DRIVERS OF VIROLOGICAL NON-SUPPRESSION AMONG ADOLESCENTS AND ADULTS ON ANTIRETROVIRAL THERAPY FOR HIV IN SAMBURU EAST AND SAMBURU CENTRAL SUB-COUNTIES IN SAMBURU COUNTY, KENYA

BY

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A THESIS SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, COLLEGE OF HEALTH SCIENCES, MOI UNIVERSITY, IN FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE MASTER OF SCIENCE IN FIELD EPIDEMIOLOGY AND LABORATORY TRAINING

DECLARATION

Student's Declaration:

I, **Elias Nkararo Lentilai**, declare that this thesis titled "*Drivers of Virological Non-Suppression among Adolescents and Adults on Antiretroviral Therapy in Samburu East and Samburu Central Sub-Counties, Kenya"* is my original work. It has not been submitted, in whole or in part, to any other institution for the award of the *Degree of Master of Science in Field Epidemiology and Laboratory Training*. All sources used have been appropriately acknowledged.

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DEDICATION

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ABSTRACT

Background: At the conclusion of 2019, Kenya achieved a 24% viral load (VL) non-suppression rate. However, based on the National AIDS and STI Control Program report in August 2018, Samburu County had a 33.2% VL non-suppression rate and was ranked as a poor-performing county in reference to the third "95" (viral suppression) strategy. However, Samburu East and Samburu Central sub-counties of Samburu County had poor VL non-suppression rates leading to high numbers of virological failures, an increase in the risk of HIV transmission, and early deaths.

Objectives: To determine the proportion of adolescents and adults with non-suppressed viral load 6 months' post ART initiation, describe socio-demographic characteristics, and determine factors associated with HIV viral load non-suppression among the adolescents and adults enrolled on ART in Samburu East and Samburu Central Sub-counties.

Methods: This was a cross-sectional study involving a review of client ART records and face-to-face interviews using a structured questionnaire amongst the adolescents and adults enrolled in ART in six health facilities offering ART services in Samburu East and Samburu Central sub-counties. Viral load non-suppression was defined as having >1000 copies of viral RNA/ml of plasma after 6 months of treatment. A total of 276 participants from eligible individuals were selected randomly using Excel-generated random numbers. Calculation of relevant statistics for continuous and categorical data was done. A bivariate logistic regression model was used to analyze data to determine predictors of virological non-suppression, and factors showing a $p<0.2$ were added to a multivariate forward logistic elimination model.

Results: The overall VL non-suppression in the two sub-counties was 26.3%. One hundred and sixty-nine 169 (67.3%) of the participants were females. The study participants' average age was 37.9 years (SD = 12.7). The average CD4 count of the study participants at baseline was 317 cells/mm³ (SD = 378.0 cells/mm³). For the WHO clinical stage, 103 (40.8%) were in stage I, 69 (27.6%) were in stage II, 70 (28.0%) were in stage III, and 9 (3.6%) were in stage IV. The independent variables that were associated with VL non-suppression include WHO clinical stage III and IV, which had higher odds of VL non-suppression (aOR = 12.20, 95% CI = 4.50 - 33.03, and poor adherence rating was also statistically associated with VL non-suppression (aOR = 5.91, 95% CI = (2.97-13.58). Regularly attending support group meetings had a protective effect against the VL non-suppression (aOR = 0.26, 95% CI = 0.10 - 0.71) on adolescents and adults on ART in Samburu East and Samburu Central sub-counties.

Conclusion: The study identified a 26.3% rate of viral load non-suppression, underscoring a significant public health concern. Major factors included late care enrollment and poor adherence. Targeted interventions that are sensitive to gender and age, early diagnosis, ongoing treatment support, and regular involvement in support groups are crucial to enhance ART adherence and achieve viral suppression.

Recommendation: The Samburu County Health Department should adopt a comprehensive strategy to reduce viral load non-suppression. Key actions include scaling up community sensitization, reinforcing ART adherence through guideline-based tools, and strengthening peer support groups to reduce stigma and improve motivation. These coordinated interventions aim to enhance treatment outcomes and achieve sustained viral suppression across the county.

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LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
APNS	Assisted Partner Notification Services
ART	Antiretroviral Therapy
CCC	Comprehensive Care Clinic/Center
CD4	Cluster of Differentiation 4
CIDP	County Integrated Development Plan
DBS	Dried Blood Spot
HIV	Human immunodeficiency virus
HTS	HIV Testing Services
IREC	Institutional Research Ethics Committee
KenPHIA	Kenya Population-based HIV Impact Assessment
KPs	Key Populations
NACC	National AIDS Control Council
NACOSTI	National Commission for Science, Technology and Innovation
NASCOP	National AIDS and STI Control Program
OPs	Opportunistic Infections
PEP	Post-exposure Prophylaxis
PEPFAR	U.S President's Emergency Plan for AIDS Relief
PLWH	People Living with HIV

PMTCT	Prevention of Mother to Child Transmission
PrEP	Pre-exposure Prophylaxis
RNA	Ribonucleic acid
STIs	Sexually Transmitted Diseases
UNAIDS	United Nations Programme on HIV/AIDS
VL	Viral load
WHO	World Health Organization
WLHIV	Women Living with HIV

OPERATIONAL DEFINITIONS

Adolescents and adults: According to WHO guidelines on when to start Antiretroviral Therapy, an adolescent is a person 10 – 19 years old.

Anti-Retro Viral therapy: the term for the use of anti-HIV medications to treat HIV-positive individuals. The typical course of treatment consists of a minimum of three medications that inhibit HIV replication; these medications are commonly referred to as highly active antiretroviral therapy.

Viral Load: In this study, the amount of HIV circulating in the body is referred to as the "viral load." It is measured in terms of the number of HIV copies per milliliter of blood (copies/mL).

Viral Non-Suppression: HIV-1 RNA viral load non-suppression is defined as having greater than 1000 circulating HIV copies per milliliter (ml) of plasma.

Poor adherence: Defined as those with an adherence level of less than 85% i.e, missed five or more drugs per month

Fair adherence: Defined as those with an adherence level of 85% to 94% i.e, missed two to four doses per month

Good adherence: Defined as those with an adherence level of greater than 94% i.e, missed less than 1 drug per month

CHAPTER ONE

1.0 Introduction

1.1 Background

The human immunodeficiency virus (HIV), responsible for inducing acquired immunodeficiency syndrome (AIDS), persists as a significant global health challenge, resulting in the mortality of approximately 33 million individuals to date. As of 2019, persons living with HIV were 38.0 million, and 690,000 AIDS-related deaths occurred globally (UNAIDS facts sheet, 2020). Africa remains most affected by HIV, where approximately 1 in 25 adults (3.7%) are infected, accounting for more than two-thirds of the global HIV infection (UNAIDS facts sheet, 2020). Major strides have been made in combating the epidemic, especially in the last 20 years, thanks to the adoption of popular programs like HIV drug access and VL surveillance. Globally, 25.4 million HIV-positive people were receiving treatment in 2019 compared to 21 million in 2017 (UNAIDS Global AIDS Update, 2020). As such, between the years 2000 and 2019, there was a 39% reduction in the worldwide occurrence of new HIV infections, accompanied by a 51% decline in HIV-related deaths. During this timeframe, the utilization of antiretroviral therapy (ART) is credited with saving 15.3 million lives. This accomplishment was a result of intensive efforts by civil society and global development partners led by nationwide HIV programs. Consequently, as accessibility to efficacious HIV prevention, diagnostics, therapeutics, and supportive interventions for opportunistic infections expands, HIV infection has transitioned into a controllable medical state, facilitating prolonged and healthful survival among individuals afflicted with HIV (WHO factsheet, 2020).

In Kenya, the initial documented incidence of HIV occurred in 1984, and by the mid-1990s, HIV had emerged as a predominant contributor to morbidity within the nation,

imposing substantial strains on both the healthcare infrastructure and the national economy (Avert, 2021). By the year 2019, it was estimated that 1.5 million (5.2%) persons were infected with HIV in Kenya, although prevalence has almost halved since 1996 which stood at 10.5% by then (UNAIDS-Kenya, 2019; Avert, 2021). In congruence with global trends, Kenya's HIV prevalence predominantly stems from sexual transmission, impacting individuals across all demographic stages, encompassing children, adolescents, and adults. Nevertheless, certain subpopulations in Kenya, such as homosexuals, sex workers, and individuals engaged in intravenous drug use, exhibit heightened vulnerability to HIV acquisition (Avert, 2021). Notably, between 2010 and 2019, AIDS-related mortality in Kenya exhibited a marked decline from 64,000 to 21,000, attributable largely to the rapid expansion of HIV treatment and care initiatives (Kenya NACC, 2014; Avert, 2021). By 2016, 64% of People Living with HIV (PLWH) in Kenya were undergoing treatment, with 51% achieving viral suppression, reflecting significant strides in combating the epidemic (UNAIDS, 2018/2019).

HIV prevalence in Samburu County (1.9%) is lower than the nationwide prevalence of 5.6% (KenPHIA, 2018). In April 2019, the County rolled out assisted partner notification services (APNS) under the Afya Nyota ya Bonde as the implementing partner for 4 months in all three sub-counties. As outlined by UNAIDS (2016), one strategy implemented to enhance HIV testing rates involved the utilization of HIV Partner Notification Services (PNS). PNS entails a voluntary procedure where individuals diagnosed with HIV are queried by trained personnel regarding their sexual or drug-injecting contacts. Subsequently, with the consent of the HIV-positive individual, these contacts are offered HIV Testing Services (HTS) (UNAIDS, 2016). By the conclusion of 2019, the implementation of the APNS targeted testing model

contributed to a 23% increase in the detection of new HIV cases in Samburu County, as per unpublished data from the Ministry of Health. This is a pointer that the HIV prevalence in Samburu County could be higher than has been estimated by previous studies, and a true one could be realized if a specific target population model for HIV testing services could be developed and implemented effectively. Based on Samburu County's HIV records, the prevalence of HIV among women surpasses that of men, with rates standing at 2.8% for women and 1.3% for men, indicating a heightened susceptibility to HIV infection among women within the county. The determinants driving HIV transmission in the region encompass various economic, social, and cultural factors, notably linked to marital status, circumcision practices, poverty, and insecurity. Socioeconomic factors exert both direct and indirect influences on HIV/AIDS prevalence rates by fostering environments conducive to risky behaviors and hindering access to comprehensive information. These determinants encompass poverty, both on individual and national scales, income disparities, gender disparities, educational attainment, urbanization, mobile population dynamics, accessibility to information and healthcare services, as well as governance structures (Bulage et al., 2017). Additionally, insecurity exacerbates impoverishment and population displacement, elevating the vulnerability of affected populations to HIV infection through the disruption of social fabric and support systems.

Tuberculosis (TB) remains a big challenge in Samburu County. As per research examining the association between HIV infection and Tuberculosis (TB), HIV-positive individuals face a markedly heightened risk of developing TB disease, with the risk escalating by at least twentyfold (Gatahu et al. 2010). Moreover, even following immune reconstitution through antiretroviral therapy, the risk of TB disease remains significantly elevated (Chaisso et al. 2017). In the year 2019, a total of 883

TB cases were notified in Samburu County with a big risk of continued transmission within the community, hence putting more risk of TB transmission on HIV-positive individuals (Samburu County TB data -unpublished MOH data).

Samburu County is divided into three sub-counties; Samburu Central, Samburu East, and Samburu North. Samburu Central has a total of 2,532 active persons enrolled in ART, Samburu East has a total of 766 active persons enrolled in ART, and Samburu North a total of 434 active persons enrolled in ART. The county is performing poorly in VL and is being ranked as the least performing, with the topmost county of Migori recording VL suppression of 94% (NASCOP dashboard, 2019). By the end of 2019, Kenya's VL suppression rate stood at 76% (UNAIDS, 2019). Attaining the 3rd 90 target for viral load (VL) suppression within Samburu County holds paramount importance for ensuring optimal viral suppression among People Living with HIV (PLWH). This endeavor not only fosters immune reconstitution but also mitigates the risk of antiretroviral therapy (ART) resistance, diminishes HIV-associated deaths and morbidity, and curtails the transmission of drug-resistant HIV mutations.

1.2 Problem Statement

Samburu County continues to experience significant challenges in achieving the third "95" of the UNAIDS 95-95-95 targets, ensuring that 95% of individuals on antiretroviral therapy (ART) attain viral load (VL) suppression. According to data sources in Samburu County, Samburu had an AIDS-related death rate of 1.8% (71 out of 3,933 deaths) in 2021, which was higher than the national average of 1.2% during the same period. Sub-county data shows even more concerning figures, with Samburu East recording an AIDS-related fatality rate of 2.1% and Samburu Central at 1.5%. In addition, the county reported 883 notified TB cases in 2019, signaling a high risk of

community transmission and increased vulnerability among HIV-positive individuals (Samburu County TB data – unpublished MOH data).

Based on the 95:95:95 HIV treatment cascade, the Samburu County Integrated Development Plan (CIDP) 2022 -2025 estimated the number of people living with HIV (PLWHIV) at 3,910. However, only 1,885 PLWHIV were enrolled in ART care, with 846 (48.6%) being virally non-suppressed, according to the earlier CIDP of 2016. Further, the National AIDS and STI Control Program (NASCOP) report for July 2017–August 2018 ranked Samburu County last (47 out of 47) in viral load suppression, with a VL non-suppression rate of 33.2% compared to the national average of 24%, despite the county being among the top performers in HIV testing and enrollment of new HIV cases in 2020. Of particular concern are Samburu East and Samburu Central sub-counties, which consistently reported the lowest viral load suppression rates in the county. According to the NASCOP viral load dashboard (2019), both adults and adolescents in these sub-counties had poor VL suppression, contributing significantly to the high overall non-suppression rate in Samburu County. These findings highlight critical gaps in treatment adherence, follow-up, and care continuity that need urgent attention.

1.3 Justification

Achieving and maintaining viral suppression is crucial for individual health and HIV prevention. In Samburu County, however, cultural practices, poverty, gender inequality, limited healthcare access, insecurity, and population mobility hinder effective HIV treatment and continuity of care. These factors contribute to high rates of virological non-suppression, particularly among adolescents and adults on ART. While strategies like Assisted Partner Notification Services (APNS) have improved HIV case detection, sustaining treatment effectiveness remains a major challenge.

Existing research provides limited insight into the unique barriers faced by populations in Samburu. This study, therefore, explores factors influencing treatment failure and viral load non-suppression in this context. These findings will support the development of tailored, context-specific interventions to improve ART adherence and outcomes, ultimately reducing HIV-related illness and transmission while advancing progress toward national and global HIV targets.

1.4 Research questions

1. What proportion of adolescents and adults who did not attain viral load suppression post-sixth month of ART treatment in Samburu East and Samburu Central Sub-counties?
2. What are the drivers of HIV virological non-suppression among adolescents and adults on antiretroviral therapy in Samburu East and Samburu Central Sub-counties?

1.5 Objectives

1.5.1 General objective

To determine the drivers of HIV virological non-suppression among adolescents and adults on ART in Samburu East and Samburu Central Sub-counties

1.5.2 Specific objectives

1. To determine the proportion of adolescents and adults with non-suppressed viral load 6 months post-ART initiation in Samburu East and Samburu Central Sub-counties
2. To describe socio-demographic characteristics of adolescents and adults with non-suppressed viral load in Samburu East and Samburu Central Sub-counties
3. To determine factors associated with HIV viral load non-suppression among the adolescents and adults enrolled on ART in Samburu East and Samburu Central Sub-counties

CHAPTER TWO

2.0 Literature review

2.1 HIV Global Burden

HIV/AIDS presents a significant worldwide health and developmental obstacle, causing severe impacts on the well-being of infected individuals, affecting entire households and communities, and disrupting the progress and economic advancement of nations affected by this issue (UNAIDS, 2016b). In 2015, an estimated 36.7 million individuals worldwide were living with HIV, with approximately 2.1 million individuals acquiring the virus during the same period. Among these, there were approximately 150,000 children, including 56,000 from the eastern and southern African regions (UNAIDS, 2016a). The ongoing expansion and enhancement of services aimed at preventing mother-to-child transmission of HIV (PMTCT) have resulted in a 66% decrease in the annual number of new infections among children globally since 2010 (HIV/AIDS, 2016). By 2015, PMTCT coverage in the eastern and southern African region had reached 90%, marking a significant increase from the 61% coverage reported in 2010 (UNAIDS, 2016c).

Antiretroviral therapy (ART) was being received by an estimated 18.2 million persons living with HIV (PLHIV) worldwide by June 2016; this represents an increase from the 15.8 million enrolled as of June 2015 (UNAIDS, 2016a). Roughly 10.3 million PLHIV were receiving ART in the East and Southern Africa areas, which makes up 54% of the PLHIV population in that region (UNAIDS, 2016c). As per the Joint United Nations Programme on HIV/AIDS (UNAIDS, 2017), certain regions like Asia-Pacific and the Caribbean have been tasked with accelerating their HIV testing and management efforts to meet the 95-95-95 targets by 2030. While other regions, like Eastern Europe and Central Asia, have made gains in increasing awareness, they

are still far behind in terms of testing for and treating viral infections. However, in regions such as the Middle East, North Africa, and Western and Central Africa, there has been a discernible rise in the levels of viral suppression. With current rates at 85-71-86, South Africa has improved its treatment coverage and is getting closer to meeting the UNAIDS target (UNAIDS, 2017).

Despite worldwide efforts to administer pivot antiretroviral therapy (ART), 81.0% of People Living with HIV (PLHIV) who began ARV treatment have achieved viral suppression, while 9% have not (UNAIDS, 2017). Over 76.0% of PLHIV in Sub-Saharan Africa who are on ART have achieved viral suppression; Kenya reports an 83.1% rate among PLHIV on ART, leaving 10.9%, or 67,029 persons, unsuppressed. Various studies have investigated factors influencing HIV viral load (Bras et al., 2016). Some studies have identified socioeconomic background as a predictor of viral load or suppression, while others have highlighted financial constraints such as the cost and logistics of transportation to health facilities as significant barriers to optimal adherence to ART and patient retention in ART programs (Richardson et al., 2014). Age was found to be independently correlated with high viral suppression in a study spanning 13 clinical sites in America; those who failed to accomplish viral load suppression had a median age of 41.1 years, while those who did were 47.1 years old (Jobanputra et al., 2015). According to a different Brazilian study, those who were married or cohabiting had a higher chance of obtaining viral suppression than people who were unmarried, widowed, or in unstable relationships (Jeri et al., 2018). Regarding education level, profession, and occupational engagement, a study across eight clinics in the UK between 2011 and 2012, using a cross-sectional survey method, revealed that education below university level and unemployment, both

associated with financial hardship, increased the odds of viral load elevation by 5:2 (Burch et al., 2016).

2.2 HIV in Sub-Saharan Africa

Sub-Saharan Africa remains profoundly impacted by the HIV/AIDS epidemic, with the prevalence of HIV infection steadily evolving into an endemic crisis within the region. Despite accounting for just over 12% of the global population, sub-Saharan Africa harbors around two-thirds of all individuals living with HIV (UNAIDS, 2011). As of 2022, the estimated adult HIV prevalence rate in the region stands at 6.2%, indicating a 1.2% increase from data presented in the 2011 UNAIDS World AIDS Day Report (UNAIDS, 2011; UNAIDS Updates, 2022). Nonetheless, actual prevalence rates fluctuate across various sub-regions within sub-Saharan Africa. According to UNAIDS 2021 data, approximately 58% of the daily 4000 new HIV infections worldwide occur within sub-Saharan Africa (UNAIDS, 2022). Currently, Southern Africa shoulders the greatest impact of the epidemic, evidenced by adult prevalence rates surpassing 20% in most countries and exceeding 30% in Eswatini and Botswana. An examination of prevalence rates across sub-Saharan Africa spanning from 2000 to 2017 revealed notable disparities at subnational levels, with certain countries exhibiting prevalence variations of more than five-fold between different districts (Dwyer et al., 2019). Despite grappling with a heightened disease burden, both Eastern and Southern Africa have exhibited remarkable resilience in their efforts to combat HIV (HIV/AIDS-UNICEF, 2022).

Within Sub-Saharan Africa, the HIV epidemic exhibits a disproportionate impact on women, evidenced by a ratio of 13 infected women for every 10 infected men, and this gender disparity is widening over time. Women are contracting HIV at younger ages compared to men, particularly evident among young people aged 15–24, where

there are 36 infected women for every 10 men. Several variables influence the transmission of HIV-1, including the prevalence of sexually transmitted diseases, cultural practices such as scarification, unsafe blood transfusions, and poor hygiene and nutrition conditions (Timberg, 2007).

Poor economic conditions and a lack of sex education exacerbate high infection rates. In some African countries, over 25% of the working adult population is HIV-positive. Economic hardships resulting from emergencies like drought or conflict can force young women and girls into survival strategies such as transactional sex (Samuels et al., 2009). Additionally, during emergencies, women may face increased risks, such as coerced unprotected sex (Samuels et al., 2009).

AIDS-denialist policies have hindered effective HIV/AIDS programs, with former South African President Thabo Mbeki's administration causing numerous preventable deaths. UNAIDS reported that 5.5 million South Africans were HIV positive in 2005, up 400,000 from the previous year (Unaids.org, 2022). In 2018, Eastern and Southern Africa had 1.8 million children and adolescents living with HIV, with 290,000 new infections reported, primarily affecting females (Unaids.org, 2022). South Africa reported a prevalence rate of 18.7% among adults aged 15–49 in 2020, with an overall population prevalence of 13% (Unaids.org, 2022). As of 2021, the HIV prevalence rate in adults aged 15–49 in Eastern and Southern Africa was 6.2% (UNAIDS, 2022).

2.3 HIV Burden in Kenya

In Kenya, the initial recognition of HIV occurred in 1984, and by the mid-1990s, it had emerged as a prominent contributor to illness within the country, imposing notable burdens on both the healthcare infrastructure and the economy (Avert, 2021). By 2019, approximately 1.5 million individuals, accounting for 5.2% of the

population, were projected to be living with HIV in Kenya, a prevalence rate nearly halved from 10.5% in 1996 (UNAIDS-Kenya, 2020; Avert, 2021). Similar to global trends, HIV transmission in Kenya is primarily through sexual contact and affects individuals of all ages and genders, including children, adolescents, and adults. However, certain populations such as homosexuals, sex workers, and individuals who inject drugs are at heightened risk of infection (Avert, 2021). From 2010 to 2021, AIDS-related deaths in Kenya decreased steadily from 64,000 to 21,000 (Kenya NACC, 2020; Avert, 2021). This progress is largely attributed to the rapid expansion of HIV treatment and care services. By 2016, 64% of persons living with HIV were receiving treatment, with 51% achieving viral suppression (UNAIDS, 2018/2019).

The HIV burden in Kenya is characterized by significant regional disparities, with some areas experiencing higher prevalence rates than others. For instance, coastal regions and specific areas within the western region have been identified as hotspots exhibiting higher HIV prevalence rates compared to other regions in Kenya. Certain key populations, including sex workers, men who have sex with men, injecting drug users, as well as adolescent girls and young women, carry a disproportionately higher burden of HIV infection in the country. Stigma, discrimination, and social marginalization exacerbate the vulnerability of these populations, preventing them from accessing services for HIV prevention, testing, and treatment (WHO, 2017).

Vertical transmission of HIV from mother to child remains a prominent issue in Kenya, despite advancements in reducing mother-to-child transmission rates through the expansion of prevention of mother-to-child transmission (PMTCT) services. Nevertheless, obstacles such as delayed initiation of antenatal care, limited accessibility to PMTCT services in remote regions, and low acceptance of HIV

testing among pregnant women persist, perpetuating the risk of continued transmission (UNAIDS, 2018).

Despite substantial efforts to expand access to HIV testing, treatment, and care services in Kenya, several challenges continue to hinder progress in effectively controlling the epidemic. Structural limitations within the health system, including resource constraints, insufficient healthcare personnel, and inconsistent service delivery, have affected the reach and quality of HIV programs. Additionally, many individuals living with HIV encounter significant barriers to accessing and consistently adhering to antiretroviral therapy (ART). These challenges are often compounded by poverty, persistent stigma and discrimination, long distances to health facilities, and limited community-based support systems (Kenya NACC, 2020; Avert, 2021). These factors collectively contribute to suboptimal treatment outcomes and threaten the sustainability of gains made in the national HIV response. The HIV burden in Kenya intersects with other health challenges, including tuberculosis (TB) and non-communicable diseases (NCDs), further complicating the response to the epidemic. HIV/TB co-infection rates remain high in Kenya, particularly among people living with HIV/AIDS, underscoring the importance of integrated HIV/TB services.

In response to the HIV burden, Kenya has developed and implemented various national policies, strategies, and programs aimed at preventing new infections, expanding access to testing and treatment, and mitigating the social and economic impact of HIV/AIDS. Partnerships with international donors, civil society organizations, and the private sector support these efforts. Moving forward, addressing the HIV burden in Kenya requires sustained political commitment, increased investment in health systems strengthening, and a comprehensive approach

that addresses the underlying social, economic, and structural determinants of the epidemic. By scaling up evidence-based interventions, promoting human rights, and fostering community engagement, Kenya aims to achieve the goal of ending the HIV/AIDS epidemic by 2030 and improving the health and well-being of all its citizens.

2.4 Risks & vulnerabilities to HIV

Key populations (KPs) are groups with a significantly higher risk of HIV due to specific behaviors and social factors. The World Health Organization (WHO) identifies five essential key populations: people who inject drugs (PWIDs), men who have sex with men (MSM), female sex workers (FSWs), transgender individuals, and people in prisons or other closed settings (WHO, 2019). Globally, members of these groups face dramatically higher risks of HIV acquisition compared to the general population. For example, the risk is estimated to be 35 times higher for PWIDs, 34 times higher for transgender women, 26 times higher for FSWs, and 25 times higher for MSM.

However, the Kenyan response to HIV disproportionately neglects these young key populations. Inadequate funding for research, HIV prevention, and treatment for this demographic exacerbates the issue. Furthermore, HIV service providers are often ill-equipped to cater to the needs of young key populations, lacking the necessary resources and training. Additionally, staff members of programs targeting Young people might not have the necessary awareness, aptitude, or understanding to interact with young important populations in an effective manner (Kenya MOH, 2016)

Key demographics and their sexual partners were responsible for 62% of new adult HIV infections worldwide in 2019 (UNAIDS, 2020). This shift towards an HIV

epidemic increasingly affecting key populations is a consequence of significant progress in HIV prevention efforts within settings characterized by high HIV prevalence in eastern and southern Africa, alongside a combination of advancements and setbacks in regions with lower prevalence rates. Addressing this trend necessitates bold action to accelerate the AIDS response, as outlined in the UNAIDS 2016–2021 Strategic Framework. This framework emphasizes a development strategy grounded in human rights principles, with the overarching goal of ensuring inclusivity and equity in the fight against AIDS, leaving no one behind.

The plan acknowledges the complexities surrounding sexual and reproductive health and rights, advocating for comprehensive sexuality education. It also calls for the repeal of punitive laws, regulations, and practices hindering the effective implementation of AIDS response efforts. These barriers include mandatory testing, travel restrictions, and laws related to HIV transmission, same-sex relationships, sex work, and drug use (UNAIDS Strategic Framework, 2016–2021).

The Global Fund Strategy 2017–2022 and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR 3.0) exemplify international directives highlighting the imperative need for high-quality data to underpin an effective HIV response. This is crucial in the context of endeavors to curtail the HIV pandemic and foster the realization of an AIDS-free generation. To optimize existing preventive and treatment service delivery systems, it is essential to comprehend the scope, distribution, and determinants of HIV epidemics at the national level, while also evaluating the efficacy and overall impact of ongoing interventions (The Global Fund Strategy 2017-2022, PEPFAR, 2023). However, assessing this need presents notable challenges, particularly for key populations disproportionately affected by HIV, such as transgender individuals, people who use drugs, men who have sex with men, female

sex workers, and incarcerated populations (UNAIDS, 2020). These key populations often remain hidden and marginalized due to stigma, discrimination, and frequent criminalization, exacerbating their vulnerability to HIV infection and transmission (Fitzgerald-Husek et al., 2017). Nevertheless, these same factors complicate efforts to characterize the HIV epidemic within these populations and evaluate its potential impact on HIV epidemics among all adults of reproductive age. The demands and experiences of key populations are frequently under-researched, especially in regions with high HIV prevalence, where these populations are often overlooked due to presumptions about their limited public health significance (Mishra, 2016).

In generalized epidemic settings, there is often a paucity of data pertaining to key populations, including persons who use drugs, homosexual males, other men who have sex with women, and female sex workers. Furthermore, data for other important population categories, such as transgender women, is even more limited. Traditional forecasting methods, like the static Modes of Transmission (MOT) model, have historically been employed to estimate the annual percentage of new HIV infections within subgroups. However, these conventional approaches, which rely solely on static HIV prevalence and projected population size, fail to consider the longer chains of secondary indirect transmissions resulting from high-risk behaviors when assessing the unmet treatment and preventive needs of key populations (Mishra, 2014). Additionally, these methods often overlook the underreporting of HIV-related risks and tend to treat key populations as discrete groups, neglecting the entire continuum of potential HIV transmission. Recent dynamic transmission modeling underscores the importance of addressing the HIV prevention and treatment needs of key populations across all HIV epidemic scenarios (Mishra, 2014).

Many countries lack comprehensive data that accurately portray the unmet needs of key populations, despite mounting evidence demonstrating the importance and overall benefits of prioritizing these groups in the implementation of effective HIV strategies (Mishra, 2016). While there is a global push for evidence-based policies, statistics often fail to feature prominently in critical documents and policy decisions, even when available. Previously, systematic reviews of key populations have meticulously identified data availability and synthesized existing data to generate estimates on various indicators, such as HIV prevalence, HIV incidence, and population size (Fitzgerald-Husek et al., 2017). However, due to the rapidly evolving techniques for estimating HIV transmission dynamics and population size, these estimates have become outdated and may no longer be relevant to key stakeholders. Furthermore, the need for current and locally relevant estimates is paramount for key populations due to ongoing stigma and the ever-changing landscape of laws and policies concerning the criminalization of behaviors associated with these populations, including same-sex behaviors, sex work, gender identity, and injectable drug use (Schwartz et al., 2015).

2.5 HIV Testing and Algorithm

Recent advancements in HIV testing, particularly the adoption of the HIV antigen/antibody (Ag/Ab) immunoassay previously known as the 4th-generation test have significantly enhanced early detection of HIV. Unlike older methods that relied solely on antibody screening and Western blot confirmation, the 2018 CDC algorithm now includes detection of HIV antigens, antibodies, and nucleic acids. This has improved the accuracy and sensitivity of diagnosis, especially during the acute infection stage when transmission risk is highest. Kenya adopted this updated algorithm in its 2018 ART Guidelines to support earlier identification and treatment. Kenya’s HIV treatment strategy prioritizes rapid initiation of antiretroviral therapy

(ART). Ideally, newly diagnosed individuals should begin ART on the same day of diagnosis, with a maximum delay of 30 days if same-day initiation is not possible. This approach aims to improve patient outcomes and reduce the spread of HIV. Routine HIV testing is recommended for all individuals aged 13 years and above in clinical settings to promote timely diagnosis and linkage to care. Although HIV testing remains voluntary, informed verbal consent is now sufficient, with written consent no longer required. Patients must still be informed before testing. Testing is the first step in the HIV care continuum. A positive result requires immediate linkage to care, education on the diagnosis, and treatment planning. Negative results provide an opportunity for prevention counseling, including information on PrEP and PEP for individuals at continued risk.

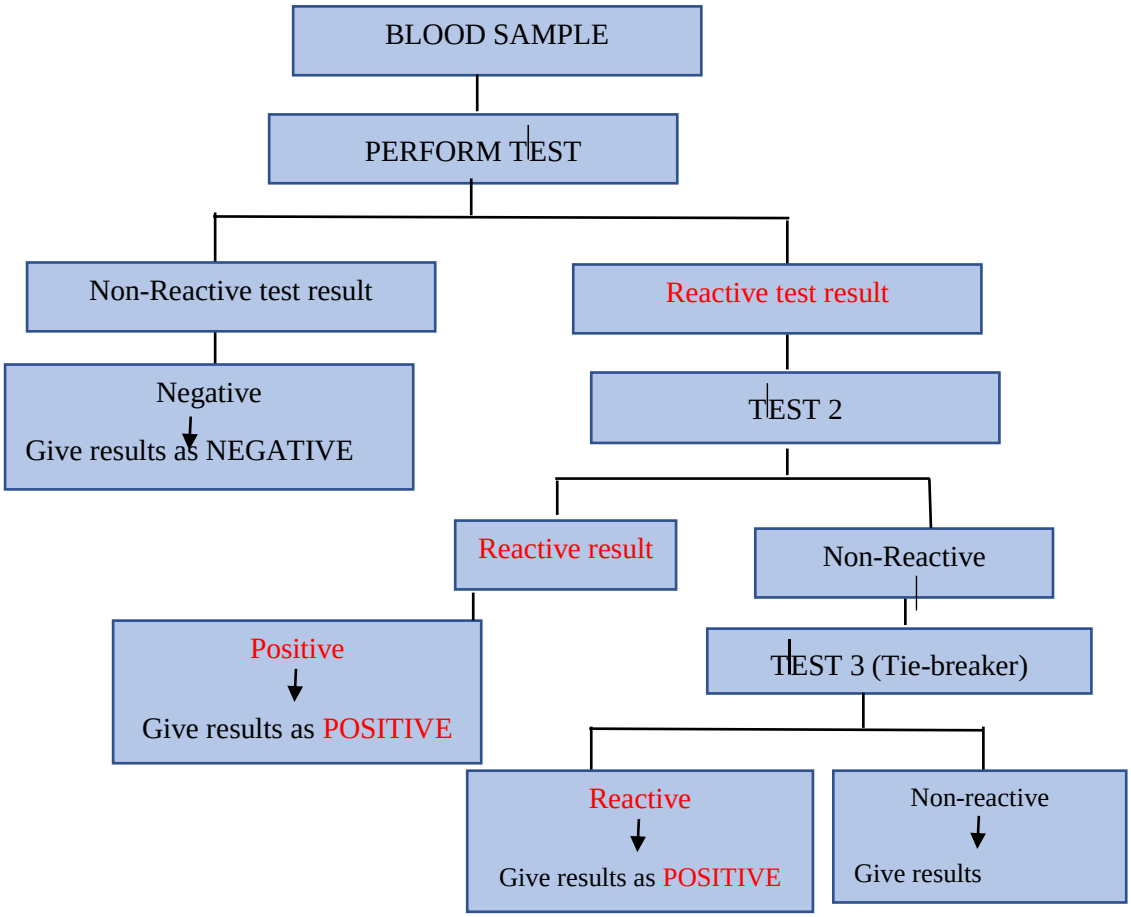


Figure 2.5: The flow chart showing serial Rapid HIV Testing Algorithm

2.6 HIV Linkage to Care

For improved prognoses in HIV/AIDS cases, timely and effective linkage to HIV treatment, care, and support services is imperative to ensure optimal patient outcomes and mitigate early deaths related to HIV/AIDS. Consequently, the latest World Health Organization (WHO) "test-and-treat" guidelines for HIV treatment and care advocate for the immediate initiation of medication upon a positive HIV test result, regardless of the individual's CD4 count (WHO, 2017). However, the commencement of treatment is dependent on effectively connecting the HIV-positive individual to an accredited HIV treatment and care facility or antiretroviral treatment program.

In May 2015, the World Health Organization (WHO) formulated strategic information guidelines aimed at standardizing crucial indicators for monitoring the public health response to HIV (WHO, 2015). These guidelines stipulate that the term "linkage to care" should be employed to delineate the timeframe commencing from an individual's HIV diagnosis and concluding with their enrollment in HIV care or treatment.

Linkage to care encompasses educating patients about the benefits of receiving care and providing supportive services, such as referral letters and aid in selecting a treatment facility and treatment plan (HIV Prevention Section Bureau of HIV/AIDS, 2013). However, this definition does not specify the timeframe considered prompt for linkage, nor does it offer guidance on the data sources suitable for populating the linkage indicator.

Linkage to care is characterized by a patient's transition into specialized HIV care subsequent to diagnosis. It is gauged by the duration between the date of HIV diagnosis and the date of initial clinic attendance, first CD4+ count or viral load test,

or, where data permits, the commencement of HIV treatment. This definition, endorsed by the WHO and refined for practical implementation, designates the first clinic visit subsequent to diagnosis as the preferred marker for assessing linkage to care. However, recognizing data constraints in some regions, experts acknowledge that baseline laboratory data, such as the date of the first CD4+ count and viral load test, can serve as valuable indicators of entry into care. In alignment with the latest WHO guidelines, it is currently advised that all newly diagnosed individuals undergo baseline CD4+ and viral load testing at their initial clinic visit (WHO, 2017). Reflecting the recent revisions to these guidelines, which advocate for the immediate initiation of antiretroviral therapy (ART) for individuals with HIV as soon as possible, regardless of CD4+ count, treatment initiation has been introduced as a key marker for care (WHO, 2016). Additionally, in instances where certain European nations lack robust surveillance capabilities to gather clinic or biomarker data, they may still have access to data on the commencement of ART, often linked to external funding for domestic treatment initiatives. In such cases, the recommended order for assessing linkage to care includes the first clinic date, CD4+ count date, viral load measurement date, and treatment start date, prioritizing the available indicators based on data availability.

The progression of linking HIV care from diagnosis to the initiation of ART can be influenced by various factors. These may include the patient or individual themselves, the healthcare provider involved, the health system in place, as well as other structural or contextual factors operating within the broader environment. Each of these elements can either facilitate or hinder the process, ultimately impacting the outcomes of care linkage in Kenya, Uganda, and South.

In Africa, researchers have examined the barriers and facilitators of care linkage (Genberg et al., 2015; Nakigozi et al., 2013; Naik et al., 2015). Various factors have been identified as obstacles to timely linkage into HIV care, including fear of stigma, reluctance to disclose one's HIV status to family or significant others, being asymptomatic at the time of diagnosis, and encountering negative attitudes from healthcare providers (Govindasamy et al., 2012; Nakigozi et al., 2013; Layer et al., 2014). Conversely, short clinic waits times, positive patient-staff relationships, and the integration of HIV testing and care services were identified as facilitators of linkage (Naik et al., 2015; Genberg et al., 2015).

2.7 The WHO Clinical staging

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) have remained major public health challenges for over two decades, posing a continued threat to global well-being. Africa hosts two-thirds of the world's HIV-positive population, with low- and middle-income countries bearing the brunt of new HIV infections worldwide. HIV's disproportionate effects in areas with insufficient resources stems from a myriad of intricate factors, including poverty, the stigma surrounding the disease, social and cultural barriers hindering testing and treatment, limited health literacy, insufficient provider training, inadequate medical resources, a shortage of qualified laboratory facilities, and inadequate infrastructure to handle the high patient load (Charles et al., 2002).

When resources are accessible, laboratory tests measuring CD4+ T cells and plasma HIV viral load are commonly conducted to assess a patient's degree of immunosuppression and the rate of breakdown in the immune system (Simon et al., 2006). These instruments are employed to track the advancement of a patient's illness and determine if they qualify for treatment.

In regions heavily impacted by the HIV/AIDS epidemic, clinicians often face resource constraints, making it challenging to conduct laboratory tests for CD4+ T-cell counts and plasma HIV viral load. To address this issue, the World Health Organization (WHO) has developed case definitions for HIV surveillance, clinical staging, and immunological classification of HIV-related diseases in both adults and children. These definitions rely solely on clinical parameters, making them suitable for facilities with limited or no access to laboratory testing. By utilizing standardized clinical parameters, clinicians can make informed medical decisions for patients with HIV/AIDS (WHO, 2005). The usefulness and accuracy of the WHO Clinical Staging system in managing HIV-infected patients have been confirmed by international studies that show concordance between laboratory markers like CD4 cell count, total lymphocyte count, and clinical manifestations included in the staging system (Kagaayi et al., 2007).

It is critical to consider the entire spectrum of infections given the trajectory of the HIV/AIDS epidemic. Along the continuum, several distinct clinical phases may be identified, and they are correlated with the severity of immunodeficiency that develops as HIV infection progresses. In the critical early months of infection, when transmission risk is greatest due to heightened levels of viremia, many persons may not know they are HIV positive despite the importance of early detection and treatment to limit viral transmission (Simon et al. 2006). In areas with limited resources, monitoring strategies that do not depend on laboratory procedures are also necessary to keep track of the growing number of patients receiving antiretroviral drugs (Colebunders et al. 2006). The purpose of the Revised WHO HIV/AIDS Clinical Staging System is to evaluate patients at baseline and to be used in the delivery of continuous care. The updated framework:

It offers advice on when to begin, stop, or change the dosage of antiretrovirals, preventive drugs, and other therapies; supports medical professionals in determining the present clinical condition of a patient; promotes the provision of diagnostic HIV testing by clinical practitioners to patients exhibiting clinical indications suggestive of HIV infection; arranges diseases into progressively more severe categories; and is helpful for surveillance since it is intended to be utilized in relation to both recent and past clinical occurrences (WHO, 2005).

2.7.1 Four Clinical Stages

Under the World Health Organization (WHO) classification for adults, patients are stratified into one of four hierarchical clinical stages, ranging from stage 1 (asymptomatic) to stage 4 (AIDS). Once a patient meets the criteria for a specific stage, they are assigned at least one of the clinical conditions associated with that stage. Upon recovery from the clinical condition leading to their placement in that stage, patients progress to a higher stage (Malamba et al., 1999).

In stage 1 of the classification system, patients are categorized as asymptomatic or presenting with persistent generalized lymphadenopathy, defined as lymphadenopathy affecting at least two sites (excluding inguinal) for a duration exceeding six months (WHO, 2005).

In stage 2, also known as the mildly symptomatic stage, patients may present with various clinical manifestations even during the early phases of HIV infection. Clinical findings characteristic of stage 2 includes recurrent respiratory infections (such as sinusitis, bronchitis, otitis media, and pharyngitis), unexplained weight loss amounting to less than 10 percent of total body weight, and a range of dermatological

conditions such as angular cheilitis, recurrent oral ulcerations, papular pruritic eruptions, seborrheic dermatitis, and fungal nail infections (WHO, 2005).

Stage 3, known as the moderately symptomatic stage, may reveal additional clinical signs as the disease progresses. Clinical manifestations characteristic of stage 3 include weight loss exceeding 10 percent of total body weight, persistent diarrhea lasting more than one month without an apparent cause, pulmonary tuberculosis, and severe systemic bacterial infections like pneumonia, pyelonephritis, empyema, pyomyositis, meningitis, bone and joint infections, and bacteremia. Additionally, mucocutaneous diseases such as gingivitis, periodontitis, acute necrotizing ulcerative stomatitis, and recurrent oral candidiasis may emerge during this stage (WHO, 2005).

Stage 4, termed the extremely symptomatic stage, encompasses all illnesses defining AIDS according to the WHO clinical classification. HIV wasting syndrome, Pneumocystis pneumonia (PCP), recurrent radiological or severe bacterial pneumonia, extrapulmonary tuberculosis, HIV encephalopathy, CNS toxoplasmosis, oralabial herpes simplex infection, esophageal candidiasis, and Kaposi's sarcoma are among the clinical manifestations that are suggestive of stage 4 disease. These symptoms allow for an AIDS diagnosis to be made presumptively based only on clinical evidence (WHO, 2005). Furthermore, cytomegaloviral (CMV) infections (CMV retinitis or infection of organs other than the liver, spleen, or lymph nodes), extrapulmonary cryptococcosis, disseminated endemic mycoses (e.g., coccidioidomycosis, penicilliosis, histoplasmosis), cryptosporidiosis, isosporiasis, disseminated non-tuberculous mycobacteria infection, tracheal, bronchial, or pulmonary candida infection, acquired HIV-associated rectal fistula, cerebral or B cell non-Hodgkin lymphoma, progressive multifocal leukoencephalopathy (PML), and HIV-associated cardiomyopathy or nephropathy also raise suspicion of stage 4 disease (WHO, 2005).

Nevertheless, additional testing is necessary because many illnesses do not present with AIDS-defining symptoms.

All adults and adolescents who are at least 15 years old fall into these categories. For infants and children under the age of 15, a modified version of the WHO Clinical Staging System is available (WHO, 2005).

Identification of these clinical symptoms outlined in the WHO classification is vital for identifying HIV-positive individuals at high risk for morbidity and mortality, akin to CD4 counts and viral load tests. By staying informed about the natural progression of HIV infection, healthcare providers can make management decisions based on the patient's clinical presentation. For surveillance purposes, the World Health Organization (WHO) defines advanced HIV/AIDS disease as any clinical stage 3 or stage 4 illness or any clinical stage with a CD4 count greater than 350 per cubic mm. This data serves to assess the disease burden and determine the necessity for antiretroviral therapy (WHO, 2005). The World Health Organization (WHO) recommends initiating antiretroviral therapy definitively in adults and adolescents diagnosed with clinical stage 4 HIV/AIDS. For those in clinical stage 3, therapy initiation is considered, while antiretroviral use for individuals in clinical stages 1 or 2 is advised only if their CD4 count exceeds 200 per cubic mm. This recommendation is anchored upon substantial data supporting the therapeutic advantages of antiretroviral medicines for individuals with advanced HIV/AIDS, as assessed clinically or immunologically. Decision-making for patients on antiretroviral medication for more than 24 weeks may be influenced by new or recurring clinical staging events. Clinical events occurring before 24 weeks of antiretroviral therapy may not properly indicate immunological decline, as they are predominantly impacted by immune reconstitution or medication toxicity (WHO, 2007). Following WHO

guidelines, the appearance of new or recurring WHO clinical stages 3 and 4 issues more than 24 weeks after the start of therapy indicates a possible risk of treatment failure (Colebunders et al., 2006).

The HIV/AIDS epidemic has wide-ranging effects on people all around the world. In addition to being disproportionately afflicted by HIV infection, inhabitants in developing nations also usually lack access to advanced technology and other resources needed for diagnosis and treatment. When doctors possess the necessary information to adopt screening measures, like the WHO Clinical Staging System, they may effectively identify early infections and provide aggressive care. As such, these tactics can be valuable tools for enhancing patient access and care delivery.

2.8 Proportion of Viral Load suppression among adolescents on ART

HIV still disproportionately affects young people, particularly those aged 10 to 24. Within this age group, adolescents aged 10 to 19 are particularly vulnerable. From 2003 to 2020, the number of AIDS-related deaths among teenagers aged 10 to 19 decreased by 10%, but the fall among children was 74% (UNICEF 2021). This suggests that HIV prevention efforts need to target this demographic specifically. The impact of HIV is especially pronounced among young women. This may be due to various factors such as biological vulnerabilities, socio-cultural norms, and limited access to healthcare and education. Addressing gender disparities in HIV prevention and treatment is crucial to effectively combat the epidemic. Disadvantaged populations, which include individuals from low-income communities, racial and ethnic minorities, les-bian, gay, bisex-u-al, trans-gen-der, queer or ques-tion-ing (LGBTQ) + youth, and those lacking access to comprehensive healthcare services, are disproportionately affected by HIV. Having this in mind, necessary interventions are

needed to address the specific needs of these populations to prevent HIV infections and early deaths due to HIV/AIDS.

Accessing necessary services, including HIV testing, coverage for antiretroviral treatment, and viral load suppression, is difficult for teenagers living with HIV (Armstrong et al., 2018). These obstacles could be brought about by a number of things, such as discrimination, stigma, ignorance, and a weak infrastructure for healthcare. Enhancing the availability of these services is essential to guaranteeing improved health results for young people living with HIV. Further research is required to determine the most effective approaches for addressing the particular difficulties adolescents encounter in connection to HIV, despite breakthroughs in HIV prevention and treatment. Research on cutting-edge preventative techniques, focused interventions for high-risk populations, and measures to increase access to healthcare services are a few examples of this.

It is imperative to monitor antiretroviral (ARV) treatment failure, and viral load assessment is endorsed as the primary approach for diagnosis and confirmation (WHO, 2013). The Global Health Sector Strategy on HIV advocates for specific targets, aiming to guarantee that 95% of people with HIV are aware of their status, 95% of those who are diagnosed receive antiretroviral therapy, and 95% of those receiving treatment—including teenagers—achieve viral load suppression (WHO, 2021). Research in Cape Town and Johannesburg, South Africa, which was done from 2004 to 2011, reveals a significant increase in viral load suppression rates, with the proportion of individuals achieving suppression doubling from less than 40% to around 80% (Sergio C. et al., 2013). In Rwanda, 86% of People Living with HIV/AIDS (PLHAs) on antiretroviral therapy (ART) achieved viral suppression

within 18 months, while in Senegal, up to 80% of PLHAs on their first-line regimen attained viral suppression after five years of treatment initiation (WHO, 2013).

A study conducted in South Africa revealed virological failure rates of 8.2% in adolescents and 5.0% in young adults, indicating a notably higher failure rate among adolescents compared to young adults (Nglazi et al., 2012). Peer-reviewed research demonstrated a significant improvement in viral suppression rates among adolescents, with the proportion increasing from 27% to 89% within 12 months post-ART initiation, as reported in six studies (Ferrand et al., 2016). In Northwestern Uganda, a study found that at 12 and 24 months, 75% and 72% of patients, respectively, had undetectable HIV RNA (<400 copies/ml). However, this study included individuals aged 15 years and above, without a specific focus on adolescents (Ahoua et al., 2009). Additionally, a study conducted in Uganda comparing children (0-18 years) and adults treated with Antiretroviral Therapy revealed that children were nearly twice as likely to experience viral failure compared to adults (Kamya et al., 2007).

2.9 Kenya AIDS Strategic Framework

The Kenya AIDS Strategic Framework (KASF) stands as a comprehensive plan designed to combat the HIV/AIDS epidemic within Kenya. Crafted through collaboration among diverse stakeholders, including governmental bodies, civil society organizations, international partners, and affected communities, this framework serves as a strategic blueprint for addressing the multifaceted challenges presented by HIV/AIDS in the nation. Central to its approach are principles of inclusivity, equity, and evidence-based methodologies, aiming to implement interventions that are both effective and sustainable. The KASF encompasses a broad

spectrum of strategies and actions tailored to meet the unique requirements of the various populations affected by HIV/AIDS across Kenya.

A foundational element of the Kenya AIDS Strategic Framework (KASF) is its focus on prevention. The framework underscores the significance of implementing comprehensive HIV prevention initiatives, particularly aimed at key populations including sex workers, men who have sex with men, injecting drug users, and adolescent girls and young women. These programs include a variety of interventions, including encouraging safer sexual practices, making condoms more accessible, providing counseling and testing services for HIV, and giving pre-exposure prophylaxis (PrEP) to those who are at a higher risk of HIV transmission.

Kenya envisions achieving freedom from new HIV infections, stigma, and AIDS-related deaths by 2030, as articulated in the Kenya AIDS Strategic Framework. Despite the considerable strides made by the Ministry of Health (MOH) in addressing HIV and tuberculosis (TB), the country grapples with a substantial burden of HIV/AIDS. With approximately 1.6 million individuals living with HIV across the nation and an estimated 101,560 new cases reported annually, HIV/AIDS remains a leading cause of mortality and a significant contributor to poor health outcomes in Kenya (NASCOP, 2014). According to UNAIDS (2018) data and the Kenya AIDS Strategic Framework for 2014/25 – 2018/2019, the number of fatalities in the country attributed to AIDS has significantly dropped, from 167,000 in 2003 to 25,000 in 2018. According to the Kenya Population-based HIV Impact Assessment (KenPHIA, 2018), the country's adult HIV prevalence rate was 4.9% in 2018. The prevalence was greater in women (6.6%) than in men (3.1%). Although there has been a slight decrease in HIV prevalence among adults aged 15-49 years, as suggested by Spectrum data, this

fall has only been noticeable since 2010. Notably, according to KenPHIA (2018), HIV prevalence varies geographically in Kenya, ranging from 19.6% in Homa Bay County to 0.1% in Garissa County.

Kenya has experienced a significant decline in annual new HIV infections, with figures dropping to less than a third of the peak observed in 1993, as reported by UNAIDS (2013). In 2016, there were roughly 62,000 new HIV infections in Kenya, marking a decrease from the 100,000 new infections recorded in 2013, reflecting a consistent downward trend (UNAIDS, 2017). Notably, remarkable progress has been achieved in specific regions, with 16 counties reporting a reduction of over 50% in new HIV infections (KMOH/NACC, 2016). This decline can be attributed to the concerted efforts of the National AIDS Control Council (NACC), which spearheads the coordination of HIV response efforts in Kenya. Initiated in 2013, the Prevention Revolution Roadmap by NACC aims to eliminate new HIV infections by 2030. Aligned with this objective, the Kenya AIDS Strategic Framework (KASF) seeks to reduce new infections by 75% through the implementation of a comprehensive approach comprising biomedical, behavioral, and structural interventions (NACC, 2014).

2.10 Antiretroviral Treatment (ART) in Kenya

Antiretroviral treatment (ART) constitutes a pivotal strategy in Kenya's HIV/AIDS response, including giving a range of antiretroviral medications to inhibit HIV replication in the body, thereby enhancing health outcomes and diminishing transmission risk. Kenya embraced the World Health Organization's (WHO) recommendations in 2015, advocating for the immediate initiation of treatment for individuals diagnosed with HIV (UNAIDS, 2016). Consequently, by 2016,

approximately 60,000 children and 940,000 adults were receiving ART, reflecting significant progress. However, there remained gaps in treatment coverage, with only 64% of adults and 65% of children requiring treatment accessing it (UNAIDS, 2017). Notably, a gender disparity was observed, with men who are HIV positive having a noticeably lower treatment rate than women. Addressing such disparities and enhancing treatment accessibility remains imperative for bolstering Kenya's HIV/AIDS response efforts.

Recent statistics reveal a concerning gender disparity in accessing HIV treatment, with only 58% of men compared to 68% of women accessing treatment (PEPFAR, 2016). Furthermore, key populations, such as men who have sex with men and female sex workers, experience significantly lower ART coverage, ranging from 6% to 34% (NASCOP, 2015). Retention in care is a crucial aspect of HIV interventions, directly impacting individual and public health outcomes as well as cost-effectiveness. In 2015, 81% of individuals initiating treatment remained in care after 12 months, demonstrating an improvement from the 2013 retention rate of 70% (KMOH/NASCOP, 2016). However, challenges persist, particularly in retaining adolescents and young people on treatment. In 2014, only 34,800 out of 141,000 adolescents (aged 10 – 19) were on ART, with just 22,600 achieving viral suppression. With 9,720 deaths linked to AIDS-related illnesses in 2014 alone, HIV/AIDS continues to be Kenya's greatest cause of mortality for adolescents and young adults (UNAIDS, 2017). Addressing these retention challenges and improving access to treatment for key populations are critical steps in enhancing Kenya's HIV/AIDS response.

2.11 ART Access and Availability:

The Kenyan government, in collaboration with international partners, has worked to expand access to antiretroviral treatment for people living with HIV/AIDS with key aspects of ART access including,

Treatment Eligibility: Kenya has followed the World Health Organization guidelines for initiating ART. Over the years, eligibility criteria have been expanded to ensure that more individuals receive treatment earlier in the course of the disease (WHO, 2015)

Decentralization of Services: ART services are available at various levels of healthcare facilities, including public hospitals, health centers, and dispensaries. This decentralized approach aims to bring treatment closer to communities, reducing travel and logistical challenges for patients.

Task Shifting: To address the shortage of healthcare professionals, Kenya has implemented task shifting. This involves training nurses and clinical officers to provide ART services, thereby increasing the availability of treatment services.

Stigma and Discrimination: HIV-related stigma remains a barrier to testing, treatment initiation, and adherence. Efforts are ongoing to reduce stigma and promote awareness.

Adherence: Ensuring consistent adherence to ART is essential for successful treatment outcomes. Factors such as pill burden, side effects, and socio-economic challenges can impact adherence.

Drug Supply and Stockouts: Ensuring a continuous supply of antiretroviral drugs is crucial to prevent treatment interruptions and drug resistance.

Pediatric Treatment: Specialized care for children living with HIV requires tailored approaches and dedicated resources.

Retention in Care: Efforts are needed to maintain individuals' engagement in care over the long term to achieve viral suppression and overall health benefits.

2.12 UNAIDS 95-95-95 strategy in Kenya

The commitment to ending the HIV/AIDS epidemic by 2030 was solidified by the United Nations Member States in 2021, marking a pivotal moment in global efforts. Central to this endeavor is the ambitious 95–95–95 strategy set forth by the Joint United Nations Programme on HIV/AIDS (UNAIDS, 2021). By 2030, the goal of this plan is to guarantee that 95% of all HIV-positive individuals know their status, 95% of those who are diagnosed receive ongoing antiretroviral therapy, and 95% of those who are receiving treatment successfully suppress their virus (UNAIDS, 2021). These targets represent significant milestones in the fight against HIV/AIDS and underscore the importance of widespread testing, access to treatment, and viral suppression in curbing the epidemic.

Adopted by United Nations Member States in June 2021, the 95–95–95 targets for HIV testing, treatment, and viral suppression alongside ambitious goals for primary prevention and supportive enablers which aim to address disparities in HIV care and improve outcomes across all sub-populations, age groups, and geographic regions (UNAIDS, 2021). The objective of ending the AIDS pandemic by 2030 would be greatly aided by meeting the UN 95-95-95 objectives by 2030. However, achieving these goals will need careful observation of trends in viral suppression and instances of viral rebound, as well as knowledge of the variables related to viral rebound.

Reaching the third 95% viral suppression remains a key challenge for Kenya, as it is for many other countries. Achieving this goal depends heavily on retention in care and adherence to treatment, both of which can be influenced by factors such as stigma, access to healthcare, and the availability of social support. Addressing the unique needs of children and adolescents living with HIV is also critical in this effort. In response, Kenya is actively working to close the remaining gaps by ensuring that all people living with HIV have access to the care and support necessary to achieve viral suppression. This includes strengthening healthcare systems, reducing stigma, improving access to treatment and other HIV services, and integrating HIV services with broader health programs, such as sexual and reproductive health services, to reach more people and improve overall health outcomes.

2.13 Viral load suppression and non-suppression

Indeed, historically, CD4+ cell count has been a crucial marker for monitoring patient response to HIV antiretroviral therapy (ART) in resource-limited settings. CD4+ cell count indicates the immune status of an individual living with HIV. However, viral load testing has emerged as a more accurate and direct measure of the effectiveness of ART. Viral load tests measure the amount of HIV's genetic material (RNA) present in a blood sample, typically quantified as the number of copies of HIV RNA per milliliter of blood. Unlike CD4+ cell count, which reflects the immune system's response to HIV, viral load testing directly assesses the level of HIV replication in the body. Monitoring viral load is crucial for assessing the effectiveness of ART in suppressing viral replication and preventing disease progression.

Although viral load testing has long been available on a large scale in high-income nations, its accessibility in environments with fewer resources has been more

restricted because of infrastructure and cost issues. Nonetheless, efforts are being made to expand access to this vital diagnostic tool in settings with limited resources as the significance of viral load testing in improving HIV treatment results has come to light. The advantage of viral load assessment lies in its capacity to identify treatment inadequacy sooner and with greater precision compared to CD4 testing. This capability empowers healthcare practitioners to offer patients tailored care interventions, including comprehensive adherence counseling or transitioning to alternative medication regimens. Historically, viral load testing has been associated with elevated costs and demanded substantial infrastructure and human capital, thereby impeding its widespread implementation in resource-constrained settings or nations.

Despite the obstacles and reservations regarding the applicability of viral load assays in resource-constrained contexts (Roberts et al., 2016), Kenya embarked on establishing a national viral load program in 2012, which has since expanded over subsequent years. Situated in sub-Saharan Africa, Kenya was poised to be among the pioneering nations to develop such a program, given its substantial HIV burden of 1.5 million individuals living with HIV, extensive coverage of patients on antiretroviral therapy (900,000), and a robust national HIV early infant diagnosis (EID) initiative (UNAIDS, 2015; NASCOP, 2016). Initially, viral load testing was targeted for patients suspected of virological failure; however, from 2014 onward, Kenyan guidelines endorsed routine testing. This entailed viral load assessments at 6 and 12 months post-ART initiation and annually thereafter for patients exhibiting undetectable viral loads. Patients with elevated viral loads (defined as ≥1000 RNA copies/mL or ≥5000 RNA copies/mL) were to undergo follow-up according to national guideline protocols (NASCOP, 2014).

The World Health Organization (WHO) suggests periodic measurement of viral load (VL) every 6 months for individuals receiving antiretroviral therapy (ART) to monitor for viral replication and confirm treatment efficacy (WHO, 2010; WHO, 2013). In Low and Middle-Income Countries (LMICs), an elevated or unsuppressed VL, defined as Ribonucleic Acid (RNA) copies exceeding >1000 copies/ml in plasma or >5000 copies/ml in Dried Blood Spot (DBS) samples, in patients on ART for at least six months, signifies failure to achieve viral suppression or rebound (WHO, 2013; Bennett et al., 2008). Virological non-suppression indicates potential therapeutic failure and/or suboptimal treatment adherence (WHO, 2013; Bennett et al., 2008). ART monitoring is crucial for ensuring treatment success, identifying adherence challenges, and determining the necessity of regimen modifications in cases of treatment failure, which can be assessed through clinical, immunological, and virological methods, with the latter providing earlier and more precise indications of treatment effectiveness (WHO, 2016).

2.14 Poor adherence to treatment

Achieving and maintaining an undetectable viral load for individuals living with HIV requires near-perfect adherence to Antiretroviral Therapy (ART), typically ranging between 90-95%. This regimen stands out as one of the most intricate and demanding medication routines prescribed in medical practice (Hickson & Warren, 2016). Antiretroviral therapy (ART) is only as effective as the patients' and society's careful adherence to the recommended medication schedule, the doctor's orders, and follow-up plans. Before starting ART, it's critical to set up adherence support plans to avoid treatment failure and the necessity to move patients to secondary or tertiary lines of ART. This proactive strategy tackles both individual and common adherence difficulties (NASCOP-Kenya, 2016).

Adolescent traits, caregiver/family dynamics, treatment regimen, and societal/cultural influences are some of the factors that can be categorized into groups that influence adherence behavior (Buchanan et al., 2012; Haberer & Mellins, 2009; Olds et al., 2015). The growth of treatment programs in settings with limited resources emphasizes how crucial it is to achieve excellent adherence to antiretroviral therapy (ART), as well as how difficult it might be (Haberer & Mellins, 2009). Research conducted in South Africa shows that, in comparison to adults, adolescents had higher rates of virologic rebound, lower rates of viral suppression and immunological recovery, and lower rates of ART adherence (Evans et al., 2013; Jean B Nachega et al., 2009). It is critical to pinpoint the unique adherence obstacles that affect kids and teenagers and provide interventions that are suited to their needs (BainBrickley et al., 2011).

Reported obstacles to adherence among adolescents include factors such as the extent of disclosure, understanding of the disease and treatment, stage of development, emotional health, aversion to medication intake, social stigma, discrimination, low self-esteem, and depressive symptoms (WHO, 2014; Yang et al., 2018). Additional challenges include defiance resulting from strained caregiver-child relationships, inadequate support structures within schools, and the absence of support systems tailored for adolescents (Bikaako Kajura et al., 2006; Sm & Medicine, 2015). Obstacles to adherence connected to caregivers include several or frequent changes in caretakers, old or illiterate caregivers, depression, substance abuse, and remote location from medical facilities. Moreover, the absence or illness of a caregiver, limited comprehension of HIV management due to inadequate counseling, financial instability, lack of emotional connection between caregiver and child, and the absence

of caregiver support networks can also present significant barriers (Bernays et al., 2014).

Several prior studies have also documented a robust connection between inadequate adherence and the failure to suppress viral load, a trend that aligns with the outcomes of this investigation. Inconsistent adherence to antiretroviral therapy (ART) has been identified as a notable factor contributing to treatment ineffectiveness and the emergence of drug resistance among individuals living with HIV. Adherence levels can be influenced by various factors, including the presence of medication side effects, patient education and counseling, and accessibility to medications (Kvarnström et al., 2021). Poor adherence, however, has a complicated and multidimensional effect on viral load suppression because it can also be caused by other factors such as complicated treatment regimens, toxicity from drugs, and co-morbidities in patients (Byrd et al., 2019). Measuring adherence has proven to be a controversial topic, with many methods employed, such as self-reported adherence, pill counts, and electronic monitoring devices used in multiple studies (Hodes et al., 2020). In this particular study, inadequate adherence was defined as a lack of adherence within the preceding six months, a criterion that mirrors established measures routinely utilized in clinical settings and the current trend of prescribing medications for multiple months for stable patients.

2.15 Effects of drugs and substance abuse in viral suppression

In the care continuum for people living with HIV (PLWH) and HIV prevention, persistent viral suppression and retention in care are essential outcomes. However, less is known about the relationship between substance abuse and long-term, persistent viral suppression. Within HIV care, the idea of "treatment as prevention" ensures that individuals with HIV follow antiretroviral medication (ART) instructions and attain undetectable viral levels.

Maintaining an undetectable viral load (<40 copies/mL) throughout several clinic visits, months, or years is known as sustained viral suppression. The percentage of teenagers globally who have continuous viral suppression varies depending on the study and tends to decline over time (Smith et al, 2011). While age-based differences are reducing, estimates comparing adolescents and young adults with older adults (ages 45 and above) indicate that young adults and adolescents will always have a lower chance of achieving viral suppression (Doshi et al, 2017). Based on these estimates, scientists have determined several variables that are associated with long-term viral inhibition. The most important ones include low adherence to antiretroviral medication (ART), which is linked to non-suppression, and lack of retention in care (Glass et al, 2012).

Individuals living with HIV frequently consume alcohol, and according to some studies, up to 42% of these individuals engage in heavy drinking (Williams et al, 2016). Moreover, differences in alcohol use have been seen in the populations of transgender women (TGW) and men who have sex with men (MSM) in both adolescence and adulthood (Talley et al., 2014). Throughout the HIV care continuum, the impacts of alcohol consumption and use are pretty well established. According to

a systematic review, alcohol use (measured in a variety of ways, such as use or abuse) is linked to suboptimal medication adherence, lower rates of linkage to and retention in care, a reduced likelihood of reaching viral suppression, and a lack of HIV testing (Vagenas et al, 2015). Comparable trends have also been noted about other substances, such as cannabis, stimulants, and general drug usage (Purkayastha et al, 2005).

Researchers have documented that men who have sex with men and transgender women groups use more drugs overall, including problematic usage, than heterosexual and cisgender people do (Newcomb et al, 2019). Furthermore, current drug use is widespread among HIV-positive individuals; a meta-analysis found that 33.6% of these individuals had indications of drug misuse (Nduka et al, 2015). Estimates of teenage substance usage vary from 4 to 37%, and research suggests that men who have sex with men, transgender women, and other gender minority youths have higher rates of substance use (Evangeli et al, 2018). Additionally, a meta-analysis has shown that current drug use is a predictor of HIV medication adherence. This means that people who report using drugs currently are more likely to experience healthcare gaps and to be non-compliant with ART regimens (Purkayastha et al, 2005). Research has shown that marijuana use, other illegal drug use, and polysubstance use are associated with non-adherence to antiretroviral therapy (ART) in adolescent samples. It has also been observed that young MSM have higher substance usage than males who have sex with women (Evangeli et al, 2018). In meta-analysis studies globally, substance abuse was the most often mentioned predictor of care retention for research based in developed countries (Buller et al, 2014). Studies conducted on adult populations indicate that drug users are among the groups with the greatest rates of HIV care attrition (Glordano et al, 2009). This is

especially true for injectable drug use, which is linked to non-suppression and non-adherence (Purkayastha et al, 2005). Cocaine and methamphetamine use are stimulants that are linked to a decreased chance of viral suppression and a higher risk of death in HIV-positive individuals (Adams et al, 2018). This includes data indicating that, when examined as a time-varying outcome, the use of stimulants is linked to decreased viral suppression over time (Carrico et al, 2019). The evidence on cannabis consumption is not as reliable. According to a study, individuals with cannabis dependence were less likely than those with non-problematic cannabis usage to consistently take their medications as prescribed (Bonn-Miller et al, 2014). Viral suppression and cannabis use did not appear to be related, according to other research (Okafor et al, 2017). Few studies have employed a prospective longitudinal method, which increases causal arguments, even though studies have looked at the cross-sectional association between drug usage and viral suppression (Adams et al, 2018). Furthermore, very few studies have looked at drug use in connection to long-term sustained viral suppression or across several drug forms at once (Adams et al, 2018). Fewer still look at this connection in samples of teenagers and young adults (Wood et al, 2017).

2.16 Socio-demographic characteristics of adolescents and adults on ART influencing viral load suppression or non-suppression

2.16.1 Age of adolescents and adults on ART and its influence on viral load non-suppression

A study conducted in Ethiopia examining factors contributing to viral load non-suppression revealed that patients aged 15 to 19 years were nearly five times more likely to experience viral non-suppression compared to those aged 50 years or older (Abraham et al., 2019). This result is in line with a recent US study that found elderly

individuals had a higher chance of experiencing viral suppression (Yehia et al., 2015). Possible explanations for this trend may include the complexities associated with pediatric and adolescent HIV treatment. Challenges such as the intricacies of administering antiretroviral (ARV) medication and the need to adjust doses as children grow can pose difficulties, particularly for clinicians lacking pediatric expertise or facing time constraints in monitoring treatment efficacy. Additionally, younger individuals may be more susceptible to stigma, fear of disclosure, and stress compared to their older counterparts (Katz et al., 2013).

Joseph D. et al. (2018) found that adolescents under the age of 15 were more likely than older patients to have an unsuppressed viral load (viral load > 400 Ribonucleic acid (RNA) copies/mL). Similar age-related results were also observed in a study involving individuals living with HIV in South Africa. Age has consistently been linked to lower probabilities of non-viral suppression in Uganda (≥ 1000 RNA copies/mL) (Bulage et al., 2017) and other European nations (> 50 RNA copies/mL) (Sabin CA et al., 2008).

2.16.2 Gender of adolescents and adults on ART and its influence on viral load non-suppression

In a research conducted in Burkina Faso among adult patients undergoing ART treatment at a public routine clinic, findings revealed a heightened likelihood of virological failure among male patients compared to their female counterparts. This susceptibility among men remained significant regardless of age, educational attainment, CD4+ T cell count upon ART initiation, initial and current antiretroviral regimens, and duration of ART treatment (Pauline et al., 2012).

Likewise, research conducted in Ethiopia demonstrated that male patients were 1.27 times more likely to experience viral load non-suppression compared to their female counterparts (Abraham et al., 2019). This observation aligns with findings from global systematic reviews (Castilha, 2014) as well as studies conducted in Nigeria (Dalhatu et al., 2004 – 2012) and Swaziland (Jobanputra). The studies suggest that the increased vulnerability of males to viral suppression may be attributed to lower engagement in healthcare-seeking behaviors.

2.16.3 Duration of ART and its influence on viral load non-suppression

As would be expected given the significant viral replication-induced CD4 cell depletion, a shorter course of antiretroviral therapy was associated with viral non-suppression. While there is some variability in the relationship between immune responses, viral non-suppression, and the length of antiretroviral therapy (ART) (Fokam et al., 2017), a South African study produced findings along these lines. According to this study, teenagers on ART for six to twelve months had a higher chance of experiencing viral non-suppression (viral load > 400 RNA copies/mL) than adolescents receiving therapy for a longer duration (Joseph D. et al., 2018). Furthermore, results from a Colombian investigation showed that, consistent with ART's mechanisms of action, a lower viral load at the time of initial clinic admission predicted viral suppression (Agwu et al., 2013).

2.17 Behavioral characteristics influencing viral load non-suppression on PLWH

Effective viral load suppression is closely linked with maintaining high levels of adherence (≥ 95%) to antiretroviral therapy (ART), which can successfully lower HIV levels to undetectable levels (Conway et al., 2007). However, achieving such high levels of adherence has proven challenging for individuals living with HIV or AIDS,

even in developed nations like the United States, where the utilization of ART among HIV-infected adults reached 85% (UNAIDS, 2017). To prevent treatment failure and the necessity of transitioning patients to second or third-line ART regimens, it is essential to establish adherence support strategies before initiating ART, addressing both common barriers and individual challenges to adherence. Since it is currently recommended that all persons living with HIV (PLWHIV) be eligible for ART, with initiation preferably occurring within two weeks of diagnosis, preventing treatment failure should begin before ART initiation. When ART is started, proper monitoring and follow-up are necessary, and adequate adherence preparation should start at the time of HIV testing (Guidelines for Use of Antiretroviral, 2018).

The primary objective of antiretroviral therapy (ART) is to mitigate HIV-associated illness and death, with effective ART reducing both viremia and the risk of HIV transmission to sexual partners by over 96% (AIDSinfo, 2016). However, despite the advantages of ART, concerns are mounting regarding treatment failure, drug resistance, and potential long-term toxicities associated with ART usage (Guidelines for use of ART, 2012; Bennett et al., 2008), particularly prevalent in eastern and southern Africa (Hamers et al., 2012). Studies conducted in certain African nations have indicated that nearly 30% of patients experience virological failure within six years of commencing ART (Giordano et al., 2007). Previous studies carried out in Uganda demonstrated that younger age, nonadherence, and active tuberculosis increased the likelihood of virological non-suppression, while the use of second or third-line antiretroviral therapy regimens provided protection against non-suppression (Bulage et al., 2017). Drug-resistant HIV strains are becoming more prevalent, which reduces treatment options and raises the risk of disease and death (Ayele et al., 2018).

Prior research conducted across various contexts has identified several factors potentially linked to virological suppression. Patients classified with WHO clinical stage 4 have shown a higher likelihood of experiencing non-suppression, whereas those undergoing regular health evaluations during clinic visits are less prone to virological failure (Huong DTM et al., 2011). Children and adolescents receiving ART demonstrate a greater propensity for elevated viral loads (Jobanputra K. et al., 2015), while inadequate transitioning of ART services from pediatric to adult care may contribute to non-suppression (Dahourou DL et al., 2017). Numerous factors have also been linked to virological non-suppression, including inadequate adherence, poorly tolerated medications, drug-food combinations, CD4 cell count, treatment history, and the existence of drug resistance (primary or transferred). Regimen withdrawal and consequent virological failure are mostly caused by suboptimal adherence and drug intolerance (d'Arminio Monforte A et al., 2000; Paredes R et al., 2010). Viral non-suppression may also be caused by patient-related factors such as co-morbidities, incomplete medication adherence, missed clinic visits, interruptions in or intermittent access to ART, and ARV regimen-related factors such as drug side effects, suboptimal pharmacokinetics, reduced virological potency, and dietary requirements (HIV/AIDS Guidelines, 2015).

Alcohol use, recreational drug use, low socioeconomic status, and moving to a different age group have all been linked in numerous international studies to non-adherence and consequent virological non-suppression, especially in younger people (Reiser et al., 2009; Peltzer et al., 2013; Garvie et al., 2010). Additionally, stigma, fear of disclosure, and stress have been highlighted as factors that may disproportionately affect younger individuals compared to older counterparts (Katz et al., 2013). Furthermore, interventions such as the utilization of peer supporters,

involvement of social workers, and training programs aimed at facilitating disclosure among healthcare workers have been shown to enhance ART adherence among young people, leading to improved virological outcomes (van Griensven et al., 2008).

2.18 Concurrent tuberculosis infection

When compared to TB patients without HIV, those living with HIV who also have TB disease had poorer treatment success rates and noticeably lower cure rates. Co-infected patients have a higher chance of dying from tuberculosis (TB), and they also deal with a number of treatment-related and disease-specific issues that have a big impact on how well they respond to therapy (Daniel et al., 2006; Luetkemeyer et al., 2010). According to research done in Uganda in 2014–15, the chance of viral load non-suppression is significantly increased when there is active tuberculosis (TB) present (Bulage et al., 2017).

In Kenya, it is customary to use the Intensive Case Finding (ICF) technique for tuberculosis screening. Isoniazid Preventive Therapy (IPT) is given as a preventive measure to people living with HIV (PLHIV) who test negative for tuberculosis (TB) and are 12 months of age or older (NTLP-K, 2013). Additionally, unless it is contraindicated by a sulfa medication allergy or CPT-related toxicity, all PLHIV get lifetime Cotrimoxazole Preventive Therapy (CPT). According to NASCOP-Kenya (2016), CPT lowers the risk of sepsis, diarrheal diseases, malaria, and common bacterial infections in addition to helping to avoid particular opportunistic infections (OIs).

To improve treatment outcomes and lower the morbidity and mortality linked to HIV/TB co-infection, it is imperative that TB screening, preventive treatments, and management methods for PLHIV be implemented.

2.19 Viral load suppression in pregnant women living with HIV (WLHIV)

To achieve and sustain optimal viral suppression throughout pregnancy, adherence evaluation and support are essential. Family planning and pre-pregnancy counseling should be encouraged and made available to prevent unwanted pregnancies, assist individuals living with HIV in fulfilling their desire to become parents, and offer a crucial chance to encourage ART adherence.

In the prevention of mother-to-child transmission of HIV (PMTCT) cascade in Eastern and Southern Africa, an estimated 95% of pregnant women living with HIV (WLHIV) in the HIV-affected regions of the world received antiretroviral medication (ART) for PMTCT in 2019 (UNAIDS, 2020). Even with this success, the population still faces significant hurdles in maintaining viral suppression and retention in care. Several studies have shown that approximately one-third of pregnant women initiating antiretroviral therapy (ART) become lost to follow-up (LTFU) during subsequent years, with 30–40% of those who remain in care failing to achieve viral load suppression postpartum (Tenthani et al., 2014; Clouse et al., 2017; Haas et al., 2016). Failure to achieve viral suppression during pregnancy and the postpartum period among women living with HIV increases the risk of HIV drug resistance development and transmission, as well as maternal morbidity and mortality, vertical transmission of HIV to infants, and horizontal transmission to partners (Myer et al., 2017). In Eastern Africa, inadequate retention in care and ART use during pregnancy and lactation contributed to an estimated 10,000 of the 26,000 new HIV infections in infants in the region in 2018 (UNAIDS, 2019). Understanding the factors affecting retention and viral suppression throughout the prevention of mother-to-child transmission (PMTCT) continuum is crucial for tailoring effective interventions for this population.

Several factors influencing viral suppression and retention throughout the prevention of mother-to-child transmission (PMTCT) continuum have been identified. Diagnosis of HIV and initiation of antiretroviral therapy (ART) during pregnancy are significant themes, with research showing that women who commence ART during pregnancy are five times more likely to discontinue treatment compared to those who start ART at a later HIV stage (Tenthani et al., 2014). Younger age, HIV-related stigma, fear of disclosure, and lack of social and psychological support have also been associated with lower rates of retention and viral suppression among pregnant women (Knettel et al., 2018). However, despite evidence suggesting ongoing attrition beyond this period, most studies have focused on retention during pregnancy or the initial 12 months post-delivery (Haas et al., 2016). Additionally, longitudinal data on retention throughout the PMTCT continuum are scarce, with the majority of studies being cross-sectional. Furthermore, breastfeeding and the risk of vertical transmission may extend beyond 18 months due to breastfeeding patterns in Eastern and Southern Africa (WHO, 2016; Myer et al., 2017).

A growing proportion of women living with HIV (WLHIV) attending PMTCT clinics initiate ART before pregnancy, adding complexity to interpretation as many studies were conducted during the 'Treat All' era of universal ART eligibility (WHO, 2016; Myer et al., 2017). Finally, there is a lack of research on retention and viral suppression in settings where HIV care is integrated with maternal and child health services. This integration is a growing trend in sub-Saharan Africa and may have different implications for retention and viral suppression compared to non-integrated services (Geldsetzer et al., 2016).

With an HIV prevalence of 6.1% among women aged between 15 and 49 years old, Kenya ranks among the countries with the highest rates of HIV infection globally (UNAIDS, 2020). In response to this, Kenya implemented the World Health Organization's Option B+ policy in 2014, recommending lifelong antiretroviral therapy (ART) for all pregnant women living with HIV (WLHIV). In 2016, the "Treat All" policy replaced this one (NASCOP, 2014, NASCOP, 2016). Significantly, less vertical transmission occurred in Kenya as a result of these policies, falling from 26% in 2009 to 11% in 2018 (NASCOP, 2012). However, there are few program-level data from the PMTCT on viral suppression and retention in the "Treat All" era.

2.20 HIV Testing and Counseling Status

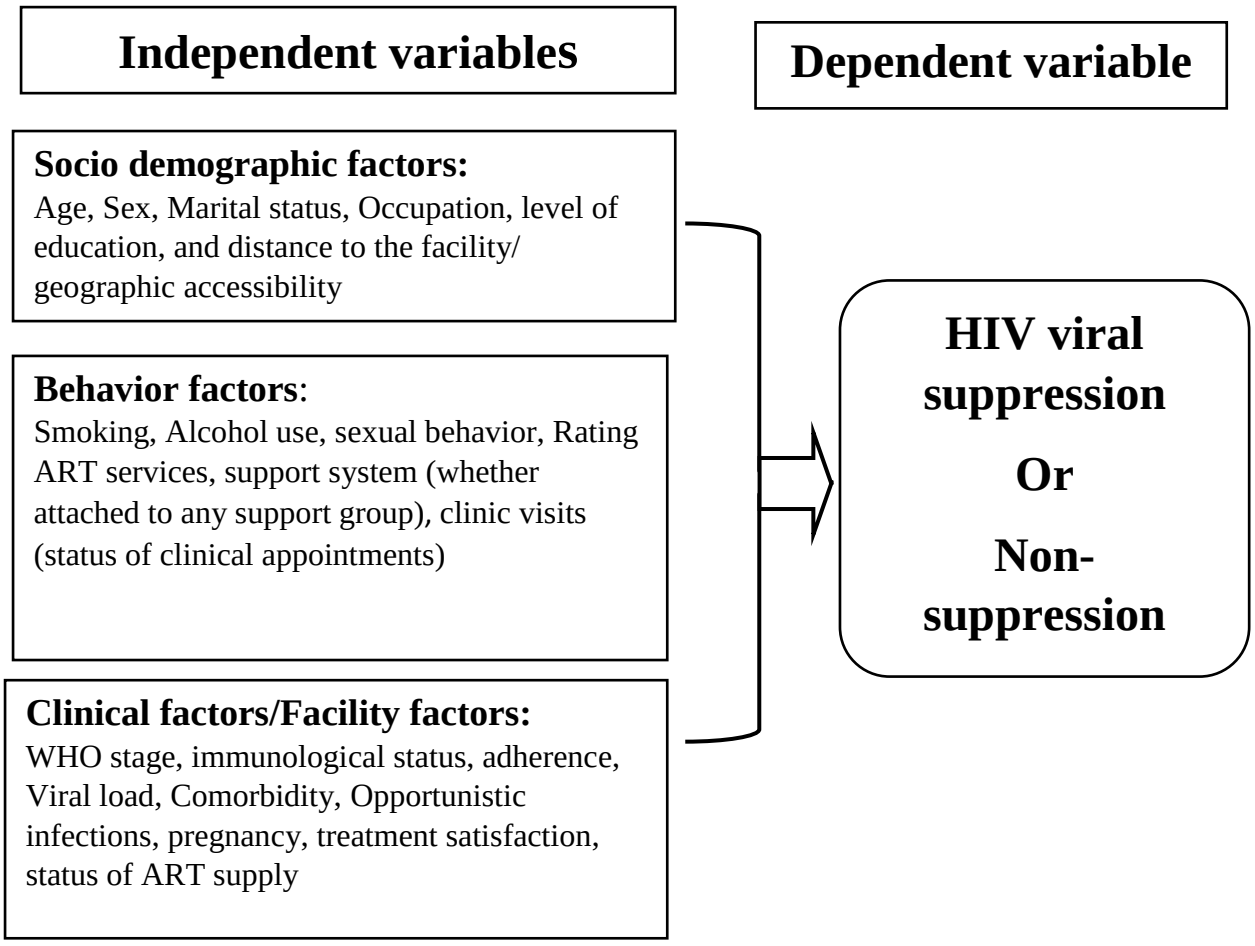
HIV testing and counseling (HTC) represent crucial initial steps for individuals with HIV in accessing care and treatment, as well as serving a pivotal role in HIV prevention for both infected and uninfected individuals. Research indicates that among people living with HIV, being aware of one's HIV status is linked to over a 60% decrease in HIV transmission due to improved risk-reduction behavior (Bunnell et al., 2006). Additionally, antiretroviral therapy (ART) is now acknowledged to offer significant HIV prevention benefits, with documented evidence showing a 96% reduction in transmission among serodiscordant couples, underscoring the importance of HIV diagnosis (Cohen et al., 2011).

To achieve universal access to HIV testing, Kenya has set a national target of 80% coverage for HIV testing and knowledge of HIV serostatus among the adult population. In 2007, only 36% of Kenyans had undergone HIV testing, with limited access to services and distance to testing sites identified as significant barriers (NASCOP, 2009). However, by 2018, innovative approaches to HIV testing had led

to significant progress, with 89% of people living with HIV aware of their status (UNAIDS, 2018).

In 2008, Kenya initiated a national HIV testing and counseling (HTC) strategy to achieve universal testing and awareness of HIV status by 2013 (NASCOP, 2010). This strategy introduced various innovative approaches to HTC beyond traditional client-initiated voluntary counseling and testing (VCT), emphasizing services provided directly to individuals. These approaches included provider-initiated testing and counseling in healthcare settings and home-based testing and counseling (HBTC) (WHO, 2007; WHO, 2012). As a result of these efforts, there was a significant increase in the number of individuals undergoing HIV testing. While approximately 860,000 individuals were tested annually in 2008, this number surged to around 9.9 million by 2015 (KMOH/NASCOP, 2016). Additionally, in May 2017, the Kenyan government introduced self-testing kits as part of the 'Be Self Sure' campaign. These kits are now accessible in health facilities and pharmacies across the country (UNAIDS, 2017).

2.21 Conceptual framework



The conceptual framework above illustrates how various factors, both independent and dependent, interact to impact the likelihood of viral load non-suppression in adolescents and adults receiving antiretroviral therapy (ART). In this investigation, the focal point is on viral load non-suppression, serving as the dependent variable. The background variables encompass age, gender, religion, and education level. Additionally, behavior factors such as tobacco and alcohol use, sexual behavior, satisfaction with ART services, support systems, and clinic attendance are examined. Furthermore, clinical factors that potentially influence viral load suppression status among adolescents and adults are considered in the framework.

CHAPTER THREE

3.0 Methodology

3.1 Study area

Samburu County is located in northern Kenya and was part of the former Rift Valley Province. It spans an area of approximately 21,000 square kilometers (about 8,000 square miles). The county extends from the northern banks of the Ewaso Ng'iro River to the southern edge of Lake Turkana. It is home to several ethnic communities, including the Samburu, Turkana, and many other tribes, with a projected population of 396,314 in 2022. The region is predominantly arid and semi-arid, characterized by scattered settlements, limited infrastructure, and a nomadic lifestyle among its residents. These geographical and socio-economic factors present unique challenges and opportunities for public health interventions and research (Fig. 2).

The two Sub-counties under study lie within the arid and semi-arid regions and are located in the northern parts of the Great Rift Valley in Kenya and are bordered by the following Counties: Marsabit (Northeast), Isiolo (East), Laikipia (South), Turkana (Northwest), and Baringo (Southwest). Samburu East covers an area of 10,050 square kilometers with more than 95% of the land classified as low-potential rangeland. It has a population of 77,994 according to the 2019 population census, with an urban population of 7,916, and 70,078 living in a rural setup. On the other hand, Samburu Central covers an area of 3,936 square kilometers with approximately 17% of the land classified as high-potential land. It has a population of 164,942 according to the 2019 population census, with an urban population of 24,663. The two sub-counties are predominantly inhabited by the Samburu community, who are nomadic pastoralists. Around 34% of the population in Samburu County possesses basic reading and writing skills, but literacy rates are anticipated to rise steadily across all education levels. Samburu County is categorized as one of the most impoverished regions, with

a poverty rate of 73.5%, exceeding the national poverty rate of 45.9%. Additionally, the inadequate road infrastructure presents a significant challenge for the county.

Six of the seventeen medical facilities in the Samburu East and Samburu Central Sub-counties that provide ART services were the sites of the study. Among the six facilities to which the study was conducted, three were from Samburu East Sub-County, namely Wamba Health Center(H/C), Archers Post H/C, Catholic Hospital Wamba, and another three facilities from Samburu Central Sub-county, namely Samburu County Referral Hospital, Kisima Model H/C, and Suguta H/C were chosen

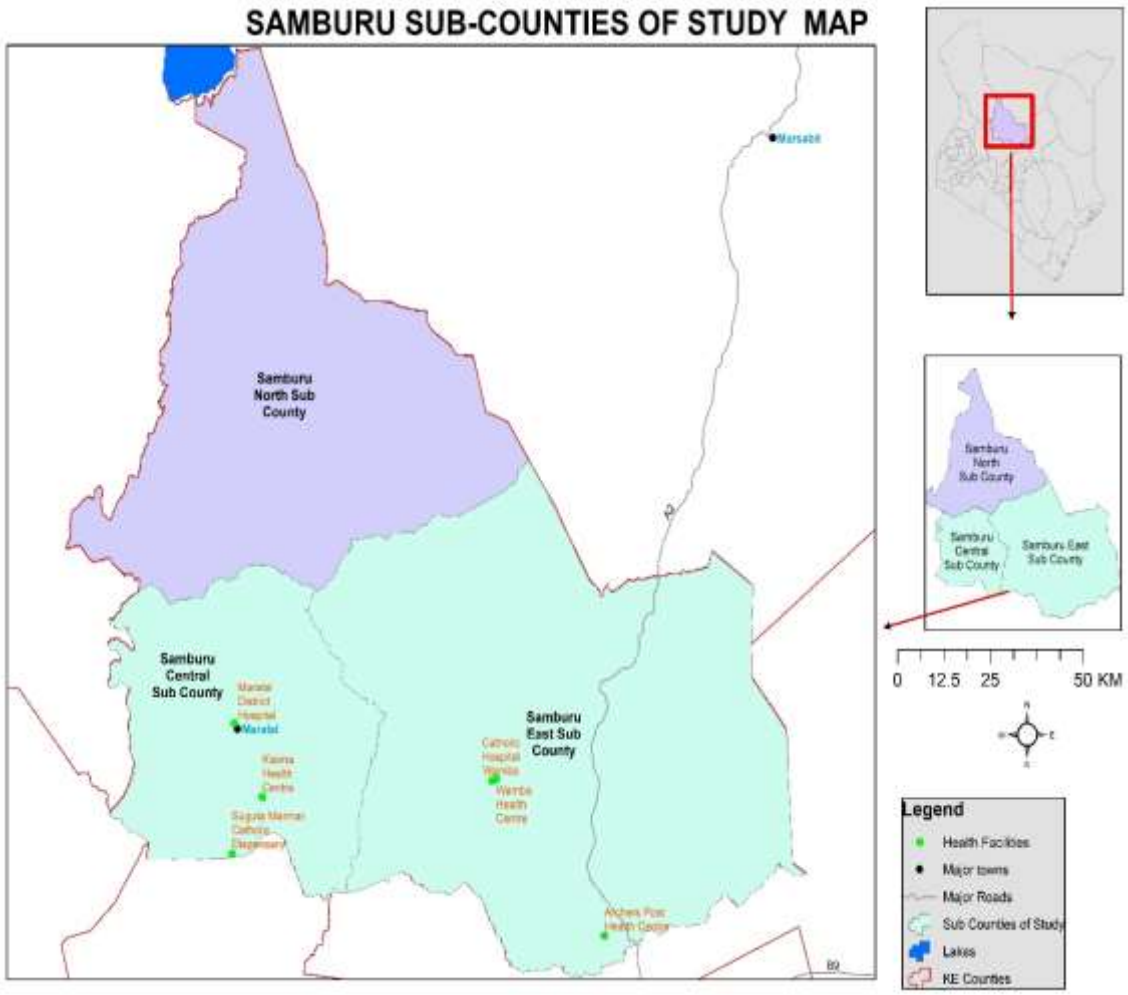


Figure 3.1: The map showing the study health facilities in Samburu East and Samburu Central Sub-Counties

3.2 Study Population

The study was conducted among adolescents 10 – 19 years old and adults enrolled on ART 6 months post-ART initiation in Samburu East and Samburu Central Sub-counties.

3.3 Study Design

A cross-sectional study involving a retrospective review of ART records from which participants were selected for face-to-face interviews.

3.4 Study period

The study period was from January 1st, 2020, to December 31st, 2021, in 6 selected health facilities offering ART services in the two Sub-counties.

3.5 Sample size determination

The sample size was calculated using Cochran's formula (1963) as shown below

$$n_0 = \frac{Z^2 pq}{e^2}$$

Where;

- e is the desired level of precision (i.e., the margin of error – 5%),
- p is the (estimated) proportion of the population which has the attribute in question (25.8% - a proportion of the non-suppressed population in a study in Kenya, Kangethe et al, 2020)
- q is 1 – p
- n_0 is the sample size
- Z^2 is the abscissa of the normal curve that cuts off an area at the tails (1 - α equals the desired confidence level, at 95%). A 95 % confidence level gives us Z values of 1.96, per the normal tables

Therefore;

$n_0 = (1.96)^2 (0.258) (0.742) / (0.05)^2 = 294$

n_0 = 294

Finite population correction factor

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

Where **n** is the sample size and **N** is the population size (**1,773** both suppressed and non-suppressed individuals in Samburu East and Samburu Central Sub-counties)

n = 294/1+(294-1)/1,773

n = 248

Adjusted for 10% non-response: $\boldsymbol{n} = \frac{\mathbf{n}}{\mathbf{1 - 0.1}}$ = 248/9

n = 276

3.6 Inclusion and exclusion criteria

3.6.1 Inclusion criteria

Adolescents and adults who were on ART care for 6 months and had undergone a viral load test six months post-ART initiation were included in the study

3.6.2 Exclusion criteria

The study excluded the following categories:

- Adults and adolescents whose outcome status could not be determined (no record of viral load values).
- Adults and adolescents who were too ill to respond

3.7 Sampling Technique

Purposive sampling was initially used to select six health facilities based on high ART patient volumes and reliable access to client records. These facilities included Wamba Health Center, Archers Post Health Center, Catholic Hospital Wamba, Samburu County Referral Hospital, Kisima Model Health Center, and Suguta Health Center. From each site, patient data were abstracted, and those meeting the inclusion criteria were compiled into a sampling frame. Simple random sampling was then employed at each facility by assigning unique identifiers to all eligible participants and selecting the required sample using Excel-generated random numbers.

A total of 276 participants were sampled using probability proportionate to size (PPS) from six facilities between January 1, 2020, and December 31, 2021 (Table 3.7). The sample included both suppressed and non-suppressed participants, reflecting the non-suppression proportion in the study population.

Table 3.7: Distribution of participants on ART across the 6 facilities according to probability proportionate to the size

	Sub-county/Facility	Number of Eligible participants	Formula used to have a sample	Number of participants sampled
	Samburu Central sub-county			
1	Samburu County Referral Hospital	913	276x913/1773	142
2	Kisima Model Health Center (H/C)	179	276x179/1773	28
3	Suguta H/C	150	276x150/1773	23
	Samburu East Sub-County			
4	Wamba H/C	182	276x182/1773	28
5	Archers Post H/C	180	276x180/1773	28
6	Catholic Hospital Wamba	172	276x172/1773	27
	Total	**1,773**		**276**

3.8 Virological criteria for determining viral load non-suppression

In this study, viral load non-suppression was defined as having ≥1,000 RNA copies/ml of plasma after six months of ART treatment. Participants whose viral load was not suppressed by the sixth month of ART were considered to have viral load non-suppression.

3.9 Adherence Rating

Adherence was rated based on the number of missed doses per month: missing 1 dose indicated good adherence (≥95% of doses taken); missing 2 to 4 doses indicated fair adherence (85–94% of doses taken); and missing 5 or more doses indicated poor adherence (<85% of doses taken).

Table 3.9: Adherence Rating based on Pill Counts

Missed doses per month	% of doses taken	Adherence rating
1 dose	≥ 95%	Good
2 – 4 doses	85 – 94%	Fair
≥ 5 doses	< 85%	Poor

3.10 Data collection

The study used a structured questionnaire (Appendix 5) and a clinical data abstraction tool (Appendix 4), developed based on existing literature. Data were collected in six health facilities (three in each sub-county) through face-to-face interviews conducted in Comprehensive Care Clinics (CCCs), followed by data abstraction from the Kenya EMR system for point-of-care sites, HTS registers, Treatment Preparation registers, Cohort registers, and MOH 731. For participants unable to travel due to distance or cost, interviews were conducted in their homes or at other preferred locations.

Trained data clerks used the clinical abstraction tool to collect information on patients' clinical and immunological status, including WHO stage at enrollment, missed appointments, opportunistic infections, CD4 count, and viral load after six months to determine viral suppression.

Community Health Volunteers (CHVs), trained in interview methods, research ethics, and confidentiality, administered the questionnaires. These were originally developed in English, then translated into Samburu and Swahili, and later back-translated into English to ensure accuracy. The questionnaire captured sociodemographic and behavioral data, including age, gender, education, occupation, marital status, religion, alcohol use, smoking, sexual behavior, accessibility to health services, and ART adherence.

3.11 Data Analysis

The analysis to identify factors linked to viral load non-suppression followed a systematic process using Stata version 15.1. Before analysis, data was stored in Excel to check completeness, cleaned, and coded to ensure accuracy and consistency. Descriptive statistics were then used to summarize the study population's characteristics, with proportions and frequencies describing categorical variables. This phase also determined the proportion of virological non-suppression among adolescents and adults on antiretroviral therapy (ART) in Samburu East and Samburu Central sub-counties.

To evaluate the strength of the association between independent variables and viral load non-suppression, crude odds ratios (ORs) were calculated using bivariate analysis. Variables with a p-value of less than 0.2 in the bivariate analysis were included in the multivariable analysis. A binary logistic regression model was then

applied to identify independent predictors of virological non-suppression, using the backward likelihood ratio method to remove variables that did not significantly contribute to the model.

Adjusted odds ratios (AORs) with 95% confidence intervals were used to measure the strength and direction of these associations. Statistical significance was set at a p-value of less than 0.05, and variables meeting this threshold were considered to have an independent association with viral load non-suppression. The final results were presented using tables, charts, and graphs to clearly interpret and communicate the findings.

3.12 Ethical Consideration

This study received ethical approval from Moi University Institutional Research and Ethics Committee and permission from the Ministry of Health, county health offices, and hospital boards. Informed consent was obtained from all participants: adults and emancipated minors provided their consent, while minors gave verbal assent with written consent from parents or guardians. To ensure privacy, interviews were conducted in confidential settings within health facilities or at participants' preferred locations with consent. Data confidentiality was upheld by coding participant information with unique identifiers and restricting access to the study team. Records linking identifiers were securely stored in health facilities. Participation was voluntary, with no impact on ART access for non-participants. The questionnaire was translated into Samburu and Swahili to ensure understanding among all participants (Appendix 1a and 1b).

CHAPTER FOUR

4.0 Results

4.1 Socio-demographic characteristics

A total of 276 participants were enrolled in the study, with 251 responding, resulting in a response rate of 90.9%. The average age of the participants was 37.9 years, with a standard deviation of 12.7 years. Participants' ages ranged from 16 to 73 years.

In Samburu East, the majority of participants were female, 69.7% compared to 66.3% in Samburu Central, with males constituting 30.3% and 33.7%, respectively. In terms of age distribution, the 30–39 age group was the most represented in both sub-counties, 31.6% in Samburu East and 33.7% in Samburu Central, followed by individuals aged 40–49 and those over 50. Marital status distribution showed that more participants in Samburu Central were married or cohabiting (53.7%) compared to 44.7% in Samburu East. In comparison, a slightly higher proportion of single or widowed individuals was observed in Samburu East (43.4%) than in Samburu Central (38.3%).

Regarding education, half of the respondents in Samburu East had no formal education, a higher proportion than the 42.3% in Samburu Central. However, Samburu Central had a greater number of individuals with secondary (16.6%) and tertiary education (15.4%) compared to Samburu East, where both levels stood at 6.6%. Employment status revealed that a larger proportion of participants in Samburu Central were employed (24.6%) than in Samburu East (10.5%), and the percentage of unemployed individuals was higher in Samburu East (71.1%) compared to 55.4% in Samburu Central. Notably, businesspersons were more common in Samburu Central (13.7%) than in Samburu East (3.9%), while the proportion of pastoralists was higher in Samburu East (14.5%) than in Samburu Central (6.3%).

Overall, the majority of participants from both sub-counties were female, accounting for 67.3% (169 individuals). Regarding education levels, 46.6% (117) had no formal education, 26.1% (73) had completed primary school, 11.6% (29) had completed secondary school, and 12.8% (32) had attained tertiary education (4.1)

Table 4.1: Socio-Demographic Characteristics of HIV Positive Adolescents and Adults at the sub-county level and overall characteristics of the two sub-counties

Samburu East			**Samburu Central**			**Overall**	
Variables	**n=76**	**Percentage (%)**	**Variables**	**n=175**	**%**	**N=251**	**%**
Sex			**Sex**				
Male	23	30.3	Male	59	33.7	82	32.7
Female	53	69.7	Female	116	66.3	169	67.3
Age			**Age**				
10-19	8	10.5	10-19	14	8.0	22	8.8
20-29	12	15.8	20-29	31	17.7	42	16.7
30-39	24	31.6	30-39	59	33.7	82	32.7
40-49	18	23.7	40-49	41	23.4	59	23.5
>50	14	18.4	>50	30	17.1	46	18.3
Marital status			**Marital status**				
Married/Cohabiting	34	44.7	Married/Cohabiting	94	53.7	128	51.0
Single/widowed	33	43.4	Single/widowed	67	38.3	99	39.4
Separated/Divorced	9	11.9	Separated/Divorced	14	8.0	24	9.6
Education Level			**Education Level**				
No education	38	50.0	No education	74	42.3	117	46.6
primary	28	36.8	primary	45	25.7	73	29.1
Secondary	5	6.6	Secondary	29	16.6	29	11.6
Tertiary	5	6.6	Tertiary	27	15.4	32	12.8
Occupation			**Occupation**				
Employed	8	10.5	Employed	43	24.6	51	20.3
Not Employed	54	71.1	Not Employed	97	55.4	151	60.2
Businessperson	3	3.9	businessperson	24	13.7	27	10.8
Pastoralist	11	14.5	Pastoralist	11	6.3	22	8.8

4.2 Clinical Characteristics

The baseline mean CD4 count of the study participants was 317 cells/mm3, with a standard variation of 378.0 cells/mm3. The patients were engaged in HIV care. Among them, 70.5% (124 individuals) had a CD4 count of less than 350 cells/mm^3. There were 75 missing CD4 records. Regarding the baseline WHO clinical stage, 40.8% (103) were in stage I, 27.6% (69) were in stage II, 28.0% (70) were in stage III, and 3.6% (9) were in stage IV. The WHO's most current clinical stage was stage I for 75.9% (190) of adolescents, stage II for 17.9% (45), stage III for 4.8% (12), and stage IV for 1.6% (4). In terms of entry point, 16.3% (41) came from the TB unit, 39.0% (98) had opportunistic infections, while the majority, 61.0% (153) were not diagnosed with any infection.

Table 4.2: Clinical characteristics of HIV HIV-positive adolescents and Adults on Anti-Retroviral Treatment in Samburu East and Samburu Central Sub-Counties

Variable	Frequency (N=251)	Proportion (%)
CD4 count at initiation of ARVs*		
<350 cells/mm^3	124	**70,45**
351-500 cells/mm^3	21	11.93
>500 cells/mm^3	31	17.05
WHO staging at ART initiation		
I	103	40.8
II	69	27.6
III	70	28.0
IV	9	3.60
WHO staging at the time of study		
I	190	75.7
II	45	17.9
III	12	4.8
IV	4	1.6
TB infection at ART initiation		
Yes	41	16.3
No	210	83.7
Other opportunistic infections		
Yes	98	39.0
No	153	61.0

***Incomplete record**

4.3 Behavioral characteristics

Eighty-seven respondents (34.7%) reported facing challenges in accessing the ART. The frequency of individuals with good adherence to ARVs is significantly higher, at 56.2% (141), i.e., they took >95% of their doses, while 18.7% (47) were poorly adherent. Regarding the attachment to any support group, 71.3% (179) were attached to different support groups, but only 65.9% (118) of those attached to the support groups regularly attended group meetings. The majority of the respondents, 79.7% (200), were nonsmokers, and 61.8% (155) responded that they don't take alcohol. On the frequency of alcohol consumption, the majority of the respondents, 42.2% (41), responded that they consumed alcohol four or fewer times a month, and 26.7% (67) revealed that they had multiple sex partners. One hundred and thirty respondents (51.8.0%) revealed that they missed taking ART dose/doses in the past since the initiation of ART, as shown in Table 4.

Table 4.3: Behavioral characteristics of HIV HIV-positive adolescents and Adults on Anti-Retroviral Treatment at Samburu East and Samburu Central Sub-Counties

Variable	Frequency (n=251)	Proportion (%)
Partner is aware of the status		
Yes	29	45.5
No	32	54.5
Face challenges in accessing ART		
Yes	87	34.7
No	164	65.3
Missed taking ART drugs		
Yes	130	51.8
No	121	48.2
Adherence		
Poor	47	18.7
Fair	63	25.1
Good	141	56.2
Level of facility		
III	77	30.7
IV	174	69.3
Attached to support group		

Yes	179	71.3
No	72	28.7
Regularly attends support group meetings (N=179)		
Yes	118	65.9
No	61	34.1
Pregnancy status during ART initiation		
Yes	23	9.2
No	228	90.8
Have a chronic disease		
Yes	23	9.2
No	228	90.8
Smoke cigarettes		
Yes	51	20.3
No	200	79.7
Take alcohol		
Yes	96	38.3
No	155	61.8
Frequency of alcohol consumption		
>three times a week	35	36.1
Two to four times month	21	21.7
Four or fewer times a week	41	42.2
Multiple sex partners		
Yes	67	26.7
No	184	73.3
Rating of ART services		
Good	229	91.2
Fair	20	8.0
Bad	2	0.8
Comfortable clinic appointments		
Yes	191	76.1
No	60	23.9

Regarding reasons for missed ART doses, the leading reason cited was ignorance, accounting for 42.52%, followed by running out of drugs at 15.75% and unknown reasons at 14.17%. Other causes include forgetting due to alcohol consumption at 7.09%, drug side effects at 6.3%, and severe illness at 4.72%. Less common reasons include lack of food, travel, and use of herbs, each at 3.15% (Fig. 4.3)

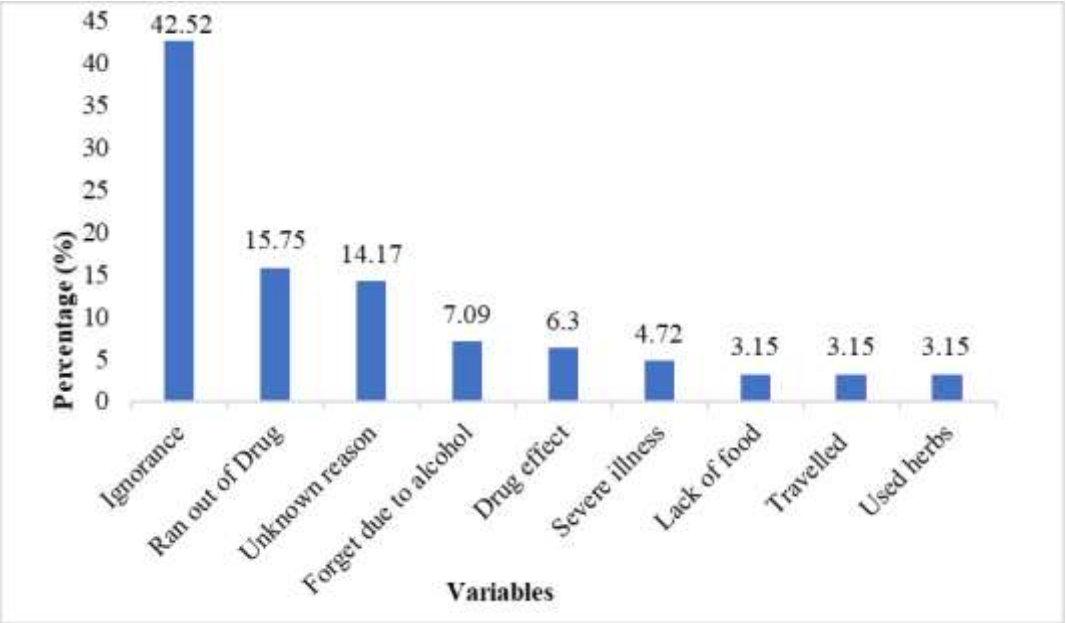


Fig 4.3: Reasons given by clients for the missed doses in Samburu East and Samburu Central Sub Counties

4.4 Proportion of adolescents and adults on ART with Viral Non-Suppression

According to this study, Samburu East and Samburu Central sub-counties recorded a viral load non-suppression rate of 26.3% during the first 6 months of treatment for patients enrolled in care from January 1, 2020, to December 31, 2021.

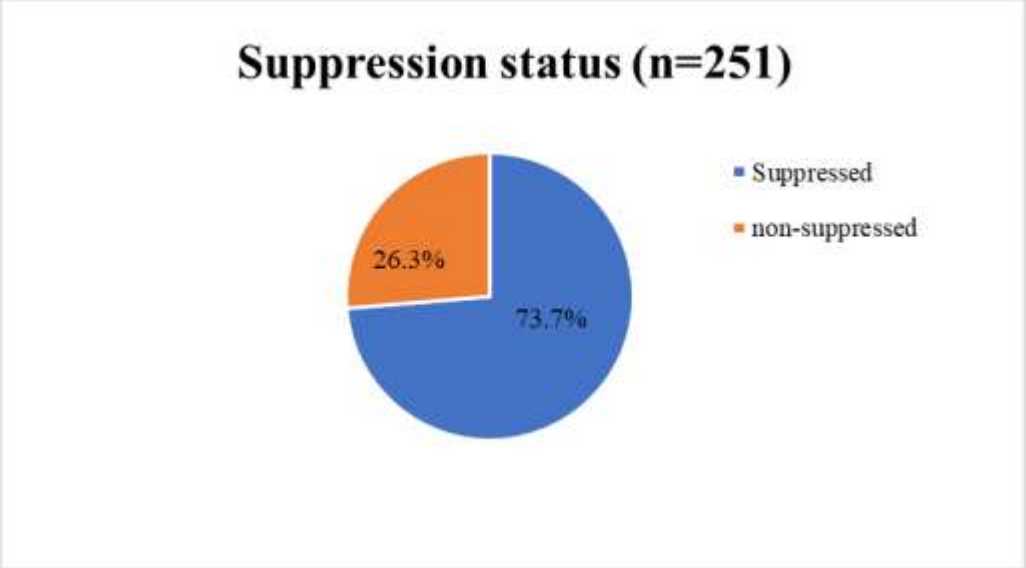


Figure 4.4: Proportion of adolescents and adults who were virally suppressed/non-suppressed in Samburu East and Samburu Central Sub Counties.

4.5 Proportion of non-suppressed VL at Sub-county level

Samburu East recorded a slightly higher non-suppression rate at 27.7% (148 individuals) compared to Samburu Central, which had a rate of 24.9% (309 individuals). This indicates that both areas face notable challenges in achieving viral suppression, with Samburu East being slightly more affected.

4.6 Factors Associated with Viral Non-Suppression

4.6.1 Bivariate analysis of socio-demographic and clinical characteristics

The results of the bivariate logistic regression modeling showed that a few variables had a significant correlation with the non-suppression of viral load. These include; the age group 10-19 years (OR_{crude} = 4.04, 95%CI = 1.46-11.20), age group 40-49 years (OR_{crude} = 2.89, 95%CI = 1.32-6.30), marital status; divorced/separated clients (OR_{crude} = 1.32, 95%CI = 0.67-2.59) and occupation; pastoralist (OR_{crude} = 3.64, 95%CI = 1.24-10.59. Significant associations were also found among the clinical characteristics of the respondents, namely; CD4 count <350 cells/mm^3 (OR_{crude} = 20.27, 95%CI = 2.67-153.47), WHO clinical stage II, III, and IV: Stage II (OR_{crude} = 3.54, 95%CI = 1.42-8.83), Stage III (OR_{crude} = 13.17, 95%CI = 5.57-31.16), and Stage IV (OR_{crude} =14.68, 95%CI = 3.27-65.81). As shown in the following table, baseline TB co-infection during the first six months of treatment was also significantly associated with viral load non-suppression: (ORcrude = 3.00, 95%CI = 1.49-6.00). The presence of opportunistic infections was found to be significantly associated with viral load non-suppression (ORcrude = 3.36, 95%CI = 1.87-6.04).

Table 4.6.1: Bivariate analysis of socio-demographic and clinical characteristics among HIV Positive Adolescents and adults on Anti-Retroviral Treatment in Samburu East and Samburu Central Sub-Counties (N-251)

Variable	VNS Freq* (n=66)	VS Freq* (n=185)	Crude Odds Ratio (95% CI)	P-value
Gender				
Male	19(28.8)	63(34.0)	Ref	
Female	47(71.2)	122(66.0)	1.27(0.69-2.36)	0.43
Age (years)				
30-39	14(21.2)	68(36.8)	Ref	
10-19	10(15.2)	12(6.5)	4.04(1.46-11.20)	0.007*
20-29	8(12.1)	34(18.4)	1.14(0.43-2.99)	0.785
40-49	22(33.3)	37(20.0)	2.89(1.32-6.30)	0.008*
Over 50	12(18.2)	34(18.4)	1.7(0.72-4.11)	0.22
Marital status				
Married/cohabiting	30(45.5)	98(53.0)	Ref	
Single/widowed	32(48.5)	67(36.2)	1.56(0.86-2.81)	0.14
Separated/ Divorced	4(6.0)	20(10.8)	0,65(0.21-2.06)	0.47
Education Level				
No education	28(42.4)	89(48.1)	Ref	
Primary or lower	24(36.4)	49(26.5)	1.56(0.82-2.97)	0.18
Secondary	9(13.6)	20(11.8)	1.43(0.58-3. 50)	0.43
Tertiary	5(7.6)	27(14.6)	0.59(0.21-1.67)	0.32
Occupation				
Employed	11(16.7)	40(21.6)	Ref	
Unemployed	39(59.1)	112(60.5)	1.27(0.59-2.71)	0.54
Business person	5(7.6)	22(11.9)	0.83(0.25-2.68)	0.75
Pastoralist	11(16.7)	11(6.0)	3.64(1.24-10.59)	0.018*
CD4 count at ART initiation				
>500 cells/mm^3	1(1.82)	30(24.79)	Ref	
<350 cells/mm^3	50(90.91)	74(61.16)	20.27(2.67-153.47)	0.004*
351-500 cells/mm^3	4(7.27)	17(14.05)	7.06(0.73-68.37)	0.092
WHO clinical stage at ART initiation				
Stage 1	8(12.1)	95(51.4)	Ref	
Stage 2	16(24.2)	53(28.6)	3.54(1.42-8.83)	0.007
Stage 3	37(56.1)	33 (17.8)	13.17(5.57-31.16)	<0.000001
Stage 4	5(7.6)	4(2.2)	14.68(3.27-65.81)	0.00002
Opportunistic infection in the first 6 months of treatment				
No	26(39.4)	127(68.7)	Ref	
Yes	40(60.6)	58(31.6)	3.36(1.87-6.04)	0.000028
TB infection in the first 6 months				
No	47(71.2)	163(88.1)	Ref	
Yes	19(28.8)	22(11.9)	3.00(1.49-6.00)	0.002

VNS Freq*- Viral load non-suppression Frequency; VS Freq*- Viral load suppression frequency

4.6.2 Bivariate analysis of Behavioral characteristics

At bivariate analysis, several behavior-related characteristics were found to be statistically significant with viral load non-suppressed. These include; challenges in accessing ART drugs (cOR = 2.18, 95% CI = 1.25-3.96), missed taking drugs/doses (cOR = 16.29, 95% CI = 6.68 – 39.67), poor adherence level < 85 (cOR = 18.98, 95% CI = 8.71 – 41.35), not regularly attending support group meetings (cOR = 4.87, 95% CI = 2.41 – 9.86), fair rating of ART services in the facilities (cOR = 3.16, 95% CI = 1.25 – 8.00), not being comfortable with clinical appointments days (cOR = 1.77, 95% CI = 0.95 – 3.33), and distance to the nearest facility (>1 hour to the nearest facility) (cOR = 1.78, 95% CI = 0.87 – 3.61) However, frequency of alcohol consumption of four or less times a month was found to be protective against virological non-suppression (cOR = 0.11, 95% CI = 0.03 – 0.39) as shown in the table below.

Table 4.6.2: Bivariate analysis for behavioral characteristics among HIV HIV-positive adolescents and adults on Anti-Retroviral Treatment at Samburu East and Samburu Central Sub-Counties (N-251)

Variable	VNS Freq* (n=66)	VS Freq* (n=185)	Crude Odds Ratio (95% CI)	P-value
Challenges in accessing ART				
No	34(51.5)	130(70.3)	Ref	
Yes	32(48.5)	55(29.7)	2.18(1.25-3.96)	0.007
Missed ARV doses				
No	6(9.1)	114(62.0)	Ref	
Yes	60(90.9)	70(38.0)	16.29(6.68-39.67)	<0.000001
Attached to any support group				
Yes	49(74.2)	130(70.3)	Ref	
No	17(25.8)	55(29.7)	1.2(0.65-2.30)	0.54
Regularly attends support group meetings				
Yes	19(39.6)	99(76.2)	Ref	
No	29(60.4)	31(22.8)	4.87(2.41-9.86)	0.000005
Chronic diseases				
Yes	6(9.1)	17(9.2)	Ref	
No	60(90.9)	168(90.8)	1.01(0.38-2.69)	0.98
Smoked cigarettes				
No	52(78.8)	142(79.8)	Ref	
Yes	14(21.2)	36(20.2)	1.06(0.53-2.12)	0.87

Consumed alcohol				
No	38(57.6)	117(63.2)	Ref	
Yes	28(42.4)	68(38.8)	1.27(0.72-2.25)	0.42
Frequency of alcohol consumption				
>three times a week	17(58.62)	18(26.47)	Ref	
Four or less times a month	4(13.79)	37(54.41)	0.11(0.03-0.39)	0.001*
Two to three times a week	8(27.59)	13(19.12)	0.65(0.22-1.96)	0.45
Multiple sex partners				
Yes	14(21.2)	53(25.6)	Ref	
No	52(78.8)	132(71.4)	1.49(0.76-2.92)	0.24
Rating of ART services				
Good	58(88.9)	182(98.4)	Ref	
Fair	10(15.15)	10(5.41)	3.16(1.25-8.00)	0.015
Bad	4(6.1)	2(1.0)	3.58(0.22-58.35)	0.37
Comfortable with clinical appointments				
Yes	44(66.7)	145(78.4)	Ref	
No	21(1.8)	39(21.2)	1.77(0.95-3.33)	0.07
Adherence rating to ARVs				
Good/Fair (≥ 85%)	30(45.5)	174(94.1)	Ref	
Poor (<85%)	36(54.5)	11(5.9)	18.98(8.71-41.35)	<0.0000001
Distance to the nearest facility				
30 mins or less	18(27.27)	68(38.8)	Ref	
30 - 60 mins	24(36.36)	66(35.7)	1.37(0.68-2.76)	0.37
>1 hour	24(36.36)	51(27.6)	1.78(0.87-3.61)	0.11

VNS Freq*- Viral load non-suppression Frequency; VS Freq*- Viral load suppression frequency

4.7 Multivariate analysis

At the multivariate analysis level, being enrolled in clinical stages 3 and 4 (adjusted odds ratio [aOR] = 12.20, 95% confidence interval [CI] = 4.50 - 33.03), poor adherence rating (aOR = 5.91, 95% CI = 2.97-13.58), and missing ARV drug doses (aOR = 14.16, 95% CI = 4.40 - 33.03) were significantly linked to higher likelihood of virological non-suppression. Conversely, regularly attending support group meetings (aOR = 0.26, 95% CI = 0.10 - 0.71) decreased the likelihood of virological non-suppression.

Table 4.7: Independent Factors associated with viral non-suppression among HIV-positive adolescents and Adults in Samburu East and Samburu Central Sub-Counties (N=251)

Variable	VNS Freq* (n=66)	VS Freq* (n=185)	aOR (95% CI)	P-value
WHO clinical staging at enrolment				
Stable (stages 1 and 2)	24(36.4)	148(80.0)	Ref	
Advanced (stage 3 and 4)	42(63.6)	37 (20.0)	12.20(4.50-33.03)	<0.00001
Missed taking ARV drugs				
No	6 (9.1)	114 (62.0)	Ref	
Yes	60 (90.9)	70 (38.0	14.16(4.40-33.03)	<0.00001
Regularly attends support group meetings				
No	29 (60.4)	31 (22.8)	Ref	
Yes	19 (39.6)	99 (76.2)	0.26(0.10-0.71)	0.008
Adherence Rating				
Good/Fair (≥ 85%)	30(45.5)	174(94.1)	Ref	
Poor (<85%)	36(54.5)	11(5.9)	5.91(2.97-13.58)	0.015

VNS Freq*- Viral load non-suppression Frequency; VS Freq*- Viral load suppression frequency

CHAPTER FIVE

5.0 DISCUSSION

This investigation aimed to determine the proportion of viral non-suppression and identify its associated factors in Samburu County. We found a viral non-suppression rate of 26.3% among the study population from Samburu East and Samburu Central sub-counties, which exceeds the national non-suppression rate of 24%. Factors contributing to HIV in the county include various social, economic, and cultural elements related to marriage, circumcision, poverty, and insecurity. This overall proportion of viral non-suppression was higher than that reported in a study conducted in Uganda (11%) (Bulage et al., 2017) and Mekelle public hospitals in Tigray, Ethiopia (11.5%) (Bulage et al., 2017). However, there is a strong agreement with data from a national teaching and referral hospital in Kenya (Kangethe et al., 2020), which reported a 25.8% viral non-suppression rate. In contrast, our study's viral suppression rate is below the UNAIDS target of 95% for people receiving antiretroviral therapy (UNAIDS, 2021). Nearly two-thirds of the participants were women, accounting for 67.3%, while men comprised 32.7%, indicating that women in the county are at a higher risk of HIV infection compared to men. This higher proportion of women aligns with the HIV prevalence trend in Kenya, where females have a higher prevalence than males. Notably, women aged 20-34 years have over three times the prevalence of men in the same age group (KENPHIA, 2018).

According to the study, Samburu East had a smaller cohort, with 534 participants, yet a slightly higher non-suppression rate of 27.7%. Although Samburu East recorded fewer total participants, its higher non-suppression rate is a concern, suggesting relatively poorer outcomes in achieving viral load suppression. This variation indicates that while both sub-counties face challenges in viral suppression, Samburu

East may require more targeted and intensified interventions.

Several factors could underlie the observed differences, including disparities in health service delivery, distance to healthcare facilities, adherence levels, follow-up mechanisms, and socio-economic or cultural barriers. The higher burden in Samburu East could reflect limited access to care, lower rates of retention on ART, or weaker patient support systems.

In Samburu East and Samburu Central sub-counties, the proportion of adolescents and adults with unsuppressed HIV viral load remains a concern, with recent data showing rates above the national average of 24%. While Kenya has made significant progress toward achieving the UNAIDS goal of 95% viral suppression by 2025, disparities persist at the sub-national level. The variations in adolescents' and adults' viral load non-suppression across health facilities and regions could be attributed to external factors, including gradual improvements in HIV care and access to services over time. To address these gaps, the County Government of Samburu has implemented strategic plans aimed at expanding ART coverage, improving retention in care, and enhancing viral suppression, especially among adolescents. These efforts are essential for improving healthcare access, strengthening HIV prevention, and ensuring that regions like Samburu East and Central are not left behind in the national response to HIV.

Compared to patients identified with clinical stages I and II, patients diagnosed with clinical stages III and IV had a 12.2-fold increased risk of virological non-suppression. This association can be attributed to the advanced nature of HIV infection at these stages, characterized by severe symptoms such as a markedly low CD4 cell count, rapid disease progression, and the presence of various opportunistic

infections, including oral candidiasis, oral hairy leukoplakia, and pulmonary tuberculosis, among others (WHO, 2017). These conditions necessitate prompt identification and management by healthcare providers to optimize the effectiveness of ART regimens and achieve viral suppression. Our findings regarding clinical staging align with research in Uganda and the Democratic Republic of Congo, indicating that individuals with advanced disease exhibit poorer viral responses (Castelnuovo et al., 2019; Buju et al., 2022). Thus, it is necessary that HIV treatment and care programs design, carry out, and assess focused interventions meant to encourage virological suppression, especially for young people and adults living with HIV who are at WHO clinical stages III and IV.

According to the study, regularly attending support group meetings was associated with a lower likelihood of viral non-suppression. Patients should be advised and motivated to engage in peer support groups or become members of organizations for People Living with HIV (PLHIV). According to Peterson et al. (2012), Haberer et al. (2010), and Krebs et al. (2008), these groups are essential in promoting disclosure, lowering stigma and discrimination, facilitating experience sharing, boosting self-esteem, encouraging patients to stay in HIV care, enhancing their coping mechanisms and psychological well-being, and assisting with medication adherence. Customizing support groups for certain populations—such as teenagers, expectant mothers, men who have sex with males, or couples in unhappy relationships—will optimize these benefits.

Additionally, this study found that the number of missed doses is a strong predictor of virological non-suppression, particularly among patients who missed more than four doses in a month. Adherence is the most important factor in determining the success

of antiretroviral therapy (ART) treatment and long-term viral suppression. Non-adherence to ART can lead to Human Immunodeficiency Virus (HIV) related morbidity and mortality. Moreover, it intensifies the risk of emerging drug-resistant HIV strains. According to earlier studies from Central Oromia, Ethiopia (Abdullahi et al., 2020) and South Eastern Ethiopia (Mamo et al., 2022), patients are more likely to skip dosages if they miss their appointments, which raises the possibility of virological failure. This observation is consistent with this research. Studies conducted in Australia (Kyaw et al., 2017) found similar patterns, with patients receiving antiretroviral therapy (ART) missing doses due to the unavailability of appointments. Missed doses can occur for a variety of reasons, such as patients running out of medication because of the long commute to the ART site, which worsens their health problems and negatively impacts treatment adherence.

Viral load non-suppression was substantially correlated with inadequate ART adherence. Compared to those with excellent or medium adherence, those with poor adherence were six times more likely to experience viral non-suppression. Achieving adherence can be challenging, particularly for first-time ART users, as they adjust to the daily dosage, manage potential adverse effects, and navigate issues over stigma and disclosure (NASCOP-Kenya, 2020). Adherence to antiretroviral medication is essential for the effective management of HIV/AIDS.

Consistently adhering to prescribed medications as instructed can aid in suppressing the virus, enhancing overall well-being, and lowering the likelihood of developing drug resistance. Addressing this challenge requires health authorities and HIV support organizations to enhance differentiated service delivery and adopt client-centered distribution approaches. This will ensure that patients have access to antiretroviral drugs (ARVs) in a consistent and timely manner, meeting their specific needs.

Additionally, patients should receive thorough instruction and counseling regarding the value of adherence, the advantages of ART, and the possible repercussions of non-adherence. Clear communication can help patients understand the significance of taking their medications as prescribed.

The study's findings also suggest that the CD4 count at the time of starting antiretroviral therapy may help predict the likelihood of not achieving viral load suppression. It was discovered that clients with a CD4 count below 350 cells/mm³ at the time of enrollment were more likely to have unsuppressed viral loads compared to their counterparts with a baseline CD4 count above 350 cells/mm³. This finding aligns with studies conducted in Uganda (Bulage et al, 2017) and Vietnam (Rangarajan et al, 2016). There is evidence to support the inverse link between CD4 count and viral replication. Stated differently, patients with weakened immune systems and those with low CD4 counts, for example, have higher rates of viral replication than those with better immune systems (WHO, 2016; Okoye et al., 2013). Additionally, individuals with compromised immunity are more susceptible to various opportunistic infections, which contribute to a cycle sustaining both compromised immunity and viral replication (Okoye et al, 2013). Conversely, a low CD4 count may also indicate viral replication caused by treatment interruption (poor adherence) or drug resistance (Xing et al, 2013). Overall, this finding underscores the importance of considering the CD4 count at the start of ART as a predictive factor for viral load suppression. Initiating ART at higher CD4 counts may enhance the chances of achieving and maintaining viral suppression, ultimately leading to better treatment outcomes for individuals with HIV.

TB co-infection at the start of antiretroviral therapy (ART) was a significant factor contributing to virological non-suppression. This finding aligns with similar studies conducted in Haiti (Louis et al, 2018), Cameroon (Zoufaly et al, 2013), and Uganda (Bulage et al, 2017). One possible explanation for this outcome could be the close relationship between HIV and TB, which may exert pressure on the patient's immune system, including a decrease in CD4 cell count. This could potentially accelerate the progression of HIV disease to an advanced stage, delaying regular treatment adherence, and ultimately resulting in viral load non-suppression (Abrams et al, 2013; Kebede et al, 2012).

A possible limitation of this study is that the socio-demographic profile of participants in Samburu East and Samburu Central revealed key differences that may influence viral load non-suppression outcomes.

CHAPTER SIX
CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion

The study revealed a 26.3% prevalence of viral load non-suppression among participants from two sub-counties, signifying a considerable public health concern. This high burden underscores the urgent need for targeted interventions aimed at improving antiretroviral therapy (ART) adherence and achieving viral suppression. The predominance of adult women in their productive age among the participants suggests that HIV programs must be gender- and age-sensitive. Furthermore, late enrollment into care and poor adherence were identified as major contributors to VNS, emphasizing the importance of early HIV diagnosis and continuous treatment support. Encouraging regular participation in support groups also emerged as a promising strategy to mitigate VNS risk and foster better treatment outcomes.

6.2 Recommendations

The Samburu County Health Department, in collaboration with relevant partners, should prioritize a comprehensive approach to address viral load non-suppression by implementing targeted and evidence-based interventions. First, community sensitization initiatives should be scaled up to promote early HIV diagnosis, timely enrollment into care, and consistent follow-ups, particularly among individuals with advanced disease stages. Second, adherence to antiretroviral therapy (ART) must be reinforced by adopting guideline-based strategies, including the use of enhanced adherence calendars or ART registers, supervised daily medication intake, and regular pill counts. Additionally, strengthening peer support groups is essential to foster experience sharing, reduce HIV-related stigma, and enhance patients' motivation and confidence in initiating and sustaining ART. These coordinated efforts are crucial for

improving treatment outcomes and achieving sustained viral suppression in the county. Finally, HIV programs should be tailored to be gender and age-sensitive, with a specific focus on addressing the unique needs of adult women in their productive age.

At the sub-county level, several issues need to be taken into account to mitigate the challenges arising from the two sub-counties. To address these challenges, recommended actions include strengthening adherence counseling and follow-up in both sub-counties, while placing additional emphasis on Samburu East. This involves enhancing case management approaches by using peer support groups, community health volunteers, and differentiated service delivery models to improve treatment outcomes. Expanding access to viral load monitoring and promptly switching patients with confirmed treatment failure to second-line therapy is also critical. Moreover, mobile outreach programs can help bridge the accessibility gap for remote or underserved populations, especially in Samburu East. Strengthening data systems for better tracking of patient outcomes and missed appointments will also support early identification and response to non-suppression.

6.3 Study Limitations and Future Research

This study has some limitations that may affect the accuracy and generalizability of the findings. First, the rate of viral non-suppression may have been underestimated due to the loss to follow-up of some adolescents and adults. The study only considered individuals who had been on ART for six months, potentially overlooking those with irregular adherence. The exclusion of participants from low-volume health facilities could have introduced bias, as such facilities often lack adequate data quality and provider mentorship, which are important for consistent care and accurate reporting. These limitations suggest that the findings may not fully represent all adolescents and young adults receiving ART in Samburu East and Samburu Central sub-counties. In both sub-counties, females made up the majority of participants, which could reflect gender-related disparities in HIV service access or utilization.

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APPENDICES

APPENDIX 1a: CONSENT FORM FOR QUESTIONNAIRE (English version)

Introduction

My name is _____ (mention your names). I am collecting data on behalf of Elias Lentilai, a student at the Moi University in Eldoret. I would like to study the drivers of viral load non-suppression among adolescents (aged 10 - 17 years) and adults (>18 years) at Samburu East and Samburu Central Sub-counties. All information gathered will be used for study purposes and results shared with the Samburu County Government to improve health outcomes for adolescents and adults served by this County. Your identity and the information collected will be kept confidential and used for the purpose of this study only. This interview will take approximately 20 minutes; however, you can freely choose not to take part in the study, this will not affect services delivered to you and you will therefore still receive your services as usual.

Risks: The questions asked in the study are related to positive living with HIV and may cause some emotional discomfort, particularly if you or your family has been negatively affected by the illness.

Benefits: Information obtained from your participation will help us to determine the factors responsible for your success or failure to suppress the virus from multiplying in your blood and therefore inform the healthcare providers about key steps to take to improve your overall treatment outcomes. There is no payment for participating in the research.

Consent: I, the signing participant, certify that I have been informed about the details regarding this survey. I have had a chance to ask questions and my questions were fully answered. I understand the objectives, the procedure and benefits of the study. Also, I was given sufficient time to reflect on the information received. I decide voluntarily to participate in this study. I have been informed that I can revoke my consent at any time without providing justification or consequences. I understand that if I have questions about the study, I can contact the responsible researcher at any time.

*Participant's signature/thumb print*_____ Date: _____

Guardian/Care-taker's signature/thumb print _____Date: _____

Interviewer's signature _____Date: _____

Contact persons: If you have any question regarding this survey, please contact Elias Lentilai, Tel. 0721 842 691, Dr Judith Mangeni, Tel. 0722 647 415, Dr Fredrick Odhiambo, Tel. 0722 390 020..

APPENDIX 1b: CONSENT FORM FOR QUESTIONNAIRE (Samburu version)

Ng'asunoto

Kaji taa nkarna……kaasita anabai tankarake Elias Lentilai yaasita nkisoma enye te University Moi ng'oji Eldoret. Naa kore inia nkisoma naipirita moyanitin naitarasunoi e mbita. Naa kore tana richata ikiyieu nikiyieleu tana kore lolo ng'anayo limatita keret aitodoyio ilo kukuu taatwa lapatin ile anang'asunoto e lolo ng'anayo. Kore tangarake lolo ikigira naa tata aadamu mbaa naipirata asat naaret aitodoyio mpijan e mbiita te nkitoo o lelero. Kaamon naake njooki ldakikani linonoo tikitam maipara naa lomon lopirita anabae.

Lning'o

Naa kore nanu ara lorio sayei, kaisherua lning'o ajo kaatilikaki pooki loipirata anabai. Kaichooki ng'amata naiparua pooki letu adamu naa kaichoki olet tee pooki. Katadamua pooki naayieuni nateyielo sii pooki supati looyeu anabai. Kaichooki ng'amati naitemu paadamu pooki laatilikakaki. Ketejo naa karoyie ajo kejing atwa ana temata. Nene yaata leyieu naiparu katilika namba naosh.

Participant's signature/thumb print_____ Date: _____

Guardian/Care-taker's signature/thumb print _____Date: _____

Interviewer's signature _____Date: _____

Contact persons: Koree tiniata olet niyieu nimparu toosho nabo yoo kuna ambai; Elias Lentilai, Tel. 0721 842 691, Dr Judith Mangeni, Tel. 0722 647 415, Dr Fredrick Odhiambo, Tel. 0722 390 020

APPENDIX 2a: ASSENT FORM (English version)

(To be read aloud to the child)

My name is _____ (mention your names). I am collecting data on behalf of Elias Lentilai, a student at the Moi University in Eldoret. I would like to study the drivers of viral load non-suppression among adolescents (aged 10 - 17 years) and adults (>18 years) at Samburu East and Samburu Central Sub-counties. All information gathered will be used for study purposes and results shared with the Samburu County Government to improve health outcomes for adolescents and adults served by this County. Your identity and the information collected will be kept confidential and used for the purpose of this study only. This interview will take approximately 20 minutes; however, you can freely choose not to take part in the study, this will not affect services delivered to you and you will therefore still receive your services as usual. We are kindly requesting for your participation in this study.

Purpose of study: This study will be looking for factors that are associated with being virally non-suppressed within the first 6 months of ART treatment. This is important because it will help us to know how to improve the number of adolescents who attain viral suppression and improve their health. Information from this study will assist in planning for better care and treatment services for adolescents.

Benefits of participation: The participant will have a chance to ask questions they may have regarding their management and these will be answered. In addition, the information collected will help Samburu County Government to understand how best they can support adolescents on treatment to attain viral suppression and hence better treatment outcomes.

Risks of participation: There are no known risks of you taking part in this study. Refusal to participate will in no way affect your treatment in this hospital.

Freedom of participation: We have permission from your parent/guardian, but we also want to make it clear that you can choose to participate or not, and even if you choose to take part, you can also withdraw from the study at any point if you change your mind.

Procedure: We will ask you a few questions using a questionnaire, and other information will be obtained from your hospital records

Will you agree to take part in this study?

(If the response is “Yes” the child is enrolled for study and if the response is “No” the child is released together with the parent/guardian)

APPENDIX 2b: ASSENT FORM (Samburu version)
Ng'asunoto

Kaji taa nkarna……kaasita anabai tankarake Elias Lentilai yaasita nkisoma enye te University Moi ng'oji Eldoret. Naa kore inia nkisoma naipirita moyanitin naitarasunoi e mbita. Naa kore tana richata ikiyieu nikiyieleu tana kore lolo ng'anayo limatita keret aitodoyio ilo kukuu taatwa lapatin ile anang'asunoto e lolo ng'anayo. Kore tangarake lolo ikigira naa tata aadamu mbaa naipirata asat naaret aitodoyio mpijan e mbiita te nkitoo o lelero. Kaamon naake njooki ldakikani linonoo tikitam maipara naa lomon lopirita anabae.

Lning'o

Naa kore nanu ara lorio sayei, kaisherua lning'o ajo kaatilikaki pooki loipirata anabai. Kaichooki ng'amata naiparua pooki letu adamu naa kaichoki olet tee pooki. Katadamua pooki naayieuni nateyielo sii pooki supati looyeu anabai. Kaichooki ng'amati naitemu paadamu pooki laatilikakaki. Ketejo naa karoyie ajo kejing atwa ana temata. Nene yaata leyieu naiparu katilika namba naosh.

Nkidimat e wolet

Ikitumo naa olet too ltoiwuo linonoo naa ikiyieu naa sii sipat tembata ino tana indim naa nijing atwa kuna temat anaa sii miindim, naa tanaa miindim naaku naa metii nyamali.

Iata sipat ajo indim ninjo iyoo nkamata ina teekuna temat?

(If the response is "Yes" the child is enrolled for study and if the response is "No" the child is released together with the parent/guardian)

APPENDIX 3: DATA ABSTRACTION FORM

Social demographic information

Gender/sex 1. Male 2. Female	**CCC No:** **Facility level/Type**
Date of birth: …../……./20… **Age in completed years** …….	**Marital status** 1. Single ( ) 2. Married ( ) 3. Separated ( ) 4. Divorced ( ) 5. Widow/Widower ( )

Clinical/Immunological information

Date of Diagnosis ……. Date of ART initiation …….	Age at ART initiation…….
CD4 at enrollment……	C4 Current……
WHO Staging at enrollment I ( ) II ( ) III ( ) IV ( )	WHO current stage I ( ) II ( ) III ( ) IV ( )
Viral load at 6 months ……copies/ml	Suppression status Suppressed ( ) Non-suppressed ( )
Clinic appointments attended Good ( ) -If client came as scheduled or before the scheduled date Fair ( ) - If the client came within 3 days after the scheduled date Poor ( ) - If the client came 3 days after the scheduled date LTFP ( ) - if clients does not visit for 90 days months or more	
Opportunistic infection/ other illnesses…….	

APPENDIX 4a: STUDY QUESTIONNAIRE (English version)

Questionnaire

Do you agree to participate in this study? YES ( ) NO ( )

Name of the interviewer_____

Date of investigation _____ _____2021

Patient study ID: _____

Instructions: Please respond to all questions where applicable

Questions:

Do you agree to participate in this study? YES ( ) NO ( )

Name of the interviewer_____

Date of investigation _____ _____2021

Instructions: Please respond to all questions where applicable

Questions:

Q3b. If married, do you have the same HIV status as your partner?

1. Yes ( )
2. No ( )

Q3c. If no for the question above, is your partner aware of your status?

1. Yes ( )
2. No ( )

Q4. What is the highest level of education that you have achieved?

1. Primary ( )
2. Secondary ( )
3. Tertiary ( )
4. None ( )

Q5. What is your occupation?

1. Unemployed ( )
2. Employed ( )
3. Private worker ( )
4. Pastoralist ( )

Q6. What is your religion?

1. Christian ( )
2. Muslim ( )
3. Traditionalist ( )
4. Don't know ( )

1. Yes ( )
2. No ( )

Q7a. Do you have any challenges accessing ARVs?

1. Yes ( )
2. No ( )

Q7b. If yes to the above question (7a), what challenges do you have in accessing ARVs?

1. Distance to the facility ( )
2. Stockouts in the facility ( )
3. Fear due to stigma ( )
4. Any other……

Q9. How much time do you spend going to a health facility?

1. <30 mins
2. 30 – 60 mins ( )
3. 61 – 120 mins ( )
4. >2 hrs ( )

Q10a. In the last 90 days have you missed taking your ARVs?

1.Yes ( )
2. No ( )

Q10b. If yes to the above question, what is the average dose/doses missed in 90 days before your first viral load test?

Missed doses per month	**% of doses taken**	**Adherence rating**
1 dose	≥ 95%	Good
2 – 4 doses	85 – 94%	Fair
≥ 5 doses	< 85%	Poor

Q11. For the days spent without taking drugs, what were the reasons behind it?

1. Severely illness ( )
2. Ignorance ( )
3. Drugs stock out ( )
4. Drugs effect ( )
5. Travelled ( )
6. alcohol effect ( )
7. Lack of Food ( )
8. Use of herbs ( )
9. Unknown reason ( )

Q12. Have you missed clinic visits for the last 3 months?

1. Yes ( )
2. No ( )

Q13.What is the reason for the missed clinics?

1. Being busy ( )
2. Distance to the facility ( )
3. Sickness ( )
4. Don't know ( )
5. Any other……

Q14a. Are you attached to any support group?

1. Yes ( )
2. No ( )

Q14b. If yes to the above question (Q14d), which support group are attached to?

1. Adolescent support group
2. PMTCT
3.

Q15. Have you had an opportunistic infection since the start of ARVs?

1.Yes ( )
2. No ( )

Q16. Have you been pregnant during the first 6 months of ART initiation? (Where applicable)

1. Yes ( )
2. No ( )

Q17a. Do you have any other chronic disease during the first 6 months of ART initiation?

1. Yes ( )
2. No ( )

Q17b. If yes to the above question, which one?

1. Diabetes ( )
2. Cancer ( )
3. Hypertension ( )
4. Renal failure ( )
5. Heart problem ( )
6. Liver failure ( )
7. Other, specify……

Q18. Do you smoke?

1. Yes ( )
2. No ( )

Q19a. Do you take alcohol?

1. Yes ( )
2. No ( )

Q19b. If yes to the above question, how frequent did you take alcohol during the first 6 months of ART treatment?

1. Monthly or less ( )
2. Two to four times a month ( )
3. Two to three times a week ( )
4. Four or more times a week ( )

Q20. Do you have more than one sexual partner?

1. Yes ( )
2. No ( )

Q21. How do you rate ART services for first 6 months of treatment?

1. Good ( )
2. Fair ( )
3. Bad ( )

Q22. Are you comfortable with the days when your appointments are scheduled?

1. Yes ( )
2. No ( )

APPENDIX 4b: STUDY QUESTIONNAIRE (Samburu version)

Kore tiniata olet anaa mbaa naipirita anarishata toosho anaamba pikitumi aatiliki lkumo: Elias Lentilai; 0721 842 691

Q3b. **Amaa tanaaikiemaki/iemishe, kenyunyuk ntae mpukunoto ee mbiita**

1. Kenyunyuk ( )
2. Menyunyuk ( )

Q3c. Amaa tanaa menyinuk ntai mpukunoto ee mbita, keyiolo Lbotei/mboitie ino/lino?

1. Keyiolo ( )
2. Meyielo ( )

Q4. Amaa tenkisoma ino, kebaa naodo nitabayie?

1. Primary ( )
2. Secondary ( )
3. Tertiary ( )
4. None ( )

Q5. Nyo iasita, aashu alo siai iata tenkishon ino?

1. Meata siai ( )
2. Kaata siai ( )
4. Laramatak leesuom ( )

Q6. Leakirukoto ira ?

1. Lenkanisa ( )
2. Silaami ( )
3. Lorere oirukurukore lkereti ( )
4. Don't know ( )

Q7. Larin aja iata peekuruni ajo iata mbita?.....

Q8. Keatai ngolikinoto niimarita nimikinjoibaki ng'oji netumieki lmairo?

1. Ketii ngolot ( )
2. Metii ngolot ( )

Q9. Keatai ngolikinot naaje nimikinjo itum lmairo lembiita?

1. Ketii ngolot ( )
2. Metii ngolot ( )

Q10. Kebaa rishina niya piibaki sipitali

1. Ldakikani eedou tee osom ( )
2. Terchet ldakikani osom o ntomoni ile ( )
3. Saa nabo metabaki saai aare ( )
4. Tekeper saai aare

Q11a. Amaa taatwa mperot ntomoni saal naima keataai mpari nitalang'a etu ima ldawa lembita?

1. Eee ( )
2. Eitu ( )

Q11b. Amaa tanaa keatai nitalang' eitu imat, mberot aja taatwa nana perot ntomoni saal?

1. Mberot 1 – 4 ( )
2. Mberot 5 - 13 ( )
3. Mberot naajol 13 ( )

Q11c. From the information on missed treatment days, what is the adherence status of the clients?

Missed average doses per month	**% medication taken**	**Adherence rating**
1 dose	> 95	Good
2 – 4 doses	85 – 94	Inadequate
> 5 doses	< 85	Poor

Q12. Amaa taatwa mperot nitalanga ilo dawa, nyo nyamali?

1. Itomoyia oleng ( )
2. Lkitarii likishiaka mimat ( )
3. Ldawai eeishunye ( )
4. Ldawai limikining'ore ( )
5. Ng'oji niayie ldawai ibelekenya ( )
6. Itejo inshiwua ( )
7. Mieata olet ( )

Q13a. Amaa taatwa lapatin uni oima keatai mparri nitalang' eitu isabaki clinic?

1. katalang'a ( )
2. Eitu alang' ( )

Q13b. Amaa tanaa keatai, mperot aja?

1. Nabo ( )
2. Arre ( )
3. Mberot naalang' arre ( )

Q13c.Kanyo piitalang'a?

1. Nyamali kitok ( )
2. Tankara ake yankadorr ( )
3. Itomoyia ( )
4. Miyiolo ( )
5. Nyo nkaibai……

Q13d. Ikiretuta dei lmarei lino tana kibisiong niimarita/ niata?

1. Kaaretuta ( )
2. Maaretuta ( )

Q13f. Kaa tururr lereto itii?

1. **Looltungana doropu**
2.

Q14. Keatai nkae moyian nikitumoaepare ana shaake niata embita?

1. Keata ( )
2. Meata ( )

Q15. Itumo shake nutai peeji itangasua aijoo ldawa le mbita taatwa lapitin ile leng'asunoto ee ldawai? (Where applicable)

1. Katumo ( )
2. Eitu atum ( )

Q16a. Keatae shaake nkae moyian niata nitibikie?

1. Keatai ( )
2. Meatai ( )

Q16b. Amaa tenaa keatai, aanabo taatua kuna?

1. Moyian e sikari ( )
2. Nayieng'i ( )
3. Moyian nikikwet lodo ( )
4. Moyian ee lairokuj ( )

5. Moyian eel tau ( )
6. Moyian ee monyua ( )
7. Nyo nkaibai……

Q17. Imat sigara/iosh mpuro?

1. Kamat ( )
2. Mamat ( )

Q18a. Imat ndarpoi?

1. Kamat ( )
2. Mamat ( )

Q18b. Amaa tanaa imat ndarpoi, tanabaa itamata?

1. Tee lapatin ile lootung'ututari ( )
2. Taatwa lapitin 6 - 12 ( )

Q19. Iata sintak?

1. Kaata ( )
2. Maata ( )

Q20. Ikiretuta matata elmairo le mbiita tenkishui ino?

1. Keisupat ( )
2. Keitorno ( )
3. Miata sipat ( )
4. Miatanijo ( )

Q21. Itumoi mperot pookin nikitegelakaki piitumore lkitarii?

1. Katumoi ( )
2. Matumoi ( )

Q22. Ikintipipi dei rishata naya nkitarii pii kutumore?

1. Kanyorr oleng ( )
2. Kanyor ( )
3. Manyor ( )

Q23. Ikintishipa iyie ramat nitumo peeji itang'aswa nkitomoyia tesipitalu etii nkimulmularoto emoyian niata tebata ee lkitarinii ?

1. Kanyorr oleng ( )
2. Kanyor ( )
3. Manyor ( )

APPENDIX 5:IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2021/76
26th July, 2021

Approval Number: 0003932

Elias Nkararo Lentilai,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Mr. Lentilai,

DRIVERS OF VIROLOGICAL NON-SUPPRESSION AMONG ADOLESCENTS AND ADULTS ON ANTIRETROVIRAL THERAPY IN SAMBURU EAST AND SAMBURU WEST SUB-COUNTIES, KENYA

This is to inform you that ***MTRH/MU-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN: 0003932.*** The approval period is ***26th July, 2021- 25th July, 2022.***
This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MTRH/MU-IREC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MTRH/MU-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MTRH/MU-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from ***MOH at the recommendation of NACOSTI*** for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MTRH/MU-IREC.***

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.

Sincerely,

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
26 JUL 2021
APPROVED
P.O. Box 4606-30100 ELDORET

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

APPENDIX 6:NACOSTI Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **696977**

Date of Issue: **24/August/2021**

RESEARCH LICENSE

This is to Certify that Mr.. Elias Nkararo Lentilai of Moi University, has been licensed to conduct research in Samburu on the topic: Drivers of Virological Non-Suppression among Adolescents and Adults on Antiretroviral Therapy in Samburu East and Samburu West Sub-Counties, Kenya for the period ending : 24/August/2022.

License No: **NACOSTI/P/21/12521**

696977

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

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