DETERMINANTS OF VIRAL LOAD SUPPRESSION AMONG ORPHANED AND VULNERABLE CHILDREN LIVING WITH HIV ON ART IN TANZANIA

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DETERMINANTS OF VIRAL LOAD SUPPRESSION AMONG ORPHANED AND VULNERABLE CHILDREN LIVING WITH HIV ON ART IN TANZANIA

By

AMAL ALLY

A Dissertation Submitted in Partial fulfillment of the Requirements for the Degree of Master of Public Health of Muhimbili University of Health and Allied Sciences,

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CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled ***Determinants of viral load suppression among Orphaned and Vulnerable Children living with HIV on ART in Tanzania,*** in partial fulfillment of the requirement for the degree of Master of Public Health of Muhimbili University of Health and Allied Sciences.

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Dr. George Ruhago

(Supervisor)

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Date

DECLARATION AND COPYRIGHT

I, **Amal Ally** declare that this dissertation is my own original work and that it has never been presented and will not be presented to any other University for a similar or any other degree award.

Signature…….. Date……

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First and above all I praise Allah for the endless blessings, good health and capability to reach where I am today.

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DEDICATION

Every challenging work needs self-effort, guidance and prayers. This work is dedicated to my parents,

Mother

whose endless love, sacrifices, encouragement, advice and prayers of day and night enabled me to achieve this success and honor.

Father

whose support for my education, encouragement to reach my goals and advice made me who I am today.

ABSTRACT

Background: In Tanzania, only 18.4% of children on Antiretroviral Therapy are virally suppressed. Although retention on ART and poor adherence remain a challenge for children living with Human Immunodeficiency Virus, Orphans and Vulnerable Children (OVC) face a greater limitation of access to and utilization of comprehensive care and treatment. In response to this, the current study assessed the determinants of Viral Load Suppression among OVC aged 0-14 years living with HIV enrolled in HIV interventions.

Methodology: This was a cross-sectional study that used secondary data from a USAID Kizazi Kipya project from 81 councils of Tanzania. Included in this study are 1,980 CLHIV (0-14 years) enrolled and served by the project for 24 months. Data analysis involved multivariate logistic regression, with viral load suppression as the outcome of interest and HIV interventions as the main independent variables.

Results: The overall viral suppression rate among the OVC was 85.3%. This rate increased from 85.3%, 89.9% to 98.8% after 6, 12, and 24 months of retention on ART, respectively. Similar rates were observed as the duration of adherence to ART increased. In the multivariate analysis, OVC attending People Living with HIV groups were 411 times more likely to be virally suppressed than those not attending (aOR = 411.25, 95% CI 168.2–1005.4). OVC enrolled in Community Health Fund (CHF) were 6 times more likely to achieve viral suppression than those without (aOR = 6.05, 95% CI 3.28–11.15). Other significant factors included food security and family size.

Conclusion: CLHIV reached by the different HIV community-based interventions were more likely to be virally suppressed than those who were not. To advance viral suppression, efforts should be made to ensure that all CLHIV are reached by the interventions as well as integrating food support in HIV treatment interventions.

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ABBREVIATION

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CBAS	Community-based Adherence Support
CBHS	Community-based HIV Services
CCW	Community Case Workers
CD4	Cluster of Differentiation
CHW	Community Health Worker
CLHIV	Children Living with HIV
CoC	Continuum of Care
COP	Chief of Party
CTC	Care and Treatment Clinic
DHIS2	Demographic Health Information System
GoT	Government of Tanzania
HBC	Home-based Care
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
HVL	HIV Viral Load
LTFU	Loss to follow up
M&E	Monitoring and Evaluation
MUHAS	Muhimbili University of Health and Allied Sciences
NGO	Non-Governmental Organization
OVC	Orphans and Vulnerable Children
PEP	Post Exposure Prophylaxis
PEPFAR	President’s Emergency Plan for AIDS Relief
PLHIV	People Living with HIV

PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-Exposure Prophylaxis
STI	Sexual Transmitted Diseases
THIS	Tanzania HIV Impact Survey
UIC	Unique Identification Code
UNAIDS	Joint United Nations Programme on HIV and AIDS
VCT	Voluntary Counselling and Testing
VLS	Viral Load Suppression
WHO	World Health Organization

DEFINITION OF THE TERMS

95-95-95 Ambitious global HIV program targets proposed by UNAIDS and adopted by each country. By 2020, 95% of all people living with HIV(PLHIV) will know their HIV status; 95% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART); and 95% of all people receiving ART will have viral load (VL) suppression (VLS).

Acquired Immunodeficiency Syndrome (AIDS) is a disease caused by infection with HIV. AIDS is the result of severe damage to the immune system, making the body vulnerable to life-threatening infections and cancers.

ART Adherence is the extent to which a person's behaviour – taking medication, following a diet and/or changing lifestyle – corresponds with agreed recommendations from a health worker.

ART Retention in HIV care means a person living with HIV who is enrolled in HIV care routinely attends these services in accordance with the need. This excludes people who have died or who were lost to follow-up.

Antiretroviral Therapy (ART) refers to a combination of three or more ARV drugs for treating HIV infection. ART involves lifelong treatment. Synonyms are combination ART and highly active ART.

Antiretroviral drugs (ARV) refer to the medicines used to treat HIV.

Continuum of HIV care refers to a comprehensive package of HIV testing, prevention, treatment, and care services provided to people at risk of acquiring HIV and people living with HIV and their families. Examples of these services include combination HIV

prevention, including PrEP; HIV testing and linkage to care; managing opportunistic infections and other comorbid conditions; initiating, maintaining and monitoring ART; switching to second-line and third-line ART; and palliative care.

HIV testing is testing for the human immune deficiency virus, the cause of AIDS.

Linkage to care is defined as a process of actions and activities that supports people testing for HIV and people diagnosed with HIV in engaging with prevention, treatment and care services as appropriate for their HIV status. For people with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment.

PrEP or Pre-exposure prophylaxis is the use of an antiretroviral medication to prevent the acquisition of HIV infection by uninfected person.

Use of ARV drugs for HIV prevention refers to the HIV prevention benefits of ARV drugs and includes ARV drugs for preventing the mother-to-child transmission (PMTCT) of HIV, ARV drugs to reduce the transmission of HIV to sero-discordant sexual partners and ARV drugs to prevent the acquisition of HIV when a person is exposed (post-exposure prophylaxis (PEP) and PrEP).

Viral Load the concentration of HIV in the blood, usually expressed as copies per millilitre (mL) of blood.

Viral Load Suppression (VLS) refers to an HIV viral load of less than 1,000 copies/Ml of blood, which is identified as the threshold for treatment success by WHO's consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.

CHAPTER ONE: INTRODUCTION

1.1 Background

HIV/AIDS remains the most serious public health challenge worldwide. Statistics show that globally, about 38.0 million people are living with HIV (PLHIV), 690,000 of whom died from AIDS-related illness in 2019. It is estimated that, 1.8 million children aged between 0-14 years are living with HIV worldwide. In 2019, 67% of all PLHIV were accessing treatment. While access to treatment was 68% among adults aged 15 years and older, so was only 53% among children aged 0-14 years [1]. This treatment gap suggested existence of more HIV treatment challenges for children than adults.

East and Southern Africa is the region hardest hit by the HIV epidemic, with new HIV infections of 730,000 people and AIDS-related deaths of about 300,000 in 2019. About 6.2% of the world's population is in East and Southern region, but over half (54%) of all PLHIV in the world (i.e. 20.6 million people) are in the region. In 2019, 1.2 million children (0-14 years) were living with HIV in East and Southern Africa [1], 74,000 new HIV infection were recorded, and only 58% of the children living with HIV accessed antiretroviral treatment [1].

Tanzania has one of the youngest populations on the African continent and on earth [2]. Children below 15 years comprise about 44% of the population. Among the population aged 0-14 years, 71.6% are under the age of 10 years [3]. In 2018, it was estimated that around 1.6 million people were living with HIV in Tanzania, 72,000 people were newly infected with HIV-and 24,000 people died from AIDS- related illness [4].

With an estimated population of 92,000 children living with HIV (CLHIV) in 2018 [4], Tanzania's HIV prevalence among children aged 0-14 years is estimated to be 0.4% (0.3% of males and 0.5% of females). It is estimated that among children aged 0-14 years living

with HIV, only 50.1% had been diagnosed with HIV [3]. Treatment coverage among children (aged 0–14 years) living with HIV remains lower than treatment coverage among adults, and it is far short of the 1.6 million targets set for 2018.

HIV treatment involves taking medicines that slow the progression of the virus in the body. All children <15 years [5, 6] of age who have a confirmed diagnosis of HIV, regardless of WHO clinical stage or CD4 cell count, ART must be taken every day as prescribed by health care provider to reduce the amount of HIV (viral load) in the blood to a very low level, this is only possible if ART adherence is maintained. Children living with HIV (CLHIV) who initiate ART upon diagnosis and adhere to their treatment regimen can have near-normal life expectancy [7]. Consequences of poor adherence to ART in children include treatment failure, HIV drug resistance, increased morbidity and mortality as well as growth and developmental faltering. Extant evidence from the Tanzania HIV Impact Survey (THIS) shows that, the overall viral load suppression among CLHIV aged 0-14 years, was 18.4% [3] in 2016/17. Therefore, Viral suppression in CLHIV remains a major challenge in Tanzania and hence a need to be addressed.

Supporting the Government of Tanzania to measurably advance the global 95-95-95 goals, OVC program delivers rapid scale-up of proven, family-centered, impact mitigation efforts for OVC, reinforced with cross-sectoral, evidence-driven interventions to reduce HIV incidence while improving performance across the HIV treatment outcome. Through OVC program, a comprehensive OVC package of interventions are implemented to children and their families with known high-risk characteristics CLHIV, HIV Exposed Infants, victims of abuse, children living and working in streets, Children living and working in mining's, children of female sex workers etc.

OVC with high-risk characteristics remains at several risks to realizing their potential, especially limited access to HIV related services, sexual and reproductive health

information, unintended pregnancy, and Sexually Transmitted Infections (STIs), particularly HIV infection. Due to CLHIV vulnerability, HIV interventions packages are designed to support CLHIV to sustain long-term adherence to treatment and retention in ART care contributing to viral suppression and hence attainment of the last 95% target of UNAIDS. CLHIV receive tailored-made service package to that are designed to support adherence to ART and retention in ART to CLHIV 0-14 years. The services include~~s~~ i) ART retention and adherence quarterly monitoring by Community Case Workers (CCWs) ii) disclosure support for CLHIV 8+ years iii) provision of health insurance coverage (CHF) to CLHIV families iv) linkage of OVC CLHIV to PLHIV groups**.**

1.2 Problem Statement

Available but underutilized HIV care and treatment services constrain viral load suppression. Accessing ART, poor ART adherence, inadequate dosing, and drug resistance are among the factors that determine treatment failure. According to the 2016/17 Tanzania HIV Impact Survey, only 52% children living with HIV were accessing antiretroviral therapy and only 18.4% of children on ART in Tanzania were virally suppressed [3]. Treatment failure is contributed by lack of sustained response to ART, which can be determined using clinical, immunologic or virologic criteria. Adherence level of >95% is needed to achieve viral suppression needed for attainment of ART benefits [6].

In 2016, OVC (with one or both parents are dead) account for 8% of the children under 18 years of age in Tanzania [8]; as many as 18% of children under age 18 do not live with either biological parent; 31% of these children were orphans due to AIDS[8]. HIV positive OVC defined as "children who live in destitute families, live without adequate adult support due to loss of one or both parents to HIV/AIDS, live outside of family care (e.g. on the streets) and children who are marginalized, stigmatized, or discriminated against".~~,~~ They face a greater limitation of access to and utilization of comprehensive care and treatment services and other lifesaving services. Studies show that pediatric ART failure rates range from 19.3% to over 32.0% in resource-limited settings [3].

In Tanzania, integration of HIV actions into the community-based interventions was explored as a complementary opportunity to address obstacles to optimal children HIV treatment outcomes. Community-based programs to promote linkage and retention in HIV care and/or ART adherence are now increasingly being recognized as an important and sustainable approach that could contribute significantly toward the UNAIDS 90-90-90 target and ultimately AIDS-free generation [9–11]. However, there has been limited documentation on the contribution of community-based interventions in improving health

outcomes of children living with HIV who are on-ART. This study aimed at determining successful community-based interventions in improving retention and adherence to ART and ultimately viral load suppression in children living with HIV enrolled in OVC interventions in Tanzania.

1.3 Conceptual Framework

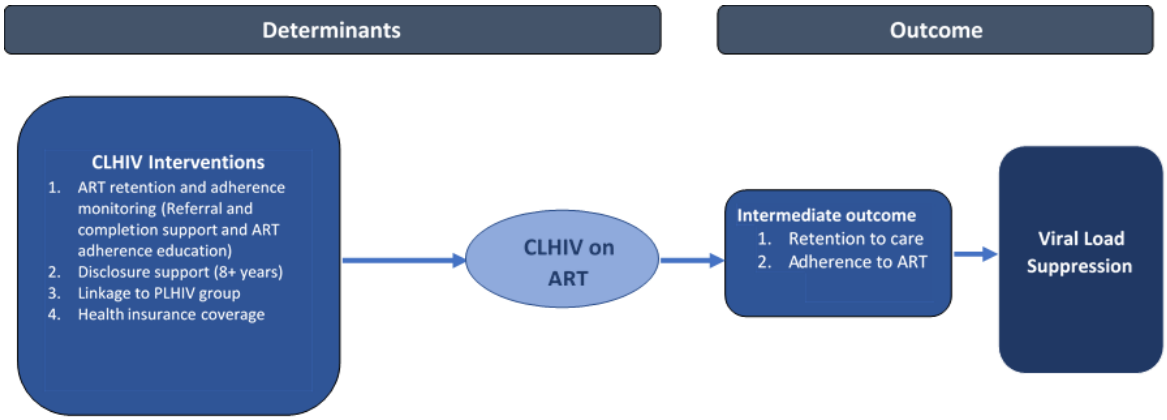


Figure 1: The conceptual framework illustrates determinants of viral load suppression among CLHIV reached with HIV interventions.

CLHIV Interventions are designed to improve CLHIV's access to utilization of care and treatment services. The CLHIV interventions package includes ART retention and adherence monitoring visits by community case workers *(includes referral and completion support and ART adherence education)*, HIV disclosure support for 8+ year old CLHIV, linkage to PLHIV group or age-appropriate clinic and health insurance coverage. Delivery of these evidence-driven family-centered interventions has a direct impact on CLHIV's overall health wellbeing, ART retention and adherence outcomes that ultimately impact CLHIV viral load suppression. Viral load suppression <1,000 copies/milliliter can therefore be attained when retention and adherence are maintained over time.

1.4 Rationale for the Study

According to National guideline for HIV/AIDS management, factors that influence adherence and retention to ART in children include i) child related (living environment, age, disclosure status and health) ii) caregiver related (reliability, education and socio-economic status of caregiver, HIV status e.tc.) and iii) System related (relationship between caregiver and clinician etc.).

Delivery of evidence-based high impact OVC interventions for CLHIV that integrate family economic strengthening and skills of the caregivers to address limited access to HIV treatment and well-being of OVC living with HIV holds promise for achieving long-term viral suppression and the nation's goals for HIV control and response and poverty reduction. Virologic suppression is the hallmark of successful HIV treatment in both adults and children. However, due to early immunologic damage and high viral loads found in many children, attaining rapid virologic suppression in children is critical [4]. Despite the reduction in morbidity and mortality, a considerable proportion of patients fail to achieve a sustained virologic response to therapy [5]. Thus, virological failure is an increasing concern globally. In Tanzania, the situation is even worse especially for children, according to the Tanzania 2016/17 HIV Impact Survey, only 18.4% of children on ART had achieved viral suppression [3]. This suggests presence of barriers which require multidimensional approaches to address.

Evidence shows that poor caregiver health is a strong predictor for poor health among OVC [12]. Routine Community Case Worker (CCW) home visits for caregivers caring for HIV positive children provides education on health, HIV, and locally available services and support (including the health insurance coverage); provide mentoring accompaniment as needed for HIV treatment, adherence; and support PMTCT uptake and adherence which increase demand for, access to, and uptake of vital HIV and other essential health services. OVC programs data indicated that community platforms

decrease stigma and discrimination, creating an environment for caregivers and CLHIV to access services.

The result from this study provides evidence on the determinants of viral load suppression that are attributable to CLHIV interventions designed to increase ART adherence and reduce loss to follow up. Evidence from this study will inform decisions to prioritize intervention packages that foster retention on and adherence to ART, reduce loss to follow up and hasten viral load suppression among CLHIV. It is envisaged that results from this study will benefit current and future OVC programs in the context of HIV in Tanzania and globally. Findings from this study will also fill information gap that is prevalent among OVC as a subpopulation, most similar studies have focused generally on children as a broad group without delving into individual sub population's characteristics and specific requirements.

1.5 Objectives

1.5.1 Broad Objectives

To assess determinants of viral load suppression among children aged 0-14 years living with HIV enrolled in HIV interventions designed for hard-to-reach OVC.

1.5.2 Specific Objectives

1. To assess CLHIV ART retention over a follow up period of 24 months.
2. To determine 24-months ART adherence among CLHIV.
3. To determine effective CLHIV interventions for attaining viral load suppression.

1.6 Research questions

1.6.1 Broad research questions

What are the determinants of viral load suppression that are associated with CLHIV interventions among 0-14 years children living with CLHIV?

1.6.2 Research questions

1. Do OVC interventions maintain retention on ART among CLHIV?
2. Do OVC interventions improve adherence to ART among CLHIV?
3. What OVC interventions are effective in suppressing viral load among CLHIV?

CHAPTER TWO: LITERATURE REVIEW

This chapter presents evidence from the literature about linkage, adherence, and viral suppression among CLHIV. Evidence and gaps in the literature were identified and discussed, and the position of this study in response to the evidence gaps were highlighted.

This chapter is organized into sections per the objectives of the study such as:

2.1 Retention to Antiretroviral Therapy

2.2 Adherence to Antiretroviral Therapy

2.3 Viral Load Suppression

2.1 Retention in ART

The success of HIV programs in children largely depend on the ability to timely link them into care and treatment programs and ensure that they are retained in those services [13]. A recent study on HIV care and treatment in children in Tanzania observed that 72% of the 29,531 children enrolled into HIV care services between 2011 and 2014 were eligible for ART at the time of enrolment. Nearly half (46%) of them were at an advanced disease stage. Mortality rate among the children was 8%, and the hazard of death was substantially higher among younger than two years-old children not on ART compared to those who were on ART [14]. The study observed several limitations to treatment success, including the fact that most children had advanced disease at the time of enrolment, majority of the children were missing baseline CD4 measurement, and lost to follow-up (LTFU) [14].

This suggested among other things that there is a limited access to CD4 testing services in the country. Based on this study, providing ART as soon as the child is diagnosed with HIV is a major factor for child survival. Despite the wealth of useful findings from this study, the data were collected from care and treatment service delivery clinics through the CTC database which is used by larger and better run clinics. Therefore, this was not

representative of smaller clinics, especially those which were unable to provide electronic data. Also, although the study included enrollment referral sources such as home-based care (HBC), voluntary counseling and testing (VCT) etc. Almost two-thirds of the children had a missing referral source. The study missed community-based contribution to the outcomes studied. Since children largely depend on parents and or caregivers for routine care as well as in such aspects as ART initiation (for CLHIV), their roles were undocumented in this study. Also, while the study notes a couple of limitations to treatment success, the success thereof was mainly enrollment and uptake of ART, with no attempt to elucidate adherence and viral suppression.

A cohort study of CLHIV in Kenya, found that LTFU (i.e. retention failure) was correlated with severe immune suppression among CLHIV [15]. Predictors of LTFU among untreated, HIV-exposed children included low weight for height, being orphaned, and having clinically advanced disease [15]. The findings suggested higher risk of infection and death among HIV-exposed but undiagnosed children. Retention was higher among HIV-exposed children who were tested and found positive. Older, exposed children were also more likely to be retained, as were children receiving food supplementation [15]. The study concluded that retention among the CLHIV and HIV-exposed children was difficult if the children were sick or malnourished. Despite the usefulness of this study and the robust statistical techniques employed, it was greatly affected by missing data which caused loss of statistical power in multivariable analysis, whereby confidence intervals of the hazard ratios were unreasonably too wide for some variables.

Another study emphasized that significant increase in ART coverage requires early identification of children needing ART, particularly those missed through traditional prevention of mother-to-child transmission (PMTCT) efforts. But even if effective strategies are employed to find these children, linkage to services and retention in care and treatment are key programmatic priorities. With the WHO’s treatment guidelines

calling for universal treatment for all CLHIV, attention must be paid at every point that children are lost from care, with a particular emphasis on ensuring proper linkage and retention in care of children known to be LHIV [13]. While this study provided useful findings, it was just a review, with no pragmatic data to support its conclusions and recommendations. The study was unable to explore how linkage and retention rates compare in children from different sociodemographic backgrounds, hence failed to recommend where to focus corrective measures.

2.2 Adherence to ART

Adherence to ART means sticking firmly to treatment regimen by taking HIV medication every day and exactly as agreed between health care provider, client and treatment supported (in case of minors) [5, 6]. Adherence to HIV treatment is an essential component to viral suppression, reduce rates of resistance, an increase in survival, improve quality of life and prevent the spread of HIV to partners and offspring. Adherence rates of >90% are needed to maximize the benefits of ART. Availability and dedicated adolescent and youth friendly services, adequate support from caregiver and other family members, life stability, early disclosure, participation of PLHIV groups, knowledge on the importance of adherence, comfortability of taking the medication and retention to ART have being identified as predictors of good adherence to HIV medication among adolescent [5, 6].

ART reduces viral load, increases CD4 count, reduces incidences of opportunistic infections and consequently improves growth and overall development of CLHIV [18,19]. These treatment benefits are not possible to achieve without consistent adherence to ART [18–21]. Therefore, adherence remains a core dimension for HIV treatment success. A cross-sectional study was conducted among children and adolescents in Mwanza, Tanzania to assess adherence to ART. The study highlighted the key challenges of poor adherence to ART in children, and ultimately concluded high rates of suboptimal

adherence among the children and adolescents studied [22]. However, this study was limited by very small sample size of only 72 participants (49 children and 23 adolescents), hence too wide confidence intervals to make the results reliable.

2.3 Viral Load Suppression

The goals of ART for children are to suppress HIV replication and therefore prevent disease progression, preserve, enhance, or reconstitute the immune system and therefore reduce opportunistic infections, reduce morbidity, promote optimal growth and development and long life prolong the survival of CLHIV and improve their quality of life [5, 6]. ART are effective and safe in suppressing viral replication when used in combination. Studies suggest that around 70% of patients on first-line ART who have a first high viral load will resuppress following an adherence intervention.

A study conducted in western Kenya on viral suppression among children <15 years of age observed that children were more likely to not be virally suppressed if their caregivers were not suppressed compared to children with suppressed caregivers. Also, caregiver's ART regimen change resulted into child viral non-suppression, as well as younger child age at ART initiation and child tuberculosis treatment all influenced viral suppression in CLHIV [23]. However, despite the significance of caregiver's viral suppression on child's, the study failed to clarify the underlying causal mechanism.

The fact that most CLHIV in Tanzania have advanced disease at the time of enrolment [14, 24, 25], suggests delay in linkage, as well as delay in seeking HIV diagnosis. Community-based health workers who routinely visit households are better positioned to partly address this through their early identification of children at risk (e.g. those who are malnourished, have HIV positive caregivers etc.) who should be referred to VCT services.

A multi-centered cohort study in South Africa using routinely collected data was conducted among children <16 who were on ART. The study noted that virological suppression until four years of ART was compared between children who received and did not receive community-based adherence support (CBAS). Children who received community-based adherence support demonstrated more advanced baseline clinical disease. A total of 5,908 viral load results were analyzed. Virological suppression was 65.6% and 55.5% in CBAS and non-CBAS children, respectively, at any time-point on treatment. The analysis indicated that, after controlling for baseline clinical, demographic, site-related variables and time on ART, children receiving CBAS were more likely to achieve virological suppression than those who did not. The effect of CBAS increased in magnitude with increasing durations of ART, and CBAS particularly improved virological suppression in a higher-risk subgroup (children younger than two years). Therefore, CBAS was associated with improved virological suppression in children receiving ART. This study suggested expanded implementation of this low-cost intervention in resource-poor settings for better HIV treatment outcome in CLHIV [26].

CHAPTER THREE: METHODOLOGY

This chapter is presented under the following subheadings: study area, study population, study design, sample size estimation, sampling technique, data collection tools and procedures, study variables, data analysis and presentation, ethical issues and limitation of the study.

3.1 Study area

This study used secondary data from a PEPFAR-supported OVC project's HIV cascade data from 81 councils in 24 regions of Tanzania Mainland and Zanzibar.

3.2 Study design

This was a cross-sectional study that used program monitoring data collected once at the end of the study period. CLHIV in this study were assessed at the 24th month (in September 2020) following continuous provision of HIV interventions from 1st October 2018 to 30th September 2020 to determine Viral Load Suppression (VLS). This study design was employed elsewhere in similar studies [27, 28].

3.3 Study population

The study involved OVC living with HIV (OVCLHIV) aged 0-14 years reached with HIV intervention over the 24 months period in the USAID Kizazi Kipya project from 1st October 2018 to 30th September 2020.

The USAID Kizazi Kipya is a five-year project (July 2016 to June 2021) funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID) and implemented by Pact Tanzania. The goal is to improve health and social well-being of orphans and vulnerable children (OVC),

young people and their families through strategic service delivery and support. The project also addresses critical barriers to service access, uptake, and adherence in order to scale up high-impact service delivery, advance 90-90-90, and improve health and social well-being outcomes among OVC and their families. It also uses existing MOHCDGEC monitoring systems, including reporting tools, and MVC service delivery and referrals forms for data collection and reporting. Through CSOs, Community Case Workers (CCWs) record routine service delivery to households for the OVC and their caregivers enrolled in the project.

The USAID Kizazi Kipya has an in-house password-protected web-based database based on DHIS2 software with robust data quality control for entry and management of household-level service delivery data and data from community-based activities. The in-house database captures individual client-level data that enables in-depth analysis and minimizes data quality issues associated with data entry (by using logic checks), aggregation of data, and timeliness of data submission. Unique sequential identification number or codes (UIC) is assigned to each beneficiary during enrollment in the project.

3.3.1 Sample size Estimation

A total of 1,980 children enrolled and served for 24 months by the USAID Kizazi Kipya project was included. This samples size is significantly higher than 254 calculated assuming that 18.4% as the level of viral suppression among 0-14 year-old children (p) according to the 2016/17 Tanzania HIV Impact Survey (THIS) [3], z = 1.96, margin of error (e) = 5% and 10% adjustment for non-response using the formular below.

$$n = \frac{Z^2 p(1-p)}{e^2}$$

Where:

n = minimum sample size required

p = proportion of CLHIV virally suppressed

z = standard normal deviation corresponding to 95% confidence level (1.96)

e = margin of error (5%)

adjusting n by 10% to account for non-response.

3.3.2 Sampling technique

This study used a non-random sampling because all children in households met one or more enrollment criteria were enrolled in the USAID Kizazi Kipya project. The enrollment criteria are published elsewhere [29] and they constitute fourteen (14) HIV-related vulnerabilities at household level. The proposed study focused to the same population that USAID Kizazi Kipya served.

3.3.3 Selection criteria

CLHIV aged 0-14 years with valid Care and Treatment (CTC) identification numbers that were enrolled in the project from 1st October 2018 and remained in the project until 30th September 2020 were eligible for inclusion in the study.

3.4 Study variables

3.4.1 Dependent variables

This study assessed one main dependent variable, namely, **viral suppression**, and two intermediate dependent variables (i.e. outcomes): retention to ART and adherence to ART.

Retention to ART

Retention was measured through CLHIV attendance of all CTC appointments for 24 months. CLHIV or their caregiver are asked if the child has been attending CTC clinic (CLHIV CTC-1 card was used for verification). This was a binary variable that was statistically coded as "1" If CLHIV attended clinic and "0" if CLHIV has not attended clinic within 3 days as scheduled.

Adherence to ART

Adherence was also an intermediate outcome. Adherence to ART was defined as taking 95% [5, 6] or more of prescribed medication in the past one months. Measuring adherence was done by assessing whether CLHIV has missed her/his ARV medication during the past 30 days. If a CLHIV missed 0-1 and 0-3 doses of ART prescribed once and twice per day respectively then CLHIV was classified as adherent and was statistically coded "1" and if CLHIV missed 2 or more and 4 or more doses of ART prescribed once or twice per day respectively then CLHIV was classified as not adherent and was coded "0".

Viral suppression

Viral suppression among CLHIV on ART was the long-term outcome. Structurally, it was a binary variable, statistically coded as '0' if viral suppression was not achieved, and '1' if the child was virally suppressed. Viral suppression in this case referred to viral load <1,000 copies per milliliter of blood as per the National Guideline for Management of HIV/AIDS [6].

3.4.2 Independent variables

The main independent variables constituted CLHIV interventions, that influenced the intermediate outcomes (Retention and Adherence to ART) which ultimately resulted in long term outcome (viral suppression). Caregiver demographic, socio-economic and household economic characteristics variables were included as indirect independent variables as a way to control their potential confounding effect on viral suppression.

CCWs household monitoring visits

CCWs provides appropriate ART treatment and adherence services during monthly household visits. During household visits, CCWs trained in ART retention and adherence provides support and address barriers on missed clinic appointments, lost to follow up, provision of escorted referrals (as needed) to health facility and support completion and deliver a tailored – made service package to CLHIV. HIV Risk Assessment Quarterly Monitoring tool (HRAQM) was used to assess CLHIV retention and adherence status by CCWs at household level.

If CLHIV received monthly monitoring visits by CCWs, was coded as "1" and those who did not received monthly monitoring visits were coded as "0".

Disclosure support

As per the Tanzanian government's guidelines[30], disclosure of the HIV status of a child should be discussed with a caregiver as early as possible by health provider. Disclose process can start as early as 4-6 years of child's age. At about 8+ years, it is recommended that child's full disclosure of HIV and AIDS status should be done in a caring and supportive manner. Through routine case management visits conducted by the CCWs at the household level, CCWs use HRAQM screening tool to establish need for child age-appropriate HIV disclosure support, support CLHIV and their caregivers to the health

facilities for disclosure counseling and provide close support to caregiver during disclosure process.

Disclosure support was done to CLHIV when he/she was aged 8 years and above. This was a binary variable that was statistically coded as “1” If the CLHIV aged 8 years or more had been informed of his/her own HIV status by his/her caregiver and “0” if not.

Attendance to PLHIV group or age-appropriate clinic

CCWs conducts household case management visit to assess CLHIV attendance to PLHIV support groups or age-appropriate clinics. Through CCWs, CLHIV and their caregivers were provided referrals and linkage to attend PLHIV support groups or age-appropriate clinics for continuous psychosocial support.

Attendance to PLHIV group or age appropriate was measured by assessing if CLHIV attended PLHIV support group or age-appropriate clinics. This was a binary variable that was statistically coded as “1” If the CLHIV was linked to PLHIV support group or age-appropriate clinics and “0” If the CLHIV did not attend PLHIV support group or age-appropriate clinics.

Health insurance coverage

CLHIV on ART face a myriad of medical, psychological, and social challenges including side effects of ART, higher vulnerability to opportunistic infections, stigma, discrimination and difficulty to access and utilize age appropriate and child friendly health services. Several factors can be attributed to low access of health care services, including the cost of health care services. As part of CLHIV service package, CCWs support provision of health insurance cards exclusively to CLHIV and their families to address barriers to access health services hindering ART retention and adherence to not only

achieve sustained viral load suppression, but to also improve the resilience and overall well-being of these children.

Health insurance was covered for the whole household. Measuring health insurance coverage was done by assessing if CLHIV was provided with health insurance coverage. This was a binary variable that was statistically coded as “1” If the CLHIV was provided with health insurance and “0” If the CLHIV was not provided with health insurance.

3.5 Data collection and procedures

This study used monitoring data from the USAID Kizazi Kipya project that was collected using multiple project tools. The tools are structured in design and were administered to CLHIV or their caregiver. The tools collected demographic information referrals provision, and HIV services utilization.

3.6 Data Management and Analysis

Datasets extracted for this study were retrieved from a password-protected project data repository. Datasets in excel format were subjected to review, cleaning, and organization. The cleaned datasets were combined into a single excel file using an excel lookup function. A pivot table was used to evaluate preliminary finding, compare data, review patterns, and explore trends. The excel dataset was then exported into Stata for further analysis. Using a statistical software (Stata version 15.0), exploratory analyses in the form of one-way tabulations (descriptive analysis) were conducted to determine distribution across different variables. This process yielded proportions, averages, and total numbers for each of the key variables. Through cross-tabulation, a comparison of each of the outcomes, e.g., variation of viral suppression among CLHIV of different clinical and social backgrounds was conducted and a Chi-square test (for categorical variables) was used to assess the degree of association between two variables.

Multivariable analysis – studying one outcome (dependent) variable with two or more independent variables at the same time – was conducted only for the main outcome – viral suppression. Since viral suppression was a binary variable, it was modeled using logistic regression [31, 32]. Adjusted odds ratios of the predictive effect of the independent variables on viral suppression and their corresponding 95% confidence intervals and p-values were presented. Data analysis was conducted using Stata (version 15.0) statistical software and all statistical inferences were made at 5% level of significance.

3.7 Ethical Issues and Consideration

Ethical clearance for this study was obtained from Muhimbili University of Health and Allied Science (MUHAS) in the Directorate of Research and Publication through Ethical Review Committee. A permission letter to use secondary data from Pact USAID Kizazi Kipya project was obtained from Pact Kizazi Kipya Chief of Party (COP) and Monitoring and Evaluation (M&E) Director. Orphaned and Vulnerable Children's data that were used for this study was de-identified using Unique Identification (UIC) to ensure confidentially is adhered to.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter covers results of the study. It presents the determinants of viral load suppression among CLHIV on ART who received CLHIV interventions for 24 months.

4.2 Children Living with HIV Profile

This study enrolled 1,980 CLHIV aged 0-14 years on ART in 81 councils across the country. Of the total CLHIV sample, female amounted to 1,016 (51.3%) and male 964 (48.7%). A half (50.1%) of the CLHIV were aged between 10-14 years, 63.8% (1,264) of the CLHIV were in school, 12.8% were not school age (age below 6 years), 13.5% had unknown school status and 10.4% were out of school (Table 1).

In relation to CLHIV caregiver characteristics, 70.5% (1,395) of the CLHIV had HIV positive caregivers, 26.3% (521) had HIV negative caregivers, 1.4% (28) had caregivers with undisclosed HIV status, and 1.8% (36) had caregivers with unknown HIV status. The majority of CLHIV (71.9%) had female caregivers; and close to a third (63.5%) resided in rural areas. Overall, CLHIV household size ranged between 2-5 family members. About a third CLHIV (35%) were from households with 2 members. With respect to food security (availability and accessibility of food), the majority of CLHIV (81.6%) were in food secure households and only 18.4% of CLHIV household were food insecure (Table 1).

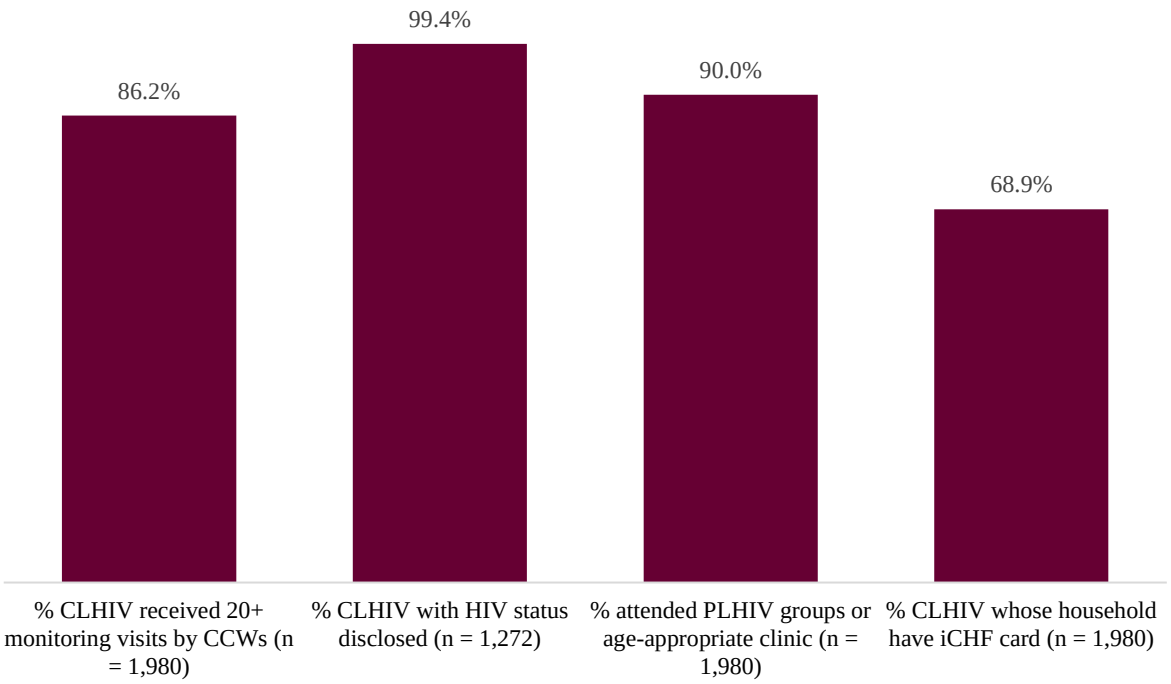
Table 1: Profile of Children Living with HIV

Variable	Number of OVC (n)	Percent (%)
OVERALL	**1,980**	**100.0**
OVC sex		
Female	1,016	51.3
Male	964	48.7
OVC Age		
00-04 years	323	16.3
05-09 years	666	33.6
10-14 years	991	50.1
School enrolment status		
In school	1,264	63.8
Not school aged	244	12.3
Out of school	205	10.4
Unknown	267	13.5
Caregiver sex		
Female	1,424	71.9
Male	556	28.1
Caregiver age		
18-24 years	15	0.8
25-45 years	886	44.8
46-65 years	832	42.0
66+ years	247	12.5
Caregiver HIV status		
Negative	521	26.3
Positive	1,395	70.5
Undisclosed	28	1.4
Unknown	36	1.8
Household Food Security		
Secured	1,616	81.6
Not secured	364	18.4
Household size		
2 people	706	35.7
3 people	490	24.8
4 people	370	18.7
5 people	414	20.9
Place of residence		
Rural	1,257	63.5
Urban	723	36.5

4.3 Coverage of CLHIV Interventions

Figure 2 shows the proportion of CLHIV intervention outcomes among the 1,980 CLHIV who received an evidence-based package of CLHIV services delivered by the CCWs through regular household visits designed to increase CLHIV retention and adherence to ART. A myriad (86.2%) of CLHIV received at least a single visit in 20+ months. Almost all CLHIV who were aged 8+ years (99.4%) had their HIV status disclosed, 90.0% of CLHIV were supported to attend PLHIV groups and 68.9% of the CLHIV's household had received health insurance (iCHF cards/ Tiba kwa Kadi.

Figure 2: Coverage of Interventions



4.4. CLHIV retention in ART for 24 months

4.4.1 CLHIV Retention in ART by CLHIV interventions

As presented in Table 2, overall, all 1,980 (100%) CLHIV were retained on ART for at least 6 months, 1,877 (94.8%) for at least 12 months, 1,725 (87.1%) for 18 months and 1,703 (86.0%) for 24 months. Retention rate varied significantly ($p<0.001$) by interventions received, those who received each of the interventions were more likely to be retained on ART for the longest duration than those who did not. For example, the 12, 18 and 24-months retention rate was higher (97.7%, 94.7% and 94.0% respectively) among CLHIV who attended PLHIV groups and lower (68.7%, 18.7% and 14.1% respectively) among those who did not attend PLHIV or age-appropriate groups, and the difference was statistically significant ($p<0.001$). Similarly, the retention rate for 6, 12 18, and 24 months was as higher as 100%, 97.6%, 93.3% and 93.0% respectively among CLHIV who were covered by health insurance and as lower as 88.6% for 12 months, 73.5% for 18 months and 70.6% for 24 months among those who did not have a health insurance cover ($p<0.001$). CLHIV retention rate for 6, 12, 18 and 24 months was also observed to be higher (100%, 99.5%, 98.7% and 98.6% respectively) among CLHIV who received monitoring visits by CCWs more frequently, and lower (65.3% for 12 months, 15.0% for 18 months and 7.7% for 24 months respectively) among CLHIV who received less frequent (< 20) monitoring visits by the CCWs ($p<0.001$).

Table 2: CLHIV Retention on ART by CLHIV Interventions (n = 1,980)

Intervention	Retention duration							
	6 months (n = 1,980)		12 months (n = 1,877)		18 months (n = 1,725)		24 months (n = 1,703)	
	%	p-value	%	p-value	%	p-value	%	p-value
OVERALL	100.0%	—	94.8%	—	87.1%		86.0%	—
Attending PLHIV Group		NA		<0.001		<0.001		<0.001
No	100.0%		68.7%		18.7%		14.1%	
Yes	100.0%		97.7%		94.7%		94.0%	
CLHIV HH has CHF Card		NA		<0.001		<0.001		<0.001
No	100.0%		88.6%		73.5%		70.6%	
Yes	100.0%		97.6%		93.3%		93.0%	
Number of household visits		NA		<0.001		<0.001		<0.001
<20 visits	100.0%		65.3%		15.0%		7.7%	
20+ vists	100.0%		99.5%		98.7%		98.6%	
OVC sex		NA		0.435		0.390		0.292
Female	100.0%		95.2%		87.8%		86.8%	
Male	100.0%		94.4%		86.4%		85.2%	
OVC Age		NA		>0.05		<0.05		<0.05
00-04 years	100.0%		94.7%		82.0%		81.1%	
05-09 years	100.0%		94.3%		87.5%		86.3%	
10-14 years	100.0%		95.2%		88.5%		87.4%	

4.4.2 CLHIV Retention on ART by CLHIV Disclosure Status

The rate of retaining CLHIV on ART by disclosure status varied across the retention duration. Overall, all 1,272 (100%) of CLHIV were retained on ART for at least 6 months, a large majority (1,209, 95.0%) for 12 months, (1,124, 88.4%) for 18 months and (1,108, 87.1%) for 24 months. The results indicate that ART retention rates were higher among CLHIV aged 8+ whose HIV status was disclosed (100%, 95.4%, 88.8% and 87.5% were retained on ART for 6 months, 18 months, 12 months and 24 months respectively) and lower (28.6% for 12 months, 14.3% for 18 and 24 months respectively) among those whose HIV status was undisclosed. The difference was statistically significant ($p<0.001$) (Table 3).

Table 3: CLHIV retention in ART by HIV Disclosure Status (n = 1,272)

Intervention	Retention duration							
	6 months (n = 1,272)		12 months (n = 1,209)		18 months (n = 1,124)		24 months (n = 1,108)	
	%	p-value	%	p-value	%	p-value	%	p-value
OVERALL	100.0%	—	95.0%		88.4%		87.1%	
HIV disclosure status		NA		<0.001		<0.001		<0.001
Disclosed	100.0%		95.4%		88.8%		87.5%	
Undisclosed	100.0%		28.6%		14.3%		14.3%	

4.5 CLHIV Adherence to ART for 24 months

4.5.1 CLHIV Adherence to ART by CLHIV interventions

The result summarizes CLHIV adherence rate in relation to CLHIV exposure to various CLHIV interventions received over the follow up period of 24 months of the study. Of the 1,980 CLHIV on ART with >95% of adherence to ART for 6, 12,18 and 24 months, 1,980 (100%), 1,768 (89.3%), 1,976 (99.8%) and 1,684 (85.1%) respectively. Adherence to ART for 18 and 24 months was slightly higher (88.6%, 85.3%) and (91.0%, 86.7%) among CLHIV age 05-09 and 10-14 years respectively and lower (85.4%, 79.6%) among 0-04 years.

In relation to the interventions, CLHIV who were linked and attended PLHIV group or age- appropriate clinics, 100%, 99.9%, 95.8% and 94.1% had adhered to ART for 6, 12, 18 and 24 months respectively compared to CLHIV who were not in PLHIV or age-appropriate clinic ($p<0.001$). CLHIV whose households had received health insurance cover, 100%, 99.9%, 94.8% and 92.9% adhered to ART for 6, 12, 18 and 24 months respectively compared to CLHIV whose households did not receive health insurance cover ($p<0.001$). Among CLHIV who received 20+ monitoring visits by Community Case Workers (CCWs), 100%, 100%, 99.4% and 98.7% adhered to ART for 6, 12, 18 and 24 months respectively compared to CLHIV who received <20 monitoring visits (98.5%) for 12 months, (26.6%) for 18 months and (0.4%) for 24 months by CCWs. The difference was statistically significant ($p<0.001$) (Table 4).

Table 4: CLHIV Adherence to ART by CLHIV interventions (n = 1,980)

Intervention	OVC adherence to ART							
	6 months (n = 1,980)		12 months (n = 1,976)		18 months (n = 1,768)		24 months (n = 1,684)	
	%	p-value	%	p-value	%	p-value	%	p-value
OVERALL	100.0%	—	99.8%	—	89.3%	—	85.1%	—
Attending PLHIV Group		NA		0.008		<0.001		<0.001
No	100.0%		99.0%		30.8%		3.5%	
Yes	100.0%		99.9%		95.8%		94.1%	
CLHIV HH has CHF Card		NA		0.057		<0.001		<0.001
No	100.0%		99.5%		77.1%		67.6%	
Yes	100.0%		99.9%		94.8%		92.9%	
Number of household visits		NA		<0.001		<0.001		<0.001
<20 visits	100.0%		98.5%		26.6%		0.4%	
20+ vists	100.0%		100.0%		99.4%		98.7%	
OVC sex		NA		0.958		0.414		0.080
Female	100.0%		99.8%		89.9%		86.4%	
Male	100.0%		99.8%		88.7%		83.6%	
OVC Age		NA		0.984		<0.05		0.002
00-04 years	100.0%		99.7%		85.4%		79.6%	
05-09 years	100.0%		100.0%		88.6%		85.3%	
10-14 years	100.0%		99.7%		91.0%		86.7%	

4.5.2 CLHIV Adherence to ART by CLHIV Disclosure Status

The result presents proportion of adherence to ART among CLHIV aged 8+ years whose HIV status was disclosed (HIV disclosure starts at the age of 4+ years depending on the child level of understanding. At the age of 8 + years, a full disclosure of HIV status is recommended[30]). Overall, all (n = 1,272) of the CLHIV were adherent to ART for 6 months, 1,269 (99.8%) for 12 months, 1,152 (90.6%) for 18 months and 1,097 (86.2%) for 24 months. Of CLHIV aged 8+ years who know their HIV status, 100%, 99.8%, 90.8% and 86.7% had adhered to ART for 6, 12, 18 and 24 months respectively compared CLHIV whose HIV status was undisclosed by the covered. The difference was statistically significant (p<0.001). (Table 5).

Table 5: CLHIV Adherence to ART by HIV disclosure status (n = 1,272)

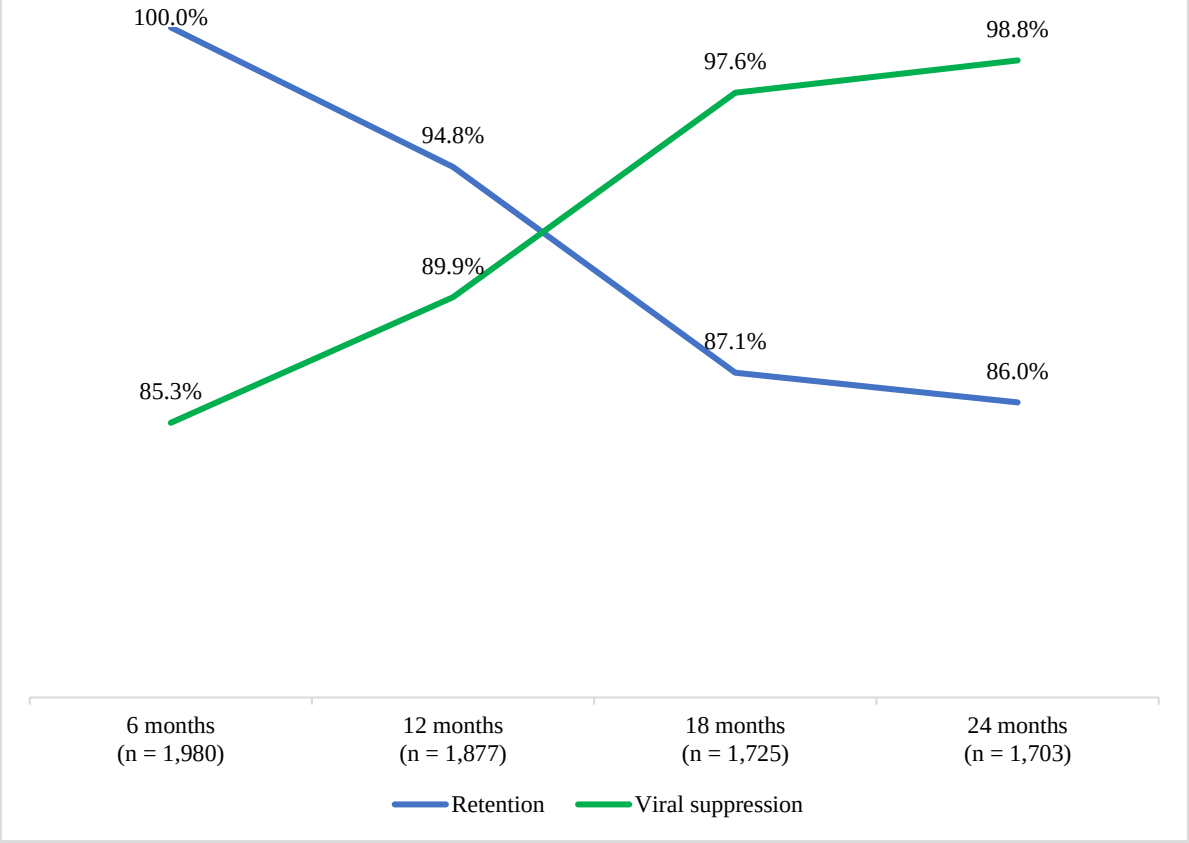
Intervention	OVC adherence to ART							
	6 months (n = 1,272)		12 months (n = 1,269)		18 months (n = 1,152)		24 months (n = 1,097)	
	%	p-value	%	p-value	%	p-value	%	p-value
OVERALL	100.0%	—	99.8%	—	90.6%	—	86.2%	—
HIV disclosure status		NA		0.897		0.047		<0.001
Disclosed	100.0%		99.8%		90.8%		86.7%	
Undisclosed	100.0%		100.0%		42.9%		0.0%	

4.6 Attaining Viral Load Suppression

4.6.1 Viral suppression rate by ART Retention at 6, 12, 18, and 24 months

As retention duration increased from 6, 12, 18 to 24 months, retention rates were respectively declining from 100.0%, 94.8%, 87.1% to 86.0%, but CLHIV viral load suppression rates were significantly increasing from 85.3%, 89.9%, 97.6% to 98.8%, respectively (Figure 3).

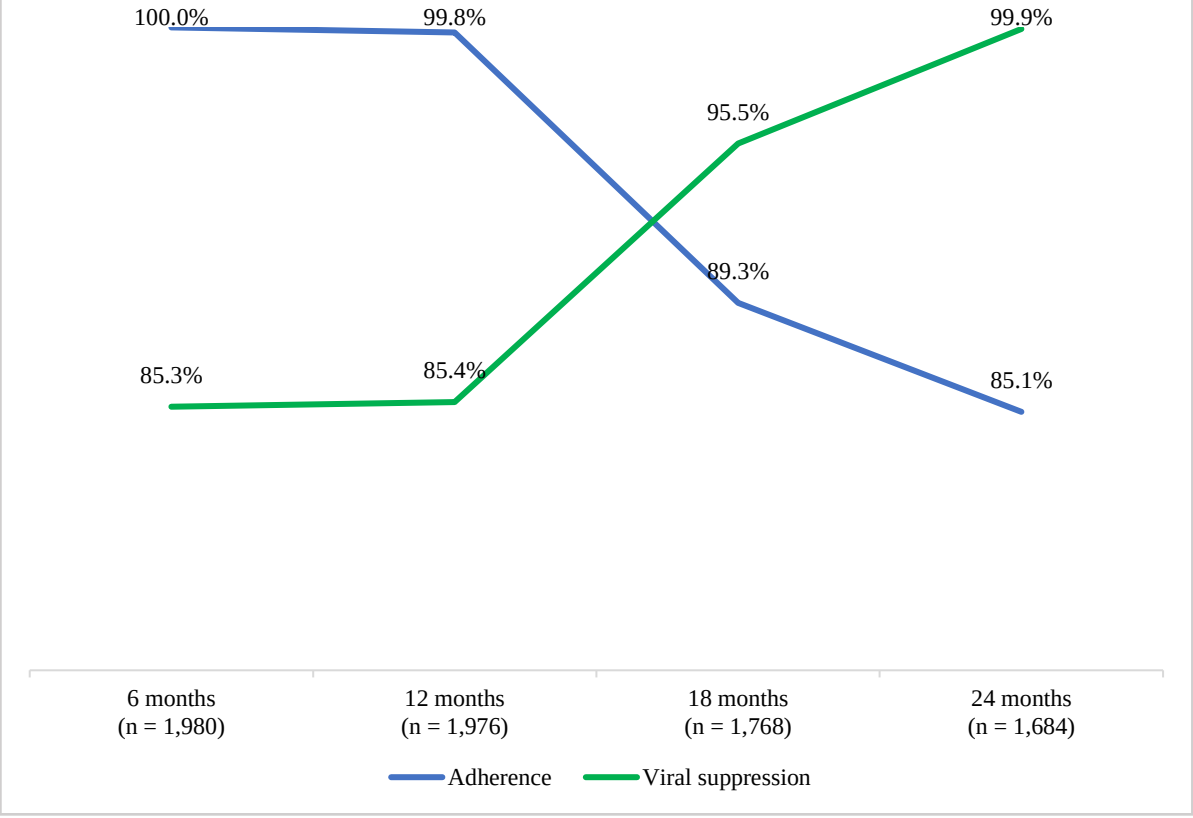
Figure 3: Viral suppression rate by ART retention at 6, 12, 18, and 24 months



4.6.2 Viral Suppression Rate by ART Adherence at 6, 12, 18, and 24 Months

As adherence duration increased from 6, 12, 18 to 24 months, adherence rates were respectively declining from 100.0%, 99.8%, 89.3% to 85.1%, but CLHIV viral load suppression rates were significantly increasing from 85.3%, 85.4%, 95.5% to 99.9% in the same period of 6, 12, 18 and 24 months, respectively. In both cases, the observed change was very rapid between 12, 18 and 24 months than between 6 and 12 months (Figure 4).

Figure 4: Viral Suppression Rate by ART Adherence at 6, 12, 18, and 24 Months



4.6.3 CLHIV Viral Suppression by CLHIV Interventions and Other Characteristics

This subsection shows viral suppression rates by different intervention received by the CLHIV. The rates are also compared across different levels of socio demographic, household, and geographical characteristics (Table 6).

Results show that overall, 85.3% (n = 1,688) of the CLHIV studied were virally suppressed after 24 months. Viral suppression rate was higher among CLHIV attending PLHIV groups than those not attending the PLHIV groups (94.1% vs. 5.6%, $p<0.001$). Similarly, viral suppression rate was higher among CLHIV whose HIV status was disclosed than in those whose HIV status was not disclosed (86.7% vs. 0.0%, $p<0.001$). CLHIV households with health insurance coverage (iCHF) were significantly associated with higher virologic suppression compared to their uninsured counterparts (93.1% vs. 67.8%, $p<0.001$). CLHIV who were visited by the Community Case Workers (98.9% vs. 0.0%, $p<0.001$) more frequently within the 24 months period were more likely to become virally suppressed compared to CLHIV who were visited less frequently within the same period (Table 6).

The association between CLHIV viral suppression and demographic characteristics indicated that viral suppression was positively associated with CLHIV's age, ranging from 80.2% among the youngest CLHIV (aged 0-4 years) to 86.6% among those aged 10-14 years ($p=0.017$). CLHIV with ART adherence level of >95% were more likely to be virally suppressed, compared to those who are less adherent to ART in the last 6 months (89.6% vs. 4.0%, $p<0.001$) (Table 6).

Food secure CLHIV households (94.0%, $p<0.001$) were more likely to be virally suppressed, compared to not secure household. Other caregiver characteristics such as sex, household size and place of residence were not significantly associated with CLHIV

virological suppression. Figure 6 depicts the relationship between CLHIV viral suppression by CLHIV interventions received and demographic characteristics (Table 6).

Table 6: CLHIV Viral Suppression by Interventions and Other Background Characteristics (N = 1,980)

	N	% Virally suppressed	p –value
OVERALL	**1,980**	**85.3**	—
Attending PLHIV Group			<0.001
No	198	5.6	
Yes	1,782	94.1	
HIV disclosure status (only age 8+ years)			<0.001
Undisclosed	7	0.0	
Disclosed	1,265	86.7	
CLHIV HH has CHF Card			<0.001
No	615	67.8	
Yes	1,365	93.1	
Number of household visits			<0.001
<20 visits	274	0.0	
20+ visits	1,706	98.9	
OVC sex			0.104
Female	1,016	86.5	
Male	964	83.9	
OVC Age			0.017
00-04 years	323	80.2	
05-09 years	666	85.7	
10-14 years	991	86.6	
School enrolment status			0.017
In school	1,264	86.0	
Not school aged	244	78.7	
Out of school	205	85.4	
Unknown	267	87.6	
OVC adherence to ART in the last 6 months			<0.001
Not adherent	101	4.0	
Adherent	1,879	89.6	
Caregiver sex			0.572
Female	1,424	85.5	
Male	556	84.5	
Caregiver age			0.004
18-24 years	15	100.0	
25-45 years	886	83.4	
46-65 years	832	88.1	
66+ years	247	81.4	
Household Food Security			<0.001
Not secured	364	46.4	
Secured	1,616	94.0	
Household size			0.208
2 people	706	87.1	
3 people	490	83.3	
4 people	370	83.5	
5 people	414	86.0	
Place of residence			0.831
Rural	1,257	85.1	
Urban	723	85.5	

4.6.4 Multivariable Analysis of Viral Suppression

Exposure to CLHIV interventions and viral suppression

Table 7, presents multivariable logistic regression model of factors associated with viral load suppression among Tanzanian CLHIV on treatment. Adjusted odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) and p-values are presented.

Results show that after adjusting for other variables in the model, CLHIV attending PLHIV groups or age-appropriate clinic were more than 411 times more likely to achieve viral suppression than those not attending the groups (aOR = 411.25, 95% CI 168.2–1005.4, p<0.001). Similarly, CLHIV in households with health insurance were 6 times more likely to be virally suppressed than those who did not have health insurance (aOR = 6.05, 95% CI 3.28-11.15 p<0.001). CLHIV with >95% adherence to ART were 149 times more likely to be virally suppressed than those not adherent to ART (aOR = 148.96, 95% CI 42.6 – 520.6, p<0.001).

Other factors associated with viral suppression.

CLHIV living in food secure households were 15 times more likely to be virally suppressed than those in food insecure households (aOR = 14.93, 95% CI 8.72-25.45 p<0.001). CLHIV in households with 5 members were almost thrice more likely to achieve viral suppression than those in smaller families of 2 people only (aOR = 2.97, 95% CI 1.25 – 7.07, p = 0.014).

CLHIV sex, age, and school enrollment status; caregiver sex, and age; and place of residence were not significantly likely to influence CLHIV's viral suppression in the multivariable analysis (Table 7).

Table 7: Multivariable Logistic Regression Analysis of Viral Suppression at 24 Months among OVC LHIV on ART in Tanzania (N = 1,980)

	Adjusted Odds Ratio (aOR)	95% Confidence Interval (CI)		p -value
		Lower limit	Upper limit	
Attending PLHIV Group				
No	1.00	—	—	—
Yes	411.25	168.2	1005.4	**<0.001**
CLHIV household with iCHF Card				
No	1.00	—	—	—
Yes	6.05	3.28	11.15	**<0.001**
OVC adherence to ART in the last 6 months				
Not adherent	1.00	—	—	—
Adherent	148.96	42.6	520.6	**<0.001**
OVC sex				
Female	1.00	—	—	—
Male	1.20	0.73	1.96	0.473
OVC Age				
00-04 years	1.00	—	—	—
05-09 years	0.26	0.05	1.25	0.092
10-14 years	0.22	0.05	1.07	0.061
School enrolment status				
In school	1.00	—	—	—
Not school aged	0.53	0.10	2.91	0.467
Out of school	0.60	0.28	1.29	0.190
Unknown	0.81	0.40	1.63	0.545
Caregiver sex				
Female	1.00	—	—	—
Male	0.86	0.50	1.49	0.586
Household Food Security				
Not secured	1.00	—	—	—
Secured	14.93	8.76	25.45	**<0.001**
Household size				
2 people	1.00	—	—	—
3 people	0.83	0.42	1.67	0.609
4 people	1.23	0.54	2.80	0.618
5 people	2.97	1.25	7.07	**0.014**
Place of residence				
Rural	1.00	—	—	—
Urban	0.90	0.53	1.53	0.699

CHAPTER FIVE: DISCUSSION

5.1 Introduction

In this chapter, findings are thoroughly interpreted and discussed in view of the objectives, as well as clarifies what they mean, and their contribution to the literature. The discussion takes off with the magnitude of viral load suppression observed by the study and goes ahead to discuss how the CLHIV interventions influenced retention and adherence to ART as intermediate outcomes, and finally how they influenced viral load suppression as the main outcome. Other factors associated with viral load suppression are also discussed.

5.2 Key Findings

This study assessed the determinants of viral load suppression among CLHIV aged 0-14 year who were on HIV treatment in Tanzania. The CLHIV were receiving HIV interventions services for 24 months, from October 2018 to September 2020. The overall viral suppression rate among the OVC was 85.3%. This rate increased from 85.3%, 89.9%, 97.6% to 98.8% for 6, 12, 18 and 24 months of retention on ART and similar increase 85.3%, 85.4%, 95.5% to 99.9% was resulted for 6, 12, 18 and 24 months of adherence to ART respectively.

In the multivariate analysis, OVC attending PLHIV groups were 411 times more likely to be virally suppressed than those not attending (aOR = 411.25, 95% CI 168.2–1005.4). OVC with health insurance (iCHF) were 6 times more likely to achieve viral suppression than those without (aOR = 6.05, 95% CI 3.28–11.15). Also, adherence to ART in the last 6 months resulted in 149 times higher likelihood of viral suppression than non–adherence (aOR = 148.96, 95% CI 42.6–520.6). OVC from food secure households were 15 times more likely to be virally suppressed than their food insecure counterparts (aOR = 14.93, 95% CI 8.76–25.45). Finally, OVC in families of 5+ people were more likely to be virally suppressed than those in families of 2 people (aOR = 2.97, 95% CI 1.25–7.07).

5.3 Viral Load Suppression Rate

Findings showed that overall, 85.3% of the 1,980 CLHIV analyzed had achieved viral suppression at the end of the 24 months period. Although this rate was 4.7% lower than the UNAIDS' third 90 of viral load suppression target of 90% by 2020 [33], it was remarkably higher than 18.4% observed among children aged 0-14 years reported by the Tanzania HIV Impact Survey (THIS) [3].

Another study in Tanzania among 0–24-year-olds found a viral load suppression rate of 65.8% [34], which is also lower than the rate seen in this study. Viral suppression rate in this study was comparable to the rate reported in Western Kenya (83%), although the study was based on the general population [35]. A study done in Rwanda reported a viral suppression rate of 61% among adolescents aged less than 19 years [36], while another study in Uganda observed a viral suppression rate of 63% [37].

In both countries, the viral load suppression rates were lower than that observed by the current study. In Tanzania (2020), USAID - PEPFAR viral load suppression (TX_PVLS) results reported 83.3% among CLHIV age 0-14 years[38]. The higher rate of viral load suppression observed in this study is attributable to attendance in PLHIV groups, health insurance, disclosure of HIV status at 8+ years and receiving household monitoring visits by CCWs. These interventions are designed to support retention and promote long-term ART adherence for ultimate achievement of viral load suppression. Therefore, given the benefits of the interventions, this study underscores the need for endless sustainability of the interventions and inclusion of all CLHIV in HIV care and treatment services in order to increase the viral load suppression rate towards 100%.

5.4 Retention, and adherence to ART in relation to HIV interventions

This study found that the overall rates of retention of CLHIV on ART were 100%, 94.8 %, 87.1% and 86.0% after 6, 12, 18 and 24 months of follow up, respectively. These rates were significantly higher for OVC who received each of the interventions than those who did not, particularly after 12, 18 and 24 months. For each of these interventions, there was no difference in retention rates after 6 months as 100% was maintained, regardless of the interventions. The contribution of the interventions on ART retention was notable after 12, 18 and 24 months, with the retention gap between those who received each of the interventions and those who did not receive them widening the longer the follow up period became. This meant that although retention was declining as the follow up period increased (possibly due to LTFU), the decline was huge in absence of the interventions and lowest with the interventions. This implied that long-term retention to ART is unlikely to be achieved without appropriate interventions, hence a need to sustain the interventions for ultimate control of the HIV epidemic in CLHIV. A study in Uganda reported a similar results on a better retention in community-based programs than facility-based ones among HIV-infected children and adolescent[39].

In presence of the interventions, the retention rates observed in the current study were higher than those reported in South Africa, where 90.2%, 82.9% and 68.3% of 10-14 year-olds adolescents were retained to ART after 4, 12 and 24 months post-initiation on ART, respectively [40]. A meta-analysis of six south African studies reported a lower retention rate among adolescents living with HIV of 83% in the first 24 months [41] compared with a retention rate of 86.0% after 24 months in this study. A study in Uganda [42] found that 90% of adolescents were retained in care after 12 months, a rate which is lower than the 12 months retention rate observed in the current study (94.8%). A study in western Kenya, revealed that caregivers reported that children were not retained to ART because caregivers had not disclosed their own status or were afraid of family/community stigma related to their HIV status or that of the child [43]. Similar studies done in Kenya, Zimbabwe and South Africa on the determinants of improved ART adherence, linkage to care/or retention in care and psychosocial well-being [44–46] showed that psychosocial

support interventions (individual counselling, support groups, family-centered services, and treatment supports) resulted into improved retention in care among adolescents. Predictive factors for children retention to treatment in another study in Western Kenya revealed that children retention to ART was influenced by caregiver's decision regarding whether a child receives treatment considering transport cost, food availability, time constrains and perceptions that the child is healthy [47]. A study conducted in South Africa presented empirical evidence on community-based adherence support as an effective way to improve patient retention among children age <16 years on ART. Results for this study has a slightly higher retention rate than that in South Africa with 90.1% (95% CI: 85.9% to 94.3%) in children on ART with patient advocates (community workers) support vs. 80.0% in children without patient advocate support, respectively)[48]. This suggests that retention of CLHIV in care and treatment services will be successful if appropriate HIV interventions are in place.

With respect to ART adherence, findings of the current study showed that adherence rate was 100.0%, 99.8%, 89.3% and 85.1% after 6, 12, 18 and 24 months of follow up, respectively. In view of the interventions, adherence rate was unalterably 100.0% after 6 months regardless of the interventions but changing afterwards: adherence was higher among CLHIV who were linked and attended in PLHIV groups than those who did not; adherence was higher among CLHIV with health insurance than those without; adherence was higher among CLHIV who received 20 or more household visits than those who were visited less than 20 times within the follow up period; and better adherence among CLHIV who received disclosure support than those who did not.

Although the rates of adherence to ART after 12 months showed variations, the rates were generally similar as the variations were statistically negligible ($p>0.05$). However, notable variations were seen at the 24 months follow up period, as adherence was significantly higher among OVC who received each of the interventions than those who did not. This meant that the contribution of the HIV interventions on ART adherence was visible at 18- and 24-months period, where receipt of some interventions (e.g. 20+ household visits) yielded adherence rate of 99.4% and 98.7%) respectively, and absence of others (e.g.

disclosure support) resulted into 42.9% and 0.0% adherence rate respectively. In general, findings of the current study suggest that without appropriate ART adherence interventions, sustained long term ART adherence is unlikely, hence the risk of unsuppressed viral loads in CLHIV.

Adherence rate at 6, 12, 18 and 24 months among CLHIV who received some interventions in this study was higher compared to another study in Tanzania where monthly attendance to PLHIV clubs (as a proxy for ART adherence) was also significantly higher (91%) compared to those who did not attend (82%) [49]. Another study in Zimbabwe has shown that participants who received Community Adolescent Treatment Supporter (CATS) intervention reported a statistically significant improvement in adherence to ART from 44.2% at baseline to 71.8% at end line [46] which is lower than the results from this study.

5.5 CLHIV viral suppression in relation to retention and adherence to ART

As already observed, the viral load suppression rate in this study was significantly higher for CLHIV who had better retention, and adherence rates than those whose retention, and adherence rates were poor. The longer the duration of retention, and adherence, the higher was the rate of viral load suppression. Viral load suppression rate was almost 100% among CLHIV who were retained on ART for 24 months as well as those who adhered to ART for 24 months. This suggested that interventions to improve and sustain retention and adherence to ART are necessary to warrant treatment success in terms of viral load suppression.

5.6 CLHIV viral suppression in relation to HIV interventions and other factors

In general, achieving viral load suppression in this study was more likely for CLHIV who received each of the interventions than CLHIV who did not. This was more evident in the multivariable analysis, whereby, after adjusting for key sociodemographic and other household and geographic characteristics, CLHIV who received each of the CLHIV interventions were more likely to be virally suppressed than CLHIV who did not receive the CLHIV interventions.

Specifically, the likelihood to achieve viral load suppression was 411 times more likely among CLHIV who attended PLHIV group or age-appropriate clinic than CLHIV who did not attend (aOR = 411.25, 95% CI 168.2–1005.4). This result is explained by the fact that CLHIV attended psychosocial activities, CLHIV and their caregiver received counseling sessions by trained provider, attended support-group sessions activities to discuss retention and adherence to ART. A study in South Africa found higher viral suppression rates among adolescents and young adults attending the adolescent clinic (91%) versus adolescents attending the standard pediatric clinic (80%) [50]. HIV viral suppression among patients 5–19 attending sites with PLHIV clubs was higher (60%) compared to those attending health facilities with no PLHIV clubs (49%) [49].

In this study, viral suppression rates 98.9% of CLHIV (0-14 years) resulted by CCWs close monitoring on CLHIV retention and adherence to ART during household monthly visits. Thus, CLHIV rarely missed their appointment to the health facilities for routine reviews and intervention. Provision of CLHIV referral for HIV services such as ART adherence, HIV disclosure support, opportunistic infections treatment by CCWs also improved retention on ART. Monitoring CLHIV who receive ART is crucial to ensure successful treatment management, treatment of opportunistic infection and identify problems related to ART retention and adherence and determine change of ART regimens in case of treatment failure [5, 6, 30].

Taken together, the interventions favorably influenced retention, and adherence to ART among the CLHIV, and ultimately contributed to viral suppression. Missed clinic and ART refill appointments have negative implication on ART intake hence poor adherence to ART. Poor retention and adherence to ART are major factors which influence viral suppression. High viral suppression can largely be explained by ART retention and adherence to ART [34].

This study has shown results of other factors which had significant predictive effect of CLHIV viral suppression. CLHIV from food secure households were more likely to be virally suppression than those from food insecure households. This finding is consistent with several studies which observed food insecurity as a barrier to ART adherence [51, 52]. Since adherence is a prerequisite for viral suppression [34], improving adherence means contributing to viral suppression. Reasons for poor adherence to ART due to food insecurity were observed in Uganda and included that ART increases appetite for food; without food, ART's side effects exacerbate; and that there are competing demands between costs of food and medical expenses, among others [51]. Therefore, there is a need to integrate nutritional support or food security intervention in HIV treatment efforts as an imperative dimension for improved treatment outcomes.

5.7 Limitations

During the 24 months of service provision, some community volunteers had dropped out and were replaced by new community volunteers. Volunteer changes affected service delivery because caregivers take time to build trust and establish new volunteer- caregiver relationship for disclosure purpose. Since HIV disclosure status requires building trust overtime, it affected timely disclosure of OVC HIV status to enable service delivery. Volunteers change over time were due to reasons such as reallocation, marriage, death and drop out.

This study relied on self-reported ART adherence, which is subject to recall bias. CLHIV adherence to ART was self-reported by CLHIV or their caregiver by asking a recall question on whether CLHIV has missed her/his ARV medication during the past 30 days. The limitation on self-reported question is the accuracy to recall the number doses/pills that were missed in the last 30 days which sometimes might not be accurate.

Few CLHIV (48) had their next HVL test three months after the study duration (30th September 2020). Having CLHIV most updated VL results before the end of the study duration might have affected CLHIV viral load suppression results positively.

Food security data used for this study was obtained once by the program at 12 months during 24 months of the study duration. Therefore, data used for analysis in this study had no additional data to make comparison of CLHIV household's food security status over time in relation to viral load suppression.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

Although the rate of viral suppression was high, CLHIV who were reached by the different community-based interventions to promote retention and adherence (PLHIV support groups or age-appropriate clinics, health insurance, and adherence support through household visits by CCWs had higher rates, and they were more likely to be virally suppressed than those who were not reached by the interventions. To advance viral suppression, efforts should be made to ensure that all CLHIV are reached by the interventions as well as integrating food support in HIV treatment interventions.

6.2 RECOMMENDATIONS

Community-based programs/interventions to promote retention and adherence should be prioritized as more beneficial way to positively influence viral suppression. More focus should be put on OVC subpopulation (Children Living with HIV, HIV Exposed Infants, victims of abuse, Children Living and working in streets, Children in Living and working in mining, Children of female sex workers etc.).

The Tanzania government should prioritize delivering of tailored-made HIV service package to CLHIV with greater limitation of access and utilization of comprehensive care and treatment services. Scaling up of PLHIV support groups or age-appropriate clinics, health insurance coverage, and adherence support through household visits by community case workers will foster retention on and adherence to ART, reduce loss to follow up and increase CLHIV viral load suppression.

Tanzania government should also integrate nutritional support or food security interventions in CLHIV treatment efforts as an imperative dimension for improved HIV treatment outcomes.

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APPENDICES

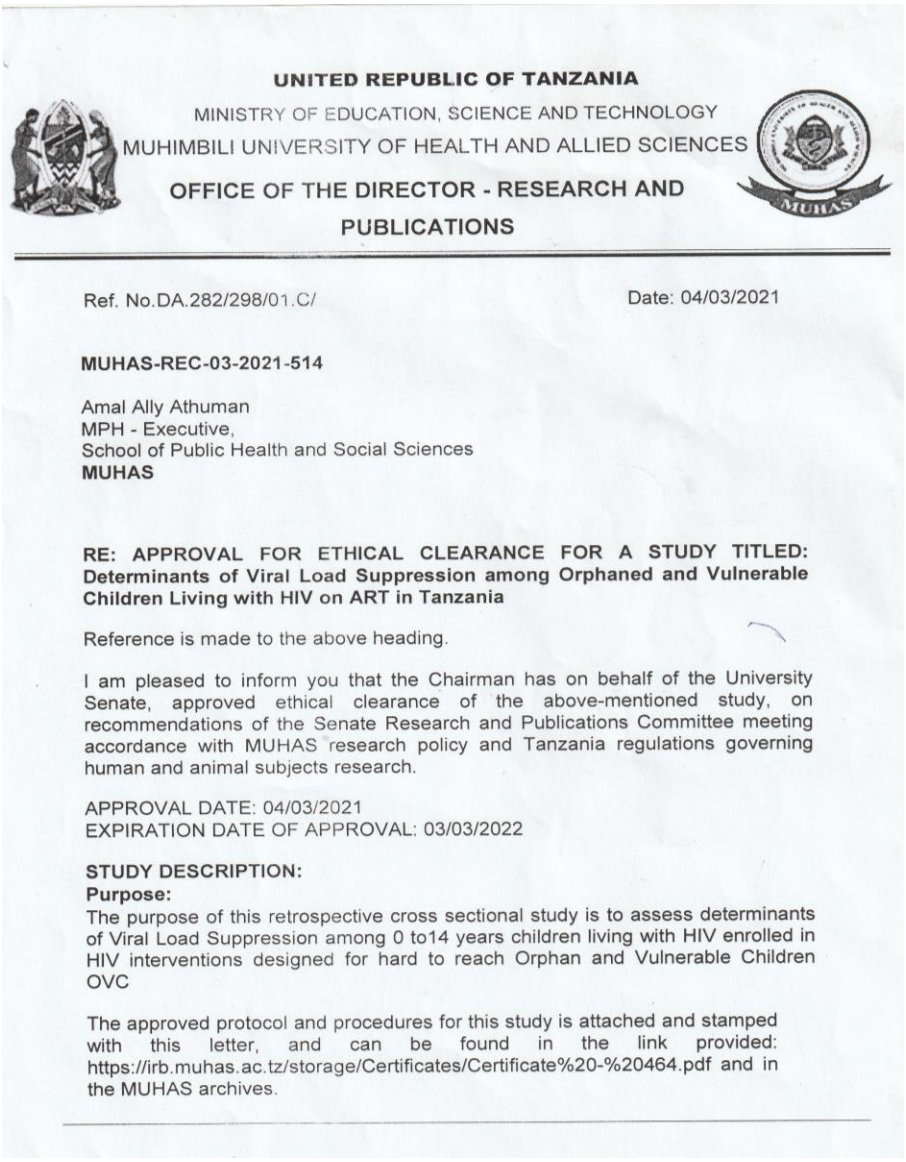
Appendix A: Study Councils and Regions in Tanzania

s/n	Region	Council
1	Arusha	Arusha CC
2	Arusha	Arusha DC
3	Dar es Salaam	Ilala MC
4	Dar es Salaam	Kigamboni MC
5	Dar es Salaam	Kinondoni MC
6	Dar es Salaam	Temeke MC
7	Dar Es Salaam	Ubungo MC
8	Dodoma	Dodoma MC
9	Geita	Bukombe DC
10	Geita	Chato DC
11	Geita	Geita DC
12	Iringa	Iringa DC
13	Iringa	Iringa MC
14	Iringa	Kilolo DC
15	Iringa	Mafinga TC
16	Iringa	Mufindi DC
17	Kagera	Bukoba DC
18	Kagera	Karagwe DC
19	Kagera	Missenyi DC
20	Kagera	Muleba DC
21	Katavi	Mpanda TC
22	Kigoma	Kigoma MC
23	Kilimanjaro	Moshi DC
24	Mara	Bunda DC
25	Mara	Rorya DC
26	Mbeya	Mbozi DC
27	Mbeya	Chunya DC
28	Mbeya	Kyela DC
29	Mbeya	Mbarali DC
30	Mbeya	Mbeya CC
31	Mbeya	Mbeya DC
32	Mbeya	Momba DC
33	Mbeya	Rungwe DC
34	Mbeya	Tunduma TC
35	Mjini Magharibi	Mjini
36	Morogoro	Ifakara TC

37	Morogoro	Morogoro MC
38	Morogoro	Kilombero DC
39	Morogoro	Kilosa DC
40	Morogoro	Mvomero DC
41	Mtwara	Masasi DC
42	Mwanza	Ilemela MC
43	Mwanza	Kwimba DC
44	Mwanza	Mwanza CC
45	Mwanza	Sengerema DC
46	Mwanza	Buchosa DC
47	Mwanza	Magu DC
48	Mwanza	Misungwi DC
49	Mwanza	Nyamagana MC
50	Njombe	Ludewa DC
51	Njombe	Makete DC
52	Njombe	Njombe DC
53	Njombe	Njombe TC
54	Njombe	Wanging'ombe DC
55	Pwani	Kibaha TC
56	Pwani	Chalinze DC
57	Pwani	Mkuranga DC
58	Rukwa	Nkasi DC
59	Rukwa	Sumbawanga DC
60	Rukwa	Sumbawanga MC
61	Ruvuma	Mbinga DC
62	Ruvuma	Mbinga TC
63	Ruvuma	Songea DC
64	Ruvuma	Songea MC
65	Ruvuma	Tunduru DC
66	Shinyanga	Kahama TC
67	Shinyanga	Kishapu DC
68	Shinyanga	Msalala DC
69	Shinyanga	Shinyanga DC
70	Shinyanga	Shinyanga MC
71	Shinyanga	Ushetu DC
72	Simiyu	Busega DC
73	Simiyu	Maswa DC
74	Singida	Iramba DC
75	Songwe	Songwe DC
76	Tabora	Igunga DC
77	Tabora	Kaliua DC

78	Tabora	Nzega DC
79	Tabora	Tabora MC
80	Tabora	Uyui DC
81	Tanga	Tanga CC

Appendix B: Ethical Clearance Letter –MUHAS



UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS

Ref. No.DA.282/298/01.C/ Date: 04/03/2021

MUHAS-REC-03-2021-514

Amal Ally Athuman
MPH - Executive,
School of Public Health and Social Sciences
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: Determinants of Viral Load Suppression among Orphaned and Vulnerable Children Living with HIV on ART in Tanzania

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 04/03/2021
EXPIRATION DATE OF APPROVAL: 03/03/2022

STUDY DESCRIPTION:
Purpose:
The purpose of this retrospective cross sectional study is to assess determinants of Viral Load Suppression among 0 to14 years children living with HIV enrolled in HIV interventions designed for hard to reach Orphan and Vulnerable Children OVC

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20464.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

Cc: Director of Postgraduate Studies

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix C: Approval Letter

pact building local promise.

Pact Tanzania
Uporoto Street Victoria
P.O. Box 6348
Ursino South Plot No. 74
Dar es Salaam, Tanzania

Phone: 255 22 2761933/4/6/7
Fax: 255 22 2761938
tanzania@pactworld.org
www.pacttz.org

7th January 2021

Ms. Amal Ally,
P.O. Box 25097,
Dar es Salaam.

Dear Madam,

PERMISSION TO USE USAID KIZAZI KIPYA PROJECT DATA FOR YOUR MPH DISSERTATION

Pact is pleased to advise that you have been granted approval to use secondary data from the USAID Kizazi Kipya project for your Master of Public Health (MPH) dissertation entitled "**Determinants of Viral Load Suppression among Orphaned and Vulnerable Children Living with HIV on ART in Tanzania.**"

Your requested data pertaining to orphaned and vulnerable children (OVC) living with HIV (OVCLHIV) aged 0-14 years reached with HIV intervention over 24 months from 1st October 2018 to 30th September 2020 in 81 councils implementing USAID Kizazi Kipya interventions is available and has all the variables you need to pursue the study.

By this approval, you are also required to submit the final report of your study to Pact for review.

Pact wishes you all the best in this study.

Sincerely,

.....
USAID Kizazi Kipya Project.
Pact, Tanzania.