need to identify these socio-demographic and behavioral factors during ART initiation, intensify patients follow up, adherence counseling to prevent suspected viral failures and follow ART treatment protocol (Bulage et al., 2017). Operational tactics, including community-based interventions, sensitization, health education and promotion are required to enhance the patients' health seeking behaviour of HIV-infected patients

(Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021). Findings from UNAIDS (2016) indicated that civil societies should increase the advocacy for scale-up of patients viral load testing, call on for affordable virological testing systems in low and middle income countries (LMICs). UNAIDS also called for pushed expanded study development of easier and cheaper viral load technology to enhance point-of-scale testing (UNAIDS, 2016).

The improvement in treatment adherence has a positive impact on patients' compliance to medication (Wakibi S., 2010). Therefore, to reduce the possible obstacles to virological suppression, partners and stakeholders should focus on reinforcing adherence counseling, information delivery, education and policy interventions (Yao et al, 2009). There is the need for ongoing treatment education, consequences of non-adherence and effective communication with patients (Njonjo, 2007) (as cited in Fong et al 2000) and adherence counseling for patients to re-suppress viral loads (Evans et al., 2018).

Active antiretroviral therapy was proofed to have intensely changed the advancement HIV transmission and infection and enhanced patients' health significantly. Consequently, failure to treatment increased mortality rate, AIDS, other sexually transmitted infections, and death. Therefore, antiretroviral therapy programs need to be strengthened to encourage early diagnose and initiation. This will enhance treatment adherence to reduce the rate of virological suppression and prevalence of HIV (Teklehaimanot and Birhanu, 2020). This will support in realizing the UNAIDS 95% viral suppression target and attain the global

sustainable development goal (SDG) 3 which indicates good health and wellbeing for all by 2030 (Bekker et al., 2018).

Therefore, the factors associated with virological failure need to be considered by health authorities in planning interventions that focus on improving viral suppression rate in HIV clients on HAART. Also, further research should be conducted in other regions in Ghana such as the Upper East Region to find the risks factors associated with viral load non-suppression in people living with HIV on HAART (Ansah, Kumah, Bawontuo, Agyei-baffour, et al., 2021).

1.5. Research questions

The study has addressed the following questions.

i. What is the prevalence of virological failure in HIV patients on active ART?
ii. Does HIV patients' adherence to antiretroviral therapy affect viral load failure?
iii. What are the socio-demographic factors associated with virological failure in HIV patients?
iv. What are the behavioral characteristics associated with virological failure in HIV patients on antiretroviral therapy?

1.6. Aims and Objectives

1.6.1. General objectives

To determine the factors associated with virological failure in HIV patients on highly active antiretroviral therapy in the Upper East Region.

1.6.2. Specific objectives

i. To determine the prevalence of virological failure in HIV patients on active ART.
ii. To determine HIV patients' antiretroviral therapy adherence level.
iii. To determine the socio-demographic characteristics associated with virological failure in patients on HAART.
iv. To determine the behavioral characteristics associated with virological failure in patients on antiretroviral therapy.

1.7. Organization of the study

The thesis was categorized into 6 key chapters. Chapter one (1) involved the introduction comprising of the research background, problem statement, research questions, research objectives, justification, conceptual framework as well as the organization of the study. The chapter (2) comprised the literature review of the study and chapter three (3) outlined the methodology used. The forth (4^{th}) chapter was data analysis; the fifth (5^{th}) chapter involved the discussion of the results, while chapter (6) consisted of conclusions and recommendations.

CHAPTER TWO

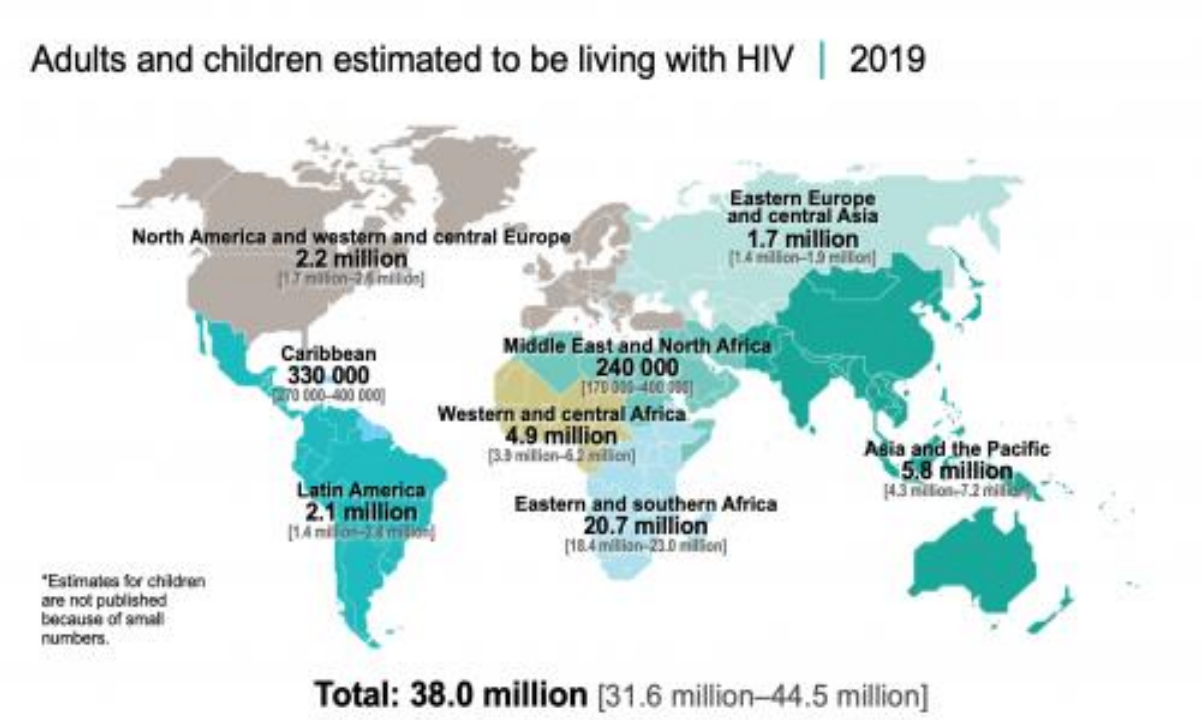
LITERATURE REVIEW

2.1. Introduction

Chapter two presented a discussion on issues investigated by the researcher. The researcher sought to investigate the factors that determine viral load failure in patients on active antiretroviral therapy in the Upper East Region. The chapter presented on epidemiology of HIV, literature reviewed on the prevalence of virological failure, patients' adherence to antiretroviral therapy, socio-demographic and behavioral factors significantly associated with virological failure in patients on HAART in the Upper East Region.

2.2. Epidemiology of Human Immunodeficiency Virus (HIV)

HIV/AIDS remains an epidemic and a global disease burden for over 30 years. From the inception of the HIV/AIDS, 79.3 million people got infected, and the number of deaths stood at 36.3 million. At the end of 2020, more than 37.7 million people globally lived with HIV with 0.7% infected adults aged 15 – 49 years. The World Health Organization (WHO) reported that nearly 1 in every 25 (3.6%) adults with the infection is living in Africa and more than 2/3 worldwide (Diress et al., 2020). For the prevalence rate of HIV among adults, Switzerland remains the highest with 27.1%, Lesotho (23.1%), Boswana (22.2%), South Africa (17.3%), Zimbabwe (13.3%), Namibia (12.7%), Muzambique (12.1%) etc. Ghana remains 28th position with 1.7% prevalence rate just above Liberia (1.5%). Kosovo in the Southeast Europe is the least of HIV/AIDS prevalence (0.00004%) in the world (World Bank, 2020).



Source: (Benjamin Ryan, 2020)

Figure 2.1: Map showing the global share of HIV infected population in 2019.

2.3. Prevalence of virological failure in HIV patients on HAART

Virological suppression in HIV patients means having viral load plasma lower than the detection level with lower quantitation limits of 20 copies/ml to 75 copies/ml. A patient achieves suppression of viral load with <1000 copies/ml (Abrams et al., 2000).

However, virological failure according to the World Health Organization (WHO) is when patients attained viral load >1000 copies/ml (WHO, 2015). Also, viral failure occurs if the viral load of repeated plasma >200 copies/ml after 6 months on antiretroviral (Abrams et al., 2000)

Antiretroviral treatment failure (virological failure) in HIV patients is caused by factors such as resistance to medication, weak absorption of medication, poor drug adherence, drug-drug interaction and insufficient dosage. In such a situation, the clinician should carry out test for drug resistance during virological failure as the client continued with the failing regimen (Abrams et al., 2000). A case-control study in 2017 found education, antiretroviral adherence, age, tuberculosis co-infection and occupation to be significant with viral load failure. Other associated factors included patients ART duration, body mass index, level of hemoglobin, WHO clinical stage, first line therapy, current CD4 count and recent white blood cells (WBC). It further indicated that, poor drug adherence, ART duration for longer years, age of patients <35 years, current CD4 count <200 cell/mm^3 had significant relationship with viral load non-suppression after possible effects of cofounding variables were adjusted (Bayu et al., 2017).

Earlier findings emphasized some factors that determined virological failure in HIV patients including clients loss to follow up history, younger age, non-adherence, being male and educational level (Palladino et al., 2013) (Anude et al., 2013) (Hassan et al., 2014). In other research found virological failure to be statistically significant with poor drug adherence, low CD4 count baseline, treatment disruptions and exposure prior to ART initiation (Meriki et al., 2014) (Greig et al., 2013).

Several studies have pointed out different contributory factors to virological non-suppression. However, poor adherence to treatment, and consequent occurrence of viral transformations which confer complete/incomplete ART resistance depended on the etiology of the problem. Therefore, in managing virological failure, health clinicians should assess patents adherence

to medication, medication resistance, and ensure appropriate antiretroviral prescription to improve the rate of viral suppression in patients on antiretroviral therapy (Abrams et al., 2000).

The researcher within the local settings would consider some major hindrances to undetectable viral load, including ART duration, doses missed, ART regimen, distance to the ART clinic, patient health, alcoholism, stigma, and timeliness of drug refill. The researcher would find these factors as hindrances to the attainment of the global UNAIDS targets of 90-90-90 and 95-95-95 to end the epidemic in 2030. Therefore, to reverse this situation and attain the goals, regular adherence counseling is required; change of drug regimens, and partner and child testing should be encouraged. Also, the differentiated service delivery (DSD) program should be fully implemented to reduce the waiting time at ART units, reduce the distance of traveling for ART, and enhance retention and care management of HIV patients.

2.4. Treatment adherence of HIV patients on HAART

According to Rahman (2019), as cited in Simoni et al. (2003), adherence involves the choice, starting, management and maintenance of antiretroviral therapy combination to regulate viral reproduction of HIV and enhance the immune system functioning. The various definitions of adherence rely the efforts of both the patients and the health professional. Health professionals must effectively engage clients in communication on taking medication and drug-related recommendations. Patients must also appreciate the practice and consent to the directives provided by the health care provider on antiretroviral therapy.

Adherence to medication involves a patient taking the recommended prescription appropriately and heed to ART appointment time to reduce the spread of the disease. Studies discovered that the ≥95% is the acceptable level of adherence treatment outcomes (Lourenço et al., 2016), which makes antiretroviral therapy very effective in ensuring low morbidity and mortality related to HIV (Bangsberg et al., 2001). Patients on antiretroviral therapy have drastically reduced the morbidity, mortality, and infectiousness of the HIV patients (Danforth et al., 2017).

Other studies discovered treatment adherence as the main determinant of treatment outcome in achieving the primary goals of care and treatment of HIV/AIDS; thus to decrease morbidity and mortality and enhance patients quality of life. These are linked to reaching an optimal viral load success. The study is further consistent with Lourenco et al. (2016) study that a sustained treatment adherence to therapy should be ≥95% to achieve an undetectable viral level as treatment outcome (Umeokonkwo et al., 2019). Antiretroviral therapy has increased survival rate, quality of livelihood decrease in transmission of HIV. Patients' treatment adherence and retention is related to successful treatment outcomes by attaining viral load suppression (Bangsberg et al., 2001; Gardner et al., 2011; Giordano et al., 2007; Park et al., 2007; Viswanathan et al., 2015).

On the other hand, poor antiretroviral therapy adherence is seen to be significant with poor treatment outcomes and caused an increased ricks of drug resistance. Poor adherence further decreases optimum clinical outcomes and lessens the achievement for the treatment goal, especially in ending the HIV/AIDS epidemic by 2030. This study further holds similar view

that patients' adherence level could be associated with patients and treatment-related factors. The complication of treatment side effects, poor health literacy, ineffective patient-clinician relationships and treatment regimen such as burden of pill and dosing frequency were found to have effects on treatment adherence of patients (Schaecher, 2013). The Joint United Nations Programme on HIV/AIDS (UNAIDS) global treatment targets (95-95-95) by 2030 rely on long-term viral suppression and optimum drug adherence and patients care (UNAIDS, 2014). All the findings from these studies have proved that patients to antiretroviral treatment of ≥95% have significant impact on viral load suppression. The primary aim of this research was to measure the factors that hinder the virological suppression of HIV patients on HAART.

2.5. Socio-demographic characteristics of HIV patients on HAART

A study by Plymoth et al., (2020a) revealed that viral load failure during antiretroviral therapy has significant relationship with male gender, young age, and progressive immunosuppression. Patients failure in viral suppression was also linked unemployment, poor housing, low educational level, and low income of social support. The above elements were found to be linked with the outcomes of communicable and non-communicable diseases which were considered as viral health determinants. Nonetheless, such relationships with regards to virological outcome were mainly investigated in developed countries, but with limited data form the low-income and high burden countries. Therefore, it was recommended that to ensure sustainability of antiretroviral in patients, knowledge on health conditions that contribute to poor viral suppression is required to develop and implement targeted interventions (Plymoth et al., 2020b). Given the above findings, the COVID-19 has contributed to high

unemployment, poverty, poor housing conditions and poor education hindered patients on ART. During this period, people stayed at home, limiting their access to ART and thereby causing patients more communicable diseases such as STIs and non-commutable diseases such as diabetes, hypertension, etc. these incidents contributed to the high virological failure in HIV patients.

Other literature indicated that HIV women have complex viral load and take antiretroviral therapy less frequent compared to men. Sero-status of HIV disclosure impact women adherence to medication and general difficult social situation and concerns for potential pregnancy risk. This makes women less likely to have complete viral suppression. The study highlighted success of treatment to be continuously significant with socio-demographic factors such as educational status, gender, race, and income that are not easily modifiable. Race is a complex system among socio-demographic characteristics including educational status, social and economic status, and healthcare accessibility. This limits the sustained commitment in HIV care and treatment, and or low annual income. This makes the patients struggle with increased survival difficulties unrelated to Human Immunodeficiency Virus (HIV). It was further revealed patients with children to care for, missed appointments days and substance use disorders contributed to virological failure (Shacham et al., 2010). However, in a study by Mosha F. (2021), more women, after12 months on treatment attained undetectable viral load compared to the male gender (Mosha, 2021). The researcher finds these two studies on women's vulnerability to HIV and virological failure as confusing and suggests that further studies regarding such topics are needed.

A study by Ayalew et al. in Ethiopia showed that the scheduling and accurateness in ascertaining failure of treatment in limited resource settings were essential but challenging. The delay in discovery of treatment failure might cause drug effects, high mortality and morbidity, and accumulation of drug resistance. The study further discovered that factors that caused the virological failure included gender, age and orphan status (Ayalew et al., 2016). Orphans face a lot of challenges in treatment and viral failure because caretakers and guardians, anemia, and poverty are independent factors that predict HIV virological failure. Therefore, orphans in treatment therapy need to be optimally managed.

Ansah, et al. in 2021 found eight variables in their study that cause virological non-suppression of clients on treatment in Kumasi, Ghana. These factors included age, gender, marital status, educational status, patients' duration on ART, patients' body weight, blood pressure and co-morbidity which were statistically significant with virological failure. Their analysis showed that male patients were 1.3 times more likely than that of female patients to have non-suppression of viral load. In health-seeking behavior, gender asymmetry was due to representation of masculinity fully implicated in the reluctance of male's to seek healthcare. A study indicated that the values with masculinity made males to be at risks of health, and socio-economic status (Ansah, Kumah, Bawontuo, Agyei-Baffour, et al., 2021).

The researcher supports Ansah et al point of view on the male's less performance on viral suppression on the basis that males have less health seeking behavior and many policies also turn to empower women to access health care systems. Therefore health education, promotion, and support strategies should be enhanced by health stakeholders

to improve male HIV patients' health-seeking behavior in viral suppression to contribute towards achieving the UNAIDS target of 95-95-95 by 2030.

Afrane et al. 2021, a study in Southern Ghana revealed that gender as the only socio-demographic factor as well as patient history of tuberculosis, severe CD4 immunodeficiency status that were significantly associated with viral load failure among clients on antiretroviral therapy. However, their study failed to reveal significant relationship in the age of children, education, employment of parents/caretakers, adherence to medication, and virological failure. They rather found female gender to be 2.5 increased odds of viral load failure than males on treatment. Similar to this study was that of Muri et al. in Tanzania where children with females guardians were 2.5 times at risk of virological non-suppression (Afrane et al., 2021). Though the study of Afrane et al was based on children, however, gender served as an important variable that cuts across as a cause for HIV children and adults virological non-suppression.

2.6. Behavioural factors of HIV patients on HAART

Human behaviours, including alcohol consumption, dietary behaviours, physical activity, smoking, sexual practices etc. play a key role in many of the leading causes of HIV death in developing and developed countries. The understanding of these behaviours and the contexts in which they occur is essential for developing effective evidence-based health behaviour change interventions and policies and for reducing avoidable mobility and mortality and improving HIV viral suppression (Danaei G., et al. (2009).

In India, study showed that alcohol consumption (62.8% - >3 drinks per day) was significant with viral load failure (Sarna et al., 2020). Research conducted by Sarna et al., (2020) indicated that alcohol consumption was 60.8% among patients on ART who consumed >2 times per month and those who consumed >3 drinks per day was 62.8%. The study concluded that alcohol intake was statistically significant with poor treatment adherence. This provided a solid prediction to viral load failure in patients on ART (Sarna et al., 2020). A literature by Asaah J. (2014) revealed that the UER led the rest of the country in terms of alcohol consumption rate and the adolescent youth are most affected group. The report found that excessive alcohol intake among women led to marital issues, pregnancy complications, HIV infection and low viraemia compared to men (Asaah J, 2014). However, Sarna et al. (2020) and Asaah J. (2014) reports on alcoholism, did not show the number of pills missed and other behaviours exhibited when patients took heavy alcohol resulting in virological failure.

In a literature in Zambia by Do and Meekers (2009), multiple sex partners among HIV patients are the strongest predictor of perceived HIV risk and virological failure. Also, men had increased odds of having multiple sex partners than women. Nevertheless, the likelihood of men to consider themselves at risk of virological failure was less (Do & Meekers, 2009). The study hypothesized that infectiousness beliefs and HIV transmission risk perceptions would prospectively predict HIV patients engaging in more condomless sex with HIV-negative and unknown HIV status sex partners. The study results showed that 44% of participants had engaged in condomless sex with HIV-negative/unknown status sex partners and these individuals demonstrated higher

rates viral load failure, STI symptoms and other opportunistic infections (Kalichman SC, 2016).

In a retrospective cohort study, the improvement in Body Mass Index (BMI) was significant and substantially higher in HIV patients due to the impact of HAART on nutritional status of HIV/AIDS patients in attaining undetectable viral load. This association showed the synergic effect of integrating food supplementation, nutritional education, and HAART on the nutritional status of HIV/AIDS patients. The study further highlighted the complementary role of an adequate and diversified diet in treatment adherence and viral load management in persons living with HIV/AIDS in resources limited settings (Scarcella P., et al. 2011).

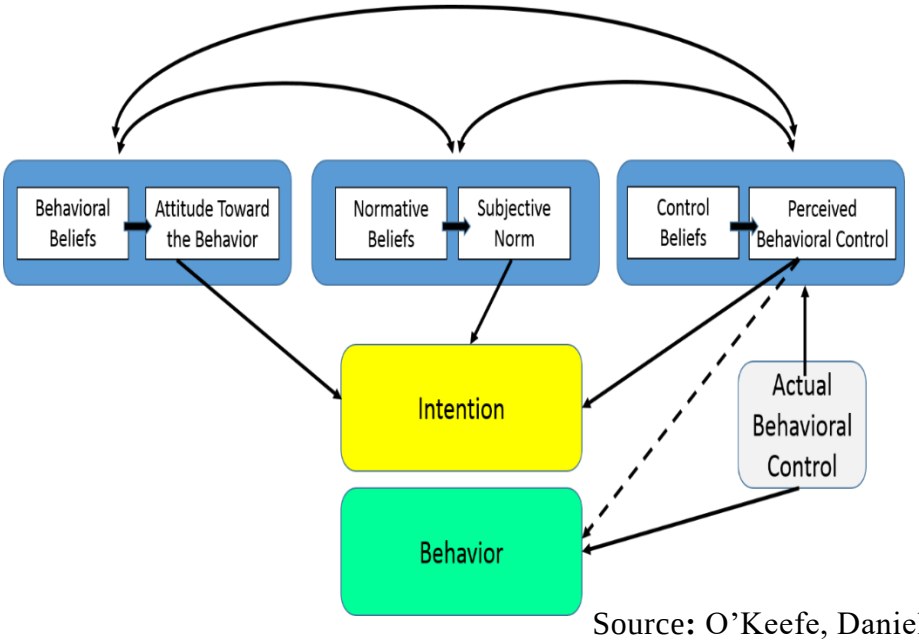
A cohort study of HIV-infected individuals on HAART in the US found that the prevalence of smoking among HIV-infected individuals is 2–3 times that of the general population, increasing the risk of HIV infection, viral load failure, and related morbidity and mortality. Current smokers were less likely to have an undetectable viral load (OR: 0.75) and more likely to have current substance abuse (OR: 2.81) and moderate to severe depression (OR: 1.50) relative to smokers who had quit smoking (Cropsey K.L., et al., 2016).

2.6.1 The Theory of Planned Behavior (TPB)

The theory of planned behavior (TPB) has been used successfully to predict and explain a wide range of health behaviors and intentions including alcohol consumption, smoking, multiple sexual partners, substance use, and adherence to medical treatment among others (Danaei G., et al. (2009). According to the theory of planned behavior, behaviors are

influenced by intentions, which are determined by attitudes, subjective norms, and perceived behavioral control (Ajzen, 1991) which affect ART adherence and viral load status of HIV patients on HAART (Sarna et al., 2020). These factors are not necessarily actively or consciously considered during decision-making but form the backdrop for the decision-making process of individuals on HIV treatment (Fishbein, M., & Ajzen, I. 1977). Also, external factors can directly force or prevent behaviors, regardless of the intention, depending on the degree to which a behavior is controlled by the individual, and the degree to which perceived behavioral control is an accurate measure of actual behavioral control in medical treatment (Ajzen, 1991).

Applying this theory (TPB) in this study would prove evidence for the effectiveness of behavior change interventions to improve ART adherence, undetectable viral load, reduce morbidity and mortality at individual, community, and population levels (Abraham C., 2009).



Source: O'Keefe, Daniel J. (2002).

Figure 2.6.1: The Theory of Planned Behavior

CHAPTER THREE

RESEARCH METHODOLOGY

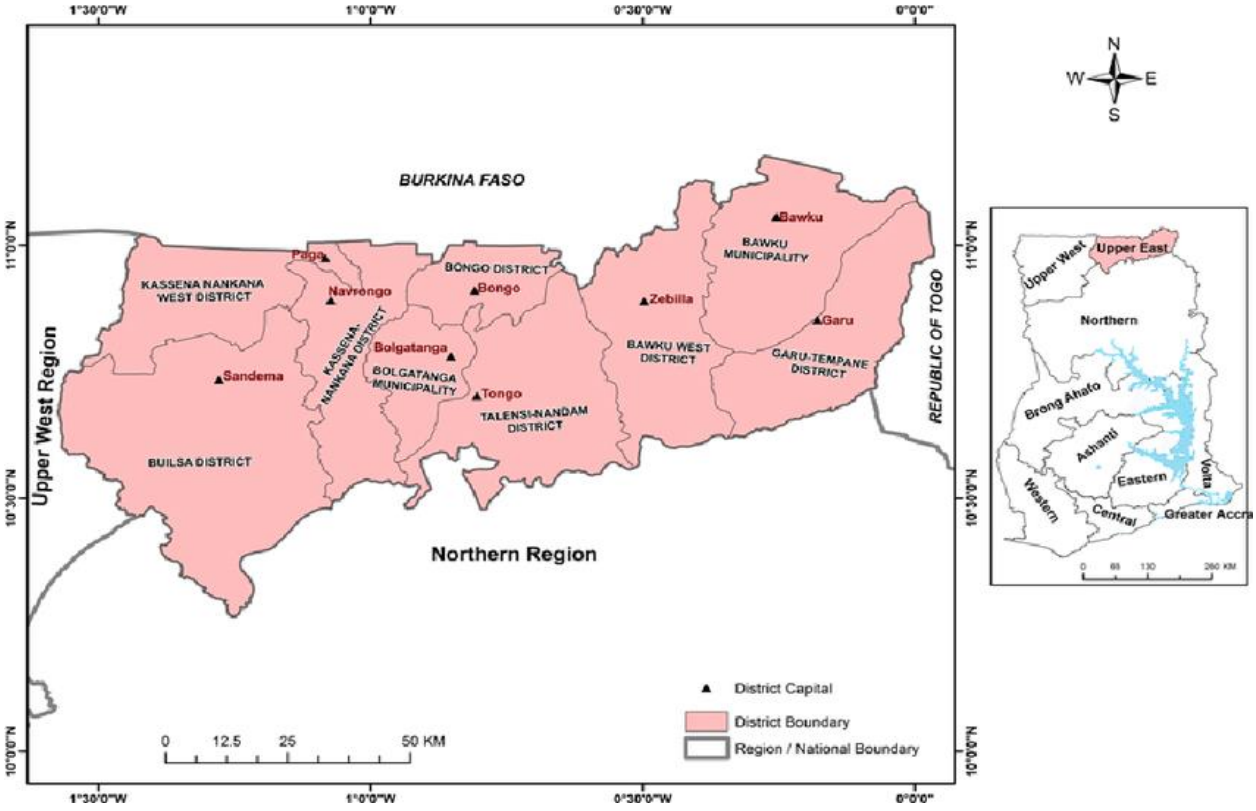
3.1. Introduction

The third chapter presented the method adopted to attain the objectives of the research. The subjects discussed included study design, study setting/location, study population, study variables, sampling, tools for data collection, pre-data collection activities, data management, data analysis and ethical consideration.

3.2. Background of the study area

The Upper East Region is in the North-Eastern part of Ghana. It occupies 8,842 square kilometers land mass area. The region shared boundaries with Togo to the East and Burkina Faso to the North in West Africa. The Upper East Region also shared borders with North-East Region (previously part of Northern Region) to the south and Upper West Region in the West (Alhassan S., 2017). At the end of 2020, the total population was 1,302,718 occupying 15 districts and municipalities. The region was sub-divided into 101 sub-districts. The total health facilities was 547 including 20 hospitals (1 regional hospital at Bolgatanga, 6 district and municipal Government hospitals, 10 private hospitals and 3 CHAG hospitals), 67 health centres, 38 clinics, 419 CHPS compound and 3 private maternity homes. Out of the 547 health service centres, 28 provided antiretroviral services with Bolgatanga Regional Hospital as the only centre with the capacity to test viral load (GhanaDistricts, 2012). The research was carried out in eight (8) ART clinics that provided comprehensive HIV care services to HIV patients in eight (8) districts in the Upper East Region of Ghana. These ART clinics were randomly selected. The selected health facilities had large number of HIV patients under care in their specific ART clinics, which

provided the tendency for ART clinics to have many patients with virological failure. Also, all these ART clinics offering ART services were identified as high HIV clinic workload facilities in the region, where more viral load tests were done from January 2020 to December 2020 (GAC, 2020).



Source: (Alhassan S., 2017).

Figure 3.2.1: Map showing administrative districts in the Upper East Region

3.3. Design

The researcher employed retrospective cross-sectional study. The records of 366 HIV patients aged ≥15 years on antiretroviral therapy for ≥6 months with a least of one (1) recorded HIV viral result at the antiretroviral (ART) clinic in 2020 was reviewed.

3.4. Study Population

The region had 4,315 active patients on antiretroviral treatment for 6 months and above at the end of 2020 (GAC, 2020). Patients aged ≥15 years and were on antiretroviral therapy for ≥6 months with at least one (1) readily available viral load result had the chance to be included in the study. However, HIV patients without viral load result, <15 years of age, lost to follow up, dead or patients who failed to consent to the study were not included.

3.5. Study variables

The main outcome variable in the study was viral non-suppression status in HIV clients on antiretroviral therapy. In the Low and Middle Income countries (LMICs), the WHO defined viral load suppression to be <1000 copies/ml, viral non-suppression to be >1000 copies/ml while viral outcome of <20 copies/ml was defined as undetectable (WHO, 2015). The independent variables were classified into social-demographic characteristics (gender, age, level of education, employment, marital status and salary/income), behavioral factors (alcohol consumption, number of sexual partners and condom use), and other variables such as adherence counseling, Art duration, ART regimen combination, challenges in getting ARVs timely, number of doses missed and ART side effects were analysed. Other variables included spouse/partner HIV status and number of viral load test done.

3.6. Sampling

3.6.1. Sample size determination

Using the Slovin's sample size formula (Ellen, 2020), a least sample of 366 was obtained with 5% margin of error from a targeted population of 4,315 patients aged ≥15 years in the Upper East Region. The formula was $n=\frac{N}{1+N\,(e)^2}$, where n=required sample, N=total HIV patients on ART, and e=error margin of 5%.

Therefore, $n=\frac{4315}{1+4315\,(0.05)^2}=\frac{4315}{1+4315\,(0.0025)}=\frac{4315}{1+10.7875}=\frac{4315}{11.7875}$, n=366.1

Total sample size for the study= 366.

3.6.2. Sampling procedure

Simple random sampling with a lottery selection technique (MS, 2016) was used to pick eight (8) ART clinics from the twenty-eight (28) ART service centres for the study. The same method was used to select the four (4) facilities from the remaining 20 ART clinics and used for the pretest. This method enabled every ART clinic in the Upper East Region to have a fair chance of being included. Consecutive sampling technique was then applied to sample 366 participants for the study (Dissertation L. , 2012). This was because the respondents and their data were readily available for the study and the researcher was interested in respondents who were on HAART with viral results at ≥6 months and ≥15 years of age.

3.7. Data Collection Tools

Quantitative data on HIV patients on antiretroviral therapy was obtained from the facilities' ART clinics. Viral load data was retrieved from the patient's folder, viral load registers or the E-Tracker database. Socio-demographic characteristics, patients' behavioral information, and age at HIV diagnose, duration on ART, type of ART regimen administered, pills missed, viral load test done were all relevant for data collection. Face-to-face data collection method was applied using 'Kobo-Collect (v1.29.3) software-based' structured questionnaire in English which contained closed-ended questions (KoBo, 2017). Respondents who could read and write were given the questionnaire to respond to.

3.8. Pre-data collection activities

The researcher was granted permission from the District Health Directorate and the facility heads in the eight (8) facilities that were selected to access information at the ART clinics. In the recruitment period, participants completed the structured survey questionnaire (SQ) upon consenting to the study. The survey questionnaires were administered by ART data managers and clinicians who were trained in data collection, and who understood the local dialect including Frafra, Kassena, Nabd, Dagbani, and Hausa in the Upper East Region. One clinical staff member from each of the eight (8) targeted ART facilities was recruited and trained to collect the data. The principal researcher audited and verified the collected data for completeness, quality, and error-free. Pre-test was carried out prior to the actual data collection, to measure the validity and consistency of responses in the questionnaire on eight (8) HIV patients in four different health centres who met the inclusion criteria but not part of

the study population. All issues realized on the study tool and processes during the pretest were addressed before the actual study started.

3.9.Data management

To ensure quality data management, the researcher employed some mechanisms to reduce data bias. The research assistants were trained on Kobo-Collect Software (KoBo, 2017), appropriate data collection, data collection procedures, and content and subject matter of the questionnaire. Ten days before the start of the study, the questionnaire was pretested to enable the data collectors to become familiar with the tools. Issues identified during the pretest were modified. Data collection was done by eight (8) skilled ART staff and supervised by the principal investigator. Daily supervision was done on-site and questionnaires were reviewed and crosschecked by the investigator for consistency, completeness and accuracy and discussed with the data collectors. The researcher carried out data cleaning in the Statistical Package for Social Sciences (SPSS) and proceeded to data analysis (Gunarto, 2019).

3.10. Data analysis

The Ghana AIDS Commission (2019) indicated that, within a month, patients who missed 0 - 1 dose of antiretroviral therapy have **good adherence** level (≥95%), patients who missed 2 - 4 doses have **fair adherence** level (≥85%), and patients with ≥5 doses missed have **poor adherence** level (<85%) (Ghana AIDS Commission, 2019). Other literature revealed that ≥95% is the required drug adherence level for successful treatment outcomes (Lourenço et al., 2016). HIV viral load achievement was categorized into three (3) including Target Not

Detected or Not Detected (<50 copies/ml), virally suppressed (<1000 copies/ml), and viral failure (≥1000 copies/ml). For simplicity in measurement, the researcher re-grouped these categories into two (2); Viral Load Suppression (<1000 copies/ml) and Virological Failure (≥1000 copies/ml). This study analysed and measured virological failure against other variables including treatment adherence, ART duration, ART regimen type, Education etc.

Data analysis was done using Statistical Package for Social Sciences (SPSS Inc, Chicago, USA) version 26.0 (Gunarto, 2019). Using descriptive statistics with frequencies and percentages, the data was described and summarized. Using the multiple logistic regression analysis, the study discovered the probabilities between the dependent variables and the Independable variables. A chi-square (X^2) test statistics was used to find the association between the various variables and virological failure among patients on ART. A confidence level of 95% during the study was administered with a 5% level of significance. The information was then presented in frequency tables, graphs and pie chart in a report (Gunarto, 2019).

3.11. Ethical considerations

Permission for ethical clearance was sought from the Ghana Health Service Ethics Review Committee (GHS-ERC:047/03/22) to carry out the research (GHS-ERC, 2021). The Regional Health Directorate of the Ghana Health Service (GHS) also granted the researcher permission to carry out the study in the Upper East Region. The purpose of the study was described to all the respondents to make informed decision to participate or not to participate in the study.

Consent form was attached to each questionnaire for every respondent to ensure the research assistants did not forget to make respondents sign before administering the questionnaire. The data collected with completed questionnaires were handled by the investigator and research assistants and kept with utmost confidentiality after data analysis.

CHAPTER FOUR

RESULTS

4.1 Socio-demographic characteristics of respondents

A total sample of 366 respondents from the ages of 15 years and above was enrolled in the study. Among the socio-demographic factors of HIV patients who participated in the study, it was found that majority (37.2%) of the respondents was within the ages of 25 – 34, while the least of the respondents representing 6% were from 55 years and above. Female participants outnumbered that of males more than two times representing 73.2% against male participants with 26.8%. Out of the 366 participants, majority of them representing 56.8% were married. A greater number of the respondents (52.5%) indicated they had no formal education and 52.5% were self-employed. The monthly earning of the respondents below GH¢ 375.00 were 60.7%, compared to 12.3% of the participants who earned more than GH¢ 1000. For the 91 respondents who were unemployed, 23.2% indicated that they depended on their families for their livelihood.

Table 4.1: Socio-demographic characteristics of respondents

Demographics Factors	Frequency (366)	Percentage (%)
Age group (years)		
15-24	46	12.6
25-34	136	37.2
35-44	107	29.2
45-54	55	15.0
≥55	22	6.0
Gender		
Male	98	26.8
Female	268	73.2
Marital Status		
Married	208	56.8
Never married	62	16.9
Divorced/Separated/Widowed	96	26.2
Educational Status		
No formal education	192	52.5
Basic	78	21.3
SHS/Voc/Tech	70	19.1
Tertiary	26	7.1
Occupation		
Public/Private employment	46	12.6
Self-employed	229	62.6
Unemployed	91	24.9
Salary/Income Level		
< GH¢ 375.00	222	60.7
GH¢ 375 – 1000	99	27.0
> GH¢ 1000	45	12.3
Dependent status		
Family	85	23.2
Friends	3	0.8
Support group	3	0.8

4.2 Behavioral characteristics of respondents

The study revealed that 73% of the participants were not taking alcohol while 27% respondents engaged in alcohol with frequency intake of 1 to 2 times a within a week. Daily consumers of alcohol, the least, were 5.7% as they took their HIV medications. From the total of 366, most (56.8%) of the respondents had no other sexual partners aside their spouses, 38.3% were either married or never married with 1 sexual partner, and 4.9% either married or never married had 2 or more sexual partners. Out of the 43.2% respondents with sexual partners, majority (38.3%) either married or never married had sexual intercourse with one (1) sexual partner within the past three months, while only 0.3% respondent never had sexual intercourse in the last 3 months with his/her spouse or sexual partner, with a reason that he/she feared to re-infect him/herself. For the 42.9% respondents who had sexual intercourse in the past 3 months, most (21.9%) of them never used condom during sexual intercourse with either their spouses or sexual partners and as low as 5.2% used condom always during sexual intercourse past 3 months. Majority (7.4%) of the respondents who never used condom during sexual intercourse with either their spouses or sexual partners gave a reason that their spouses/sexual partners may not suspect their HIV status, 6.8% disliked condom, 3.8% had desire for children, 2.5% spouses and/or sexual partners were HIV positive, and the least of 1.4% did not have access to condom for use.

Table 4.2: Behavioral characteristics of respondents

Variables	Frequency (366)	Percentage (%)
Alcohol Intake		
Yes	99	27.0
No	267	73.0
Frequency of Alcohol Intake		
1 to 2 time a week	52	14.2
≥3 times a week	26	7.1
Daily	21	5.7
Number of Sexual Partners		
1 sexual partner	140	38.3
≥2 sexual partners	18	4.9
None	208	56.8
Number of Sexual Partners with Sex		
1 sexual partner	140	38.3
≥2 sexual partners	17	4.6
Never	1	0.3
Reasons for Not Having Sex		
Fear of infecting self	1	0.3
Frequency of Condom Use		
Every time	19	5.2
Sometimes	58	15.8
Never	80	21.9
Reasons for Non-Condom Use		
Partner is HIV positive	9	2.5
Partner may suspect	27	7.4
Dislike for condom	25	6.8
Desire for children	14	3.8
Condom not available	5	1.4

4.3 Antiretroviral Therapy Adherence of Respondents

Most (30.9%) of the respondents were diagnosed and confirmed HIV positive within the ages of 25-34 years, which is slightly higher as compared to 29.0% of the respondents diagnosed HIV positive within the age range of 34-44 years. The minority (8.5%) diagnosed and confirmed HIV positive were the old age group of 55 years and above. Respondents who received adherence counseling before starting their treatment were 97.3%. The study also revealed that, 58.7% of the participants were on HIV treatment for 3 years and above, with least duration of less than 1 year (9.8%). For antiretroviral therapy (ART), majority (76.5%) was on Tenofovir+Lamivudine+Dolutegravir (TLD: 300mg+300mg+50mg) regimen. Also, 89.1% of patients found it easy taking the antiretrovirals (ARVs) without complains while 84.2% of the respondents did not have any problem in getting the antiretrovirals timely. Out of the 15.8% who complained of untimely nature of getting ARVs, most 10.7% of them indicated that distance to the ART site was a major challenge. A greater number of respondents representing 62.6% either did not miss or missed only one (1) dose of antiretroviral within the month, 12% missed doses within the range of 2-4, while 25.4% missed 5 or more doses of antiretroviral within a month. Figure 4.1 below shows that most patients representing 29% who missed their medication indicated that they ran out of pills (ARVs), 9.8% forgot to take their drugs, 6.6% missed dose due to drug side effects, 4.9% felt sick, while the minority 1.9% missed their pills due to stigma. Overall, 62.2% adherence to medication was considered as ‘good’ and respondents who ‘poorly’ adhered to medication were 25.4%. The study further revealed that, 89.6% did not experience any side effects of the antiretrovirals, and for the 10.4 that experienced

some adverse effects, 4.4% said they experienced nausea. Majority (68.3%) did not know their partners and/or sexual partner's HIV status, 16.1% respondents' spouses and/or sexual partners were HIV negative while spouses and/or sexual partners of 15.6% respondents were HIV positive. 13.4% of respondents' spouses and/or sexual partners who were HIV positive were on treatment. Most (48.4%) of the respondent who were diagnosed HIV positive had poor health before starting ARVs. On the other hand, 95.9% of the respondents who had poor health before HIV diagnose achieved good health after they started ARVs, with only 0.3% respondent with poor health.

Table 4.3: Antiretroviral Therapy Adherence of Respondents

Variables	Frequency (366)	Percentage (%)
Age at HIV Diagnose		
15 - 24	56	15.3
25 - 34	113	30.9
35 - 44	106	29.0
45 - 54	60	16.4
≥55	31	8.5
Adherence Counseling		
Yes	356	97.3
No	10	2.7
ART Duration		
< 1 year	36	9.8
1 – 3 years	115	31.4
≥3 years	215	58.7
ARVs Combination		
Tenofovir+Lamivudine+Efavirenz	65	17.8
Tenofovir+Lamivudine+Dolutegravir	280	76.5
Zidovudine+Lamivudine+Dolutegravir	21	5.7
Ease of taking ART		
Easy	326	89.1
Difficult	40	10.9
Having Problem Getting ART Timely		
Yes	58	15.8
No	308	84.2
Challenges in Getting ART Timely		
Distance to ART	39	10.7
Shortage of ART at site	3	0.8
ART clinic close early	5	1.4
Poor health	7	1.9
Stigma	4	1.1

Variables	Frequency (366)	Percentage (%)
Reasons Doses Missed		
Stigma	7	1.9
Felt sick/ill	18	4.9
Side effects	24	6.6
Forgot to take	36	9.8
Ran out of pills	106	29.0
ART Adherence Level		
Good	229	62.6
Fair	44	12.0
Poor	93	25.4
ART Having Side Effects		
Yes	38	10.4
No	328	89.6
ART side effects		
Nausea	16	4.4
Vomiting	3	0.8
Diarrhoea	7	1.9
Nightmares/vivid dreams	11	3.0
Skin rashes	1	0.3
Spouse/Partner HIV Status		
HIV positive	57	15.6
HIV negative	59	16.1
Don't know	250	68.3
Spouse/partner on treatment		
Yes	49	13.4
No	7	1.9
Don't know	1	0.3
Health Before ART Started		
Good	37	10.1
Fair	152	41.5
Poor	177	48.4
Health After ART Started		
Good	351	95.9
Fair	14	3.8
Poor	1	0.3

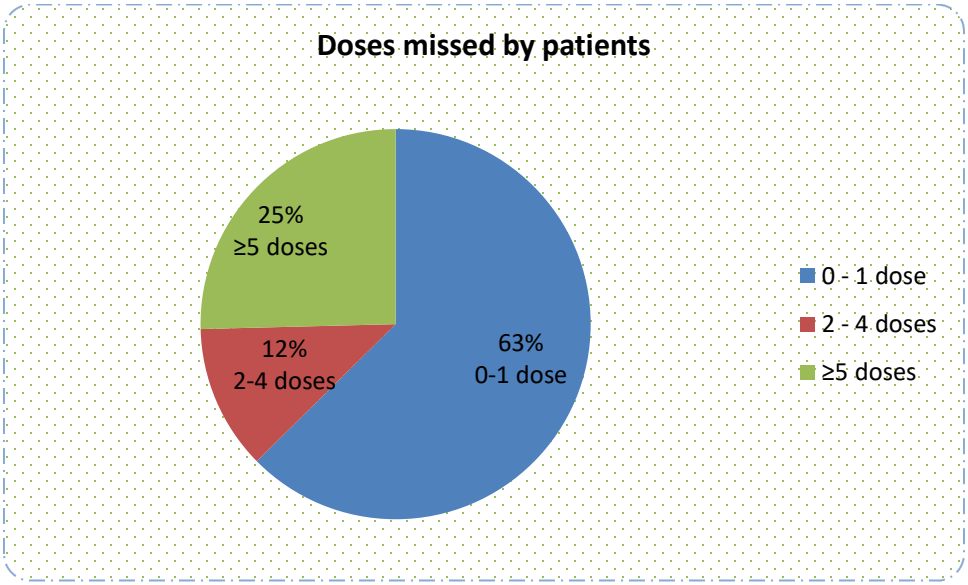


Figure 4.1: Number of doses missed by patients on antiretroviral therapy

4.4 HIV Viral Load Testing of Respondents

Out of the 366 respondents, majority of the participants 97.3% received enhanced adherence counselling. All the 366 participants in the study had undertaken viral load test with majority, 69.1% did only one (1) viral load test. For reasons of undertaken the viral load test, 91.0% tested to monitor their response to ART, 39.3% indicated that they wanted to check disease (HIV) progress, while 13.1% who undergone viral load test to check infectious level (suppression). 47.0% of the respondents had their viral results ≥1000 copies/ml (VL failure), 35.8% attained <1000 copies/ml (VL suppression) while 17.2% had Target Not Detected (complete VL suppression). Majority of the participants 53% achieved viral suppression (<1000 copies/ml and Target Not Detected). Viral load results were interpreted to 92.6% respondents while 7.4% did not receive any interpretation of their

viral load results. Of the 47% of the respondents who failed viral load (≥1000 copies/ml), 35.5% said it could lead to opportunistic infection, 35.2% said the failure could cause new HIV infections, 33.1% indicated reduction in survival rate, 31.7% stated that the VL failure of HIV could lead to AIDS and 5.5% indicated that the VL failure could cause drug resistance. Out of the 15.6% of participants whose spouses and/or sexual partners were HIV positive, 45.6% of the patients said they were not the source of infection to their spouses and/or sexual partners, 35.1% indicated that they infected their spouses and/or sexual partners whilst 19.3% patients did not know whether they or they did not infect their spouses and/or sexual partners with HIV.

Table 4.4: HIV viral load testing of Respondents

Variables	Frequency (366)	Percentage (%)
Received Enhanced Adherence Counseling		
Yes	356	97.3
No	10	2.7
Viral Load Test Done		
Yes	366	100.0
Number of Viral Load Test Done		
1 time	253	69.1
2 times	105	28.7
3 times	8	2.2
VL to Check Disease Progress		
Check disease progress	144	39.3
VL to Monitor Response to ART		
Monitor response to ART	333	91.0
VL to Check Infectious Level		
Check infectious level	48	13.1
Viral Load Results		
< 1000 copies/ml	131	35.8
≥ 1000 copies/ml	172	47.0
Target Not Detected	63	17.2
Results Interpreted to Respondent		
Yes	339	92.6
No	27	7.4
Viral Load Result Status		
VL Suppressed	194	53.0
VL Failed (Unsuppressed)	172	47.0
VL Failure Leads to Further Infection		
Can cause further infection	129	35.2
VL Failure Increases to AIDS		
Increase to stage 3/AIDS	116	31.7

Variables	Frequency (366)	Percentage (%)
VL Failure Leads to Opportunistic Infection		
Opportunistic infection	130	35.5
VL Failure Causes Drug Resistance		
Drug resistance	20	5.5
VL Failure Reduces Survival Rate		
Reduce survival rate	121	33.1
Spouses/Partners Infected by Respondent		
Yes	20	35.1
No	26	45.6
Don't know	11	19.3

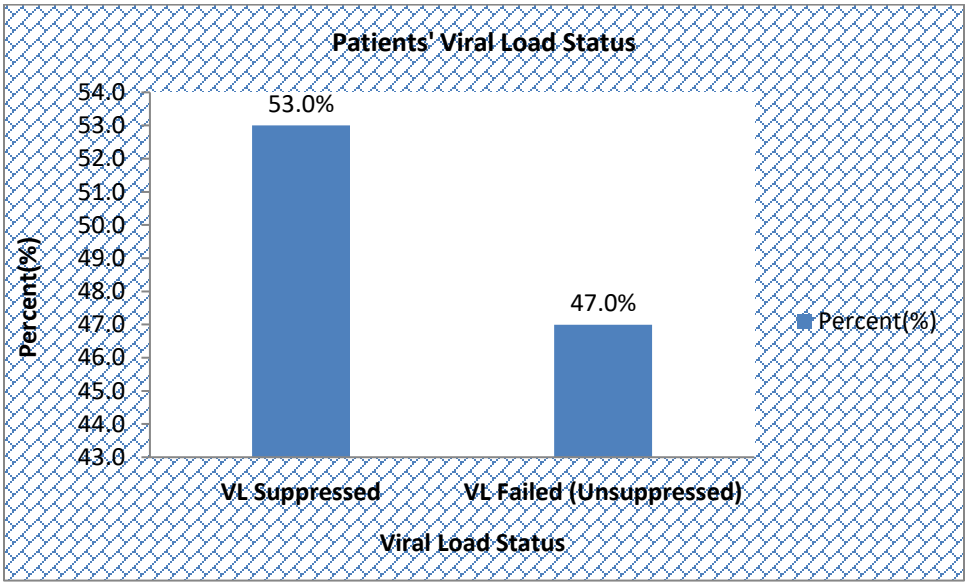


Figure 4.2: Viral Load Status of Respondents

4.5 Bivariate analysis of the determinants to HIV Viral Load Failure

The study results revealed that there was no association between gender and virological failure in patients on antiretroviral therapy with P-value=0.232 (χ^2 =1.429). Number of years HIV patients take drugs was found to have a significant relationship with virological failure (χ^2 =12.192, P-value=0.016). Marital status of the respondents was insignificant with viral load non-suppression with a P-value of 0.374 (χ^2=1.967). The study discovered that educational status was statistically significant with viral load failure among patients on highly active antiretroviral therapy (χ^2=17.999, P-value<0.001). Viral load non-suppression (viral load failure) in clients on antiretroviral therapy was found to be associated with occupation of the patients as there was significant relationship at 5% significant level between patients' occupation and viral load failure (χ^2=7.890, P-value=0.019). The levels of salary or income of the respondents on ART was significantly associated with virological failure with a P-value of <0.001 and chi-square (χ^2) value of 28.395.

There was no significant relationship at 5% significant level between alcohol intake by patients on antiretroviral therapy and virological failure (χ^2=0.129, P-value=0.719).

The cross-tabulation analysis indicated that the age at which patients were diagnosed with human immunodeficiency virus (HIV) was statistically significantly (χ^2=30.784, P-value<0.001) associated with virological failure. The study revealed that adherence to counseling with P-value=0.653 was not significantly associated with viral load failure among patients on antiretroviral therapy (χ^2=0.202). Patients' duration (in years) on antiretroviral therapy (ART) was statistically significantly associated (P-value=0.n017) with non-suppression of viral load at 5% (χ^2=8.175). There was also significant association between antiretroviral therapy

combinations for patients on ARVs and non-suppression (failure) of viral load (χ^2=15.841, P-value<0.001). Getting timely medications was not associated with viral load failure (χ^2=0.130, P-value=0.719). The study showed that viral load failure was associated with doses missed by HIV patients on antiretroviral therapy (χ^2=90.797, P-value<0.001). Statistically, the association between the side effects of antiretroviral treatment and virological failure was not significant (χ^2=0.154, P-value=0.694). Clients' health status before they started antiretroviral treatment was found to be statistically significantly associated with HIV viral load non-suppression (χ^2=12.697).

In the bivariate analysis, the study did not find any significant association between enhanced adherence counseling and viral load failure (χ^2=0.698, P-value=0.43). The number of viral load test done by patients on highly active antiretroviral therapy was associated with viral load failure in patients at 5% significant level (χ^2=15.403, P-value<0.001).

Table 4.5 Bivariate analysis of determinants to HIV Viral Load Failure

Variables	Frequency	Viral Load Suppressed	Viral Load Failed (Unsuppressed)	χ^2	P-value
Gender					
Male	98	57 (58.20%)	41 (41.80%)	1.429	0.232
Female	268	137 (51.10%)	131 (48.90%)		
Age					
15 – 24	46	28 (60.9%)	18 (39.1%)		
25 – 34	136	59 (43.4%)	77 (56.6%)		
35 – 44	107	66 (61.7%)	41 (38.3%)	12.192	**0.016***
45 – 54	55	26 (47.3%)	29 (52.7%)		
≥ 55	22	15 (68.2%)	7 (31.8%)		
Marital status					
Married	208	115 (55.30%)	93 (44.70%)		
Never married	62	34 (54.80%)	28 (45.20%)	1.967	0.374
Divorced/Separated/Widowed	96	45 (46.90%)	51 (53.10%)		
Education					
No formal education	192	89 (46.40%)	103 (53.60%)		
Basic	78	40 (51.30%)	38 (48.70%)	17.999	**<0.001***
SHS/Voc/Tech	70	42 (60.00%)	28 (40.00%)		
Tertiary	26	23 (88.50%)	3 (11.50%)		
Occupation					
Public/Private employment	46	33 (71.70%)	13 (28.30%)		
Self-employed	229	118 (51.50%)	111 (48.50%)	7.890	**0.019***
Unemployed	91	43 (47.30%)	48 (52.70%)		
Salary/Income					
< GH¢ 375.00	222	95 (42.80%)	127 (57.20%)		
GH¢ 375 - 1000	99	62 (62.60%)	37 (37.40%)	28.395	**<0.001***
> GH¢ 1000	45	37 (82.20%)	8 (17.80%)		
Alcohol Intake					
Yes	99	54 (54.40%)	45 (45.50%)	0.129	0.719
No	267	140 (52.40%)	127 (47.60%)		
Age at HIV Diagnose					
15 – 24	56	40 (71.40%)	16 (28.60%)		
25 – 34	113	55 (48.70%)	58 (51.30%)		
35 – 44	106	37 (34.90%)	69 (65.10%)	30.784	**<0.001***
45 – 54	60	41 (68.30%)	19 (31.70%)		
≥55	31	21 (67.70%)	10 (32.30%)		

P-Value < 0.050

Variables	Frequency	Viral Load Suppressed	Viral Load Failed (Unsuppressed)	χ^2	P-value
Adherence Counseling					
Yes	356	188 (52.80%)	168 (47.20%)	0.202	0.653
No	10	6 (60.00%)	4 (40.00%)		
ART Duration					
< 1 year	36	27 (75.00%)	9 (25.00%)		
1 – 3 years	115	61 (53.00%)	54 (47.00%)	8.175	**0.017***
≥3 years	215	106 (49.30%)	109 (50.70%)		
ART Combination					
Tenofovir+Lamivudine+Efavirenz	65	20 (30.80%)	45 (69.20%)		
Tenofovir+Lamivudine+Dolutegravir	280	161 (57.50%)	119 (42.50%)	15.841	**<0.001***
Zidovudine+Lamivudine+Dolutegravir	21	13 (61.90%)	8 (38.10%)		
Problem in Getting ART Timely					
Yes	58	32 (55.20%)	26 (44.80)	0.130	0.719
No	308	162 (52.60%)	146 (47.40%)		
Number of Doses Missed					
0 - 1 dose	229	161 (70.30%)	68 (29.70%)		
2 - 4 doses	44	22 (50.00%)	22 (50.00)	90.979	**<0.001***
≥5 doses	93	11 (11.80%)	82 (88.20%)		
ART Side Effects					
Yes	38	19 (50.00%)	19 (50.00%)	0.154	0.694
No	328	175 (53.40%)	153 (46.60%)		
Health Before Starting ART					
Good	37	27 (73.00%)	10 (27.00%)		
Fair	152	66 (43.40%)	86 (56.60%)	12.697	**0.002***
Poor	177	101 (57.10%)	76 (42.90%)		
Enhanced Adherence Counseling					
Yes	356	190 (53.40%)	166 (46.60%)	0.698	0.403
No	10	4 (40.00%)	6 (60.00%)		
Number of Viral Load Test Done					
1 time	253	150 (59.30%)	103 (40.70%)		
2 times	105	43 (41.00%)	62 (59.00%)	15.403	**<0.001***
3 times	8	1 (12.50%)	7 (87.50%)		
Interpretation of Viral Load Result					
Yes	339	183 (54.00%)	156 (46.00%)	1.760	0.185
No	27	11 (40.70%)	16 (59.30%)		

4.6 Viral load failure in HIV patients on antiretroviral therapy (ART)

The researcher conducted logistic regression analysis on the various factors that were statistically significant at 95% Confident Interval (C.I.) with P-value ≤0.050. The model showed that only eight (8) out of the eighteen (18) variables were statistically significant and also had association with HIV virological failure in HIV patients on HAART. These significant variables include the educational level, monthly salary/income, alcohol intake, ART duration, ART combination, problems in getting ART timely, number of doses missed, and the number of viral load test done.

The levels of education among Non-formal, Basic and SHS/Voc/Tech respondents were statistically significant with HIV viral load failure (P-value=0.001, P-value=002, P-value=0.014) respectively. These results implied that respondents with non-formal education had 8.873 increased odds in virological failure (OR=8.873, 95% C.I.= 2.578 - 30.541), those with basic education were 7.283 times more likely to develop virological failure (OR=7.283, 95% C.I.= 2.020 - 26.259) compared to participants with tertiary education, while the odds of viral load failure were 5.111-fold (OR=5.111, 95% C.I.= 1.400 - 18.654) higher in patients with SHS/Voc/Tech education compared to tertiary education of respondents on antiretroviral therapy. The study also found significant relationship between respondents whose salaries or incomes were below < GH¢ 375.00 per month with a P-value of 0.009 and viral load failure. Therefore, the odds of virological failure among low salary or income earners increased by 8.134 (OR=8.134, 95% C.I. = 1.697 - 38.995) compared to respondents who received GH¢ 1000.00 and above per month.

The study also established an association between alcohol consumption and viral load failure in HIV patients on HAART. The results, with a P-value of 0.029 and odds ratio of 0.425 (95% C.I. =0.197 - 0.915), revealed that there is 57.5% decreased odds in virological failure among patients who took alcohol compared to respondents who did not take in alcohol while on antiretroviral therapy.

In the multiple logistics regression analysis, patients on antiretrovirals for less than one (1) year statistically significant (P-value=0.034) with viral load failure. These patients were 0.29 times (OR=0.293, 95% C.I. = 0.094 - 0.912) less likely to attain viral load failure compared to patients on antiretrovirals for 3 years and above. Patients who were put on Tenofovir+Lamivudine+Efavirenz combination were 4.883 times (OR=4.883, 95% C.I. = 1.172 - 20.346) more likely to fail viral load suppression compared to patients on Zidovudine+Lamivudine+Dolutegravir regimen. The problems in getting antiretroviral therapy timely by patients on antiretrovirals was significantly associated (P-value=0.013) with viral load failure. This resulted in the odds of 70.4% decreased in viral load un-suppression (OR=0.296, 95% C.I. = 0.113 - 0.775). The study further revealed 97.7% (OR=0.023, 95% C.I. = 0.008 - 0.064) and 88.7% (OR=0.113, 95% C.I. = 0.036 - 0.351) decreased odds of viral load failure among clients who missed their medication within the ranges of 2-4 and ≥5 doses respectively within a month compared to clients who missed 1 dose or did not miss at all.

Patients who did viral load test once were statistically significantly associated with virological failure with P-value of 0.030. Two (2) times viral load test among clients had borderline P-value of 0.050. This result suggested that patients who had undergone viral load test once were 93.8% (OR=0.062, 95% C.I. = 0.005 - 0.763) less likely to attain non-

suppressed viral load than patients with 3 times viral load test. However, enhanced adherence counselling was not associated with viral load failure in clients on treatment at 5% significant level (P-value=0.586).

Table 4.6: Viral load failure in HIV patients on antiretroviral therapy (ART)

Variables	Frequency	Odds Ratio	P-Value	95% C.I.
Gender				
Male	98	Ref		
Female	268	0.688	0.298	0.340 - 1.392
Age				
15 – 24	46	Ref		
25 – 34	136	1.728	0.395	0.490 - 6.091
35 – 44	107	1.272	0.720	0.342 - 4.735
45 – 54	55	1.647	0.494	0.394 - 6.883
≥ 55	22	0.881	0.887	0.154 - 5.045
Marital status				
Married	208	0.721	0.386	0.344 - 1.510
Never married	62	0.386	0.109	0.121 - 1.236
Divorced/Separated/Widowed	96	Ref		
Education				
No formal education	192	8.873	**0.001***	2.578 - 30.541
Basic	78	7.283	**0.002***	2.020 - 26.259
SHS/Voc/Tech	70	5.111	**0.014***	1.400 - 18.654
Tertiary	26	Ref		
Occupation				
Public/Private employment	46	1.666	0.496	0.383 - 7.248
Self-employed	229	1.172	0.714	0.502 - 2.734
Unemployed	91	Ref		
Monthly salary/income				
< GH¢ 375.00	222	8.134	**0.009***	1.697 - 38.995
GH¢ 375 - 1000	99	2.726	0.186	0.617 - 12.052
> GH¢ 1000	45	Ref		
Alcohol intake				
Yes	99	0.425	**0.029***	0.197 - 0.915
No	267	Ref		
Age at HIV diagnose (years)				
15-24	56	0.819	0.778	0.204 - 3.288
25-34	113	2.942	0.100	0.814 - 10.635
35-44	106	2.708	0.114	0.788 - 9.310
45-54	60	1.724	0.442	0.430 - 6.908
≥55	31	Ref		

P-Value < 0.050

Variables	Frequency	Odds Ratio	P-Value	95% C.I.
Adherence counseling				
Yes	356	2.383	0.417	0.292 - 19.42
No	10	Ref		
ART duration				
< 1 year	36	0.293	**0.034***	0.094 - 0.912
1 – 3 years	115	0.616	0.143	0.322 - 1.178
≥3 years	215	Ref		
ART combination				
Tenofovir+Lamivudine+Efavirenz	65	4.883	**0.029***	1.172 - 20.346
Tenofovir+Lamivudine+Dolutegravir	280	1.776	0.395	0.473 - 6.662
Zidovudine+Lamivudine+Dolutegravir	21	Ref		
Problem in getting ART timely				
Yes	58	0.296	**0.013***	0.113 - 0.775
No	308	Ref		
Number of doses missed				
0 - 1 dose	229	Ref		
2 - 4 doses	44	0.023	**<0.001***	0.008 - 0.064
≥5 doses	93	0.113	**<0.001***	0.036 - 0.351
ART side effects				
Yes	38	0.439	0.126	0.153 - 1.261
No	328	Ref		
Health before starting ART				
Good	37	Ref		
Fair	152	0.746	0.636	0.222 - 2.507
Poor	177	0.459	0.202	0.138 - 1.521
Viral load counseling				
Yes	356	0.594	0.586	0.091 - 3.867
No	10	Ref		
Number of viral load test done				
1 time	253	0.062	**0.030***	0.005 - 0.763
2 times	105	0.080	**0.050***	0.006 - 1.004
3 times	8	Ref		
Interpretation of viral load				
Yes	339	0.402	0.161	0.113 - 1.436
No	27	Ref		

CHAPTER FIVE

DISCUSSION

5.1 Introduction

The study was conducted to determine the various factors that were associated with virological failure amongst patients on highly active antiretroviral therapy (HAART) in the Upper East Region. The study revealed that about 47.0% of patients on antiretroviral therapy with recorded viral load attained virological failure. The analysis conducted demonstrated that factors such as non-formal, basic and SHS/Voc/Tech education, salary/income below < GH¢ 375.00, alcohol intake, duration on antiretroviral therapy for <1 year, Tenofovir+Lamivudine+Efavirenz combination therapy, problems in getting ARVs timely, number of doses missed, and 1 or 2 times viral load test done were significantly associated with virological failure among patents on treatment.

5.2 Prevalence of virological failure in patients on HAART

The viral suppression rate (53%) in patients on antiretroviral therapy in this study was lower compared to the set target of the UNAIDS 90% for 2020 in the Upper East Region. However, the proportion of the virological failure (47.0%) among the patients was high but an increased performance compared to the Ghana AIDS Commission reported rate of 49% viral load failure in the region (GAC, 2019a). The failure rate (47.0%) found in this study could be connected to the high rate of patients running out of pill. A research carried out in Kumasi found 23.6% of viral load failure in Patients on antiretroviral therapy (Ansah, Kumah, Bawontuo, Agyei-

Baffour, et al., 2021). Another study in Ho, Volta Region found 31.3% viral load failure among HIV positive clients on antiretroviral (Lokpo et al., 2020). A review in Zimbabwe found 14% high viral load among clients on HIV treatment. The results of these studies had lower proportions of viral load failure compared to the current study (47.0%) in the Upper East Region. These tend to suggest that there might be some variations in HIV patients in achieving virological suppression based to availability and accessibility to antiretroviral therapy.

The multiple logistic regression analysis did not find any significant relationship between viral load failure and age, gender, marital status, occupation, adherence/viral load counseling, ART side effects, and interpretation of viral load results. Age was significant (P-value=0.016) with viral load failure in the bivariate analysis. The prevalence rate of virological failure among patients aged between 25-34 years was reported to be 56.6%. A study reported young age to be associated with virological failure contradicting this study results (Parienti et al., 2004). The difference might be attributed to the 24 months viral load follow-up in their research and 6 months to 12 months viral load follow up in this current study. The analysis also revealed that high proportion of females (73.2%) took the viral load test compared to males (26.8%). The high uptake of the viral load among females probably was due to their healthcare seeking behaviour by quickly finding remedy to their health condition compared to men. This explanation was consistent with a literature in Tanzania that men having sex with men have low health seeking behaviour due to stigma (Magesa et al., 2014).

The prevalence rate of viral failure in patients with no education was 52.5% while those with low education were 40.4%. Between 2011 and 2012, a research in the United Kingdom revealed that education below the university level had increased odds of virological failure amongst patients on antiretroviral therapy (Burch et al., 2014). Contrarily, Wiewel EW. observed in a study that educational level was not associated with viral load non-suppression (Wiewel EW., 2014). Although this research did not find any association between occupation and virological failure in the multiple logistic regression analysis, statistically, Burch et al., 2014 did find that unemployment was statistically significant with virological failure.

Viral load failure was more prevalent (60.7%) among respondents with <GH¢ 375.00 salary/income. Poverty leads to high dependency and risk of health conditions including viral load failure (Barnett & Weston, 2008). In view of this, Nabubelo et al. (2021) indicated that prevalence of viral load non-suppression was high among women with low income who depended on other peoples for financial support (Nobubelo et al, 2021). This current literature however did not find dependency to be associated with virological failure. Alcohol consumption was statistically significant (P-value=0.029) with viral load failure with prevalence rate of 45.5%. The finding was consistent with Sarna et al., (2020) who proved that alcohol intake was strongly associated with poor treatment adherence and strongly predict virological failure in patients on ART.

Tenofovir+Lamivudine+Efavirenz (TLE) regimen played significant part in viral load failure in the study. A prevalence rate of 69.2% was observed among patients who took the TLE regimen combination. Contradicting this result, other literature

highlighted that TLE tablet regimen provided benefits and satisfaction to patients in ensuring adherence and high viral suppression rate (Rangarajan et al., 2016). The type of ART regimen such as high TLE is one of the reasons for which patients missed doses due to its side effects. From this study finding, patients who missed ≥5 doses of regimen in a month had a prevalence rate of 88.2% of viral load failure. An Australian study similarly proved that patients who missed their refill appointment and missed ≥5 doses of medication were likely to attain high prevalence of virological failure (Kyaw et al., 2017). Also, the prevalence rates among HIV patients who took one (1) time viral load test was 40.7%, while patients with two (2) times viral load tests was 59.0%. The possibilities for patients missing pills were poor adherence to counseling and weak combination of treatment regimen. The finding is in line with the WHO recommendations that adherence counseling, regimen switch and repeat viral load test should be provided to clients who missed drugs and suspected to fail viral suppression (≥1000 copies/ml) (Diress et al., 2020).

These challenges might be reasons that contributed to Ghana's failure to meet the UNAIDS third 90% target of viral suppression rate in 2020. Therefore, National AIDS Control Programme, Ghana AIDS Commission, Ghana Health Service and researchers need to investigate further to detect local constrains such as patients and clinicians knowledge on viral load, availability of commodities and equipment, and blood sample procedures to enhance measures of viral load testing and suppression.

5.3 Patients' adherence to antiretroviral therapy

Adherence to antiretroviral therapy by patients depends much on the number of doses missed by clients and determines the amount of viral suppression. There was high antiretroviral therapy adherence level of 62.6% among the patients who participated in the study. One would have expected however that this high ART adherence would have corresponded with high percentage of viral load suppression among patients as viral load suppression rate was only slightly above average (53%) compared to viral load failure rate 47%. Similarly, a study in the Democratic Republic of Togo also found 62.6% ART adherence among patients (Potchoo et al., 2010). However, a literature in Iran discovered 75.4% antiretroviral therapy adherence (Mohammed A. et al, 2019) and another study found 66% ART adherence amongst patients in Brazil (Bonolo P. et al, 2013) which were all higher than in this study, Contrarily, antiretroviral therapy adherence among patients in South East Nigerian study was reported to be low (25%) (Uzochukwu et al., 2009). These discrepancies might be due to the study instruments, individual behavior and culture in the various study settings.

As high as 97.3% of the respondents reported that they received adherence counseling though this study did not find any association between adherence and virological failure. A study in Ethiopia revealed that 66.4% attained viral suppression after enhanced adherence counseling (Diress et al., 2020) which contradicts this research.

Some literature on adolescence regarding adherence to treatment showed that 23.8% forgot to take their medication and 11.0% had worsen illness which is much higher than the 9.8% found in this study.

5.4 Factors associated with virological failure in HIV patients

The study did not find any association between viral load failure and gender (P-value=1.429) and marital status (P-value=1.927). However, some literature revealed that women had higher probability of viral suppression compared to men (aOR=1.24) possibly due to the biological and behavioral differences (Pillay et al., 2020). Age was insignificant in the multiple logistic regression analysis, but statistically significantly associated with virological failure in in the bivariate analysis. Habtamu et al (2020) found that patients who were <35 years of age had 2.4 times increased odds of virological failure.

The analysis also showed that patients on antiretroviral therapy with non-formal, basic and SHS/Voc/Tech education among the socio-demographic factors were 8.873, 7.283 and 5.111 times more likely to fail viral suppression respectively compared to patients who attained tertiary education. This results is consistent with other literature that patients on antiretroviral therapy with lower level or no education experienced high viral load outcome (Gidey Brhane et al., 2017). Ansah, et al. (2021) in Kumasi also observed that lower level of education increased the risks of virological failure in HIV patients on antiretroviral therapy (Ansah, Kumah, Bawontuo, Agyei-baffour, et al., 2021). The assumption is that people with higher

education experience better health including self-reported health, healthy lifestyle, low mortality, morbidity and disability. However, some other literature highlighted that treatment success (viral load suppression) was continuously associated with the level of education of clients on ART (Shacham et al., 2010). The situation can be reversed with improved adherence counseling, health education, demand creation for viral load test and relevant information on antiretroviral therapy for patients with lower of no education.

The bivariate analysis revealed that most of the patients 60.7% on antiretroviral earned salary/income lower than GH¢ 375.00 per month. Out of this number, 57.2% failed to achieve viral suppression (χ^2=28.395, P-value<0.001). Also, 27.1% earned monthly salary/income between GH¢375.00 and GH¢1000.00, out of which 37.4% of patients had virological failure. Respondents who earned high salary/income above GH¢1000.00 per month were 12.3%, out of which 17.8% did not achieve viral suppression. This failure rate among low salary/income earners, due to low minimum wage, might have health effects and force patients to make unintentional choice among basic essentials like healthy food and shelter resulting in missed doses and great risk of viral load failure (Medicine, 2016). This finding on low salary/income affecting viral load failure was consistent with the study in Harare which posited that low income was associated with high viral load (≥1000 copies/ml) in patients on antiretroviral therapy (Chawana et al., 2014).

Out of the 27% of patients on antiretroviral therapy who consumed alcohol, 45.5% had non-suppression of their viral load. Statistically, in the multiple logistic regression analysis, alcohol intake was significantly associated (P-value=0.029) with virological failure among patients on ART. In a cohort study, it was revealed that the frequency of alcohol consumption was statistically significant with increased viral load plasma of patients on ART. As low as 29% – 33% achieved viral load suppression compared to about 69% viral load failure among alcohol drinkers (Baum et al., 2010). The failure rate was higher than findings in this study. The current study is also consistent with Samet et al. (2004) observation that alcohol intake affect the metabolism of antiretroviral medications and less than half of patients at risks of drinking adhered to medication, thereby increasing viral load in patients (Samet et al., 2004). A study in Philadelphia also established association between daily alcohol consumers and viral load detection, however, regular alcohol consumption was not significant with viral load detection (Wu et al., 2011). These variations possibly might be due to the quantity of alcohol intake and the number of different alcoholic drinks mixed altogether probably with non-alcoholic substances and consumed by patients. Therefore interventions or policies are required to promote alcoholic abstinence or limit the quantity of individual alcohol usage to enhance viral load suppression among patients on antiretroviral therapy.

Statistically, the study found significant relationship (P-value=0.034) between the duration (<1- year) on antiretroviral therapy and viral load detection by patients compared to patients on ART above 1-year. Several studies found similar results. In

South Africa, a study reported that adolescents on antiretroviral from 6-12 months had increased odds of virological failure compared to patients on longer treatment (Joseph D. et al, 2018). Also, a multi-country study in Vietnam showed 88.5% viral suppression rate among clients on ART after 1-year compared to those below 1-year on medication. Possible reasons might be that patients may forget taking their medication at initial stages, and also resort to traditional and spiritual healing treatment. As suggested by some researchers that the relationship between ART duration and HIV viral load failures has not been consistent (Fokam J. et al., 2017). Contradicting this study, a review with 100 HIV male patients in Vietnam found that patients on treatment for at least 6 months had 73% rate of achieving viral load suppression of <1000 copies/ml. Other studies in Gabon (Liégeois F. et al, 2012) and Muzambique (Rupérez et al., 2015) also contradicted this current study with the results that clients on treatment for >5 years rather attained increased odd of viral load failure.

Therefore, further research is required to confirm these contradictions on the association between patients' number of years on antiretroviral (ART duration) and virological failure.

About 18% of the clients were kept on Tenofovir+Lamivudine+Efavirenz (TLE) tablet regimen while majority (76.5%) were on the new tablet regimen of Tenofovir+Lamivudine+Dolutegravir (TLD), and 5.7% on other regimen. Efavirenz based regimen (EFV600) was the preferred first-line treatment by WHO for HIV type-1 patients. Due to major complains and side effects experienced by patients,

Efavirenz-based regimen was replaced with Dolutegravir-based and low Efavirenz-based regimen in 2018 by WHO (N Engl J, 2019). However, in 2020 which was the UNAIDS target year for achieving the 90-90-90, the high Efavirenz-based regimen (EFV 600) was still taken by patients in Ghana. This study found that, patients on the Efavirenz-based (TLE) combination were 4.88 time more likely to attain viral load failure (OR=4.883, 95% C.I.=1.172 - 20.346). This finding contradicts with other body of literature which highlighted the benefits and satisfaction of patients on TLE regimen in ensuring adherence and achieving viral load suppression (Rangarajan et al., 2016). However, their study was done in 2016 before WHO approval to switch from high Efavirenz-based to Dolutegravir-based regimen. To enhance viral load suppression in patients on antiretroviral, health authorities should ensure adequate availability of the new regimen, educate clients on its efficacy and provide sources for patients to report common side effects. This will ensure adherence and reduce viral load failure to achieve the new UNAIDs 95% by 2030.

The untimely nature of HIV patients in refilling their medications was also statistically significantly associated non-suppressed viral load. For those who could not refill their ARVs in time, 15.8% (58/366) mentioned several reasons including distance to ART site (10.7%), poor health (1.9%), ART clinic closed early (1.4%), stigma (1.1%), and shortage of ARVs at clinic (0.8%). Similar study in Vietnam found 20.6% among patients who had late appointments and 6.2% treatment interruptions (late refill) which were significantly associated with virological failure (Rangarajan et al., 2016). The untimeliness of refill of doses causes patients to miss

their doses severally and thereby increasing viral load failure. ART pharmacy staff should therefore provide refill date to patients and authorities should design systems to track clients whose refill dates are due.

Findings in this study revealed that, the number of doses missed was statistically significantly (P-value<0.001) associated with virological failure in patients who missed 2 or more doses within a month. This result concords with the literature in North East Ethiopia that patients who missed their appointment were likely to miss their doses and increase the odds of virological failure (Habtamu et al, 2020). Other literature from Nyanmar (Fong et al., 2013) and Australia (Kyaw et al., 2017) also agreed with this findings that missed appointments causing missed doses among patients on ART was statistically significantly associated with viral load failure. The amount of doses missed might be caused by patients running out of pills due to far distance to the ART site. This results in poor adherence, treatment and increases health conditions in patients. To reverse this situation, health authorities and HIV support groups should enhance the differentiated service delivery (DSD) and client demand creation to ensure regular and timely supply of ARVs to patients.

The World Health Organization (WHO) recommended that viral load testing is done at 6 months to 12 months after patients are initiated on treatment, and thereafter repeated every 12 months on stable clients with viral suppression. Patients with virological failure at initial testing should have a repeated test every 3 months until viral load is achieved (Joint UNAIDS, 2016). Therefore, whether clients achieve or

fail viral suppression, repeated viral loads testing is necessary for every client on ART as a gold standard for treatment monitoring. The multiple logistic regression analysis in this study found that respondents with 1-time viral load test (p-value=0.030) or 2-times viral load test (P-value=0.050) had borderline statistically significantly associated with virological failure compared to clients with 3 times viral load test.

This study supported the WHO recommendations that adherence counseling, regimen switch and repeat viral load test should be provided to clients with suspected viral load failure (≥1000 copies/ml) (Diress et al., 2020).

5.5 Limitations

The foremost strength in the research was the inclusion of all public hospitals in the Upper East Region except Bawku Presbyterian Hospital due to the conflict in Bawku. Also, personnel with vast experience in HIV services were employed to collect the data. The limitations of this study included the exclusion of children below 15 years who equally undertook viral load testing. Also, The Dolutegravir-based regimen was introduced late in Upper East region in 2019 with the aim to help patients achieve viral load suppression fast to attain the UNAIDS third 90% in 2020. Thirdly, only one viral load test result per client collected in 2020 was used to analyze the results. Inclusion of previous results for patients who did 2 or more VL test could have increased the suppression rate. Lastly, there could be selection bias introduced in the study since the data was collected mostly from respondents with regular follow-up. These limitations, however, did not have negative effects on the findings of this study.

CHAPTER SIX

FINDINGS, CONCLUSION AND RECOMMENDATION

6.1 Summary of Key findings

HIV/AIDS is one of the leading causes of global disease burden with no proven cure. Nevertheless, clinically, researchers have been able to discover antiretroviral therapy to manage and prolong the life of HIV patients. Antiretroviral therapy has brought massive improvement in patients' health and reduced the morbidity and mortality rates in the Upper East Region. The current health conditions among HIV patients according to the World Health Organization (2019) are patients' adherence to treatment and viral load suppression to help attain the new UNAIDS third 95% target by 2030.

Therefore, this study focused on the factors that determined virological failure in HIV patients on highly active antiretroviral therapy in the Upper East Region of Ghana.

The research discovered that 53% of patients on antiretroviral therapy achieved viral suppression (<1000 copies/ml) below the 2020 UNAIDS 90% target, while 47% of the patients had failed viral suppression below average. The various levels of education were significantly associated with viral load failure in patients on ART. Respondents (57.2%) who had monthly salary/income less than GH¢375.00 failed to attain suppressed viral load compared to patients who earned above GH¢375.00. Also, consumption of alcohol played a role in determining patients viral load failure of 45.5% below average level. Patients who were initiated on antiretroviral treatment for less than one (1) year had association (P-

value=0.034) with failure in patients viral load. Antiretroviral therapy regimen combination (Tenofovir+Lamivudine+Efavirenz) contributed to 69.2% virological failure in patients.

The study further revealed that challenges in getting antiretroviral refill timly made patients missed doses and therefore contributed to 44.8% viral load non-suppression. In addition, patients who missed more than one (1) dose of medication with <95% adherence to therapy had failed viral suppression (P-value<0.001). 40.7% and 59.0% of patients on antiretroviral therapy who did one (1) or two (2) times viral load test respectively were statistically significantly associated with virological failure.

6.2 Conclusion

This study found that educational status, salary/income, alcohol consumption, ART duration, ART combination regimen, timeliness of getting antiretroviral, number of doses missed, number of viral load test done were statistically significantly associated with virological failure in patients on antiretroviral therapy in the Upper East Region. However, the study did not discover any significant relationship between virological failure, and gender, age, marital status, occupation, adherence counseling and ART side effects.

The proportion of viral load achievement of 53% little above average fell short of the UNAIDS 90% suppression target for 2020. Strategic health interventions and study recommendations can help attain the new UNAIDS set target of 95% viral suppression by 2030 in the Upper East Region of Ghana.

6.3 Recommendation

To support in attaining the new UNAIDS target of 95% viral suppression rate by 2030 in the Upper East Region, the researcher recommended the following;

1. Health authorities should enforce the differentiated Service Delivery (DSD) to provide easy accessibility of antiretroviral therapy for patients. This will reduce the distance to access treatment for HIV, improve adherence level and reduce viral failure.
2. ART clinicians should educate clients on demand creation to enable patients make decision on where and when they can conveniently access antiretroviral therapy and do viral load testing.
3. Also, ART counselors should provide Enhanced Adherence Counseling (EAC) for clients who missed their refill date and medications, have poor adherence, and attained viral load of ≥ 1000 copies/ml (viral failure). This will improve treatment adherence and boost patients' immune system to achieve viral suppression.
4. The Ghana AIDS Commission and Ghana Health Service should engage, and train qualified pharmaceutical stores staff on HIV testing and counseling, and stock antiretroviral therapy. This would ensure an easy access to ARVs and enhance adherence level.
5. In addition, treatment supporter initiative should be strengthened to help patients ensure enhanced adherence to therapy, boost immune system and to achieve viral load suppression.
6. All clients who are still on the high Tenofovir+Lamivudine+Efavirenz based regimen combinations should be switched to low Efavirenz or Dolutegravir based regimen

combination to improve drug tolerance, avoid severe side effects, and fast track viral suppression achievement.

7. Patients with complete viral load failure should be given second-line regimen to avoid drug resistance and improve suppression rate.
8. In addition, further research is required to reveal other risk factors associated with viral load non-suppression in HIV patients on ART.

REFERENCES

Abrams, E., Ammann, A., Anderson, M., Bernstein, L., & Baker, C. (2000). Guidelines for the use of antiretroviral agents in pediatric HIV Infection January 7, 2000. *HIV Clinical Trials*, *1*(3), 58–99. https://doi.org/10.1310/EC1D-A9JN-J0HB-24PY

Abraham C., Kelly M. P., West R., Michie S. The UK National Institute for Health and Clinical Excellence public health guidance on behaviour change: A brief introduction. *Psychology, Health and Medicine.* 2009;(1):1–8. doi: 10.1080/13548500802537903.

Adobea Y Owusu, K. T. A. (2020). STATISTICAL , SOCIAL AND ECONOMIC Current HIV / AIDS Status , Access to Antiretroviral Treatment , and HIV-Related Stigma in Ghana. *Isser*, *6*, 2014–2018.

Afrane, A. K. A., Goka, B. Q., Renner, L., Yawson, A. E., Alhassan, Y., Owiafe, S. N., Agyeman, S., Sagoe, K. W. C., & Kwara, A. (2021). *HIV virological non-suppression and its associated factors in children on antiretroviral therapy at a major treatment centre in Southern Ghana : a cross-sectional study*. 1–11.

Ajzen, I. (1991). *Organizational Behavior and Human Decision Processes* (Vol. 50).

Alhassan S., Hadwen W. (2017). Challenges and Opportunities for Mainstreaming Climate Change Adaptation into WaSH Development Planning in Ghana. Vol 14. 10.3390/ijerph14070749. (Vol. 14).

Ansah, D. K. O., Kumah, E., Bawontuo, V., Agyei-Baffour, P., & Afriyie, E. K. (2021). Determinants of viral load non-suppression among people living with HIV on antiretroviral therapy in Kumasi, Ghana. *Ghana Medical Journal*, *55*(2), 111–117. https://doi.org/10.4314/GMJ.V55I2.3

Ansah, D. K. O., Kumah, E., Bawontuo, V., Agyei-baffour, P., & Emmanuel, K. (2021). *Determinants of viral load non-suppression among people living with HIV on anti-retroviral therapy in Kumasi , Ghana*. *55*(2).

Anude, C. J., Eze, E., Onyegbutulem, H. C., Charurat, M., Etiebet, M. A., Ajayi, S., Dakum, P., Akinwande, O., Beyrer, C., Abimiku, A., & Blattner, W. (2013). Immuno-virologic outcomes and immuno-virologic discordance among adults alive and on anti-retroviral therapy at 12 months in Nigeria. *BMC Infectious Diseases*, *13*(1). https://doi.org/10.1186/1471-2334-13-113

Asaah, J. (2014). *Alcohol Consumption Among Youth On The Increase In Upper East Region.*

Atugba, T.A., Aninagyei, E., Binka, F.N. *et al.* Factors Influencing HIV Status Disclosure to Partners Among Antiretroviral Therapy Clients in the Upper East Region, Ghana. *AIDS Behav* **26**, 2653–2663 (2022). https://doi.org/10.1007/s10461-022-03612-w

Ayalew, M. B., Kumilachew, D., Belay, A., Getu, S., Teju, D., Endale, D., Tsegaye, Y., & Wale, Z. (2016). First-line antiretroviral treatment failure and associated factors in HIV patients at the university of Gondar teaching hospital, Gondar, Northwest Ethiopia. *HIV/AIDS - Research and Palliative Care*, *8*, 141–146.

https://doi.org/10.2147/HIV.S112048

Bangsberg, D. R., Perry, S., Charlebois, E. D., Clark, R. A., Roberston, M., Zolopa, A. R., & Moss, A. (2001). Non-adherence to highly active antiretroviral therapy predicts progression to AIDS. *Aids*, *15*(9), 1181–1183. https://doi.org/10.1097/00002030-200106150-00015

Barnett, T., & Weston, M. (2008). Wealth, health, HIV and the economics of hope. *AIDS (London, England)*, *22 Suppl 2*. https://doi.org/10.1097/01.aids.0000327434.28538.51

Baum, M. K., Rafie, C., Lai, S., Sales, S., Page, J. B., & Campa, A. (2010). Alcohol use accelerates HIV disease progression. *AIDS Research and Human Retroviruses*, *26*(5), 511–518. https://doi.org/10.1089/aid.2009.0211

Bayu, B., Tariku, A., Bulti, A. B., Habitu, Y. A., Derso, T., & Teshome, D. F. (2017). Determinants of virological failure among patients on highly active antiretroviral therapy in University of Gondar Referral Hospital, Northwest Ethiopia: A case-control study. *HIV/AIDS - Research and Palliative Care*, *9*, 153–159. https://doi.org/10.2147/HIV.S139516

Bekker, L. G., Alleyne, G., Baral, S., Cepeda, J., Daskalakis, D., Dowdy, D., Dybul, M., Eholie, S., Esom, K., Garnett, G., Grimsrud, A., Hakim, J., Havlir, D., Isbell, M. T., Johnson, L., Kamarulzaman, A., Kasaie, P., Kazatchkine, M., Kilonzo, N., … Beyrer, C. (2018). Advancing global health and strengthening the HIV response in the era of the Sustainable Development Goals: the International AIDS Society—Lancet Commission. *The Lancet*, *392*(10144), 312–358. https://doi.org/10.1016/S0140-

6736(18)31070-5

Benjamin Ryan. (2020). *Global HIV Treatment Rates Rise, but Progress Is Uneven*.

Bonolo P. et al. (2013). *Gender differences in non-adherence among Brazilian patients initiating antiretroviral therapy.*

Bulage, L., Ssewanyana, I., Nankabirwa, V., Nsubuga, F., Kihembo, C., Pande, G., Ario, A. R., Matovu, J. K. B., Wanyenze, R. K., & Kiyaga, C. (2017). Factors Associated with Virological Non-suppression among HIV-Positive Patients on Antiretroviral Therapy in Uganda, August 2014-July 2015. *BMC Infectious Diseases*, *17*(1). https://doi.org/10.1186/s12879-017-2428-3

Burch et al. (2014). *Socio-economic factors and virological suppression among people diagnosed with HIV in the United Kingdom:*

Chawana, T. D., Reid, A., Bwakura, T., Gavi, S., & Nhachi, C. F. B. (2014). *Factors influencing treatment failure in HIV positive adult patients on first line antiretroviral therapy*. *60*.

Chou, R., Dana, T., Grusing, S., & Bougatsos, C. (2019). Screening for HIV Infection in Asymptomatic, Nonpregnant Adolescents and Adults. *Jama*, *321*(23), 2337. https://doi.org/10.1001/jama.2019.2592

Cropsey KL, Willig JH, Mugavero MJ, Crane HM, McCullumsmith C, Lawrence S, Raper JL, Mathews WC, Boswell S, Kitahata MM, Schumacher JE, Saag MS; CFAR Network of Integrated Clinical Systems. Cigarette Smokers are Less Likely to Have Undetectable

Viral Loads: Results From Four HIV Clinics. J Addict Med. 2016 Jan-Feb;10(1):13-9. doi: 10.1097/ADM.0000000000000172. PMID: 26656939; PMCID: PMC4733609.

Danaei G., Ding E. L., Mozaffarian D., Taylor B., Rehm J., Murray C. J., Ezzati M. The preventable causes of death in the United States: Comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Medicine.* 2009;(4):e1000058. doi: 10.1371/journal.pmed.1000058. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

Danforth, K., Granich, R., Wiedeman, D., & Baxi, S. (2017). *Chapter 2Global Mortality and Morbidity of HIV / AIDS*. 2011–2013.

Diress, G., Dagne, S., Alemnew, B., Adane, S., & Addisu, A. (2020). Viral Load Suppression after Enhanced Adherence Counseling and Its Predictors among High Viral Load HIV Seropositive People in North Wollo Zone Public Hospitals, Northeast Ethiopia, 2019: Retrospective Cohort Study. *AIDS Research and Treatment*, *2020*. https://doi.org/10.1155/2020/8909232

Do, M., & Meekers, D. (2009). Multiple sex partners and perceived risk of HIV infection in Zambia: Attitudinal determinants and gender differences. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, *21*(10), 1211–1221. https://doi.org/10.1080/09540120902730047

Ellen, S. (2020). Slovin's formula sampling techniques. *Sciencing*, 1. https://sciencing.com/how-6188297-do-determine-audit-sample-size-.html

Evans, D., Dahlberg, S., Berhanu, R., Sineke, T., Govathson, C., Jonker, I., Lönnermark, E., & Fox, M. P. (2018). Social and behavioral factors associated with failing second-line ART–results from a cohort study at the Themba Lethu Clinic, Johannesburg, South Africa. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, *30*(7), 863–870. https://doi.org/10.1080/09540121.2017.1417527

Fishbein, M., & Ajzen, I. (1977). Belief, attitude, intention, and behavior: An introduction to theory and research. Addison-Wesley.

Fokam J. et al. (2017). *Immuno-virological response and associated factors amongst HIV-1 vertically infected adolescents in Yaounde-Cameroon.*

Fong, R., Cheng, A. C., Vujovic, O., & Hoy, J. F. (2013). Factors associated with virological failure in a cohort of combination antiretroviral therapy-treated patients managed at a tertiary referral centre. *Sexual Health*, *10*(5), 442–447. https://doi.org/10.1071/SH13043

Gardner, E. M., McLees, M. P., Steiner, J. F., Del Rio, C., & Burman, W. J. (2011). The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. *Clinical Infectious Diseases*, *52*(6), 793–800. https://doi.org/10.1093/cid/ciq243

Ghana AIDS Commission. (2019). *National HIV and AIDS Policy*. *September*, 1–41. https://ghanaids.gov.gh/mcadmin/Uploads/nationalHIVandAIDSPolicy.pdf

GHS. (2019). *HIV Hotspot Regions in Ghana.*

GHS-ERC. (2021). *GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE RECOMMENDED FORMAT FOR A RESEARCH PROTOCOL* . Ghana.

Gidey Brhane, B., Nibret, E., & Kahsu Abay, G. (2017). HIV/AIDS Treatment Failure and its Determinant Factors among First Line HAART Patients at Felege-Hiwot Referral Hospital, Bahir Dar, Northwest Ethiopia. *Journal of AIDS & Clinical Research*, *8*(11). https://doi.org/10.4172/2155-6113.1000744

Giordano, T. P., Gilford, A. L., White, A. C., Suarez-Almazor, M. E., Babeneck, L., Hartman, C., Backus, L. I., Mole, L. A., & Morgan, R. O. (2007). Retention in care: A challenge to survival with HIV infection. *Clinical Infectious Diseases*, *44*(11), 1493–1499. https://doi.org/10.1086/516778

Greig, J. E., du Cros, P. A., Mills, C., Ugwoeruchukwu, W., Etsetowaghan, A., Grillo, A., Tayo-Adetoro, A., Omiyale, K., Spelman, T., & O'Brien, D. P. (2013). Predictors of Raised Viral Load during Antiretroviral Therapy in Patients with and without Prior Antiretroviral Use: A Cross-Sectional Study. *PLoS ONE*, *8*(8). https://doi.org/10.1371/journal.pone.0071407

Gunarto, H. (2019). *Parametric & Nonparametric Data Analysis for Social Research: IBM SPSS.* LAP Academic Publishing. ISBN 978-6200118721.

Habtamu et al. (2020). Determinants of virological failure among adults on first-line highly active antiretroviral therapy at public health facilities in Kombolcha town, Northeast, Ethiopia: A case-control study. *BMJ Open*, *10*(7). https://doi.org/10.1136/bmjopen-2019-036223

Hassan, A. S., Nabwera, H. M., Mwaringa, S. M., Obonyo, C. A., Sanders, E. J., Rinke de Wit, T. F., Cane, P. A., & Berkley, J. A. (2014). HIV-1 virologic failure and acquired drug resistance among first-line antiretroviral experienced adults at a rural HIV clinic in coastal Kenya: A cross-sectional study. *AIDS Research and Therapy*, *11*(1). https://doi.org/10.1186/1742-6405-11-9

Jobanputra, K., Parker, L. A., Azih, C., Okello, V., Maphalala, G., Kershberger, B., Khogali, M., Lujan, J., Antierens, A., Teck, R., Ellman, T., Kosgei, R., & Reid, T. (2015). Factors associated with virological failure and suppression after enhanced adherence counselling, in children, adolescents and adults on antiretroviral therapy for HIV in Swaziland. *PLoS ONE*, *10*(2). https://doi.org/10.1371/journal.pone.0116144

Joint UNAIDS. (2016). *The need for routine viral load testing*.

Joseph D. et al. (2018). *Factors associated with recent unsuppressed viral load in HIV-1-infected patients in care on first-line antiretroviral therapy in South Africa*.

Kalichman SC, Cherry C, Kalichman MO, Washington C, Grebler T, Hoyt G, Merely C, Welles B. Sexual Behaviors and Transmission Risks Among People Living with HIV: Beliefs, Perceptions, and Challenges to Using Treatments as Prevention. Arch Sex Behav. 2016 Aug;45(6):1421-30. doi: 10.1007/s10508-015-0559-4. Epub 2015 Aug 21. PMID: 26292837; PMCID: PMC4761529.

Kazooba, P., Mayanja, B. N., Levin, J., Masiira, B., & Kaleebu, P. (2018). Virological failure on first-line antiretroviral therapy; associated factors and a pragmatic approach for switching to second line therapy–Evidence from a prospective cohort study in rural

south-western Uganda, 2004-2011. *Pan African Medical Journal*, *29*. https://doi.org/10.11604/pamj.2018.29.191.11940

KoBo. (2017). *PREPARING FOR MOBILE DATA.*

Kyaw, N. T. T., Harries, A. D., Kumar, A. M. V., Oo, M. M., Kyaw, K. W. Y., Win, T., Aung, T. K., Min, A. C., & Oo, H. N. (2017). High rate of virological failure and low rate of switching to second-line treatment among adolescents and adults living with HIV on firstline ART in Myanmar, 2005-2015. *PLoS ONE*, *12*(2). https://doi.org/10.1371/journal.pone.0171780

Liégeois F. et al. (2012). *Vi- rological failure rates and HIV-1 drug resistance patterns in patients on first-line anti-retroviral treat- ment in semirural and rural Gabon*.

Lokpo, S. Y., Ofori-Attah, P. J., Ameke, L. S., Obirikorang, C., Orish, V. N., Kpene, G. E., Agboli, E., Kye-Duodu, G., Deku, J. G., Awadzi, B. K., Noagbe, M., & Tetteh Quarshie, S. (2020). Viral Suppression and Its Associated Factors in HIV Patients on Highly Active Antiretroviral Therapy (HAART): A Retrospective Study in the Ho Municipality, Ghana. *AIDS Research and Treatment*, *2020*(3). https://doi.org/10.1155/2020/9247451

Magesa, D. J., Mtui, L. J., Abdul, M., Kayange, A., Chiduo, R., Leshabari, M. T., Kayombo, E., & Tungaraza, D. (2014). Barriers to men who have sex with men attending HIV related health services in dar es salaam, Tanzania. *Tanzania Journal of Health Research*, *16*(2). https://doi.org/10.4314/thrb.v16i2.8

Marsh, K., Eaton, J. W., Mahy, M., Sabin, K., Autenrieth, C. S., Wanyeki, I., Daher, J., &

Ghys, P. D. (2019). Global, regional and country-level 90-90-90 estimates for 2018: Assessing progress towards the 2020 target. *Aids*, *33*(April 2019), S213–S226. https://doi.org/10.1097/QAD.0000000000002355

Medicine, E. (2016). *Are low wages an occupational health hazard ?* 4–5.

Meriki, H. D., Tufon, K. A., Afegenwi, M. H., Nyindem, B. A., Atanga, P. N., Anong, D. N., Cho-Ngwa, F., & Nkuo-Akenji, T. (2014). Immuno-haematologic and virologic responses and predictors of virologic failure in HIV-1 infected adults on first-line antiretroviral therapy in Cameroon. *Infectious Diseases of Poverty*, *3*(1). https://doi.org/10.1186/2049-9957-3-5

Mohammed A. et al. (2019). *Antiretroviral therapy adherence and its determinant factors among people living with HIV/AIDS: a case study in Iran*.

Mosha, F. (2021). Gender Differences in Human Immunodeficiency Virus (HIV) Disease Progression and Treatment Outcomes. *AIDS Updates - Recent Advances and New Perspectives*. https://doi.org/10.5772/intechopen.92898

N Engl J. (2019). *Dolutegravir-Based or Low-Dose Efavirenz–Based Regimen for the Treatment of HIV-1*.

Njonjo, T. W. (2007). *Assessment of Patients Antiretroviral Therapy Knowledge*. 1–86.

Nobubelo et al. (2021). *HIV viral load non-suppression and associated factors among pregnant and postpartum women in rural northeastern South Africa: a cross-sectional survey*.

O'Keefe, Daniel J. Persuasion: Theory & Research. 2nd ed. Thousand Oaks: Sage Publications, 2002. Print.

Palladino, C., Briz, V., Bellón, J. M., Bártolo, I., Carvalho, P., Camacho, R., Muñoz-Fernández, M. Á., Bastos, R., Manuel, R., Casanovas, J., & Taveira, N. (2013). Predictors of attrition and immunological failure in HIV-1 patients on highly active antiretroviral therapy from different healthcare settings in mozambique. *PLoS ONE*, *8*(12). https://doi.org/10.1371/journal.pone.0082718

Parienti et al. (2004). *Predictors of virologic failure and resistance in HIV-infected patients treated with nevirapine- or efavirenz-based antiretroviral therapy*.

Park, W. B., Choe, P. G., Kim, S. H., Jo, J. H., Bang, J. H., Kim, H. B., Kim, N. J., Oh, M., & Choe, K. W. (2007). One-year adherence to clinic visits after highly active antiretroviral therapy: A predictor of clinical progress in HIV patients. *Journal of Internal Medicine*, *261*(3), 268–275. https://doi.org/10.1111/j.1365-2796.2006.01762.x

Pillay, T., Cornell, M., Fox, M. P., Euvrard, J., Fatti, G., Technau, K. G., Sipambo, N., Prozesky, H., Eley, B., Tanser, F., & Johnson, L. F. (2020). Recording of HIV viral loads and viral suppression in South African patients receiving antiretroviral treatment: A multicentre cohort study. *Antiviral Therapy*, *25*(5), 257–266. https://doi.org/10.3851/IMP3371

Plymoth, M., Sanders, E. J., Van Der Elst, E. M., Medstrand, P., Tesfaye, F., Winqvist, N., Balcha, T., & Bjorkman, P. (2020a). Socio-economic condition and lack of virological suppression among adults and adolescents receiving antiretroviral therapy in Ethiopia.

PLoS ONE, *15*(12 December). https://doi.org/10.1371/journal.pone.0244066

Plymoth, M., Sanders, E. J., Van Der Elst, E. M., Medstrand, P., Tesfaye, F., Winqvist, N., Balcha, T., & Bjorkman, P. (2020b). Socio-economic condition and lack of virological suppression among adults and adolescents receiving antiretroviral therapy in Ethiopia. *PLoS ONE*, *15*(12 December), 1–18. https://doi.org/10.1371/journal.pone.0244066

Potchoo, Y., Tchamdja, K., Balogou, A., Pitche, V. P., Guissou, I. P., & Kassang, E. K. (2010). Knowledge and adherence to antiretroviral therapy among adult people living with HIV/AIDS treated in the health care centers of the association "Espoir Vie Togo" in Togo, West Africa. *BMC Clinical Pharmacology*, *10*. https://doi.org/10.1186/1472-6904-10-11

Rahman, A. A. (2019). *Attaining the 90-90-90 Targets: Barriers and Facilitators to Retention in Care and Adherence to Antiretroviral Therapy in a Ghanaian Referral Hospital*. *June*, 1–90.

Rangarajan, S., Colby, D. J., Giang, L. T., Bui, D. D., Hung Nguyen, H., Tou, P. B., Danh, T. T., Tran, N. B. C., Nguyen, D. A., Hoang Nguyen, B. T., Doan, V. T. N., Nguyen, N. Q., Pham, V. P., Dao, D. u. G., Chen, M., Zeng, Y., Van Tieu, T. T., Tran, M. H., Le, T. H., … West, G. (2016). Factors associated with HIV viral load suppression on antiretroviral therapy in Vietnam. *Journal of Virus Eradication*, *2*(2), 94–101. https://doi.org/10.1016/s2055-6640(20)30466-0

Rupérez, M., Pou, C., Maculuve, S., Cedeño, S., Luis, L., Rodríguez, J., Letang, E., Moltó, J., Macete, E., Clotet, B., Alonso, P., Menéndez, C., Naniche, D., & Paredes, R. (2015).

Determinants of virological failure and antiretroviral drug resistance in Mozambique. *Journal of Antimicrobial Chemotherapy*, *70*(9), 2639–2647. https://doi.org/10.1093/jac/dkv143

Samet, J. H., Horton, N. J., Meli, S., Freedberg, K. A., & Palepu, A. (2004). Alcohol Consumption and Antiretroviral Adherence among HIV-Infected Persons with Alcohol Problems. *Alcoholism: Clinical and Experimental Research*, *28*(4), 572–577. https://doi.org/10.1097/01.ALC.0000122103.74491.78

Sarna, A., Singh, R. J., Schensul, J. J., Gaikwad, S. S., Joshi, K., Malye, R., Mahapatra, B., Ha, T., & Schensul, S. (2020). Viral load outcomes in a cohort of alcohol-consuming people living with HIV receiving antiretroviral therapy in Mumbai, India. *International Journal of STD and AIDS*, *31*(8), 763–772. https://doi.org/10.1177/0956462420921731

Scarcella P, Buonomo E, Zimba I, Doro Altan AM, Germano P, Palombi L, Marazzi MC. The impact of integrating food supplementation, nutritional education, and HAART (Highly Active Antiretroviral Therapy) on the nutritional status of patients living with HIV/AIDS in Mozambique: results from the DREAM Programme. Ig Sanita Pubbl. 2011 Jan-Feb;67(1):41-52. PMID: 21468153.

Schaecher, K. L. (2013). The importance of treatment adherence in HIV. *American Journal of Managed Care*, *19*(12 SUPPL.), 231–237.

Shacham, E., Nurutdinova, D., Onen, N., Stamm, K., & Overton, E. T. (2010). The interplay of sociodemographic factors on virologic suppression among a U.S. outpatient HIV

clinic population. *AIDS Patient Care and STDs*, *24*(4), 229–235. https://doi.org/10.1089/apc.2009.0275

Teklehaimanot and Birhanu. (2020). *Prevalence and Predictors of Virological Failure Among Adults Living with HIV in South Wollo Zone, Northeast Ethiopia: A Retrospective Cohort Study*.

Umeokonkwo, C. D., Onoka, C. A., Agu, P. A., Ossai, E. N., Balogun, M. S., & Ogbonnaya, L. U. (2019). Retention in care and adherence to HIV and AIDS treatment in Anambra State Nigeria. *BMC Infectious Diseases*, *19*(1). https://doi.org/10.1186/s12879-019-4293-8

UNAIDS., World Health Organization., UNAIDS, & Update, T. (2003). Progress report on the Global Response to the HIV/AIDS Epidemic, 2003 : follow-up to the 2001 United Nations General Assembly Special Session on HIV/AIDS. *ONUSIDA Collection Meilleures Pratiques Actualisation*, *June*. http://whqlibdoc.who.int/publications/2004/9291732907.pdf%5Cnhttp://whqlibdoc.who.int/unaids/2003/9291733288_fre.pdf%5Cnhttp://whqlibdoc.who.int/publications/2004/9291732893.pdf%5Cnhttp://whqlibdoc.who.int/unaids/2005/GTT_guidance_note_fre.pdf%5Cnhttp://whqlibdoc.who.int/publications/2003/9291732001_fre.pdf%5Cnhttp://whqlibdoc.who.int/unaids/2003/9291733296_spa.pdf%5Cnhttp://whqlibdoc.who.int/unaids/2005/GTT_guidance_note_spa.pdf%5Cnhttp://whqlibdoc.who.int/unaids/2003/929173327X_eng.pdf%5Cnhttp://whqlibdoc.who.int/una

UNAIDS. (2014). UNAIDS Goal 90-90-90: An ambitious treatment target to help end the AIDS epidemic. *Http://Www.Unaids.Org/Sites/Default/Files/Media_Asset/90-90-90_En_0.Pdf*, 40.

UNAIDS. (2016). The need for routine viral load testing. *Unaids 2016 Reference*, 1–12. https://www.unaids.org/sites/default/files/media_asset/JC2845_en.pdf%0Ahttp://www.unaids.org/sites/default/files/media_asset/JC2845_en.pdf

"US Dept of Health and Human Services." (2017). Viral suppression. *AIDSInfo*, *3*. https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/1650/viral-suppression

Uzochukwu, B. S. C., Onwujekwe, O. E., Onoka, A. C., Okoli, C., Uguru, N. P., & Chukwuogo, O. I. (2009). Determinants of non-adherence to subsidized anti-retroviral treatment in southeast Nigeria. *Health Policy and Planning*, *24*(3), 189–196. https://doi.org/10.1093/heapol/czp006

Viswanathan, S., Detels, R., Mehta, S. H., Macatangay, B. J. C., Kirk, G. D., & Jacobson, L. P. (2015). Level of Adherence and HIV RNA Suppression in the Current Era of Highly Active Antiretroviral Therapy (HAART). *AIDS and Behavior*, *19*(4), 601–611. https://doi.org/10.1007/s10461-014-0927-4

Wakibi S. (2010). *Prevalence and predictors of non-adherence, and incident of tratement failure amng patients of HAART in Kenya*.

WHO. (2015). *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Clinical Guidelines: Antiretroviral <erapy*.

Wiewel EW. (2014). *Association of neighborhood-level socioeconomic status (SES) with time from HIV diagnosis to viral suppression among newly diagnosed*.

World Bank. (2020). *List of countries by HIV/AIDS adult prevalence rate*.

Wu, E. S., Metzger, D. S., Lynch, K. G., & Douglas, S. D. (2011). Association between alcohol use and HIV viral load. *Journal of Acquired Immune Deficiency Syndromes*,

56(5). https://doi.org/10.1097/QAI.0b013e31820dc1c8

Yao et al. (2009). *knowledge and adherence to ART among adults people living with HIV/AIDS*.

Yusuff Adebayo, A., Adrian, R., Aniekan, E., Melody, O., Ouma Atieno, S., Oladunni Abimbola, A., Alumuku Iordepuun, M., Amusile, O., Damilola Quazeem, O., Bamisaiye, A., Abdulhafeez Ayodele, M., & Don Eliseo, L.-P. (2021). Towards 90-90-90 Target: COVID-19 and HIV Response in Africa. *Journal of Infectious Diseases and Epidemiology*, *7*(2). https://doi.org/10.23937/2474-3658/1510191

APPENDICES

Appendix i: Sample size calculation for each randomly selected ART clinic.

Target population = 4315

Total sample size = 366

Sample size for each of the eight (8) ART clinics:

Formula: $n = \frac{a}{p} x\ 100 = ?\%.\quad \frac{?\%}{100\%} x\ s.$

Where n=ART sample size for the study, a=ART active clients with viral load test, p=study target population, and s=total sample size.

1. **Regional Hospital, Bolgatanga**: $n = \frac{1274}{4315} * 100 = 29.5\%.\ \frac{29.5\%}{100\%} * 366 =$ **108 sample size.**
2. **War Memorial Hospital**: $n = \frac{759}{4315} * 100 = 17.59\%.\quad \frac{17.59\%}{100\%} * 366 =$ **64 sample size.**
3. **Bongo Hospital**: $n = \frac{737}{4315} * 100 = 17.08\%.\quad \frac{17.08\%}{100\%} * 366 =$ **63 sample size.**
4. **Zebilla Hospital**: $n = \frac{426}{4315} * 100 = 9.87\%.\quad \frac{9.87\%}{100\%} * 366 =$ **36 sample size.**
5. **Sandema Hospital**: $n = \frac{379}{4315} * 100 = 8.78\%.\quad \frac{8.78\%}{100\%} * 366 =$ **32 sample size.**
6. **Tongo Hospital**: $n = \frac{268}{4315} * 100 = 6.21\%.\quad \frac{6.21\%}{100\%} * 366 =$ **23 sample size.**
7. **Kongo-Logre Health Centre**: $n = \frac{267}{4315} * 100 = 6.19\%.\quad \frac{6.19\%}{100\%} * 366 =$ **23 sample size.**
8. **Paga Hospital**: $n = \frac{205}{4315} * 100 = 4.75\%.\quad \frac{4.75\%}{100\%} * 366 =$ **17 sample size.**
9. **Total participants = 366**

Appendix ii. Consent Forms

STUDY TITLE: DETERMINANTS OF VIROLOGICAL FAILURE IN HIV PATIENTS ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART) IN THE UPPER EAST REGION.

PARTICIPANTS' STATEMENT

I have acknowledged that I had the aim and contents of participants' information sheet read, and all questions satisfactorily explained to me in the **(…….) language** I understand. I have also understood the contents and any possible consequences and my right to participate or not in the study even after signing the consent form. I have agreed to voluntarily part-take in the study.

Participant's name: ……..

Participant's signature: …… OR Thumb Print: …… Date: ……

STATEMENT OF THE INTERPRETER

I interpreted the purpose and contents of the Participants' Information Sheet to the participant to the best of my ability in the (…….) **language** to his/her proper understanding.

I also duly interpreted the questions, answers and clarifications sort by the participant to his/her satisfaction.

Interpreter's name: …….

Interpreter's signature: …… OR Thumb Print …….....

Date: …….. Contact: ……

STATEMENT OF WITNESS

I was present when the purpose and contents of the Participant Information Sheet was read and clarified to the participant satisfactorily in the (……) language he/she understood well.

The participant was given the chance to ask questions and seek for clarifications which were duly responded to his/her satisfaction before he/she voluntarily agreed to take part in the study.

Name of Witness……. Sign/Thumb print:…….

Date:…… Contact Details……

STATEMENT OF THE INVESTIGATOR

I certify that the participant has been offered sufficient time to read and learn about the study. All questions and concerns raised by the participant have been duly addressed.

Researcher's name: …… Signature:……..

Date:……. Contact …….

PARENT/GUARDIAN INFORMED CONSENT FORM FOR ADOLESCENT (<18 YEARS)

I ……. Permit my child …… to participate in the study entitled; "Determinants of virological failure in HIV patients on highly active antiretroviral therapy in the Upper East Region." The purpose and the content of the study have been explained to me and questions duly responded to my satisfaction in the (……) **language** I understand well. I have understood my child's right to refuse to partake or withdraw from participating in the study is respected and his/her responses and identity will be secured and confidential. I therefore voluntarily give consent for my child to participate in the study.

……. ……..

Parent/Guardian's signature Date

……. ……

Investigator's signature Date

ASSENT FORM FOR PARTICIPANTS UNDER 18 YEARS

Please I am …………………………… form the University for Development Studies. I am carrying out a research on the Determinant of Virological Failure in HIV Patients on Highly Active Antiretroviral Therapy in the Upper East Region. We ask you to participate in the study because your mother/father/guardian has recommended you.

During the study, we will ask you some questions about your HIV issues and keep all your answers confidential. Only people from the university and your healthcare worker working on the study will see your responses.

Please note that;

1. You do not have to be in this study if you do not want to take part. You will not get into any problem with us or your parent/guardian if you do not participate.
2. Also, you may decide to stop being in the study at any time. If you not want to answer a particular question, please skip it.
3. Your parent/guardian agreed for you to take part in the study. Even if they agreed, you still have the right to take part or not to take part.
4. You can ask any question now or later during the study. But if you think of any question after the study, you or your parent/guardian can contact me on 0207503565.

Please sign this form if you;

1. Have understood what you are to do in this study
2. Have your questions answered satisfactorily
3. Have spoken to your parent/guardian about this study
4. Agree to participate in the study

Your signature:……………….. Your name:,, Date: ………………

Name of parent/Legal guardian: ……………………………………………

Researcher's signature: ……………………………. Date: ………………………

Appendix iii: Study Questionnaire

QUESTIONNAIRE

UNIVERSITY FOR DEVELOPMENT STUDIES

SCHOOL OF PUBLIC HEALTH

The researcher is a master's student of the school of Public Health in the University for Development Studies. The purpose of this research is to investigate the **"Determinants of Virological Failure in HIV Patients on Highly Active Antiretroviral Therapy (HAART) in the Upper East Region"**. He is therefore seeking your assistance to provide candid responses to the following questionnaire (approximately 7 – 10 minutes). Please, be rest assured that the responses you will provide in this questionnaire will be kept strictly confidential and will be used purposely for academic research with no part of your identity attached to the responses you may provide. The questionnaire is designed in a Kobo-Collect Based Software.

Researcher's name: Mutaka, Awell Olives

Complete the following questions.

i. Date of interview: …..…/…..…/…….

ii. Municipal/District of interview (Pease tick - √)

- ○ Bawku West
- ○ Bolga Municipal
- ○ Bongo
- ○ Builsa North
- ○ K.N. Municipal
- ○ K.N. West
- ○ Nabdam
- ○ Talensi

iii. Facility with ART clinic (Pease tick - √)

- ○ Zebilla Hospital
- ○ Regional Hospital
- ○ Bongo Hospital
- ○ Sandema Hospital
- ○ War Memorial Hospital
- ○ Paga Hospital
- ○ Kongo-Logre Health Centre
- ○ Talensi District Hospital

QID	Question	Coding Categories	Skip model	Labels
Section A: Socio-Demographics of Respondents Instruction: Please complete this section by circling the following answer's number. **Example. Book …. ①**				
1	Gender of respondents	Male: ……..0 Female: ……..……1		Gender
2	Age of respondents	15 – 24: ……..0 25 – 34: ……..……1 35 – 44: ……...2 45 - 54:…….....3 ≥55: ……4		Age
3	Marital status of respondent.	Married: ……..0 Never married: …..……..1 Divorced/Separated/Widowed:3		Marital_status
4	Respondent level of education	No formal education: …….0 Basic: ……..1 SHS/Voc/Tech:..……..2 Tertiary: ……..3		Educational_level
5	Occupation of respondent.	Public/Private employment:.0 Self-employment: …...…....1 Unemployed: ……...2	If ***employed***, skip to QID 8.	Occupation
6	What is respondent's monthly salary or income?	Less than GH¢ 375.00: ….0 From GH¢ 375 - 1000: .....1 Above GH¢ 1000: ..…....2		Salary_Income

7	Whom does respondent depend on for financial support?	Family: …….……0 Friends: ……1 Support group: ..……....2		Whom_depend_on
Section B: Behavioral characteristics of Respondents				
8	Does respondent currently drink alcohol?	Yes: ……..0 No: ……...1	If ***No***, skip to QID 10.	Alcohol_intake
9	How often does respondent drink alcohol?	Daily: ……,..0 1 to 2 times a week: …….1 ≥ 3: ……2		Freq_alcohol_intake
10	How many sexual partners does respondent have? (**excluding spouse**)	1 sexual partner:……0 2 or more sexual partners:.1 None: ……....2	If ***None***, skip to QID 15.	Num-sexual_partners
11	How many sexual partner(s) did respondent have sexual inter-course with in last 3 months?	1 sexual partner:……0 2 or more sexual partners:.1 Never: ……....2	If ***1 or 2***, skip to QID 13.	Num_partners_wt_sex
12	Why has respondent Never had sexual intercourse? (***circle all that apply***)	Poor health: ……..0 Fear of infecting partner:...1 Fear of re-infecting self:…2 To abstain:…….….3	Skip to QID 15.	Why_no_sex
13	How often has respondent used condom during sex in the last 3 months?	Every time: ……0 Sometimes: ……1 Never: ……2	If ***1 or 2***, skip to QID 15.	Condom-use
14	Why has respondent Never used condom during sex? **(*circle all that apply*)**	Partner is HIV positive: …0 Partner may suspect: .....1 Dislike for condom:……2 Desire for children: ….....3 Condom not available: …..4		Reasons_for_non-condom_use
Section C: Antiretroviral therapy adherence of Respondents				
15	What was respondent age at HIV diagnosed?	15 – 24: ……...0 25 – 34: ……..…..1 35 – 44: ……...2 45 - 54:…….....3 ≥55: ……..4		Age_diagnosed_HIV

16	Did respondent receive adherence counseling after HIV diagnose?	Yes: …….....0 No: …….....1		Received_counseling
17	How long has respondent been taking ART up-to 2020?	<1 year.: ……..……..0 1-3 years: ……..1 3 or more years: ……2		ART_duration
18	What ARV combination was respondent put on in 2020? (***Patient or service provider can provide)***.	Teno+Lami+Efav:……..0 Teno+Lami+Dolut: ……...1 Zido+Lami+Dolut:…….2		ARV_combination
19	How did respondent find taking the ART in 2020?	Easy: ……0 Difficult: ……..1		Ease_of_taking_ART
20	Did respondent had problem getting ARVs in time in 2020?	Yes: ……0 No: …….....1	If ***No***, skip to QID 22.	Problem_getting ART_timely
21	Which of these reasons gave respondent problems in receiving ART in time? ***(Circle all that apply)***.	Distance to the ART: .....0 Shortage of ART at site:..1 ART clinic close early:...2 Poor health:…….3 Stigma: ……4		Reasons_not_getting_ART_timely
22	How many dose(s) of ART did respondent miss in the past one (1) month?	0 – 1 dose: ……....….0 2-4 doses: …..…….....1 5 doses and above: ….....2	If ***None,*** skip to QID 24.	No._doses_missed
	ART adherence level	Good ……0 Fair ……..1 Poor …….2		
23	Why did respondent miss his/her ART dose(s)? ***(Circle all that apply)***.	Forgot to take: .....0 Side effects: .....1 Ran out of pills: .....2 Felt sick/ill: …….3 Stigma: ……4		Reasons_dose_missed
24	Did respondent experience any side effects in taking ART in 2020?	Yes: ……....0 No: ……..1	If ***No***, skip to QID 26.	Have_side_effect

25	What side effect did respondent experience? ***(Circle all that apply).***	Nausea: ……0 Vomiting: ……1 Diarrhoea: ……2 Nightmares/vivid dreams:.3 Skin rash: ……4		ART_Side_effects
26	What is respondent's spouse or sexual partner's HIV status?	HIV positive: ……....0 HIV negative: …….....1 Don't know: …….2	If ***Negative or Don't Know,*** skip to QID 28. Also skip QID 38.	Spouse/partner_HIV _status
27	Is respondent's positive spouse or sexual partner on ART?	Yes: ……....0 No: ……..1 Don't know: ……2		Spouse/Partner_on_ ART
28	How would respondent rate his/her health ***BEFORE*** ART?	Good: ……..0 Fair: ……1 Poor: ……2		Health_before_ART
29	How would respondent rate his/her health ***AFTER*** starting ART?	Good: ……..0 Fair: ……....1 Poor: ……...2		Health_after_ART
Section D: HIV viral load testing of Respondents				
30	Has respondent ever receive counseling on HIV viral load testing?	Yes: ……0 No: ……..1		Received_VL_couns el
31	Did respondent undergo enhanced adherence counseling in 2020?	Yes: ……0 No: ……..1	If ***No***, dis-qualify the participant and end the interview.	Any_VL_test_done
32	How many times has respondent undergone a viral load (VL) test in 2020?	1 time: ……0 2 times: ……1 3 times:……...……..…2		Num_VL_test

33	What were the reasons respondents took the VL test? **(circle all that apply)**	Check disease progress: ….0 Monitor response to ART: .1 Check infectious level: …...2		Why_VL_test
34	What was respondent **Last** viral load result in 2020?	**<** 1000 copies/ml:.....0 **≥** 1000 copies/ml:……...1 Target Not Detected: ……2		VL_result
35	Did the service provider interpret the VL result(s) to respondent?	Yes: ……....0 No: ……...1		Interpret_VL_results
36	Respondent's viral load results status.	VL Suppressed: ……...0 VL Failed (Unsuppressed): .1	If VL suppressed skip QID 37.	
37	If respondent failed his/her last VL(s), what is the implication? **(*Circle all that apply*).**	I can infect others: ……...0 Increase to stage 3/AIDS:.1 Opportunistic infections:..2 Drug resistance: ……...3 Reduces survival rate: ….4		Implication_of_VLF
38	If spouse/sexual partner is positive (**QID 26**), was he/she infected by respondent?	Yes: ……..0 No: ……...1 Don't know: ……..…..2	If spouse/ partner were **HIV negative or Don't know in QID 26**, skip QID 38.	Respondent_infect-spouse/partner

This concludes our interview. Thank you very much for your participation.