SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

VIRAL LOAD SUPRESSION AND ITS ASSOCIATED FACTORS AMONG PEOPLE LIVING WITH HIV IN THE NINGO PRAMPRAM DISTRICT AND SHAI OSUDOKU HOSPITAL

BY

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THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF MSc IN CLINICAL TRIALS DEGREE

APRIL, 2022

DECLARATION

I, Mercy Bransah by this means declare that aside references to works by other persons which have been righty acknowledged, this dissertation "Viral load suppression and its associated factors among people living with HIV in the Ningo Prampram and Shai Osudoku hospital" is as a result of my own independent research under the guidance of the undersigned supervisor in the award of a master of science degree.

..... **03-11-2022**

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(Student)

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Dr. Harriet Affran- Bonful …….. Date

(SUPERVISOR)

DEDICATION

This work is completely dedicated to our Heavenly Father, whose constant strength and abundant grace and mercies led me through my studies. To the entire Bransah and Duku family especially my husband Philip Bransah and my children Nana Enyimpa Bransah and N'Adom Kofi Bransah. Your inspiration cannot be quantified. My late dad, Mr Hosea Kwesi Duku, this is for you. My mum, Mrs Joyce Duku, a true gem to me and my siblings.

ACKNOWEDGEMENT

Foremost, my heartfelt appreciation goes to Dr. Harriet Affran-Bonful of the Department of Epidemiology and Disease Control, School of Public Health, University of Ghana. My supervisor extraordinaire. Your soft spoken words got me on my toes to get this study done. With a grateful heart, I say thank you and appreciate every minute of your academic mentoring you gave me.

Thanks to the National AIDS/STI Control Program for giving me help. The district director of health service of Ningo Prampram district, Mrs Gifty O. Ansah, Management of Prampram polyclinic and Old Ningo health center. Not forgetting Shai Osudoku hospital. Am thankful.

To you Isumaila Issah, George King Ahiable, Bridget Crankson and all the ART team members of Prampram polyclinic, Shai Osudoku and Ningo health center for your enormous support.

I appreciate you for all your contributions in diverse ways.

ABSTRACT

Introduction

Institution of the ambitious "90-90-90" strategy by 2020 (90% of all HIV-positive individuals will be aware of their status, 90% of those who have been diagnosed with HIV will start and maintain antiretroviral therapy, and 90% of those who are on antiretroviral therapy will have viral suppression) called for robust policies by countries in other to combat HIV/AIDS. The lack of data on the third "90" especially in resource-low Countries is a challenge in the record of this strategy. There is also a lack of regional data in Ghana. In this study, viral suppression among HIV-positive individuals receiving antiretroviral therapy (ART) in a Ghanaian medical facility was evaluated together with the proportion of factors that affect viral suppression.

Methodology: A retrospective analysis of secondary data was designed for 479 HIV registrants on highly active antiretroviral therapies for at least six months at the ART Centers in the Ningo Prampram district and Shai Osudoku hospital. Marital status, education, occupation, age, gender and clinic attendance were included in the demographic data. Type of medication and current viral load results were taken from patients' medical records. The primary outcome, which was divided into viral suppression and viral failure, was viral suppression after six months on ART. In accordance with WHO criteria, viral load suppression (<1000 copies/ml) and viral load failure (≥1000 copies/ml) were used to categorize viral suppression and failure. For the purposes of this study, regular monthly clinic visits for HAART medicine and other clinical treatments throughout the past year were referred to as scheduled clinic attendance. Data analysis was employed using STATA 16/IC 16 software. Summarization of data for categorical variables was done using descriptive statistics. Proportions, means and standard deviation were computed for continuous variables. A significance level of 5% was adopted. Chi Square was used to assess the parameters that contributed to viral load suppression, and logistic regression was used to ascertain how much ART and clinical factors affected viral load suppression.

Results: The mean age of the respondents was 41.5 ± 11.5 years. Majority of the PLHIV (61.2%) were within the age group of 30-49 years. Out of the 479 HIV patients, 64.9% achieved viral suppression. Sex (OR=0.63, 95%CI=0.42-0.95), marital status and scheduled visit attendance were

significant at the crude level analysis. But only marital status maintained its statistical significance after adjusting with other variables. Compared with individuals who were single PLHIV those who were divorced or separated had 3.5 times the likelihood of having suppressed VL (OR = 3.54, 95%CI = 1.25-10.06). Also, widows were 3 times more likely to achieve VL suppression compared to those who were single. (OR =3.05, 95%CI =0.78 - 12.00). PLHIV who divorced/separated had 3.5 times odds of having suppressed VL compared to the single participants. (OR =3.52, 95%CI = 1.13 -11.00). All other factors were not significantly associated with achieving VL suppression, $p<0.05$

Conclusion: The proportion of PLHIV in the Ningo Prampram and Shai Osudoku hospital was 64.9%, below the WHO 90% target with suppressed viral load. Marital status was the only sociodemographic factor identified to be associated with viral load suppression. There was no disease-related, ART-related factor affecting viral load suppression.

Recommendations: Based on the findings of this study, marital status was a good predictor of VLS and should be highlighted in management policies. Client marital status should be a guide in counselling sessions as a strategy to achieving VLS.Patients who are married should be commended and encouraged to continue to serve as checks for each other. Others who are not married should not be looked down on but counselled on the importance of marital status helping in achieving VLS. In the facility level, married couple living with HIV can be selected as peer educators during counselling sessions with the health staffs to help in educating their peers.

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LIST OF ABBREVIATIONS

3TC	Lamivudine
ABC	Abacavir
ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV	Atazanavir
AZT	Zidovudine
CD4	Cluster of Differentiation 4 d4T
EFV	Efavirenz
GHS	Ghana Health Service
GHS/ ERC	Ghana Health Service Ethics Review Committee
HAART	Highly Active Antiretroviral Treatment
HIV	Human Immunodeficiency Virus
LPV/r	Lopinavir/ritonavir
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NNRTIs	Non-Nucleoside Reverse Transcriptase Inhibitors

NVP	Nevirapine
PIs	Protease Inhibitors
PLHIV	People Living with HIV/AIDS
PV	Pharmacovigilance
TB	Tuberculosis
TDF	Tenofovir
UNAIDs	Joint United Nations Programme on HIV/AIDS
WHO	World health organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

High-quality antiretroviral therapy (ART) access has contributed to a robust immune reconstitution, better clinical outcomes and lower mortality rate in people living with HIV (WHO, 2010). Advanced studies on HIV vaccines with promising outcomes are being explored in some candidates in Thailand, South Africa and Rwanda (Medlock, 2017). This outcome will add up to the giant strides being added to the strategies to ending the pandemic since it discovery. Clinical examination and laboratory tests has always played a critical role in evaluating individuals on ART. Viral load testing, however, is the recommended method for measuring, evaluating, and establishing treatment failure (WHO, 2015). Monitoring of viral load done routinely also has the potential of enabling more targeted adherence interventions that will help preserve the efficacy of ART (WHO, 2013).

In HIV, viral load suppression is defined as a VL test result below a detectable limit or a specified threshold in the previous year (Kay et al, 2016; Schmidt, 2021). Drain et al., (2019) advocate a level of 1,000 copies/ml as viral load suppression. The ideal recommendation for undetectable VL is less than 200 copies/ml (CDC, 2021).

With 38 million people living with the disease worldwide (WHO, 2019), 25.7 million people in Africa are burdened with the disease (WHO, 2018). Sub-saharan Africa recorded 69% out of the total (UNAIDS, 2019). Furthermore, each year, more than 1 million adults and children die from HIV/AIDS in Africa alone. (WHO, 2019).

In 2019, the prevalence rate in Ghana stood at 1.7% out of which 2.47% were in the Greater Accra region (NACP Report, 2020). District analysis revealed a much higher prevalence (2.5%) in the Ningo Prampram district and 1.8% in the Shai Osudoku district (NACP Report, 2020).

With the 90-90-90 approach (The 90-90-90 approach project in 2013 by the UNAIDS was defined as; by 2020, 90% of people with HIV will be aware of their status, 90% of those who are HIV-positive will receive sustained antiretroviral therapy, as well as 90% of those taking antiretroviral medication will have viral suppression.) which ended in 2020, UNAIDS launched the 95-95-95 strategy in 2014. It aspires to end the AIDS pandemic by 2030 by having 95 percent of all PLHIV identified, 95 percent on ART, and 95 percent of those on treatment have viral suppression (VS). Ghana made great strides by achieving an increase of 73% of PLHIV with suppressed viral load in 2019 out of the last 90 in the 90 90 90 approach (NACP, 2019). On a district and facility basis, the associated parameters affecting viral load suppression are, however, insufficiently studied (Lokpo et al, 2020).

1.2 Problem Statement

Just like other chronic conditions that requires constancy in medication, high levels of ART medication adherence are needed in order for a patient on ARVs to achieve viral load suppression. A very low level viral load helps keep the immune system working and preventing illness. In the global picture, viral load suppression among PLHIV on ARTs stands at 85% of Americans, 64% of Europeans, and 71.6% of Africans have as of 2019, according to recorded data. (WHO, 2019). According to reports from 2019, 68% of PLHIV in Ghana had viral suppression. A crude suppression rate of 73% in 2020, out of which is still below the threshold of the 90% target for PLHIV set by the UNAIDS by 2020 (NACP report, 2020). A number of factors can be attributed to maintaining a low viral. Consequentially, high VL is not just a threat to the health of the

individual patient, but a serious public health concern. At the patient level, viral high loads can lead to a low CD4+ cell count, risk of developing HIV-related diseases and progression to Acquired Immune Deficiency Syndrome (AIDS). At the community level, there is a greater risk of the patient being a "transmission potential" to the spread of the disease.

There has been a scale-up of programs by the health ministry through the National AIDS/STI Control Program (NACP) which has contributed greatly in awareness creation of the disease and the need for adherence to ART in achieving viral suppression. Free yearly viral load testing for those on ART to help reduce the burden of cost on the patients is an integral strategy in it management. Other implemented strategies include counselling, medication adherence monitoring, provision of medical care, and psychosocial support to client. (Ghana Health Service, 2019). Despite Greater Accra's high HIV prevalence of 1.8% in 2020, which was higher than the country's prevalence with 0.12 AIDS-related fatalities, based on a review of the literature indicates that the parameters relating to viral load reduction has not been probed in the Ningo Prampram district and Shai Osudoku hospital (Ghana AIDS Commission, 2019). This study seeks to generate information to fill the gaps by pointing out some of the specific factors that affects VLS. With the support of these identified causes, the Ningo Prampram district and Shai Osudoku hospital can build targeted initiatives to address the issues in this study.

1.3 Conceptual Framework

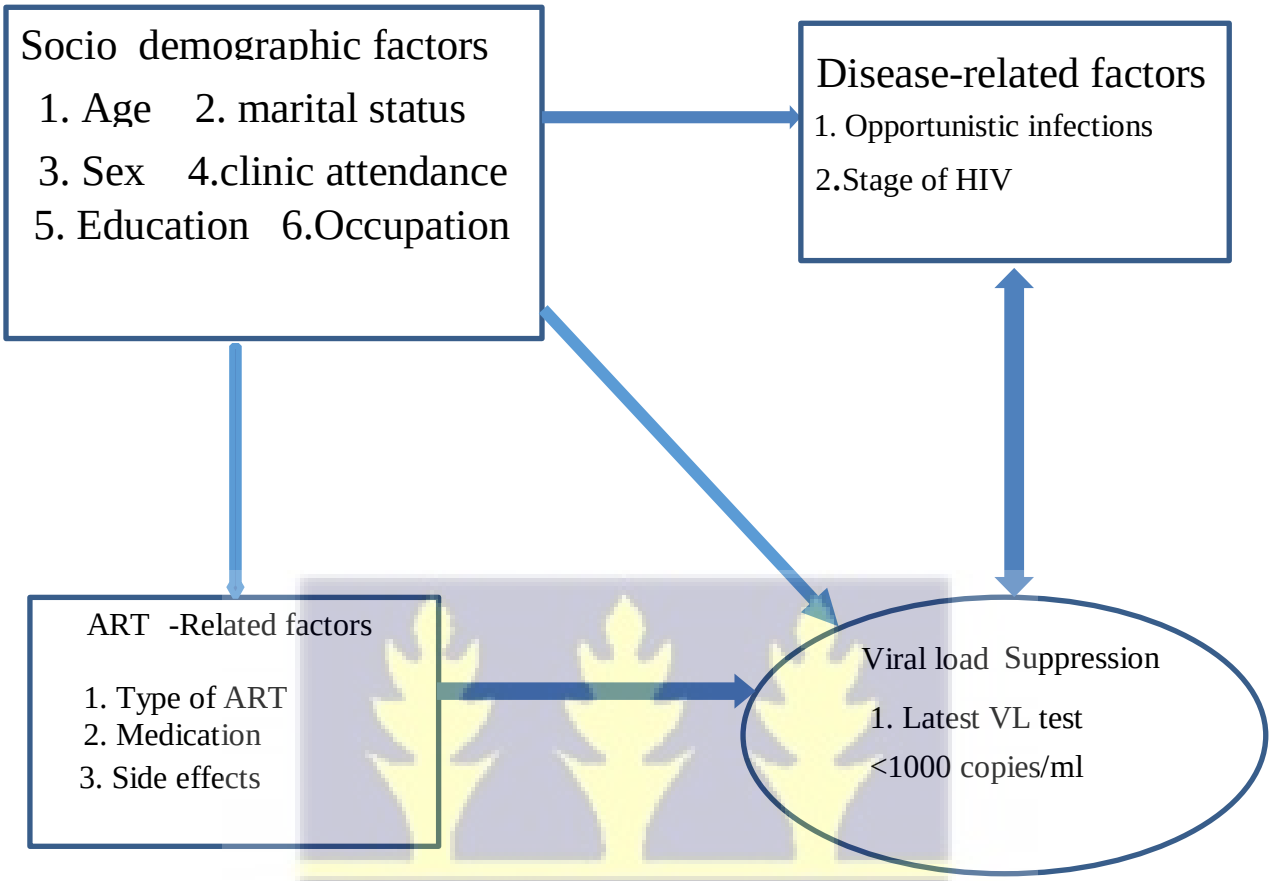

Figure 1. 1: A conceptual framework of associated factors affecting viral load suppression in people living with HIV.

1.3.1 Narrative of the conceptual framework

The conceptual framework is based on literature findings that describes associated factors affecting viral load suppression. These factors include socio demographic, ART-related and disease-related factors. Socio demographic factors describe determinants that can affect viral load suppression directly or indirectly. These include age, sex educational level, occupation and clinic attendance. These factors can act either independently or as a group to directly affect VL suppression (as in age and clinic attendance) or indirectly (age, sex, occupation and residence) (Farokhzadian, & Nikooie, 2019). Higher VL increases the chances of transmission of the virus, reduced immunity and progression of the disease. Routine testing helps to identify some factors such; non adherence to medication, treatment failure, wrong dose of ART (Kay et al, 2016). An ideal of undetectable VL is recommended (WHO, 2019) but low VL will mean that the ART is working which will reduce other long term of AIDS complications and high CD4 counts cells. This can help cause restoration of immune system fight infections. ART- related factors are very crucial to achieving VL suppression in terms of patient's adherence to ARVs. They include the type of ART regimen and side effects. The disease-related factors include-WHO clinical stage and the presence of opportunistic infections such as cytomegalovirus (CMV), HIV-related encephalopathy, herpes simplex virus (HSV), certain cancers including kaposi sarcoma.

1.4 Justification

In 2019, 68% of PLHIV achieved a suppressed viral load out of the projected 90% (NACP report, 2019). As more people gain access to ARTs, there is a need for identifying some of the factors accounting to not achieving the intended target of 90%. This will help in the development of new initiatives that will ensure that patients adhere and are retained in treatment in order to achieve a suppression in viral load levels. .

It is anticipated that through this study, associated factors to achieving VL suppression which might be unknown to the health professionals will be identified. The result will be beneficial to the patient in assessing the effectiveness of the national HIV management program at the district level and inform future clinical quality by the ART clinical staffs. Identified challenges will help the district health management team, National AIDS/ STI Control program (NACP) and the health ministry as a whole the opportunity to design and implement effective strategies to enhance quality of life of patients.

1.5 Research questions

1. What proportion of PLHIV in the Shai Osudoku Hospital and Ningo Prampram district have viral loads that are suppressed (<1000 copies/ml)?
2. What sociodemographic characteristics are associated to the suppression of viral load in PLHIV?
3. What are the disease- related factors associated with viral load suppression?
4. What are the ART-related factors associated with VLS (<1000 copies/ml) in PLHIV?

1.6 General Objective

To determine viral load suppression among people living with HIV on HAART for at least twelve months and the factors associated with failure to achieving viral suppression (<1000 copies/ml) in the Ningo Prampram district and Shai Osudoku Hospital.

1.6.1 Specific Objectives

1. To determine the proportion of PLHIV on ART with viral load levels that are suppressed (<1000 copies/ml)

2. To determine the sociodemographic factors associated with viral load suppression
3. To identify the disease- related factors associated with viral load suppression among PLHIV.
4. To determine ART-related factors associated in achieving viral load suppression (<1000 copies/ml) in people living with HIV

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 General Overview

In 2019, 1.7 million people were predicted to have HIV/AIDS, with a global incidence: prevalence ratio of 4.4 percent. This represents a 37.7% increase over the previous year's figures (WHO, 2020). A 7.0% reduction in the recorded estimates was seen in 2010 reflecting a good headway made against the epidemic in the past years. The ratio fell gradually from 7.0% in 2010 to 3.5% in 2019, 31% achieving viral suppression (UNAIDS, 2020).

An estimated 12.1 million AIDS-related deaths have been averted since 2010 with the increased access to antiretroviral therapy yet more people are dying each year. However, 1.5 million new HIV infections and 680,000 AIDS-related deaths were reported in 2020. (UNAIDS, 2020). A total of 84% of PLHIV got to know their HIV status, 87% of those who knew their HIV status were able to access ART medications and 90% of those on treatment were virally suppressed(UNAIDS, 2020). The third target "90" targets was achieved as a results of robust policies in place.

2.2. HIV Viral Load

Introduction

Monitoring viral suppression best involves quantifying viral load (VL). This test gives the clients a dimension of the condition and motivational adherence to treatment (WHO, 2017). A recommendation of 1000 copies/ml as a threshold by WHO and 5000 copies/ml for dry blood spots (Well et al, 2017).

Dried blood spot specimens, a reliable sample to confirm or rule out HIV infections in low-resource setting countries. A treatment failure threshold of 1,000 copies/ml can be used to estimate

the HIV viral load in capillary or venous whole blood. The preference of plasma specimens to dried blood spot specimens is endorsed. However, dried blood spot specimens can also be employed in situations where routine VL monitoring is prevented by logistical, operational, or infrastructure challenges (WHO, 2017).

Twenty- seven million people where estimated to test for viral load in 2018 worldwide (WHO, 2017). This demand was proposed in order for all countries help achieve the 90–90-90 targets set for 2020. Along with monitoring and evaluation of the patient condition, regular monitoring of VL can be carried out at 6, 12 and then every 12 months only if the patient is consistent on ART medication (WHO, 2015). This protocol is not actualized in most settings. This is due to the sophisticated laboratory assay of VL testing and it's associated countless logistical hindrances as well as purchase of cold-chain dependent kits (Yoshino et al, 2021). To encourage adherence, early identification of virologic failures, and prompt switch to second-line regimens with improvement in clinical outcomes, same day results is advised (Meloni et al 2019). Clinicians are able to transition failing patients to new drug regimens as soon as possible with this timely VL testing. This helps prevent cumulation of drug resistance mutations thus spreading of highly resistant virus strains are reduced (Coker et al, 2015).

Virological failure (VF) is defined as VL equal or exceeding 1,000 copies/ml based on two measurements taken back-to-back over a three-month period, with at least 6 months of adherence support following the first viral load test at least 6 months after the commencement of the antiretroviral therapy (WHO, 2017).

2.2.1 Viral Load Estimation Methods

HIV VL technologies can be broadly classified into;

Nucleic Acid Test (NAT) and Non-Nucleic Acid Test (non-NAT) -based technologies. These technologies are distinct in their operations quantifying HIV virions circulating in the body.

Nucleic Acid Test technologies are used to ascertain and measure viral RNA; whereas non-NAT technologies detect and quantify it (UNITAID, 2015).

2.2.2 NAT

They are regarded as the benchmarks for measuring the HIV-1 viral load because they quantify HIV RNA making them highly sensitive (WHO, 2015). Exposure to the virus within 10 to 33 days can be detected with this test by relying on amplification of intended regions of viral nucleic acid for detection (UNITAID, 2015).. COBAS® System (Roche), m2000 System (Abbott), NucliSENS® HIV Solution (bioMérieux) all operates using this technology (UNITAID, 2015).

Advantages of NAT

- A well evaluated and validated approach;
- Quality assured kits are available
- Results can easily be interpreted.
- There are variations of the assays in sample preparation and amplification/detection methodologies. (UNITAID 2015)

Disadvantages of NAT

- They require trained manpower,
- It takes longer time for results to be produced
- They require sophisticated infrastructure
- Larger number of samples are needed for batch processing
- It is expensive to run.

2.2.3 Non-NAT-Based Technologies

This a highly specific technology because their operation of evaluating HIV specific enzymes and proteins. Different assays can be used to evaluate the levels of reverse transcriptase (RT) and circulating p24 protein in the body (UNITAID 2015)

2.2.4 RT Technologies.

RT assays detect the viral enzyme in the progression of the HIV virus and quantify the levels in the blood as it enters the human host (UNTAID, 2015). Due to its hazardous nature,RT assays has now been simplified and made less hazardous. The performance of the assay was first supported by a radioisotope, a scintillation counter, and an ultracentrifuge. The only current RT platform is for in vitro use , the ExaVir™ Load, manufactured by Cavidi AB.

2.2.5 Point of Care (POC)

The complex nature of the various technologies in VL quantification, are commonly only offered in centralized laboratories in large towns with constrained capacity (Ritchie, 2014). Challenges to this technology are similar across countries with it being expensive, complexity and skilled human resource in its operation. (UNITAID 2015). The need to regionalize care and testing to the local primary health care centers has arisen as ART programs have expanded. Delays in obtaining results are attributed to the incremental volumes of VL testing samples to the centralized laboratories with low capacities (Bwana, 2019). Peripheral HIV centers transport patient specimens to central laboratories which requires effective courier system. Results are sent in a well-structured information management system within a limited period of time (Villa et al, 2020).

Point of care (POC) technologies may be a possible solution to VL testing. It is highly recommended by WHO in resource-limited settings only if they simplify HIV virologic monitoring without dwindling the quality of patient care (UNAIDS, 2014). Affordability, sensitivity and specificity with it also being user-friendly are the recommended qualities. They should also provide a rapid results, equipment-free and delivered to those who need the test (WHO, 2015). The first to receive WHO endorsement was the Cepheid Expert HIV-1 viral load assay. It operates

by targeting a specific genomic region of HIV-1 to detect all strains of HIV-1, including HIV Group M subtypes in the plasma specimen (UNITAID, 2015). Additionally mPIMA™ HIV 1/2 system (Alere Technologies GmbH Jena, Germany) and SAMBA platforms (Diagnostics for the Real World, Little Chesterford, United Kingdom) have also been approved for use by the World Health Organization (UNITAID, 2015;Jani et, 2016;Murray et al, 2017)

2.3 Factors associated with viral load suppression

Three general categories can be used to classify the variables that influence viral load suppression; Sociodemographic, ART related and disease related factors according to this study.

2.3.1 Sociodemographic factors

2.3.1.1 Sex

Globally, there is an annual decrease in the number of new infections in women and girls. A recorded decrease of 27% and a comparable 18% in men and boys since 2010. Women and girls continue to be most affected accounting 59% of all new HIV infections in 2019 (CDC, 2020). Also with a fewer new infection rate of 48% of the total infection among women and girls than among men and boys (52%),globally. In 2020, adolescent girls and young women (aged 15 to 24 years) account for twenty five percent of HIV infections in sub-Saharan Africa, even though they represent just 10% of the population (UNAID data, 2021) High treatment coverage resulting in viral suppression among men does not only prevent a threat to their own health. They also prevent a high vulnerability to HIV infection in women in conjunction with other preventive services especially (Gonar, 2019).

Though numerous studies show viral load in women who are not on ART appears to be lower compared to men, gender appears not to affect VL suppression rates whiles on ART (Rangarajan et al, 2016). Findings from a study by Faradzan et al, (2016) shows single viral load measure being

lower in women than in men. But the period from HIV to AIDS is comparable for men and women with the same high viral loads. Trichavaroj et al in 2011, also studied large sample size of Thai men and women with the non-B HIV subtype. After controlling for CD4+ T-cell count in both sexes, they discovered no variations in HIV RNA levels. Previous studies found Seroconversion of HIV tends to dissipate years after infection with a demonstrated viral load differences in males and females. There is a chance that biological differences explain why women have lower viral loads than men, despite the fact that the mechanism is uncertain. Also, the possibility of lower viremia or an high viral clearance in women, or both (Kipp et al., 2010;Rangaranjan et al, 2016).

2.3.1.2 Age

In sub-Saharan Africa, children ages 0 to 14 made for 9% of all new infections in 2019. (UNAID, 2020).

Poor adherence to ART was associated with younger age with a corresponding higher viral loads (Hadland et al 2012; Cohen et al 2013). This is supported by Mujugiraet al, (2016). They again found low rates of HIV-1 virologic suppression among younger age groups. Nonadherence to ART accounted for such record. Factors contributing to nonadherence also affected viral suppression. Delayance in HAART introduction, high CD4 count prior to HAART intervention and HIV-1-associated stigma and discrimination affected nonadherence and viral suppression. Others were anxiety, depression, influence by a lack of disclosure and a sense of immunity to the effects of the HIV-1 infection. . Use of alcohol and other recreational drugs coupled with low socioeconomic status were also reported (Hadland et al, 2012; Peltzer et al, 2013; Haberer et al, 2013; Cohen et al, 2013). Conversely, Lokpo et al in 2020 observed no remarkable associated differences between the various age groups in the rate of viral suppression.

2.3.1.3 Clinic attendance

Just like other chronic conditions that requires constancy in medication, high levels of ART medication adherence are needed in order for a patient on ARVs to achieve viral load suppression (Lokpo et al, 2020). This will require scheduled and consistent clinic attendance for the supply of the ART medication. Other clinical managements are also seen in the process. Low-setting countries have a challenge in retaining these patients in care and adhering to treatment (Brennan et al, 2010). There is a break of the continuous supply of ART as a results of missed medical appointment or ARV collection. This in the long term affect viral suppression (Giordano et al, 2014). Failure to achieving viral suppression due to poor adherence to treatment from missed visits can result viral rebound due to failure to initially suppress the virus (Mugavero et al, 2017; Berg et al, 2015). A study done in South Africa by Brennan et al in 2010 showed more than 35% of patients who did not attend at least one clinic visit were associated with negative outcomes. These findings were in line with what Mugavero et al (2017) reported in their study. Age was a common factor in most studies affecting clinic attendance. The likelihood of older patients adhering to clinic visits and achieving virologic suppression was high compared to their younger counterparts (COHERE, 2016; Brennan et al, 2010).

2.3.1.5 Drug related factors associated with viral load suppression

2.3.1.6 HAART

Low resource settings once considered ART medications as too expensive and complicated. A global estimation of 27.5 million [26.5 million–27.7 million] PLHIV were to be on it at the end of 2020 (UNAID, 2020). Highly active antiretroviral therapy (HAART), an important component of the overall management plan for patients with HIV/AIDS. The introduction of HAART has advanced a sustained suppression of viral replication with an incomplete restoration and

preservation of the immune system. Sudden decrease in opportunistic infections complication and reduction of mortality were observed in PLHIV on HAART (Ngina et al, 2018). Access to HAART by PLHIV were 17 million at the end of 2015. An incremental coverages to 21.7 million and 23.3 million people in 2017 and 2018 respectively (UNAID, 2019).Viral replication are interrupted upon initiation onto ART. A decreased viremia slows down progression of the disease with a resultant improvement in prognosis

Pregnant and lactating mothers are initiated on ART regardless of their clinical staging of classification and CD4 cell count. Other groups include children and adolescents which helps improve their clinical outcomes and prognosis due to early initiation (WHO, 2015).

Newer classes of drugs, integrase inhibitors are now available and inexpensive for low- and middle-income countries. Efforts have been made to the reduction in the time between HIV diagnosis and the start of ART based on a person's readiness due to safety and efficacy of the drugs. (WHO, 2015). Twenty six drugs have been approved by the US food and drug administration with which include pre-exposure prophylaxis (PrEp). This is giving to non-infected person who have been exposed to the infection helping to reduce the viral acquisition by the non-infected person. HIV drug resistant viruses have emerge due to this practice being cited as a major factor (FDA, 2010).

According to the national guidelines, the following classes of antiretroviral drugs have been recommended for use in Ghana: Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Nucleotide Reverse Transcriptase Inhibitors (NTRTIS), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIS), Protease Inhibitors (PIs), and Integrase Strand Transfer Inhibitors (INSTI). Highly active retroviral therapy is a combination of at least 3 potent antiretrovirals that work collectively to suppress viral replication and restore the immune system. A fixed-dose combination comprising of a non-thymidine backbone (TDF+ FTC or TDF +3TC) and one NNRT (EFV) to be

taken once a day is the recommended drug regimen among adults and adolescents. An initiation of a 2nd line drug treatment is recommended when there is failure to the 1st line of therapy as evidenced by the high viral load test. Third line regimen is also available for patients with similar failure to the second line of therapy a indicated by both viral load and drug resistance tests (Ghana Health Service, 2016; Conteh-Barrat, 2020). In 2020 PLHIV on HAART medication were able to reach the expected 90% viral suppression by WHO. (UNAIDS, 2020). The WHO recommend the first line HIV drug regimen, AZT/3TC/EFV. It's effectiveness against the virus can results in viral suppression. (Barry et al, 2013). In line with this fact, PLHIV on first line ART had the highest percentage of viral load suppression in this study (65.2%) while third line had (33.3%). Second and third-line ART regimen are recorded to have a high virologic failure compared to the first-line regimen (Kiweewa et al, 2019).

According to Desta et al, (2020) there were high levels of viral load recorded in PLHIV who were not adherent to ART medication. Several studies can be attributed as such (Kiweewa et al, 2019; Bayu et al, 2017). Luque-Fernandez enumerated the benefits of adherance to HAART as an important factor in achieving viral suppression.

2.3.1.7 Side Effects

The WHO recommend the first line HIV drug regimen, AZT/3TC/EFV. It's effectiveness against the virus can results in viral suppression. (Barry et al, 2013). In line with this fact, PLHIV on first line ART had the highest percentage of viral load suppression in this study (65.2%) while third line had (33.3%). Second and third-line ART regimen are recorded to have a high virologic failure compared to the first-line regimen (Kiweewa et al, 2019).

The World Health Organization in 2013, proposed that antiretroviral therapy (ART) should be given to persons testing to HIV regardless of his/her CD4+ count. However, application of this

guideline is faced with challenges especially in Sub Sahara Africa. Side effects of the drugs, drug resistance-mutations and notable burdens in finances were some of their challenges.

Adverse effects managements remains an integral part of chronic antiretroviral therapy. Drug tolerability of HAART have seen major improvements since early days but adverse effects still remains a challenge (Calmy et al, 2009). Many adverse effects are likely to be multifactorial. Solutions to adverse effects are geared towards adherence with remarkable viral suppression. Discontinuation of that specific drug, adjusting or switching dose are frequent solutions employed. To increase drug tolerability, supportive treatment are initiated in case there are any side effects.. For instance, statins have been shown to lower hypercholesterolemia brought on by HAART. Metformin and other anti-diabetic drugs can be used to manage insulin resistance brought on by HAART (Calmy et al, 2009).

2.3.1.8 Disease related factors

WHO Clinical Stage of HIV/AIDS

Clinical staging for HIV/AIDS was developed originally for resource limited settings by the WHO. It is a guideline for managing PLHIV with medical conditions. Clinicians rely on it based on the clinical parameters of the patients for classification and management of the diseased state of the patient (Weinberg and Kovarik, 2010; Conteh-Barret, 2020). Viral load estimation and CD4+ T cells are mainly used to assess the immunosuppressed state of PLHIV.

Primary HIV Infection: Acute retroviral syndrome with no symptoms.

Clinical Stage 1: Asymptomatic generalized lymphadenopathy that persists (PGL).

Clinical Stage 2: Recurrent respiratory tract infections (RTIs, sinusitis, bronchitis, otitis media, pharyngitis), herpes zoster, angular cheilitis, recurrent oral ulcerations, papular pruritic eruptions, seborrhoeic dermatitis, fungal nail infections of fingers

Clinical Stage 3: Severe weight loss (>10% of presumed or measured body weight), unexplained chronic diarrhoea (intermittent or constant for more than one month), unexplained persistent fever (intermittent or constant for more than one month), oral candidiasis, oral hairy leukoplakia, pulmonary tuberculosis (TB) diagnosed in the last two years, severe presumed bacterial infections (e.g. pneumonia, empyema).

Conditions requiring confirmatory diagnostic testing More than one month of unexplained anaemia (<8 g/dl), neutropenia (<500/mm3), or thrombocytopenia (<50 000/mm3)

Clinical Stage 4: Conditions in which a preliminary diagnosis can be made based on clinical signs or simple tests; HIV wasting syndrome Pneumocystis pneumonia, recurrent severe or radiological bacterial pneumonia, chronic herpes simplex infection (orolabial, genital, or anorectal infection lasting more than one month), oesophageal candidiasis, extrapulmonary tuberculosis, Kaposi's sarcoma, Central nervous system (CNS), toxoplasmosis, HIV encephalopathy.

Extrapulmonary cryptococcosis, including meningitis, disseminated non-tuberculous mycobacteria infection, progressive multifocal leukoencephalopathy (PML), candida of the trachea, bronchi, or lungs, cryptosporidiosis, isosporiasis, visceral herpes simplex infection, cytomegalovirus (CMV) infection (retinitis or of an organ other than liver (WHO, 2016)

Opportunistic infections (OI's)

Continuous loss of CD4+ cells causes reduction in the CD4+ cells count. These cells are paramount to the body in fighting infection. Low CD4+ cells count (<200 cells/mil) predisposes to illness in a severer form (CDC, 2021). These infections take advantage of the reduced body's immunity hence their name "opportunistic infections". Common OIs among PLHIV are Candidiasis, invasive cervical cancer, Cryptococcosis, Coccidioidomycosis, Cytomegalovirus (CMV), Herpes

simplex virus (HSV), Kaposi's sarcoma (KS), Tuberculosis (TB), Pneumocystis pneumonia (PCP), Toxoplasmosis and others (CDC, 2021). Some of these OI's are less common due to the introduction of ARV's and constant VL monitoring.

Among the list of the OI's, 73% of the cases of cryptococcal meningitis out of 223 100 incidence were seen in sub-Saharan Africa. A high estimated global death of 181 100 was recorded in the same 2014 (WHO, 2020). Pneumocystis jirovecii pneumonia, is considered a global burden with also high morbidity and mortality especially Asia. Data on sub-Saharan Africa is inaccurate partly because they are poorly characterized due to lack of appropriate diagnostic facilities.

Summary of Literature Review

At the end of 2020, 66% of PLHIV were able to achieve viral load suppression out of the 37.7 million people who were infected worldwide. Numerous studies reviewed reported associated factors which affected the inability to reach the last "90" in the 90-90-90 strategy. Identifiable factors where grouped into socio demographic, disease-related and drug-related factors. Some of these factors affected VLS directly or indirectly.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was analytic cross sectional retrospective, facility-based study. Medical records of consented 470 HIV patients on HAART for at least 12 months with ages between 18-60 years of age were reviewed. Their latest HIV RNA viral load result available were studied after a year on medication. A data extraction tool using kobo collect application tool was used to extract information about demographics, clinical and laboratory status of the patients.

3.2 Study location

The study was conducted in the Ningo Prampram district and Shai Osudoku Hospital. The Ningo Prampram district has a polyclinic which is the biggest government health facility, one health center and 8 CHPS compounds. The district is a fishing community with Prampram as the district capital. ART services are only available at Prampram Polyclinic and the Old Ningo Health Centre, which are easily accessible and functionally active in terms of ART in the district. The largest polyclinic in the area is located in the district. There is also one health center at Old Ningo with several smaller CHPS compounds. The ART centers were both set up in June 2019 after several referrals to Tema general hospital ART center. There are currently 5 staffs managing both centers on out-patients basis. Sharing borders to the north, east, south and west by Shai Osudoku , Ada West, Gulf of Guinea and Kpone Katamanso district respectively. The current population of the district is 87,393 (Ghana statistical service, 2020). The Shai Osudoku hospital is also the biggest hospital in the Shai Osudoku district with a population of 105,610 (Ghana statistical service, 2020). North Tongu District, Yilo Krobo Municipality, and Upper Manya District border the district on the north-east, Akwapim North Municipality on the west, Kpone Katamanso Municipality on the

south-west, Ningo Prampram district on the South, and Ada West district on the east (Ghana statistical service, 2020). It currently has 1300 active PLHIV on their list with 4 staffs managing the center. Korle-bu teaching hospital is the only recommended government hospital running all the samples of VL in Greater Accra region. With the current breakdown of the PCR machine of Korle-Bu teaching hospital during the period of the study, all samples were sent to the Eastern regional hospital, Koforidua for VL testing. The two centers in the Ningo Prampram district provides comprehensive HIV/AIDS care and treatment services to 1334 clients as of June 2021; 374 males, 960 females and 47 children. Whiles out of the 1300 active PLHIV attending the Shai Osudoku hospital, 973 were females, 94 children and 233 males. Newly diagnosed patients were usually assessed clinically and laboratory investigations done to assess the health status and readiness for therapy initiation. ART adherence counselling were done as prescribed by the national guidelines. Two sessions of adherence counselling are scheduled, and conducted. A monthly supply is then served and follow-ups are done to ensure compliance. VL test is then scheduled for a year after drug supply and compliance. A suppressed VL is a good indicator of compliance of the medication, hence a good control of the disease

3.3 Study Variables

The variables included independent and dependent variables (Table 3)

3.3.1 Dependent Variable

The viral load suppression is the dependent variable. A viral load test result below a specified detectable limit or threshold during the most recent VL test in one year is classified as viral load suppression in HIV (Kay et al, 2016; Schmidt, 2021). A recommended level of <1,000 copies/ml by Drain et al, (2019). An undetectable VL, which is the ideal recommendation is defined as < 200 copies/ml (CDC, 2021).

3.3.2 Independent variables

These are;

1. Demographic factors; age, sex, educational level, clinic attendance, occupation and marital status.

2. ART related factors; current type of medication, side effects.

3. Disease related factors; WHO clinical stage of disease.

Table 3. 1: Study variables, operational definition, type and scale of measurement

Variables	Operational Definitions	Types Of Variable	Scale of Measurement
DEPENDENT VARIABLE			
Viral Load	Viral Load Suppression (less than 1000 copies/ml)	Categorical	1.Virologic failure (≥1000 copies/ml) 2. Viral suppression (<1000 copies/ml)
INDEPENDENT VARIABLE			
SOCIODEMOGRAPHIC FACTORS			
Age	How old is the respondent at the time of data collection	Continuous	Ratio
Sex	What is the biological gender of the respondent	Binary	Male Female
Education	Highest level of education	Ordinal	1.No education 2.Primary 3.Secondary 4. Tertiary
Occupation	What does the respondent do to earn a living	Categorical	1. Formal wok 2. Non- formal work 3. None

Clinic attendance	Have you been attending your scheduled visit	Discrete	Ratio
Marital status	What is the marital status of the respondent	Categorical	1.Single 2.Married 3. Divorced / Separated 4.Widowed
DRUG-RELATED VARIABLES DRUG-RELATED VARIABLES			
Current drug regimen	Which line of ART medication Is respondent currently on	Categorical	1. First line 2. Second line 3. Third line
Side effects			
Skin rash	Has the respondent reported with any kind of rash whiles on ART?	Discrete	1. Yes 2. No 3. Never

Table 3. 2: Study variables, Operational definition, type and scale of measurement

Anaemia	Has she been low HB levels while on ART?	Discrete	1. Yes 2. No 3. Never
Abdominal pains	Are you experiencing any abdominal pains while on ART drug	Discrete	1.Yes 2.No 3. Never
Hyperglycemia	Has the respondent presented with any signs of hypoglycemia? Has the respondent presented with hyperglycemia?	Discrete	**1. Yes** **2. No** **3. Never** **1. Yes**
Diarrhea >3 days	Any report of diarrhea for more than 3 days?	Discrete	**2. No** **3. Never**
Hepatotoxicity	Any recorded diagnosis of hepatotoxicity?	Discrete	**1. Yes** **2. No** **3. Never**

Depression	Any reported signs and symptoms of depression?	Discrete	**1. Yes** **2. No** **3. Never**
Weight loss	Any evidence of weight loss record?	Discrete	**1. Yes** **2. No** **3. Never**
Pain/numbness/tingling extremities	Any report of pain or numbness of the extremities?	Discrete	**1. Yes** **2. No** **3. Never**
Bone dysfunction	Any diagnosis of bone dysfunction recorded?	Discrete	**1. Yes** **2. No** **3. Never**
DISEASE RELATED VARIABLES			
WHO Clinical stage of the disease	What is the current stage of disease severity based on WHO clinical stage.	Categorical	1. Stage I 2. Stage II 3. Stage III 4. Stage IV
Herpes Zooster	Has respondent ever reported with such opportunistic infection?	Discrete	1.Yes 2.No 3. Never
TB meningitis	Has the respondent ever been diagnosed as such?	Discrete	1. Yes 2. No 3. Never
Cryptococcal Meningitis	Has the respondent been diagnosed as such?	Discrete	1. Yes 2. No 3. Never

Cerebral Toxoplasmosis	Has respondent been diagnosed as such?	Discrete	1. Yes 2. No 3. Never
Pneumocystis jeroveci pneumonia	Has respondent been diagnosed with such an opportunistic infection?	Discrete	1. Yes 2. No 3. Never
Pulmonary Tuberculosis	Has respondent been diagnosed with such an opportunistic infection?	Discrete	1. Yes 2. No 3. Never
Cytomegalovirus Rhinitis	Has respondent been diagnosed with such an opportunistic infection?	Discrete	1. Yes 2. No 3. Never
Esophageal Candidiasis	Has respondent been diagnosed with such an opportunistic infection?	Discrete	1. Yes 2. No 3. Never
Oral Candidiasis	Has respondent reported with this type of opportunistic infection?	Discrete	1. Yes 2. No 3. Never

3.4 Inclusion Criteria

These were confirmed HIV-positive individuals between the ages of 18 to 60.

ART must have been taken for at least six months, and a full medical record is necessary for analysis.

3.5 Exclusion Criteria

Women who were pregnant, seriously ill patients, and those who were admitted were exempted.

3.6 Study Population

This entailed consented HIV/AIDS patients with a latest viral load test whiles on ARV for more 12months at the Prampram polyclinic, Old Ningo health center and Shai Osudoku ART clinics. This was in line with the clinical guideline of National AIDS/STI Control Program (NACP, 2021).

3.6.1 Sample Size Determination

Using the modified Cochrane's formula

$$N = \boldsymbol{Z2\ 1} - \frac{\alpha}{2}\frac{\boldsymbol{P(1-P)x\ Deff}}{\boldsymbol{e2\ (1-\alpha/R)}}$$

Where P is the Prevalence of viral load,

Deff ; design effect = 1.1

1-R = no response rate

E= margin of error, 50%

Z 1-α/2 = Standard normal variate

Adjusting for 10% missing records, a total of 479 participants will be required

$$\frac{1.96(2) \times 0.5\ (1-0.5)}{(0.05)2\ (1-0.1)} \times 1.1$$

N= 469.5, n= 470 participants

3.6.2 Sampling Procedure

Purposive sampling method was employed in the selection of the folders with all the records of the HIV patients on ART at the health facility with a viral load test result were reviewed

3.7 Data Collection Technique

A total of 479 patients clinical information from their folders were captured onto the kobo collect application tool. These participants were on ARV medications for more than six months, and either had a VL available or had blood samples taken in order to estimate their virus loads.

Individual folders were removed from pack with about 18 folders being worked on daily basis by the PI and the research assistant. Data collection lasted for eight weeks.

3.8 Data Quality Control

3.8.1 Training of Research Assistants

Two staffs of the ART Clinic assisted in the data collection process. They were trained on how to search for folders which have been filed according to numbers for easy identification for data extraction. Emphasis was also placed on the purpose of the study and research ethics during the training.

3.8.2 Pretesting of data collection tools

The data extraction tool was pre-tested among a group of 20 similar study population at the ART clinic of the Tema general hospital. This helped in the evaluation of the time needed in the data collection, assessment completeness and discrepancies in the tool. Identified gaps were modified and corrected before the actual data collection.

3.9.3 Data Handling

Research assistants were monitored by the principal investigator during the use of the data extraction tool. Electronic data files were password protected. Access was only limited to the PI, and the Supervisor of the study.

3.10 Data Processing and Analysis

Collected data was reviewed for completeness before entry into Kobo collect application software which was subsequently imported into Excel and subsequently to Stata version 16 for cleaning and analysis. Data was summarized using graphs, Based on the distribution of the data, frequency and percentages for categorical variables, mean and standard deviation or median or interquartile range for continuous variables. Responses to the dependent variable, VL suppression in PLHIV, were divided into two categories: virologic failure and viral suppression with undetectable viral load

levels as part of viral load suppression. Viral load and undetectable viral load where good outcome against viral load failure that is why it fell under viral load suppression.

This was then translated into binary variables for logistic regression analysis. Univariable and multivariable logistic regression analysis were used to assess the socio-demographic, drug related factor and disease related factors that affect VL suppression

A p-value of less or equal to 0.5 was used to retain variables for both univariable and multivariable logistic regression analyses. In the multivariable analyses, adjusted Odds Ratios (aOR) with respective 95% Confidence Interval and p-value were reported. The goodness of fit was used to check using the command 'logitgof''. Any association with a p-value of less than 0.05 were considered significant.

3.11 Ethical Consideration

Ethical approval for the study was secured from the Ghana Health Service Ethics Review Committee with ID number GHSERC:051/09/21. Authorization was sought from the National AIDS Commission Program (NACP). Facility approval were also asked fort by the district health management teams of the two districts prior to data collection.

3.12 Risk and Benefit

Patient records were used for analysis hence no risk. The names of patients were not extracted to maintain anonymity. The report's findings will be use to improve care in the management of PLHIV as benefit.

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

This chapter present results of collected data on 479 PLHIV on medication. A total of 479 folders were assessed with complete information on 470 folders. The study investigated the viral load suppression among PLHIV in the Ningo Prampram district and Shai Osudoku Hospital. Factors included were the demographic characteristics of PLHIV in relation to viral suppression, drug-related factors with viral load suppression. Disease-related factors with viral load suppression. Viral load was also classified as virologic failure and viral suppression with the association of the above factors determined.

4.2 Sociodemographic characteristics of respondents

The survey recruited 479 persons living with HIV (PLHIV). The mean age of the respondents were 41.5 ± 11.5 years. With majority of them (61.2%) within the age of 30-49 years. Most of the PLHIV (70.5%) were females. Majority of the PLHIV (78.1%) had some form of formal education. About half of them (47.8%) attained primary education while a fifth (21.9%) of them did not have any formal education. Most of the PLHIV (86.8%) were employed. However, most of them (79.1%) were in the informal sector. Most of them (36.4%) were married while about a quarter (26.8%) were either divorced or separated (Table 1).

Table 4. 1: Sociodemographic characteristics of respondents

Variables	Frequency	Percentage
Age		
<30	69	14.5
30-49	292	61.2
50-69	109	22.8
>70	7	1.5
Sex		
Female	337	70.5
Male	141	29.5
Level of education		
No formal education	95	21.9
Primary	207	47.8
Secondary	105	24.3
Tertiary	26	6.0
Employment status		
Unemployed	63	13.2
Employed	413	86.8
Employment type		
None	66	16.0
Non-formal work	326	79.1
Formal work	20	4.9
Scheduled visit attendance		
No	260	54.3
Partially	81	16.9
Yes	138	28.8
Marital status		
Single	103	22.8
Married	164	36.4
Divorced/Separated	121	26.8
Widowed	63	14.0

4.3 Proportion of Respondents on ART with Suppressed Viral Load Levels (<1000 copies/ml)

Of the total 479 PLHIV, the proportion of PLHIV on ART with suppressed viral load level was 64.9% (CI = 60.5 - 69.0) as shown in the figure 1.

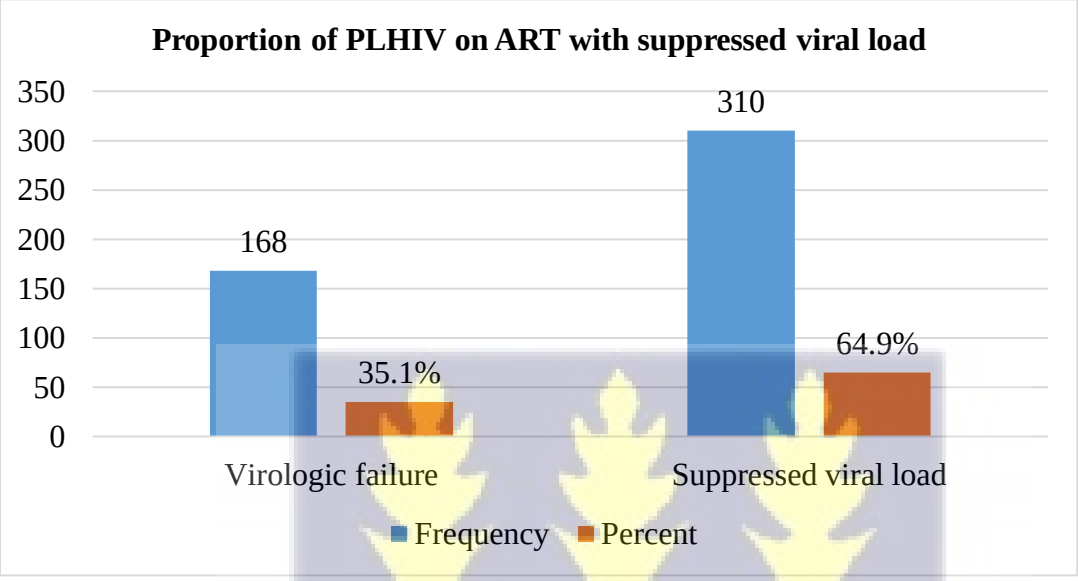

Figure 4. 1: Proportion of PLHIV on ART with suppressed viral load

4.4 Association of sociodemographic factors with viral load suppression

The epidemiological characteristics of HIV and the sociodemographic parameters are as shown in table 4.2. The PLHIV in the age group (30-49) had the highest number with viral load suppression (183) compared to 5 among those who were 70 years and above. The percentage of viral load suppression among the different age groups were: < 30 (63.8%), 30-49 (62.9%), 50-69 (70.6%) and >70 (71.4%) (X^2 = 2.27, p = 0.519).

Majority of the females 229 () had viral load suppression compared to 81 among the men. Sex was significantly associated with viral load suppression (X^2 = 5.01, p-value = 0.025). The PLHIV who had primary education had the highest number of persons with suppressed viral load (59.2%)

compared to those with tertiary education who had the least number (61.5%). Most of the PLHIV (64.8%) who were employed had suppressed viral load compared to the (65.1%) who were unemployed. Again, the most of the PLHIV (63.7%) who were working in the informal sector had suppressed viral load compare those with formal work (65%). Scheduled visit attendance was significantly associated with viral load suppression. (X^2 = 6.71, p-value = 0.035). PLHIV who were married had the highest number of viral suppressions (65.6%) compared to the widowed (71.4%). The chi square or fisher's exact test showed that viral load suppressions among participants had no significant differences ($p<0.05$) with age, level of education, employment status, employment type and marital status.

Table 4. 2: Bivariate analysis of the association between sociodemographic factors and viral load suppression

Variables	Virologic failure	V L Suppression	X^2	p-value
Age				
<30	25 (36.2)	44 (63.8)	2.27	0.519†
30-49	108 (37.1)	183 (62.9)		
50-69	32 (29.4)	77 (70.6)		
>70	2 (28.6)	5 (71.4)		
Sex				
Female	107 (31.9)	229 (68.1)	5.01	0.025*
Male	60 (42.6)	81 (57.4)		
Level of education				
No formal education	31 (32.6)	64 (67.4)	3.02	0.388
Primary	84 (40.8)	122 (59.2)		
Secondary	34 (32.4)	71 (67.6)		
Tertiary	10 (38.5)	16 (61.5)		
Employment status				
Unemployed	22 (34.9)	41 (65.1)	0.00	0.966
Employed	145 (35.2)	267 (64.8)		
Employment type				
None	20 (30.3)	46 (69.7)	0.87	0.648

Non-formal work	118 (36.3)	207 (63.7)		
Formal work	7 (35.0)	13 (65.0)		
Scheduled visit attendance				
No	80 (30.8)	180 (69.2)	6.71	0.035*
Partially	37 (46.2)	43 (53.8)		
Yes	51 (37.0)	87 (63.0)		
Marital status				
Single	46 (44.7)	57 (55.3)	5.14	0.016*
Married	56 (34.4)	107 (65.6)		
Divorced/Separated	42 (34.7)	79 (65.3)		
Widowed	18 (28.6)	45 (71.4)		

***Significance at p<0.05, †Fishers exact chi square**

4.5 Bivariate Analysis of the Association between Drug-Related Factors and Viral Load Suppression

The chi square test of associations established that all the drug-related factors were not significant (p>0.05). The characteristic distribution of drug-related factors is shown in table 4.3. First line had the highest percentage of viral load suppression in this study (65.2%) while third line had (33.3%). PLHIV with hyperglycemia had a higher percentage viral load suppression compared to those without hyperglycemia. This association is not significant (X^2 = 0.13, p =718). The number of those without a diarrhea of more than three days who had viral load suppression was 3 compared to the 0 who presented with diarrhea of more than three days. Out of the 2 PLHIV who reportedly presented with hepatotoxicity, 1 had VL suppression while 2 out of those without hepatotoxicity had VL suppression. Five of the participants had depression, of which 1 had VL suppression. Out of the 15 PLHIV who reported to have had weight loss, 3 (20.0%) had VL suppression. None of the PLHIV who experienced pain or numbness or tingling sensations in their extremities had a VL suppression. Also, all those with bone dysfunction did not have VL suppression.

Table 4. 3: Association of drug-related factors with viral load suppression

Variables	Virologic failure	VL Suppression	X^2	p-value
Current ART medication				
First line	165 (34.8)	309 (65.2)	1.33	0.249†
Third line	2 (66.7)	1 (33.3)		
Hyperglycemia				
Yes	4 (80.0)	1 (20.0)	0.13	0.718†
No	13 (86.7)	2 (13.3)		
Diarrhea >3 days				
Yes	3 (100.0)	0 (0)	4.84	0.184†
No	14 (82.3)	3 (17.7)		
Hepatotoxicity				
Yes	1 (50.0)	1 (50.0)	2.14	0.144
No	16 (88.9)	2 (11.1)		
Depression				
Yes	4 (80.0)	1 (20.0)	2.52	0.284†
No	8 (100.0)	0 (0)		
Never	5 (71.4)	2 (28.6)		
Weight loss				
Yes	2 (100.0)	0 (0)	1.18	0.555†
No	12 (80.0)	3 (20.0)		
Never	3 (100.0)	0 (0)		
Pain/numbness/tingling extremities				
Yes	7 (100.0)	0 (0)	1.96	0.375†
No	6 (75.0)	2 (25.0)		
Never	4 (80.0)	1 (20.0)		
Bone dysfunction				
Yes	3 (100.0)	0 (0)	0.65	0.721†
No	10 (83.3)	2 (16.7)		
Never	4 (80.0)	1 (20.0)		

***Significance at p<0.05, †Fishers exact chi square**

4.5 Bivariate Analysis of the Association between Disease-related Factors and Viral Load Suppression.

Those in stage I of the disease with VL suppression were 2 compared to 0 among those in the third stage of the disease. Of the 18 PLHIV who did not have both herpes zoster, 3 had VL suppression. Same applies with those who did not have TB meningitis. The percentage of PLHIV with suppressed VL who did not have cryptococcal meningitis at the time of interview was 17.7% compared to the 0% who never contracted the disease at all. Those with suppressed VL who never had cerebral toxoplasmosis was high 3 compared to those who did not have cerebral toxoplasmosis 0. Out of the 17 PLHIV who did not have Pneumocystis jeroveci pneumonia, 3 had VL suppression compared to the 0 never had Pneumocystis jeroveci pneumonia. Those who answered yes to pulmonary tuberculosis and Cytomegalovirus rhinitis did not have VL suppression. The chi square test of associations established related factors were not significant ($p<0.05$).

Table 4. 4: Association between disease-related factors and viral load suppression

Variables	Virologic failure	VL Suppression	X^2	p-value
WHO Clinical stage of the disease				
Stage I	10 (83.3)	2 (16.7)	0.65	0.721†
Stage II	4 (80.0)	1 (20.0)		
Stage III	3 (100.0)	0 (0)		
Herpes Zooster				
Yes	2 (100.0)	0 (0)	0.39	0.531†
No	15 (83.3)	3 (16.7)		
TB meningitis				
Yes	2 (100.0)	0 (0)	1.18	0.555†
No	12 (80.0)	3 (20.0)		
Never	3 (100.0)	0 (0)		
Cryptococcal Meningitis				
No	14 (82.3)	3 (17.7)	0.62	0.430
Never	3 (100.0)	0 (0.0)		
Cerebral Toxoplasmosis				
No	2 (100.0)	0 (0)	0.39	0.531†
Never	15 (83.3)	3 (16.7)		
Pneumocystis jeroveci pneumonia				
No	14 (82.3)	3 (17.7)	0.62	0.430†
Never	3 (100)	0 (0)		
Pulmonary tuberculosis				
Yes	2 (100.0)	0 (0)	0.67	0.715†
No	12 (85.7)	2 (14.3)		
Never	3 (75.0)	1 (25.0)		
Cytomegalovirus rhinitis				
Yes	4 (100.0)	0 (0)	1.90	0.387†
No	10 (76.9)	3 (23.1)		
Never	3 (100.0)	0 (0)		
Esophageal candidiasis				
No	14 (82.3)	3 (17.7)	0.62	0.430†
Never	3 (100.0)	0 (0)		

***Significance at p<0.05, †Fishers exact chi square**

4.7 Multiple logistic regression analysis for factors associated with viral load suppression

In the crude analysis, marital status, sex and schedule clinic attendance were statistically significant. For example sex (OR=0.63, 95%CI = 0.42 - 0.95). But only marital status was significantly associated with viral load suppression after adjusting for all other variables in the multiple logistic regression model. When compared to single participants in the study, PLHIV who were divorced/separated had 3.5 times the odds of having suppressed VL (OR =3.52, 95%CI = 1.13 -11.00). Married participants had almost three times increased odds of achieving viral load suppression compared to single participants (OR = 2.74, 95%CI = 0.90 - 8.33)**.** Also, the odds of achieving viral load suppression was 3 times higher among widows compared to those who were single (OR=

3.05, 95%CI =0.78 - 12.00)

However sex and scheduled clinic attendance were not predictors of viral load suppression ($p>0.05$).

Table 4. 5: Multiple logistic regression analysis for factors associated with viral load suppression

Variable	Virologic failure	Suppressed viral load	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Age						
<30	25 (36.2)	44 (63.8)	1			
30-49	108 (37.1)	183 (62.9)	0.96 (0.56 - 1.66)	0.89		
50-69	32 (29.4)	77 (70.6)	1.37 (0 .72 - 2.60)	0.34		
>70	2 (28.6)	5 (71.4)	1.42 (0.26 - 7.87)	0.69		
Sex						
Female	107 (31.9)	229 (68.1)	1		1	
Male	60 (42.6)	81 (57.4)	0.63 (0.42 - 0.95)	0.03*	0.87 (0.38 - 1.97)	0.739
Level of education						
No formal education	31 (32.6)	64 (67.4)	1		1	
Primary	84 (40.8)	122 (59.2)	0.70 (0.42 - 1.17)	0.18	0.74 (0.28 - 1.93)	0.53
Secondary	34 (32.4)	71 (67.6)	1.01 (0.56 - 1.83)	0.97	0.66 (0.22 - 1.97)	0.45
Tertiary	10 (38.5)	16 (61.5)	0.78 (0.32 - 1.90)	0.58	1.72 (0.31 - 9.45)	0.53
Employment type						
None	20 (30.3)	46 (69.7)	1			
Non-formal work	118 (36.3)	207 (63.7)	0.76 (0.43 - 1.35)	0.35		
Formal work	7 (35.0)	13 (65.0)	0.81 (0.28 - 2.33)	0.69		
Scheduled visit attendance						
No	80 (30.8)	180 (69.2)	1		1	
Partially	37 (46.2)	43 (53.8)	0.52 (0.31 - 0.86)	0.01*	0.49 (0.18 - 1.33)	0.16
Yes	51 (37.0)	87 (63.0)	0.76 (0.49 - 1.17)	0.21	0.46 (0.19 - 1.08)	0.08
Marital status						
Single	46 (44.7)	57 (55.3)	1		1	
Married	56 (34.4)	107 (65.6)	1.54 (0.93 - 2.56)	0.09	2.74 (0.90 - 8.33)	0.076
Divorced/Separated	42 (34.7)	79 (65.3)	1.52 (0.89 - 2.60)	0.13	3.52 (1.13 - 11.00)	0.03*
Widowed	18 (28.6)	45 (71.4)	2.02 (1.03 - 3.95)	0.04	3.05 (0.78 - 12.00)	0.11
Current ART medication						
First line	165 (34.8)	309 (65.2)	1			
Third line	2 (66.7)	1 (33.3)	0.27 (0.024 - 3.00)	0.28		

Hyperglycemia						
Yes	4 (80.0)	1 (20.0)	1			
No	13 (86.7)	2 (13.3)				
Diarrhea >3 days						
No	14 (82.3)	3 (17.7)	1		1	
Yes	3 (100.0)	0 (0)	0.20 (0.02 - 1.84)	0.16	0.16 (0.02 - 1.64)	0.12
Weight loss						
No	12 (80.0)	3 (20.0)				
Yes	2 (100.0)	0 (0)	1.10 (0.57 - 2.12)	0.77		
Pain/numbness/tingling extremities						
No	6 (75.0)	2 (25.0)	1			
Yes	7 (100.0)	0 (0)	1.76 (0.51 - 6.10)	0.38		
Pulmonary tuberculosis						
No	12 (85.7)	2 (14.3)	1			
Yes	2 (100.0)	0 (0)	0.27 (0.028 - 2.67)	0.26		
Cytomegalovirus rhinitis						
No	10 (76.9)	3 (23.1)	1			
Yes	4 (100.0)	0 (0)	1.7 (0.15 - 19.16)			

***Significance at p<0.05**

CHAPTER FIVE

5.0 DISCUSSIONS

The study determined viral load suppression among PLHIV on HAART for at least twelve months, as well as the factors associated with failure to achieve viral suppression (1000 copies/ml) in the Ningo Prampram district and at Shai Osudoku Hospital. This study recorded a 64.9% of PLHIV with viral suppression on ART. This is lower than 73%, the national statistics (Ghana AIDS Commission, 2020) but higher than the 24% and 41% reported in Sierra Leone and Senegal, respectively in 2018 (UNAID, 2019). This however shows a significant gap in the 90-90-90 indicator for Ningo Prampram and Shai Osudoku hospital. Comparable to this work is a study by Lokpo et al, 2020; conducted in the Ho municipality. A record of 69% was noted. Eighty six percent of PLHIV was also recorded by Bvochora et al, (2016) in Zimbabwe. A high record of 93% was seen by Rangarajan et al, 2016 in Vietnamese four provinces (Rangarajan et al, 2016).

In this study, females constituted 70.5% (337), forming majority of the total participant in this research. Similarly, a study by Lokpo et al in 2020 reported 81.3% of the total population of PLHIV in his study being females. Same can be attributed to Kwarisiima et al (2019) of 66% of his study sample. The female reproductive organ's anatomic structure makes them more vulnerable to HIV infection (WHO, 2018). Additionally, the high health seeking behaviors in females in the developing countries can be attributable (Lokpo et al 2020; Bila & Egrot, 2009).

In the crude analysis, Sex was significantly associated with VL suppression. However, this was not the case in the adjusted analysis, though females (68.1%)) had VL suppression compared to (57.4%) males which was an improvement for the females compared to the national figures of 62% for both sexes. In 2011, Trichavaroj et al discovered no gender differences in HIV RNA levels after controlling for CD4+ T-cell count. Sex was again insignificant in a study by Rangjaran et al, (2016)

Findings of this study are inconsistent with data from Faradzan et al, (2016). Also concluding that single viral load measure lower in women than in men. Reasons to this significance was not investigated. But the assumption that women having lower viral loads than men owing to biological factors has been made. Also, the possibility of lower production of virus or a high viral clearance in women, or both (Farzadegan et al, 1998; Sterling et al, 2011).

According to Desta et al, 2020 there were high level of viral load recorded in PLHIV who were not adherent to ART medication. Several studies can be attributed as such (Kiweewa et al, 2019; Bayu et al, 2017). Though no data was collected on the medication adherence in this current study, Luque-Fernandez enumerated such benefits as a crucial parameter to achieving viral suppression. Lopko et al, (2020) linked clinic attendance as a measure of drug adherence. In their study 57% of PLHIV who did not regularly attend scheduled visits were not virally suppressed. Significantly to this study, majority of those who did not visit the health facility for their scheduled visit (180) had a suppressed viral load at the bivariate level. Reasons to this effect is not known to this study but further study is recommended to elicit such factors. Failure to attending regular schedules were attributed lack of money for transportation, switch to herbal medications, spiritual reasons which patients end up in prayer camps. Scheduled visit attendance was then not statistically significantly associated with viral load suppression after ad. ($X^2 = 6.71$, p-value = 0.035).

Only marital status was statistically significant in this study hence a good predictor of VLS. Reasons to this finding is not known to this study hence further studies are recommended. Similarly Haas et al., 2019 in their study agreed to this assertion. But Miller et al., (2021), Rangarajan et al., (2016), Gabagaya et al., (2021) in their studies conversely reported marital status as not a predictor for VLS

The WHO recommend the first line HIV drug regimen, AZT/3TC/EFV. It's effectiveness against the virus can results in viral suppression. (Barry et al, 2013). In line with this fact, PLHIV on first line ART had the highest percentage of viral load suppression in this study (65.2%) while third line had (33.3%) at the bivariate level but was statistical insignificance at the adjusted logistic regression analysis. Second and third-line ART regimen were recorded to have a high virologic failure compared to the first-line regimen according to Kiweewa et al, (2019).

The major strength of this study is the large sample size which was significant for the power of the study compared to Lokpo et al, (2020) 284 participants, Trinh et al, (2016) 228 participants , Hussen et al., (2019) 152 participants, Hander et al, (2019) 342 participants, who used small sample sizes.

In summary, findings of this study showed factors affecting viral suppression. Majority of the PLHIV have achieved viral suppression especially females even though they formed majority if the study. This proves the effectiveness of various policies put in place in achieving the 95-95-95 strategy even though Ghana fell short of the just ended 90-90-90 strategy in 2020. Marital status was found to be a predictor of viral suppression. Scheduled clinic attendance, age, sex and diarrhea > 3days were all not predictors of VLS in this study. Diseases affecting PLHIV where found not to affect viral suppression provided patients continues to take their ART medications.

5.1 Study Limitation

Selection bias of patients' records posed a limitation to this study due to records selected from available VL results. This could have been avoided if current VL results were released. This was due to the faulty national VL machine.

Irregular clinic attendance and lack of regular follow-up also affected the sample size of this study. There was again no temporal relationship established.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATION

The purpose of this study was to identify viral load suppression among PLHIV on HAART for at least twelve months, as well as the factors associated with failure to achieve viral suppression (1000 copies/ml) in the Ningo Prampram district and Shai Osudoku Hospital.

In accordance with the findings of the study, the proportion of PLHIV on ART with suppressed viral load levels (1000 copies/ml) was low in contrast to the overall proportion.

Marital status was the only sociodemographic factor that affected viral load suppression.

There was no disease- related factor affecting viral load suppression among PLHIV in the Ningo Prampram and Shai Osudoku hospital.

There was again no ART-related factor associated in achieving viral load suppression (<1000 copies/ml) in people living with HIV.

6.1 Recommendations

Based on the findings of this study, marital status was a good predictor of VLS and should be highlighted in management policies. Regarding individual levels, patients who are married should be commended and encouraged to continue to serve as checks for each other. Others who are not married should not be looked down on but counselled on the importance of marital status helping in achieving VLS. At the facility level, married couple living with HIV can be selected as peer educators during counselling sessions with the health staffs to help in educating their peers.

The Ghana AIDS Commission should again adopt different method to assessing viral load in low resource countries as recommended by the WHO. This will help solve the problem of delayed results as a results of constant breakdown of the VL machine

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Appendix 1: Questionnaire

HIV in the Ningo Prampram district and Shai Osudoku Hospital

Patient's ID

_____

Date

yyyy-mm-dd _____

Facility

_____

Patient Folder Number

_____

Is the patient's age recorded in the folder?

- ◯ Yes
- ◯ No

If Yes, what is the patient's age in years according to the folder?

_____

Record date of Birth in Folder/Card

yyyy-mm-dd _____

Sex

- ◯ Male
- ◯ Female

Is the patient's level of education recorded in the folder?

- ◯ Yes
- ◯ No

If Yes, what is the highest level of education?

- No Education
- Primary
- Secondary
- Tertiary

Is patient's means of earning a living recorded in the folder?

- ◯ Yes
- ◯ No

If Yes, what does the patient do to earn a living?

- Formal work
- Non-formal work
- Unemployed

If formal work, please specify

_____

If non-formal work, please specify

_____

Has patient been attending scheduled visits?

- ◯ Yes
- ◯ No
- ◯ Partially

What is the patient's marital status?

- ◯ Single
- ◯ Married
- ◯ Divorced
- ◯ Widowed
- ◯ Cohabiting

Which one of ART medication is the patient on?

Drug information according to clinical notes

- ◯ First line
- ◯ Second line
- ◯ Third line

Any of the following adverse events recorded in the folder of patient?

- [ ] Skin rash
- [ ] Anemia
- [ ] Abdominal pains
- [ ] Hyperglycemia
- [ ] Diarrhea >3 days
- [ ] Hepatotoxicity
- [ ] Depression
- [ ] Weight loss
- [ ] Pain/Numbness in the extremities
- [ ] Bone dysfunction
- [ ] Pruritus
- [ ] Dyspnea
- [ ] Palpitations
- [ ] Tremor
- [ ] Others (specify)

Others, please specify

_____

Has there been a current viral load test?

- ◯ Yes
- ◯ No

If yes, what is the latest results (in copies/ml?

_____

Has the patient achieved viral load suppression?

- ◯ Yes
- ◯ No

What are the reasons for failing to do viral load test of patient?

_____

In the next set of questions, enter results for the past 3 viral load information.
Note that this does not include the latest VL test results provided earlier.

_____

Was target detected for results 1?

- ◯ Yes
- ◯ No

Viral load measurement value 1 (in copies/mil)

_____

Has the patient achieved viral load suppression 1

Yes

No

Was target detected for result 2?

◯ Yes

◯ No

Viral load measurement value 2 (in copies/mil)

_____

Has the patient achieved viral load suppression 2

Yes

No

Was target detected for result 3?

◯ Yes

◯ No

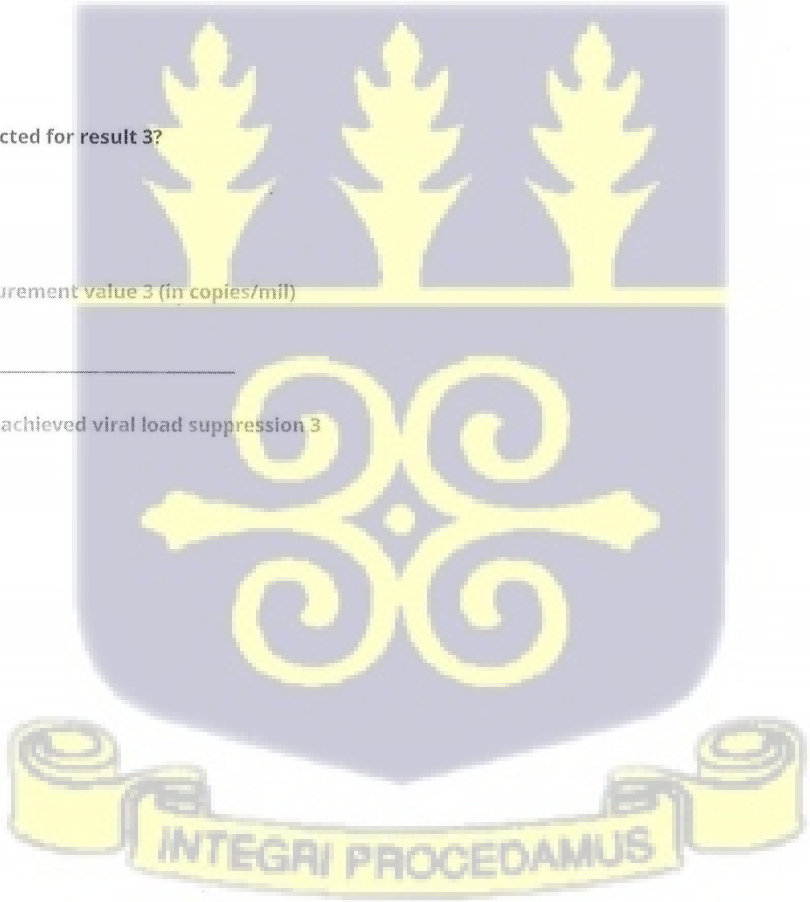
Viral load measurement value 3 (in copies/mil)

_____

Has the patient achieved viral load suppression 3

Yes

No



Appendix 1: Ethical Approval Letter

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

My Ref. GHS/RDD/ERC/Admin/App (2158
Your Ref. No.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
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Digital Address: GA-050-3303
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Tel: +233-302-681109
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Email: ethics.research@ghsmail.org
25th November, 2021

Mercy Bransah
Prampram Polyclinic
P.O. Box 37, Prampram

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 051/09/21**
Study Title	Viral Load Suppression and its Associated Factors among People with HIV in the Ningo Prampram District
Approval Date	25th November, 2021
Expiry Date	24th November, 2022
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED... .....
Dr. James Akazili
(Head, Ethics & Research Management Department)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

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My Ref.ghs/rdd/erc/Admin/amend/app/ 22
Your Ref. No.

21st March 2022

Mercy Bransah
School of Public Health
University of Ghana
Legon, Accra

RE: Request for Ethical Approval to Amended Protocol

Reference is made to your letter dated 2nd November 2021 on the above subject matter.

The Ghana Health Service Ethics Review Committee (GHS-ERC) has reviewed the documents submitted, and the rationale for the request for amendment. The GHS-ERC has given approval for the amendment to be implemented.

GHS-ERC Number	**GHSERC: 051/09/21**
Study Title	Viral Load Suppression and its Associated Factors among People Living with HIV in the Ningo Prampram District and Shai Osudoku Hospital
Effective Date for Approval of Amendment	21st March 2022
Expiry Date	24th November 2022
GHS-ERC Decision	**Amendment Version 3 dated 2nd February 2022 Approved**

The approval covers the following only:

- **See attached appendix for details of the amendment.**

The following applies:

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC).
- Renewal of ethical approval if the study lasts for more than 12 months.
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.

1

- Submission of a final report **after completion** of the study.
- Informing ERC if study is discontinued and reasons why.
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol.

SIGNED..... .....

Dr. James Akazili
(Head, Ethics & Research Management Department)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

Appendix: Details of amendment

Amendment Justification table

Old site	New site	Justification
Ningo Prampram district	Shai Osudoku hospital	Due the constant breakdown of the national viral load machine, results of viral load test have still not been received by most ART centers since 2019 though blood samples have been sent with several assurances of receiving results. Also, documentation of results in one of the study site made my sample short since I was retrieving secondary data from the patient's records. So it has deemed it necessary to add an additional site to make up for the short fall.