

FACTORS ASSOCIATED WITH HIV RNA VIRAL NON-SUPPRESSION AMONG CHILDREN AND ADOLESCENTS LIVING WITH HIV ATTENDING PUBLIC HEALTH FACILITIES IN GULU CITY, UGANDA

VENTRINA LANYERO, MBChB

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DECLARATION

I VENTRINA LANYERO do declare to the best of my knowledge that this dissertation that I am submitting to the Institute of Research and Graduate Studies in partial fulfillment of the requirement for the award of a Master of Public Health Degree of Gulu University is my own and has not been submitted to any other university or institute for any other award whatsoever.

Name: VENTRINA LANYERO

Signature.....

Date.....17th November 2026.....

APPROVAL

This dissertation has been written under our supervision and is ready for submission.

1. Dr. Emmanuel Ochola, MBChB MSc

Signature..... Date..17/4/2025

2. Dr. Felix Bongomin, MB ChB, MSc, MMed, FECMM

Signature..... Date..17/11/2025

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OPERATIONAL DEFINITIONS

HIV RNA viral non-suppression: Viral load copies greater or equals to 1,000 copies/ml of blood after at least 6 months of antiretroviral therapy in a treatment naïve patient.

HIV RNA viral suppression: Viral load copies less than 1,000 copies/ml of blood.

A Child: A person 0 to 9 years of age.

An Adolescent: A person 10 to 19 years of age.

Treatment Naïve: Children and Adolescents with HIV who have never been on antiretroviral drugs.

Antiretroviral therapy: A combination of drugs that treat people infected with HIV.

Factors Associated: according to this study, this meant a situation that influences the result/outcome.

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LIST OF ABBREVIATIONS

ART	Antiretroviral Therapy
CAWH	Children and Adolescents with HIV
CCM	Cryptococcal Meningitis
CD4	CD4 T Lymphocytes
CPHL	Central Public Health Laboratory
HC	Health Center
HIV	Human Immunodeficiency Virus
JCRC	Joint Clinical Research Center
RNA	Ribonucleic Acid
SOPs	Standard Operating Procedure
TB	Tuberculosis
UNAIDS	Joint United Nations Program for HIV and AIDS
VL	Viral Load
WHO	World Health Organization
FBIM	Facility Based Individual Management
FBG	Facility Based Group
FTDR	Fast Track Drug Refill
CDDP	Community Drug Distribution Point
CCLAD	Community Client Led ART Distribution

ABSTRACT

Background: Viral load testing is the gold standard for anti-retroviral therapy (ART) monitoring. Achieving viral suppression is central to abating HIV complication. Evidence suggests that children and adolescents with HIV (CAWH) have much lower viral load suppression rates. However, data on the incidence of viral load non-suppression and its associated factors among CAWH in Northern Uganda is scarce.

Objective: To assess the factors associated with HIV RNA viral load non-suppression among CAWH in Gulu city, Uganda.

Methods: A retrospective cohort study, utilizing a data abstraction tool to collect information on HIV RNA viral load non suppression at 6, 12, 18, 24 months and at the latest follow-up among 218 CAWH at public facilities in Gulu city. Bivariate and multivariate Cox proportional hazards models were used to identify the factors associated with viral load non suppression. Hazard ratio with 95% CI and p-value were used to assess the strength and statistical significance of association.

Results: The median age of the 218 participants was 12.5 (IQR: 7-18) years and majority (70.2%, n=153) were female. A total of 99 (45.4%) had viral load non-suppression during the follow-up period. The overall incidence rate of HIV viral load non suppression was 10.3 cases per 100 person-years and the median time to viral load non-suppression was 0.49 years. Age<5 years [Adjusted Hazard Ratio (aHR)]:2.59; 95% CI: 1.30-5.17), poor adherence to ART (aHR:1.96; 95% CI: 1.21-3.17), non-disclosure (aHR:2.19; 95% CI: 1.27-3.80), late WHO clinical stage (Stage III and IV) (aHR:3.07; 95% CI: 1.41-6.69), and having economic challenges (aHR:2.13; 95% CI: 1.32-3.42) were significantly associated with viral non suppression.

Conclusion: HIV viral load non suppression among CAWH was high. The time to non-viral load suppression after ART initiation was 6months. Age less than five years, poor adherence to ART, non-disclosure of HIV status, advanced WHO clinical stage, and having economic challenges were associated with viral non suppression. There is need for continuous adherence monitoring and economic empowerment of caregivers of CAWH, with more attention given to children under five years.

Keywords: HIV, ART, Viral load, Non-suppression, Children and Adolescents, Uganda

CHAPTER ONE: INTRODUCTION

1:1 Background

Globally, HIV remains a major public health burden that has claimed over 40 million lives with new infections emerging across all countries in the world (World Health Organization, 2015). Some countries with previously low case detection have demonstrated increasing trends of new infections (Haris & Abbas, 2024). Approximately, 38 million people were estimated to be living with HIV, of which two thirds are in African countries (Amuche, Emmanuel, & Innocent, 2017). Eastern and Southern Africa are the most affected regions with over 20 million people affected, which contributes to about 54% of all people living with HIV in the world (Parker et al., 2021). In December 2020, the Joint United Nations Programs on HIV/AIDS (UNAIDS) released a set of ambitious targets calling for 95% of all people with HIV(PWH) to know their HIV status, 95% of all people with diagnosed HIV infection to receive sustained antiretroviral therapy, and 95% of all people receiving antiretroviral therapy to have viral suppression by 2025 (UNAIDS, 2022).

Periodic viral load testing is the gold standard for HIV monitoring, the most accurate way to determining whether anti- retroviral drug is suppressing HIV viral replication (World Health Organisation, 2016). Achieving viral suppression (VS) protects the body's immune system, helps PWH stay healthy and prevents transmission of HIV to other people (World Health Organisation, 2023). However, a non-suppressed viral load suggests treatment provision needs attention, including offering adherence support such as community-based adherence support services (World Health Organisation, 2016). Adult, children and adolescents who are newly initiated on ART should have a viral load test done at month 6 and month 12 and thereafter, they should access viral load test 6 monthly (World Health Organisation, 2016). Globally, the proportion of children and adolescents with viral suppression was 78%, 72% and 65% at one, two and 3years respectively after ART initiation (Han et al., 2021). Viral suppression amongst children in low- and middle-income countries (LMIC) after 6months on first line ART initiation, a pooled proportion of 62.2% in the early, 74.3% in the intermediate and 80.9% in the study period (Boerma et al., 2017). After 12 months, 64.7% of the children in the early, 74.2% in the intermediate and 72.7% in the study period had viral suppression (Boerma et al., 2017).

In Uganda, HIV viral load testing and viral suppression rates among children and adolescents remain suboptimal despite improvements in viral load coverage, with over 30 percent of young adolescents and nearly half of the adolescents did not access viral load test in 2017 (Natukunda,

Kirabira, Ong, Shibanuma, & Jimba, 2019). Unfortunately, VS rates did not even reach 75% for adolescents who had viral load test done; far much below the target of 95% (Natukunda et al., 2019).

Studies have revealed several factors including Age, being male, age 16-19years, Education level, duration on ART therapy, WHO clinical staging 2, Second line ART regimen and presence of comorbidities, treatment failures, and repeat testing after suspected failure (Bulage et al., 2017; Maena et al., 2021; Nabukeera, Kagaayi, Makumbi, Mugerwa, & Matovu, 2021; Nanyeenya et al., 2024). However, data on the proportion and factors associated with HIV RNA Viral non-suppression amongst children and Adolescents is still low in our setting. Therefore, this study aimed to assess the incidence of HIV RNA Viral non-suppression and its associated factors among CAWH at public health facilities in Gulu city, Uganda.

1.2 Problem statement

Despite receiving antiretroviral therapy (ART), CAWH across the globe experience substantial AIDS related mortality and morbidity (A. L. Slogrove & Sohn, 2018). HIV associated mortality was the 8th leading cause of adolescent death globally and the 4th leading cause in low- and middle-income countries (LMIC) (Amy L Slogrove, Mahy, Armstrong, & Davies, 2017). The high mortality rate may be due to part in low level of ART adherence that is associated with viral non-suppression. In Uganda, there are about 95,000 CAWH, out of those on ART, approximately 60% have viral non-suppression compared to the adults. (Musiime-Mwase et al., 2024). This falls short of the expected 95% UNAIDS target (Frescura et al., 2022). Compared to the Adult clients in care, viral non-suppression is much higher among children and adolescents (Ministry of Health, 2018). Establishing viral non-suppression among Adolescents is critical for timely detection of treatment failures (Bulage et al., 2017)**.** This study therefore aims to determine the incidence and factors associated with viral non-suppression among children and adolescents living with HIV attending care at Public health facilities in Gulu city. There is paucity of data on viral non-suppression in public health facilities and yet majority of rural population receive care from public health facilities.

1.3 Justification

Viral non-suppression remains a problem among children and adolescents 0-19 years of age. There exists a huge gap in viral suppression among children, adolescents and adults living with HIV in care, more in Northern Uganda as compared to other regions in Uganda (Odongo et al., 2023). However, there has been no specific study conducted to ascertain the exact prevalence

and factors associated with viral non-suppression among children and adolescents living with HIV in northern Uganda, Acholi subregion. Most of the clients living with HIV are vulnerable, living in remote places and mostly access services from public facilities at no additional fee.

Knowing the Proportion of children and Adolescents with HIV RNA Viral non- suppression will aid in ensuring their clinical care processes are well streamlined, coordinated and treatment failures are detected early. Information on the factors associated with HIV RNA Viral non-suppression will help to mitigate the challenges, aid in development of a framework for policy makers to adapt and implement, appropriation of resources to address the keychallenges and close the gaps associated with viral non-suppression hence increasing viral suppression amongst children and Adolescents. It will as well provide basic knowledge for other studies in the areas of HIV RNAViral non-suppression.

1.4 Research questions

1. What is the incidence of HIV RNA viral non-suppression among CAWH attending care at Public Health facilities in Gulu City, Uganda?
2. What are the factors associated HIV RNA viral non-suppression among CAWH attending care at Public Health facilities in Gulu City, Uganda?

1.5 General objective

To determine the incidence of HIV RNA Viral non-suppression and its associated factors among CAWH attending care at Public Health Facilities in Gulu City, Uganda.

1.6 Specific objectives

1. To assess the incidence of HIV RNA viral non-suppression among CAWH attending care at Public Health facilities in GuluCity, Uganda.
2. To determine the factors associated with HIV RNA viral non-suppression among CAWH at Public Health facilities in Gulu City, Uganda.

1.7 Conceptual Framework

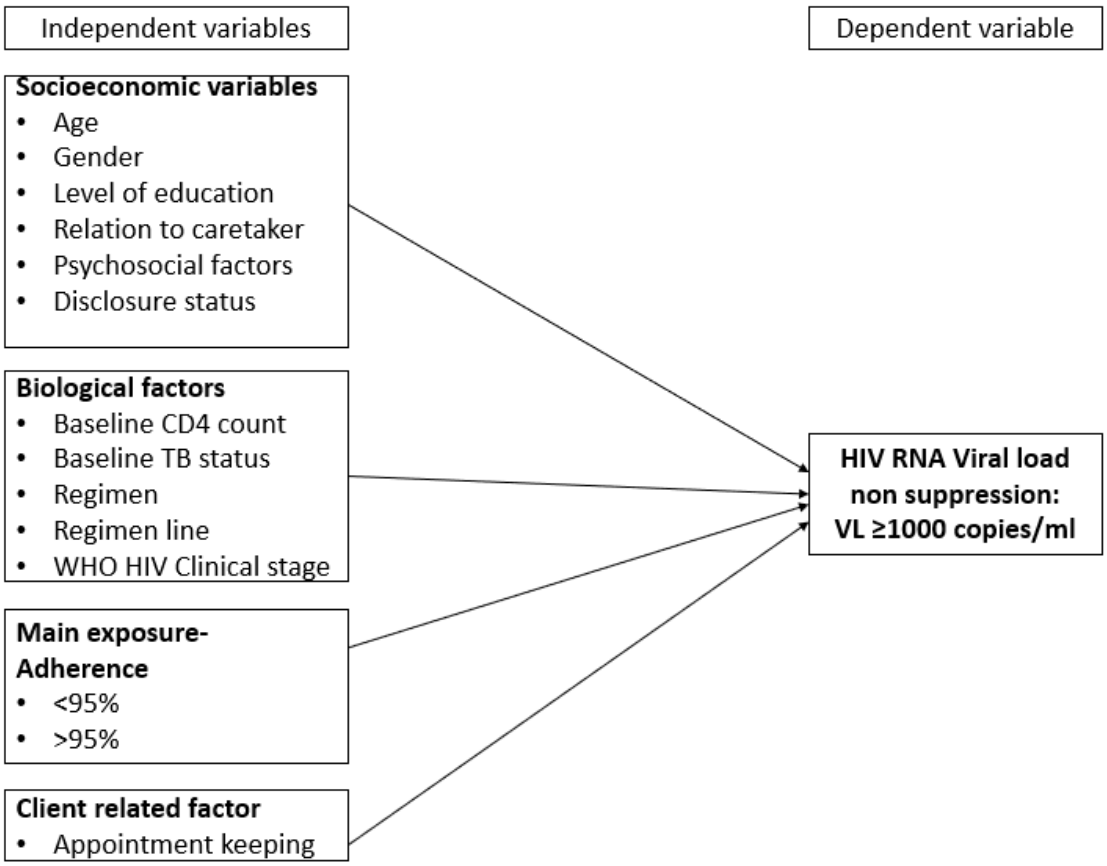


Figure 1: Conceptual framework

There are many noticeable factors that are directly or indirectly associated with HIV RNA viral non-suppression among children and adolescents living with HIV. These can be categorized into socioeconomic factors which include age, gender, level of education, caretaker relationship with child or adolescent, disclosure status and psychosocial factors; Biological factors which include baseline CD4, Initial Viral load test results at 6months post initiation, duration on ART and regimen line; medical related factors which include WHO clinical staging and Presence of comorbidities; adherence on ART which can either be <95% or >95%.

1.7 Hypothesis

CAWH with poor adherence, non-disclosure of HIV status, WHO clinical stage III and IV are more likely to have viral non suppression.

CHAPTER TWO: LITERATURE REVIEW

2.1 Global burden of pediatric HIV

Despite significant progress in the global HIV response, children and adolescents remain highly affected by the epidemic (UNICEF, 2024). Globally, about 40.0 million people were estimated to be living with HIV, of which 2.38 million were children aged 0-19 (UNICEF, 2024). Progress in reduction of new infection amongst children under 5 has stagnated in recent years. Over 250,000 new HIV infections and 90,000 AIDS related deaths were observed among children and adolescents in 2021 (UNAIDS, 2023). Children infected and affected by HIV in sub-Saharan Africa face a lot of challenges including limited access to pediatric HIV services, delay in making a diagnosis, limited infant feeding choices, malnutrition, delay in disclosure, treatment failure and limited ART regimen (Ubesie, 2012).

The prevalence of HIV among children aged 0-14 is 0.5% which corresponds to approximately 95,000 children living with HIV in Uganda (Uganda Population Based HIV Impact Assessment Report, 2017). Further, the prevalence is four times higher among females 15-19 years of age compared to the males (Uganda Population Based HIV Impact Assessment Report, 2017). Two thirds of all new HIV infection are found in adolescent girls in Uganda (UNAIDS, 2023). Some of the key predisposing factors include gender inequality making it difficult for the girls to initiate safe sexual practices, transactional and cross generation sex (Kyegombe et al., 2020). There exists a huge gap between the children, adolescents and adults in access to HIV care and treatment services

2.2 Incidence of HIV RNA Viral non-suppression

The incidence of HIV RNA Viral non-suppression among children and adolescents varies across different settings. A study by Boerma *et al* revealed a viral load non suppression rate of 6.7 (95% CI 4.9–9.1) per 100 person-years among children in Sub-Saharan Africa and 8.9 (95% CI 7.4–10.6) per 100 persons-years in Asia (Boerma et al., 2017). In a retrospective study conducted among children and adolescent HIV care clinics in Tabora Tanzania, the overall rate of viral load non-suppression was 1.38 per 100 person-months (PM) of observation, with higher rates observed among males (1.7 per 100 PM) compared to females (1.1 per 100 PM), and among those not in school (2.9 per 100 PM) versus those with a diploma (2.3 per 100 PM). VL non-suppression rates were 1.1 per 100 PM for primary school attendees and 0.5 per 100 PM for secondary school attendees. Additionally, non-suppression was more prevalent among those without tuberculosis (2.8 per 100 PM) compared to those with it (1.4 per 100 PM), and those on a second-line ART regimen (6.3 per 100 PM) versus a first-line regimen (1.3 per 100 PM).

Further, non-suppression rates for those on LPV/r-based regimens were 2.1 per 100 PM and overall, 32.8% of CAWH had virologic non-suppression (Mchomvu, Hussein, & Matee, 2022). In Uganda, a study by Mwase et al showed an incidence rate viral load non suppression among CAWH of 3.9 per 100 person-years (Musiime-Mwase et al., 2024).

Children and adolescents have much lower viral load suppression rates. In Uganda, viral load coverage for children living with HIV below 15years of age has doubled over 3 years with a viral suppression rate of 70% (Gordon, Talbert, Mugisha, & Herbert, 2022). Additionally, about 68% of young adolescents and 54% of older adolescents accessed viral load test in 2017 with suppression rates at 73% and 72% respectively (Gordon et al., 2022). Thus, viral suppression rates have remained suboptimal. The proportion of children (0-14years) living with HIV receiving ART who had a non-suppressed viral load after 6months of ART at the Pediatric HIV/AIDS clinic at JCRC was 23% (Nabukeera et al., 2021).

2.3 Factors associated with viral non-suppression among children andAdolescents living with HIV on ART

2.3.1 Age

A cross-sectional study conducted in Cambodia showed that the proportions of Adolescents having viral load >1000 copies/ml was significantly higher among adolescents receiving HIV care in an adult clinic compared to those receiving carein the pediatric clinic (38.3% vs 16%). Several other studies have also revealed that being an adolescent is associated with viral load non-suppression (Chhim et al., 2018; Nabukeera et al., 2021).

2.3.2 Sex

A cross sectional analysis done in Malawi showed that gender differences did exist with more males (47%) being non-suppressed than females (D. Umar et al., 2020). Females were 2.5 times more likely to have viral non-suppression compared to when compared with male study participants (Afrane et al., 2021) and another cross sectional study conducted in Eastern Uganda showed that the proportion ofmale children with non-suppressed viral load was slightly higher than that of female children (Maena et al., 2021).

2.3.3 Advanced HIV disease

There is a strong association of advanced HIV disease and viral non-suppression. Across-sectional analysis done in Ghana showed that children who had severe CD4 immune

suppression at recruitment was 25 times more likely to have viral none suppression compared to those with CD4 within normal range. Participants with prior history of TB were more likely to have viral non-suppression (Afrane et al., 2021). A retrospective cohort study conducted at JCRC Lubowa in Kampala, Uganda showed that being at WHO clinical stage 3 and stage 4 at baseline was highly associated with viral non-suppression.80% of children in WHO stage 4 had a non-suppressed viral load at 6months of treatment (Nabukeera et al., 2021). Being in WHO clinical stage 4 was a high predictor of viral non-suppression A retrospective study conducted in Tabora, Tanzania showed the major characteristics among those with viral non-suppression were; TB/HIV coinfection,WHO stage 3 (Mchomvu et al., 2022).

2.3.4 Adherence

Adherence on ART is a main exposure to viral non-suppression. Adherence can be measured as Good (> or equals 95%), Fair (94% to > or equals 85%) and Poor (<85%). In a retrospective chart review analysis conducted at Kitebi, Kawala and Kisenyi health centres in Kampala, 100% of all the adolescents who were virallysuppressed had good ART adherence levels (Kansiime & Gwokyalya, 2022). The proportion of HIV positive children on ART who had non-suppressed viral loadafter 6months was higher in children with adherence levels of 84%-94% (Nabukeera et al., 2021).

2.3.5 ART regimen line

A child or adolescent can either be on first, second- or third-line ART regimen. The decision to switch a client from one regimen line to another is based on the treatment outcome: virologic, immunological, or clinical. A descriptive cross-sectional study conducted using routinely collected program data from viral load samples collected across the country for testing at the CentralPublic Health Laboratory (CPHL) in Uganda showed that being on second- or third-line ART regimen protected patients against viral non-suppression (Bulage et al., 2017). In a retrospective study conducted in Tabora Tanzania, the proportion of viral non-suppression among those on second line ART regimen was higher compared to those on first line ART regimen (Mchomvu et al., 2022). Patients on third line ART regimen are least likely to have viral load non-suppression compared to their counter parts on 1st and 2nd line Regimen (van Wyk & Roomaney, 2024)

2.3.6 Appointment keeping

Clients in care are expected to keep their scheduled clinic appointment days as per recommendation of the reviewing clinician to promptly access required services and as well clinical review which highly contributes to good clinical outcome. An inductive qualitative study conducted in Ethiopia noted that fear of going to the hospital alone or having problems with transportation money were describedas reasons for missing appointment. The adolescents felt overwhelmed by their problems and lacked patience to follow treatment adherence and retention in care properly and sometimes skipped their appointment day (Tunje, Jerene, & Kristensson Hallström, 2021). A retrospective study conducted in Mbita county hospital in Kenya showed a decline in viral suppression rates with increasing months of missed appointment (Omoto, 2023)

2.3.7 Level of education

In a retrospective descriptive cross-sectional study conducted among people living with HIV attending care at a medical Centre in Nigeria, subjects with formal education had a significant viral load suppression compared to those who lacked formal education (Abdullahi et al., 2021).

2.4 Research gaps

The studies cited were mostly conducted in Cambodia, Ghana, Malawi, Tanzania, Ethiopia and those cited from Uganda were conducted in Central and Eastern Uganda. Northern Region: Acholi subregion still has a huge burden of viral load non- suppression among children and Adolescents living with HIV. The results of previous studies may not be representative of Viral non-suppression among the target population. Most studies conducted were either focused on children 0 -14 years or adolescents 15 -24 years of age and adults. Very few of the studies concentrated on the age bracket 0-19years. The studies cited did not comprehensively exhaust the factors associated with viral non-suppression which this study intends to do.

CHAPTER THREE: METHODS

3.1 Study design

A retrospective cohort study design (January 2018 to September 2022) through review of medical records to establish the incidence of viral load non-suppression and associated factors among children and adolescents (0-19 years) living with HIV receiving ART. The follow up of participants for a given period of time enables the assessment of the incidence of the viral load non suppression.

3.2 Study setting

This study was conducted at all public health facilities offering comprehensive HIV prevention, care and treatment services in Gulu city, Northern Uganda. The selected facilities include Gulu Regional Refferal Hospital, Aywee HC3, Bardege HC3, Laroo HC3,Layibi Techo HC3 and Gulu Police HC3. Within the study period, Gulu RRH, Aywee HC3, Bardege HC3, Layibi Techo HC3, Laroo HC3, Gulu Polic HC3 enrolled into care about 159, 24, 36, 21, 20 and 12 children and adolescents respectively. Gulu Regional Referral Hospital is a high-volume health facility and a referral point with an ART clinic that is fully operational weekly from Monday to Friday Tuesday as a special clinic day for children and Adolescents. The other public health facilities operate ART clinic on selected days in the week. There are dedicated health workers; medical officers, clinical officers, nurses, laboratory technicians, counsellors and community health workers among others. The health workers attached to these clinics have received comprehensive training in the HIV RNA Viral load monitoring.

Study population

Records of Children and Adolescents (0-19 years of age) living with HIV receiving comprehensive HIV care and treatment services at Public Healthfacilities in Gulu city, enrolled between January 2018 and September 2022 to get at least 2 years of follow up.

Eligibility Criteria

3.2.1 Inclusion criteria

1. Children and Adolescents (0-19years of age) in care who were enrolled between January 2018 and September 2022.

2. Treatment naïve children and adolescents initiated on first-line ART

3. Treatment follow-up of at least 6 months

3.4.2 Exclusion criteria

CAWH with missing viral loads and/or missing 75% of predefined variables in the data abstraction sheet.

CAWH transferred in from other facilities

3.5 Sample Size Estimation

Sample size was estimated using Cochran's Modified Formula for Finite Populations

$$n = \frac{n_0}{1+\frac{n0-1}{N}}$$

Where; n_0: Cochran's sample size computed using the formula for ideal sample size;

N: the size of the population

$$n = \frac{385}{1+\frac{385-1}{503}}$$

n = 218 participants

Figure 2 is a flow chart of the study participants, a total of 218 participants were enrolled. Their distribution per facility was as follows: Gulu Regional Refferal Hospital (n=136), Aywee HC3 (n=17), Bardege HC3 (n=32), Laroo HC3 (n=12), Layibi Techo HC3 (n=15) and Gulu Police HC3 (n=6).

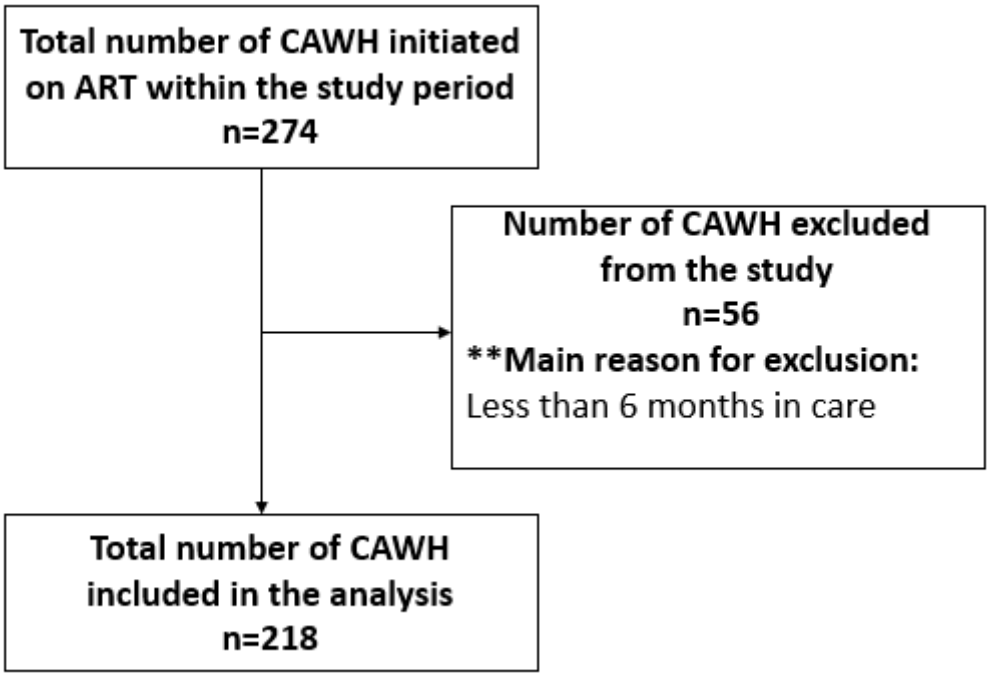


Figure 2: Flow chart of the study participants

3.6 Sampling

The children and adolescents for the study were selected from the Electronic Medical Records or ART register using consecutive sampling.

3.7 Data abstraction

During the study period, the research assistant would go to the ART clinic, work with the technical team in the clinic to retrieve client files under study and extract the needed information as per the data abstraction tool (Appendix 1). Data were abstracted from the following sources: client treatment Files, PreART register and Uganda Electronic Medical Records (EMR).

3.8 Study variables

3.8.1 Dependent variable

The dependent variable was viral load non-suppression defined as a viral load count ≥1,000 copies/ml of blood.

3.8.2 Independent variables

Socio-demographic factors: Age, sex, education status, district of residence, relationship of treatment supporter to client, and care entry point, disclosure status, psychosocial factors

Clinical factors: Baseline CD4 count, Baseline WHO clinical stage, Baseline TB status, Side

effects of ART, Hepatitis B status, DSDM Approach, Regimen line, ART regimen.

3.9 Data management

Data collected were entered using an electronic form designed in Kobo Toolbox (Cambridge, Massachusetts, USA). KoBo Toolbox is an open-source software developed by the Harvard Humanitarian Initiative with support from United Nations agencies, CISCO, and partners to support data management by researchers and humanitarian organizations. The servers are secure and encrypted with strong safeguards and protection against data loss. Only investigators had access to the data. On a daily basis, the principal investigator checked the data for completeness. Data were downloaded from Kobo Toolbox in an Excel format.

3.10 Data analysis

Data downloaded from Kobo Toolbox were exported into Stata version 18.0 for cleaning and analysis. Categorical variables were summarized as proportions and continuous variables as mean and standard deviation for parametric variables or median and interquartile range (IQR) for non-parametric variables. The incidence rate of viral load non suppression was calculated per 100 person-years of follow-up. Time to viral load non suppression was computed from the date of ART initiation to the time the event occurred (first viral load non suppression). Bivariate and multivariate Cox proportional hazards models were used to assess the association between viral load non suppression and participant characteristics. Variables with a p-value less than 0.2 at bivariate analysis were included in the final multivariate model. We adjusted for potential confounders including disclosure status and psychosocial factors. Hazard ratio with 95% CI and p-value were used to assess the strength of association and statistical significance.

3.11 Ethical considerations

Ethical approval and a waiver of informed consent were obtained from Gulu University Research and Ethics committee (GUREC) since only records of participants undy study were reviewed and there was no physical interaction. Permission to conduct the study was sought from Gulu City Health Officer and Gulu Regional Referral Hospital Research and Ethics committee. Permission to conduct the study was also sought from the facility incharges of public facilities under the study before starting the data abstraction process. Confidentiality of the participants information was maintained.

CHAPTER FOUR: RESULTS

4.1 Sociodemographic characteristics

A total of 218 medical records were included in the analysis. The median age of participants was 12.5 years (IQR: 7 to 18 years). Majority (70.2%) of the study participants were female and 158 (72.5%) reported mother as their treatment supporter. Amongst those aged 5 to 19 years, 139 (70.9%) were in school (Table 1).

Table 1: Sociodemographic characteristics of the participants

Characteristic (n=218)	Frequency (n)	Percentage (%)
Age in years	12.5	
<5	22	10.1
5 to 9	60	27.5
10 to 19	136	62.4
Sex		
1. Female	153	70.2
2. Male	65	29.8
In school (5-19 years)		
1. Yes	139	70.9
2. No	57	29.1
District		
1. Gulu city	175	80.3
2. Omoro	15	6.9
3. Nwoya	4	1.8
4. Gulu district	19	8.7
5. Other*	5	2.3
Relationship of treatment supporter to index client		
1. Mother	158	72.5
2. Father	19	8.7
4. Grand parent	10	4.6
5. Sibling	6	2.8
6. Other**	25	11.5
Care entry point		
1. Out Patient Department (OPD)	84	38.5
2. ART Clinic	75	34.4
3. MCH	41	18.8
4. Community	2	0.9
5. Other***	16	7.3
Disclosure status		
Yes	165	75.7
No	53	24.3
Psychosocial factors		
Economic challenges	63	28.9
Food insecurity	5	26.1

Anger	11	5.0
Fear	9	4.1
Stigma	8	3.7
Stress	8	3.7
Dysfunctional family	9	4.1
Others[#]	18	8.3

*Amuru, Masindi, Pader,Omoro

**Aunt, friend, husband, spouse, boyfriend, step mother, mother-in-law, wife, watoto

***Acute care clinic, Adolescents clinic, Inpatient department, Nutrition, Outreach

#Non-disclosure, pill burden, denial, spiritual issues, long distances

4.2 Clinical characteristics of the participants

At baseline, most participants (86.2%, n=188) were in WHO clinical stage I, 77.1% (n=168) were under Facility Based Individual Management (FBIM) approach under the Differentiated Service Delivery Model (DSDM). Baseline median CD4 cell count of the participants was 365 (200-641). Fifty-three participants (24.3%) had not been disclosed to their HIV status. Regarding psychosocial factors, 28.9%(n=63) had economic challenges and 26.1%(n=57) faced food insecurity. During the follow-up period, 47 participants were transferred out, 12 dropped and 19 lost to follow-up. Details are in Table 2.

Table 2: Clinical characteristics of the participants

Characteristic	**At Baseline n=218 n (%)**	**At 6 months n=218 n (%)**	**At 12 months n=197 n (%)**	**At 18 months n=181 n (%)**	**At 24 months n=166 n (%)**	**Current n=152 n (%)**
WHO Clinical staging						
I	188 (86.2)	207 (94.9)	193 (91.9)	175 (96.7)	164 (98.8)	151 (99.3)
II	16 (7.3)	5 (2.3)	3 (1.5)	4 (2.2)	1 (0.6)	0 (0.0)
III	12 (5.5)	6 (2.8)	1 (0.5)	2 (1.1)	1 (0.6)	1 (0.7)
VI	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TB status						
Yes	5 (2.3)	7 (3.2)	2 (1.0)	2 (1.1)	2 (1.2)	1 (0.7)
No	206 (94.5)	209 (95.9)	195 (99.0)	179 (98.9)	164 (98.8)	151 (99.3)
Presumed	7 (3.2)	2 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Advanced HIV disease status						
No	195 (89.4)	208 (95.4)	192 (97.5)	177 (97.8)	163 (98.2)	150 (98.7)
Yes	23 (10.6)	10 (4.6)	5 (2.5)	4 (2.2)	3 (1.8)	2 (1.3)
Side effects of ART at baseline						
Yes	1 (0.5)	1 (0.5)	1 (0.6)	0 (0.0)	1 (0.7)	1 (0.8)
No	196 (99.5)	196 (99.5)	175 (99.4)	160 (100.0)	144 (99.3)	130 (99.2)

Hepatitis B status						
Yes	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
No	7 (3.2)	14 (6.4)	11 (5.6)	13 (7.2)	16 (9.6)	12 (7.9)
Unknown	210 (96.3)	204 (93.6)	186 (94.4)	168 (92.8)	150 (90.4)	140 (92.1)
DSDM Approach						
FBIM	168 (77.1)	170 (78.0)	138 (70.1)	110 (60.8)	100 (60.2)	93 (61.2)
FTDR	2 (0.9)	7 (3.2)	17 (8.6)	24 (13.2)	23 (13.9)	29 (19.1)
FBG	48 (22.0)	41 (18.8)	41 (20.8)	41 (22.6)	35 (21.1)	20 (13.2)
CDDP	0 (0.0)	0 (0.0)	1 (0.5)	4 (2.2)	6 (3.6)	9 (5.9)
CCLAD	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	2 (1.2)	1 (0.7)
Client status						
Active	218 (100.0)	197 (90.4)	181 (91.9)	166 (91.7)	151 (91.0)	140 (92.1)
Missed	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Loss to follow up	0 (0.0)	6 (2.8)	4 (2.0)	2 (1.1)	5 (3.0)	2 (1.3)
Dropped	0 (0.0)	1 (0.5)	3 (1.5)	1 (0.6)	4 (2.4)	3 (2.0)
Transferred out	0 (0.0)	14 (6.4)	8 (4.1)	12 (6.6)	6 (3.6)	7 (4.6)
ART regimen						
TDF/3TC/DTG	47 (23.9)	63 (28.9)	69 (39.2)	66 (41.2)	67 (46.2)	63 (48.1)
ABC/3TC/DTG	27 (13.7)	44 (20.2)	41 (23.3)	47 (29.4)	56 (38.6)	67 (51.1)
ABC/3TC/LPVr	52 (26.4)	51 (23.4)	40 (22.7)	32 (20.0)	20 (13.8)	0 (0.0)
AZT/3TC/LPVr	2 (1.0)	2 (0.9)	1 (0.6)	2 (1.2)	0 (0.0)	0 (0.0)
TDF/3TC/ATVr	1 (0.5)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ABC/3TC/ATVr	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TDF/3TC/LPVr	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Other	68 (34.5)	56 (25.7)	25 (14.2)	13 (8.1)	1 (0.7)	1 (0.8)
Regimen Line						
First Line	218 (100)	217 (99.5)	196 (99.5)	181 (100.0)	166 (100.0)	151 (99.3)
Second Line	0 (0.0)	1 (0.5)	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.7)
CD4testresult	N=65	N=20	N=15	N=12	N=14	N=5
Median (IQR)	365 (200-641)	828 (534.5-996)	791 (640-1286)	706 (382.5-952.5)	888 (601-1053)	607 (555-860)
<200	6 (9.2)	0 (0.0)	0 (0.0)	2 (16.7)	1 (7.1)	1 (20.0)
>200	59 (90.8)	20 (100.0)	15 (100.0)	10 (83.3)	13 (92.9)	4 (80.0)
Adherence						
>95% (Good)	N/A	188 (86.2)	167 (84.8)	151 (83.4)	147 (88.6)	
<95%- 85% (Fair)		19 (8.7)	23 (11.7)	23 (12.7)	12 (7.2)	
<85%(Poor)		11 (5.0)	7 (3.6)	7 (3.9)	7 (4.2)	
Evidence of IAC						
Yes	0 (0.0)	44 (20.2)	39 (19.8)	23 (12.7)	30 (18.1)	22 (14.5)
No	0 (0.0)	9 (4.1)	8 (4.1)	7 (3.9)	8 (4.8)	11 (7.2)
N/A	218 (100.0)	165 (75.7)	150 (76.1)	151 (83.4)	128 (77.1)	119 (78.3)

4.3 HIV viral load non suppression among children and adolescents on ART in Northern Uganda

Two hundred eighteen participants were followed up, the median follow-up time was 4.5 (3.3-5.6) years, and the total person-time observation was 958.8 person-years. During the study period, 45.4% (n=99) had a non-suppressed viral load. At 6 months, viral load non suppression was 22.9%, decreased to 14.4% at 18 months, increased to 19.3% at 24 months, and then dropped to 15.1% at the latest follow-up. The overall incidence rate of HIV viral load non suppression was 10.3 (95% CI: 8.5-12.6) per 100 person years after ART treatment initiation. The median time to viral load non suppression was 0.49 years (95% CI: 0.49-0.98). This is shown in figure 3 and figure 4

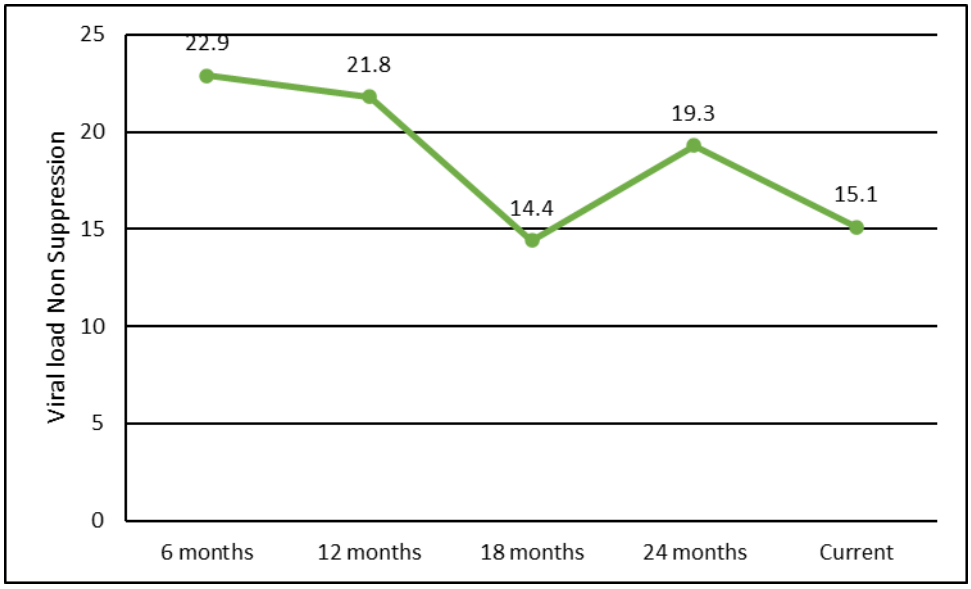


Figure 3: Trends in HIV viral load non suppression

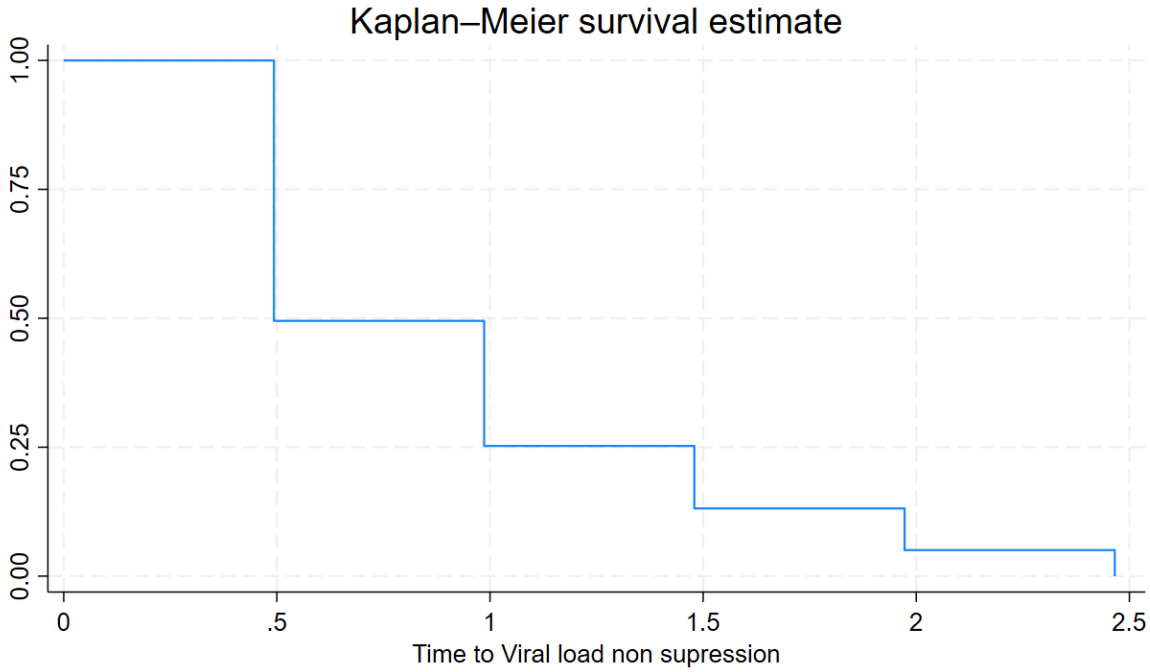


Figure 4: Time to viral load non suppression

4.4 Bivariate analysis of factors associated with HIV viral load non suppression among children and adolescents on ART in Northern Uganda.

At bivariate analysis, Age<5 years (Crude Hazard Ratio (cHR):2.44; 95% CI: 1.29-4.62), poor adherence to ART (cHR:2.32; 95% CI: 1.40-3.83), non-disclosure (cHR:2.25; 95% CI: 1.47-3.45) having economic challenges (cHR:1.60; 95% CI: 1.04-2.45) were associated with HIV viral load non suppression.

Table 3:Bivariate analysis of factors associated with HIV viral load non suppression among children and adolescents on ART in Northern Uganda.

	Suppressed VL	Non suppressed VL	Crude Hazard Ratio (cHR)	P-value
N	119 (54.6%)	99 (45.4%)		
Age in years				
<5	9 (7.6%)	13 (13.1%)	2.44 (1.29-4.62)	0.006
5 to 9	22 (18.5%)	38 (38.4%)	1	
10 to 19	88 (73.9%)	48 (48.5%)	0.76 (0.49-1.16)	0.199
Sex				
1. Female	83 (69.7%)	70 (70.7%)	1	
2. Male	36 (30.3%)	29 (29.3%)	0.80 (0.52-1.24)	0.327
Care entry point				
1. Out Patient Department (OPD)	45 (37.8%)	39 (39.4%)	1	
2. ART Clinic	45 (37.8%)	30 (30.3%)	0.83 (0.52-1.34)	0.448
3. MCH	18 (15.1%)	23 (23.2%)	1.00 (0.59-1.69)	0.997

4. Community	1 (0.8%)	1 (1.0%)	0.77 (0.11-5.63)	0.798
5. Other	10 (8.4%)	6 (6.1%)	0.89 (0.38-2.11)	0.795
DSDM Approach				
1. FBIM	94 (79.0%)	74 (74.7%)	1	
2. FTDR	1 (0.8%)	1 (1.0%)	1.39 (0.19-10.05)	0.746
3. FBG	24 (20.2%)	24 (24.2%)	0.75 (0.47-1.19)	0.232
Poor adherence to ART				
No	111 (93.3%)	79 (79.8%)	1	
Yes	8 (6.7%)	20 (20.2%)	2.32 (1.40-3.83)	0.001
Disclosure status				
1. Yes	99 (83.2%)	66 (66.7%)	1	
2. No	20 (16.8%)	33 (33.3%)	2.25 (1.47-3.45)	<0.001
≥3 missed appointments				
No	34 (28.6%)	15 (15.2%)	1	
Yes	85 (71.4%)	84 (84.8%)	1.29 (0.75-2.26)	0.355
Relationship of treatment supporter				
Parent	86 (72.3%)	72 (72.7%)	1	
Other	33 (27.7%)	27 (27.3%)	0.98 (0.62-1.54)	0.915
CD4 test result at baseline				
<200	4 (10.0%)	2 (8.0%)	1	
>200	36 (90.0%)	23 (92.0%)	2.85 (0.38-21.4)	0.310
WHO Clinical staging at baseline				
I and II	113 (95.0%)	91 (91.9%)	1	
III and IV	6 (5.0%)	8 (8.1%)	2.04 (0.98-4.21)	0.055
Psychosocial factors				
Economic challenges	31 (26.1%)	32 (32.3%)	1.60 (1.04-2.45)	0.032
Food insecurity	26 (21.8%)	31 (31.3%)	1.12 (0.73-1.72)	0.596
Anger	5 (4.2%)	6 (6.1%)	2.12 (0.92-4.87)	0.076
Fear	3 (2.5%)	6 (6.1%)	2.03 (0.88-4.65)	0.095
Dysfunctional family	1 (0.8%)	8 (8.1%)	1.51 (0.73-3.11)	0.268
Stress	5 (4.2%)	3 (3.0%)	0.39 (0.12-1.27)	0.117
Stigma/discrimination	6 (5.0%)	2 (2.0%)	0.64 (0.16-2.61)	0.534

cHR: Crude Hazard Ratio; CI: Confidence Interval

4.5 Multivariate analysis of factors associated with HIV RNA viral non suppression among children and adolescents on ART in Northern Uganda.

At multivariate analysis, children aged less than 5 years had 2.59 times higher hazards of HIV viral load non suppression as compared to those with aged 5 to 9 years (aHR (Adjusted Hazard Ratio):2.59; 95% CI: 1.30-5.17). Children with poor adherence to ART had 1.96 times higher hazards of HIV viral load non suppression as compared to those with good adherence to ART (aHR:1.96; 95% CI: 1.21-3.17). Non-disclosure was associated with 2.19 times higher hazards of HIV viral load non suppression as compared to HIV status disclosure (aHR:2.19; 95% CI:

1.27-3.80). Late WHO clinical stage (aHR:3.07; 95% CI: 1.41-6.69) and having economic challenges (aHR:2.13; 95% CI: 1.32-3.42) were also associated with higher hazards of HIV viral load non suppression.

Table 4: Multivariate analysis of factors associated with HIV viral load non suppression among children and adolescents on ART in Northern Uganda.

Variable	Adjusted HR (95% CI)	P-value
Age in years		
<5	2.59 (1.30-5.17)	0.007*
5 to 9	1	
10 to 19	0.89 (0.55-1.45)	0.653
Poor adherence to ART		
No	1	
Yes	1.96 (1.21-3.17)	0.006*
Disclosure status		
1. Yes	1	
2. No	2.19 (1.27-3.80)	0.005*
WHO Clinical staging at baseline		
I and II	1	
III and IV	3.07 (1.41-6.69)	0.005*
Psychosocial factors		
Economic challenges	2.13 (1.32-3.42)	0.002*
Anger	1.58 (0.54-4.63)	0.401
Fear	1.65 (0.59-4.61)	0.336
Stress	0.64 (0.18-2.20)	0.475

*P-value<0.05; aHR: Adjusted Hazard Ratio; CI: Confidence Interval

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Summary of key findings

This study aimed to assess the incidence of HIV viral load non suppression and its predictors among children and adolescents in Northern Uganda. The overall incidence rate of HIV viral load non suppression was 10.3 cases per 100 person-years and the median time to viral load non-suppression was 0.49 years. There was a decrease in viral load non suppression from 22.9% at 6 months to 14.4% at 18 months, then a rise to 19.3% at 24 months followed by a drop to 15.1% at the latest follow-up. Age less than 5 years, poor adherence to ART, HIV status non-disclosure, advanced WHO clinical stage (III and IV) and having economic challenges were associated with HIV viral load non suppression.

5.2 Incidence of viral load non suppression

This study revealed a high incidence rate of HIV viral load non suppression (10.3 per person-years) among children and adolescents, with 45.4% of the participants having a non-suppressed viral load during the follow-up period. This finding is higher than the pooled cumulative incidence in a multicenter analysis, which was 6.2 per person-years for Sub Saharan Africa (Boerma et al., 2017). It is also higher than the 3.9 per 100 person-years reported in a study done in Uganda (Musiime-Mwase et al., 2024). This difference in incidence rate could be attributed to the fact that these studies considered two high viral load counts > 1000 copies/mL while this study considered at least one high viral load counts > 1000 copies/mL.

The median time to viral load non suppression in this study was 0.49 years after ART initiation. This finding supports literature that reports that a significant number of children and adolescents face challenges in achieving viral suppression soon after starting ART (Nabukeera et al., 2021). Regarding the trends of HIV viral load non suppression, whilst some improvement occurred over time, a big proportion of participants continue to struggle with achieving viral suppression. Consistent with our finding, several other studies have reported high prevalence of viral load non suppression among CAWH (Desta et al., 2020; Simms et al., 2021; E. Umar et al., 2019). This underscores the urgency for interventions aimed at improving adherence and support systems for children and adolescents.

5.3 Factors associated with viral load non suppression

In this study, the hazard of HIV viral load non suppression was 2.91 times more among children aged less than five years than those aged 5 to 9 years. Similar findings have been reported in studies done in Uganda, and Tanzania (Diocles et al., 2024; Nabukeera et al., 2021). Children

under five years often face difficulty in swallowing ART formulations due to poor palatability, and pill burden (Schlatter, Deathe, & Vreeman, 2016). Additionally, the complexity of storing liquid formulations which can potentially affect treatment potency may also explain the low levels of virological suppression in this population (Schlatter et al., 2016). Pediatric HIV-programs could explore the possibility of manufacturing child-friendly ART, palatable, easy-to-swallow and store, and as well support caregivers of children below 5 years on ART to enhance adherence, to ensure virological suppression.

The hazard of HIV viral load non suppression was 1.73 times greater among patients with poor adherence compared to those with good adherence. Several other studies have also found an association between poor adherence to ART and non-viral load suppression (Bulage et al., 2017; Daskalopoulou et al., 2017; Kabiibi, Tamukong, Muyindike, & Yadesa, 2024; Quaker, Shirima, & Msuya, 2024). Poor adherence to ART causes treatment failure which leads to viral load non suppression as HIV replication is not well suppressed (Mageda et al., 2023). This highlights the need for continuous adherence monitoring and counselling in children and adolescents living with HIV.

Consistent with previous literature (Buju et al., 2022; Nabukeera et al., 2021; Quaker et al., 2024), advanced WHO clinical stage was associated with viral load non suppression. Biological factors including severe illness and other underlying disorders, coupled with psychological factors could have contributed to viral load non suppression among patients in advanced WHO clinical stages (Quaker et al., 2024). Targeted interventions that address the unique needs of individuals in the advanced stages of HIV could improve viral load suppression rates in this group.

This study also showed that non-disclosure was a predictor for HIV viral load non suppression. Similar findings have been reported in other studies (Brittain et al., 2019; Daskalopoulou et al., 2017; Modi, 2018). Non-disclosure leads to reduced treatment engagement hindering adherence to ART, which can result in VL non-suppression (Izudi, Cattamanchi, Castelnuovo, & King, 2024). This finding emphasizes the importance of status disclosure for effective management of HIV among children and adolescents.

Having economic challenges was associated with HIV viral load non suppression. This finding is line with previous studies that showed that household economic instability is associated with adverse HIV treatment outcomes including poor ART adherence and viral load non suppression (Bosma et al., 2024; Kikaire et al., 2021). Limited financial resources can make it difficult for

patients to regularly attend clinic appointments which can lead to poor ART adherence and HIV viral load non suppression.

5.4 Study strengths and limitations

This study utilized data from all public health facilities that provide ART services in Gulu city, these findings maybe generalizable to routine health care of children and adolescents living with HIV in the country.

Due to the retrospective nature of this study, we had no control of the data quality. Missing data in some files was also a challenge. Further, this study couldn't ascertain the outcomes of the participants who were loss to follow-up/ transferred out, which could potentially understate the outcome estimates. However, during the analysis, these cases were treated as censored data.

5.5 Areas for future research

Future research could explore interventions to promote ART adherence among CAWH.

Future research could also assess the impact of disclosure timing, and strategies on treatment adherence and viral suppression.

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion

HIV viral load non-suppression among CAWH was high. The time to non-viral load suppression after ART initiation was 6 months. Age less than five years, poor adherence to ART, non-disclosure of HIV status, advanced WHO clinical stage, having economic challenges were associated viral load non-suppression.

6.2 Recommendations

Train health care providers: Continuous adherence monitoring and counselling in children and adolescents living with HIV through engagement of trained health workers is key in promoting viral suppression.

Peer support initiative: There is need for interventions aimed at improving adherence and support systems for children and adolescents living with HIV; setting up functional and operational adolescent friendly health service centre point, recruitment and training of front line health service providers.

Economic empowerment: There is need to empower parents and caregivers of CAWH economically to improve viral load non suppression. Economic empowerment of caregivers through skills training or startup capital as a source of livelihood.

Advocacy campaigns: Dissemination of literacy materials interpreted in the local language to all caregivers of CAWH. This will offer more insight, knowledge and desired skills required to offer support needed to achieve viral non suppression. These should be availed in collaboration with Ministry of Health Uganda.

More attention and support should be given to caregivers of children below 5 years on ART to promote adherence in this population through peer/health worker attachment and routine home visit to ascertain and address identified barriers. The involvement of the Orphan and Vulnerable children initiative is very key in implementation, meaningful attachment and a well streamlined follow up processes.

Policy support: There is need to empower parents and caregivers with necessary tools and guidance needed for appropriate disclosure of the HIV status to children and adolescents. This will improve their involvement in care and treatment outcomes.

Technology based interventions: Daily mobile phone-based adherence reminders to caregivers of CAWH. Operationalize online peer support group engagement of the adolescent where they are able to network and support one another

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APPENDICES

APPENDIX I: Data Abstraction tool

Participants number …….

ART cohort ……..

Duration on ART…..... …(months)

Fill in the space provided

Socioeconomic factors

Age .....(Years)

Sex…

1. Female 2. Male

In school (5-19years)

1. Yes 2. No

District …….

Relationship of treatment supporter to index

client …….

Care entry point…….

Medically related factors

	WHO Clinical staging	**Nutritional Status**	**TB Status**	**Advanced HIV disease status**	**Side effects of ART**	**Hepatitis B status**	**DSDM Approach**	**Client status (Active, missed, lost to follow up, Dropped, Transferred out or Dead)**
Baseline								
6months								
12months								
18months								
24months								
Current								

Biological factors

ART Regimen (the exact regimen)

1. TDF/3TC/DTG
2. ABC/3TC/DTG
3. ABC/3TC/LPVr
4. ABC/3TC/ATVr
5. AZT/3TC/DTG
6. AZT/3TC/ATVr
7. AZT/3TC/LPVr
8. TDF/3TC/ATVr
9. TDF/3TC/LPVr
10. TDF/3TC/DTG/DRV/RTV
11. ABC/3TC/DTG/DRV/RTV
12. Others (Specify)

Regimen Line

1. First Line
2. Second Line
3. Third Line

	ART Regimen	**Regimen Line**	**CD4 test result**	**Viral load test copies**	**Viral load status(suppressed/non suppressed)**	**If client is unsuppressed, Evidence of IAC(Yes/No)**
Baseline						
6months						
12months						
18months						
24months						
Current						

List all psychosocial issues identified

1.

2.

3.

4.

5.

Disclosure status ……..

Adherence

1. >95% (Good) 2. <95%- 85%(Fair) 3. <85%(Poor)

Look at 3 consecutive visits within each 6months of the study period

	Encounters	**Adherence score**
0-6months	**1**	
	2	
	3	
>6-12 months	**1**	
	2	
	3	
>12-18months	**1**	
	2	
	3	
>18-24months	**1**	
	2	
	3	
Current		

Client related factor

Appointment Keeping

Number of scheduled appointments observed in the study Period …….

Number of scheduled appointments not observed in the study period ……

APPENDIX II: COVID-19 Prevention and Control

Measures for the Prevention and control of risk of spread of COVID-19 during the implementation of research

Study Title: FACTORS ASSOCIATED WITH HIV RNA VIRAL NON-SUPPRESSION AMONG CHILDREN AND ADOLESCENTS LIVING WITH HIV ATTENDING PUBLIC HEALTH FACILITIES IN GULU CITY, UGANDA

Principal Investigator: Ventrina Lanyero

Introduction:

The novel Coronavirus is transmitted from human to human through droplets and direct or close personal contact with an infected individual. Novel Coronavirus signs of infection include respiratory symptoms, fever, cough, shortness of breath, and breathing difficulties. In more severe cases, the infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death.

Implementation of the prevention and control measures

In the implementation of the research activities, the investigators are committed to ensuring the safety of its research team, research participants, and communities where the study will be conducted. The study team undertakes to comply with the Standard Operating Procedures issued by the Ministry of Health, and presidential directives to mitigate against the risk of infection of COVID-19, effectively respond to any COVID-19 case that may occur in the process of carrying out the study

Procedures to be followed during the implementation of the research.

A. Prior to data collection and training

1. **Health guidance:** There will be sensitization and awareness, to equip the research team and participants with knowledge of signs and symptoms of the COVID-19, and preventive measures such as hand hygiene before placing and removing the mask, as well as storage of the mask, social distancing.
2. **Wearing face coverings:** All researchers and research assistants and any other individuals engaged in research activities that require interaction with fellow researchers or research participants or the community members will have to wear a face mask that fully covers the mouth and nose in the situations required by the Health Ministry guidance. The study will provide face masks for individuals who do not have them.
3. **Physical Distancing:** There will be reasonable social distance during the orientation and data abstraction exercise
4. **Good hygiene:** All team members will be required to wash their hands or use hand sanitizers regularly. Hand washing equipment shall made available at all times. All surfaces and equipment shall be sanitized frequently.

B. During data collection

1. **Personal Protective Equipment (PPE):** All research assistants involved in data abstraction will use a properly fitted face mask. Enumerators/Researchers and research participants will wash hands with soap and water or use hand sanitizer prior to the interaction. Handshakes and hugging are prohibited.

C. During Dissemination/Community engagement

1. **Community Engagement:** Researchers and research participants will wear masks, wash hands with soap and water or use hand sanitizer prior to the event.
2. **Equipment sanitization:** Shared devices used during community engagements shall be sanitized regularly.

These preventive measures will be continuously reviewed based on new information and guidelines communicated by the Ministry of Health.

APPENDIX III: Request for Waiver of Consent

Gulu University

Faculty of Medicine

Department of public Health

Date: 5th October 2023

To:
THE CHAIR,
Gulu University Research and Ethics Committee,
P.O.BOX 166,
Gulu, Uganda

Dear Sir/Madam:

RE: Request for Waiver of Informed Consent

This is to kindly request for a waiver of informed consent for a retrospective cohort study to be conducted on factors associated with HIV RNA Viral non-suppression among children and adolescents living with HIV at Public Health facilities in Gulu city. I will be reviewing only records of participants under study, there will be no physical interaction with any of the participants. All required information will be abstracted from client records either through electronic medical records, client files or ART register.
Thank you for your time and attention, and I look forward to your positive response.

Sincerely,

Ventrina Lanyero

APPENDIX IV: Ethical Approval

GULU UNIVERSITY
P.O. Box 166, Gulu (U)
Website: www.gu.ac.ug
Email: gurec@gu.ac.ug
Tel: +256 471 432 096
Fax: +256 471 432 913
Mob: +256 772 964 491
+256 776 812 147
RESEARCH ETHICS COMMITTEE

01/11/2023

To: Ventrina Lanyero

Gulu University
+256 777362293

Type: Initial Review

Re: GUREC-2023-633: FACTORS ASSOCIATED WITH HIV RNA VIRAL NON-SUPPRESSION AMONG CHILDREN AND ADOLESCENTS LIVING WITH HIV ATTENDING PUBLIC HEALTH FACILITIES IN GULU CITY, UGANDA

I am pleased to inform you that at the **103rd** convened meeting on **15/06/2023**, the Gulu University REC meeting voted to approve the above referenced application.
Approval of the research is for the period of **01/11/2023** to **01/11/2024.**

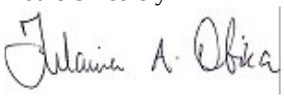
As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the REC for re-review and approval **prior** to the activation of the changes.
3. Reports of unanticipated problems involving risks to participants or any new information which could change the risk benefit: ratio must be submitted to the REC.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by participants and/or witnesses should be retained on file. The REC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Continuing review application must be submitted to the REC **eight weeks** prior to the expiration date of **01/11/2024** in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study.
6. The REC application number assigned to the research should be cited in any correspondence with the REC of record.
7. You are required to register the research protocol with the Uganda National Council for Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

The following is the list of all documents approved in this application by Gulu University REC:

No.	Document Title	Language	Version Number	Version Date
1	Informed Consent Waiver	English	2.0	2023-10-27
2	Covid-19 risk management plan	English	2.0	2023-10-17
3	Data collection tools	English	2.0	2023-10-17
4	Protocol	English	2.0	2023-10-17

Yours Sincerely



APPENDIX V: Permission from Gulu City Health Officer

GULU CITY COUNCIL

CITY HEALTH OFFICE

P.O. BOX 140, GULU. Email: okellodan@gmail.com

Mob: 0783771117

GCC/HEA/307/1

8th April, 2024

LANYERO VENTRINA

Research Student

Gulu University.

RE: PERMISSION TO CONDUCT A RESEARCH STUDY IN GULU CITY

This is to inform you that your request to carryout research within the Health care facilities in Gulu City is considered and permission is hereby granted to you to carry out data collection on the topic titled **"Factors associated with HIV RNA viral non-suppression among children and adolescents living with HIV attending public health facilities in Gulu city, Uganda"** w.e.f 8th April 2024.

However, your attention is drawn to section J-f of the Uganda Government standing orders 2021 and Circular standing Instruction No.3 of 2011, relating to research and data collection in Public service.

The In Charges of the Health Centres are hereby requested to render to you all the necessary assistance that you may require.

Yours faithfully

Dr. Okello Daniel

City Health Officer- Gulu City

CITY HEALTH OFFICER
08 APR 2024
GULU CITY
P.O. BOX 140, GULU.

APPENDIX VI: Permission from Gulu Regional Referral Hospital Research and Ethics Committee

Hospital Director's 256- (0)774408225
REC Administration :256 (0) 772060564
E-mail: guluhospital@gmail.com
Website: https://guluhospital.net
In any correspondence on this matter quote:
REC/2024/03/27

THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH
GULU REGIONAL REFERRAL HOSPITAL
P. O. Box 160,
Gulu, Uganda.

Date: 9th / April / 2024

RESEARCH AND ETHICS COMMITTEE

VENTRINA LANYERO
0777362293
GULU UNIVERSITY

RE: GUREC-2023-633: FACTORS ASSOCIATED WITH RNA VIRAL NON-SUPPRESSION AMONG CHILDREN AND ADOLESCENTS LIVING WITH HIV ATTENDING PUBLIC HEALTH FACILITIES IN GULU CITY, UGANDA. CASE STUDY OF GULU REFIONAL REFERRAL HOSPITAL

This is to inform you that the Gulu Regional Referral Hospital, Research and Ethics Committee (GRRHREC) has approved your study documents for the above referenced research study. Note that this approval expires after one year; the current approval is therefore valid until Date: 9**th/April/2025**. Continued approval is conditional upon your compliance with the following requirements:

1. No other consent forms, questionnaire and /or advertisement documents should be used.
2. Consent forms must be voluntarily signed by study subjects prior to commencement of data collection. Queries raised regarding consent too should be addressed.
3. Study bias aversion strategies should be employed as discussed to improve quality and reliability of findings.
4. All the protocol amendments and changes to other research documents must be re submitted to the GUREC for approval and made known to the Gulu RRH REC.
5. Significant changes to the current protocol and all anticipated problems that may involve risks to study subjects or patient information or that may affect integrity of the research must be promptly reported to GUREC and Gulu RRH REC.
6. Specification of support required from GRRH and inputs from the researcher (Research Assistants, Stationary etc.) to the Department.
7. Renewal of the study approval is upon feedback from the continuing research and will be done within 2 months prior to the expiry of the current protocol approval date.

You will be required to share the study findings with the GRRHREC and the responsible Departments to support our efforts to improve quality of patient care.

Yours Faithfully

GULU REGIONAL REFERRAL HOSPITAL P.O. BOX 160 GULU
For DIRECTOR
09 APR 2024

Dr. Baifa Arwinyo
OBGY, Chair GRRHREC
For Hospital Director-GRRH