KAMUZU UNIVERSITY
OF HEALTH SCIENCES

CERTIFICATE OF ETHICS APPROVAL

This is to certify that the COMREC, has reviewed and approved a study entitled:

P.10/25-1848 - Factors contributing to poor adherence to ART among under five children at light house at Queen Elizabeth central hospital by **Ms. Tagwa Elmahi**

on

02/01/2026

As you proceed with the implementation of your study, we would like you to adhere to international ethical guidelines, national guidelines and all requirements by COMREC some of which are indicated on the next page for your study.

Prof. Eric Umar (Comrec Chairperson)

Approved by
College of Medicine
02/01/2026
(COMREC)
Research and Ethics Committee

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

REQUIREMENTS FOR YOUR COMREC APPROVED RESEARCH PROTOCOL

1. Pay the research overhead fees to College of Medicine or Kamuzu College Of Nursing (depending on your affiliation) as required for all approved studies (except undergraduate studies).
2. You should note that the COMREC Sub-Committee on Research Participants' Safety will monitor the conduct of the approved protocol and any deviation from the approved protocol may result in your study being stopped.
3. You will provide an end of study (close-out) report.
4. All COMREC approvals of new applications and progress reports are valid for one year only. Therefore all approved studies running for more than one year are subject to continuing review annually. You are required to submit a progress report to COMREC within 90-30 days before the expiration date. Your current expiration date is **.** Studies shall be considered lapsed and inactive if continuing review application is not received one month after the expiry of the previous approval. In that case, all study related operations should cease immediately except those that are necessary for the welfare of subjects
5. All investigators who are Medical Practitioners must be fully registered with the appropriate regulatory body.

The following documents have been approved in this application

No.	Document Title	Language	Version Number	Version Date
1	Protocol	English	Version 2.0	2025-12-09

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

Study Title

Factors contributing to poor adherence to ART among under five children

Investigators

Principal Investigator

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Qualifications: BPharm (Omdurman Islamic University), MPH Candidate
Academic Title: Postgraduate Student
Institutional Affiliation: Department of Public Health, Kamuzu University of Health Sciences (KUHeS)
Role: Principal Investigator – responsible for study design, ethical approval, data collection, analysis, and report writing.

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Institution Under Whose Umbrella the Research Will Be Conducted

- Kamuzu University of Health Sciences (KUHeS)
- Queen Elizabeth Central Hospital (QECH)

Contents

List of Abbreviations

COM	- College of Medicine
COMREC	- College of Medicine Research Ethics Committee
QECH	– Queen Elizabeth Central Hospital
AIDS	_ Acquired Immunodeficiency Syndrome
HIV	_ Human Immunodeficiency Virus
ART	_ Antiretroviral Therapy
NAC	_ National AIDs commission
MOH	_Ministry of health
EGPAF	_Elizabeth Glaser Pediatric AIDs Foundation
CTC	_Care and Treatment Cards

Executive summary

Type of research study

This study is quantitative cross sectional descriptive study designed to identify key factors contributing to poor adherence to ART among under five.

The problem

The HIV/AIDS epidemic continues to strain Malawi's healthcare system while affecting children at unequal rates. The population of children under five years living with HIV constitutes a group facing extreme morbidity and mortality risks. Antiretroviral therapy (ART) transformed HIV into a chronic manageable condition yet young children's poor ART adherence still disrupts treatment success. The lack of proper adherence leads to virological failure while promoting disease progression and the emergence of drug-resistant HIV strains which threaten individual and public health [23]. Numerous age-related and situational challenges make ART adherence difficult for children under five, including caregiver reliance for medication delivery, unpleasant drug taste, intricate dosing schedules, and common infections like diarrhea that disrupt drug absorption [23] . The combination of caregiver-related elements including stigma and poverty along with caregiver mental health issues and misunderstanding of HIV treatment creates additional barriers to consistent adherence [24]

Current Pediatric HIV programs in Malawi and similar low-income settings have primarily concentrated their efforts on starting ART treatments and decreasing initial death rates. These essential efforts have been critical yet research shows a significant gap in understanding why young children under five struggle with ART adherence. The majority of adherence interventions apply broad methods

intended for older children and adults which may fail to address specific factors affecting this younger demographic [23] .

Objectives

Our main objective is to identify various factors that contribute to poor adherence to ART among under five children attending Queen Elizabeth hospital.

Our specific objectives:

1. To assess the level of ART adherence among HIV-positive children under five at Queen Elizabeth Central Hospital, Malawi.
2. To examine the association between child-related factors (e.g., age, comorbidities, medication palatability) and ART adherence.
3. To determine the influence of caregiver-related factors (e.g., caregiver age, education level) on ART adherence.
4. ~~To evaluate the impact of health system–related factors (e.g., waiting time, distance to hospital, appointment follow-ups) on ART adherence.~~
4. To examine the influence of health system factors on ART adherence.
5. ~~To assess the relationship between socioeconomic factors (e.g., access to health care, transportation) and ART adherence.~~
5. To assess the impact of socioeconomic factors on ART adherence.

Methods

We will conduct a quantitative cross-sectional descriptive study using secondary data from patient records at the Lighthouse Clinic, Queen Elizabeth Central Hospital. The study will be conducted in association with with Lighthouse Clinic team.

The data extraction will be carried out in collaboration with the Lighthouse Clinic team and trained research assistants to ensure accuracy and completeness of extraction. This data collection will take place in october 2025. This study will look at the record of children under five years living with HIV on ART to measure non-adherence level.

We will use systematic random sampling to select eligible records of children aged under 5 receiving ART at Lighthouse Clinic. Data on caregivers, children, socioeconomic factors, and health system will be collected using structured

and pre-tested questionnaire. Trainings will be held for all data collectors before data collection is commenced

Expected findings and dissemination

We will expect that a mixture of factors, including child factors, caregiver-related factors, socio-economic and health system influences, will be found to contribute to poor adherence to antiretroviral treatment (ART) in children under five years. Possible contributing factors might include the lack of caregiver knowledge, economic difficulties, stigma, bitterness of drugs, and healthcare system-related barriers such as stock-outs or long distances to health facilities.

We will expect that the analysis will identify some socio-demographic factors (like care giver educational level, household income, and HIV disclosure status) associated with poor adherence to ART. The findings will help propose interventions that target these factors in order to improve ART adherence among these populations.

After completion of the study we will complete our analysis and will disseminate results to stakeholders in Malawi including those based at QECH and to COMREC, and at international conferences. Ultimately, we will publish our results in open-access journals to share our results widely.

Background

With the introduction of ART, life for people living with and affected by HIV/AIDS improved considerably, as it made the HIV infection into a manageable chronic condition. However, all ART is adherence-dependent, and any poor level of adherence will precipitate resistance, treatment failure, and increased mortality. This issue has become especially dangerous in children under five years due to physiological, developmental, and social factors. This background reviews the burden of pediatric HIV, underscores the importance of ART, and examines barriers to adherence faced by this vulnerable group.

Global Burden of HIV/AIDS and Pediatric HIV

Attention has been paid to prevention, testing, and treatment of HIV/AIDS; however, it remains a significant public health challenge on a global scale. Forecast estimates suggest that by end of 2023, 39.9 million people will be living with HIV, with 65% of these resided in the WHO African Region [1]. People living with HIV in Malawi is about 1.64 million, which puts Malawi among the most affected countries with a skewed burden among women and children [2,4]. Children still lag behind adults in HIV diagnosis, ART initiation, and viral suppression in Malawi. Currently, over 1.3 million children (aged 0–14) living with HIV in sub-Saharan Africa [5].In Malawi the HIV prevalence rate among children is 0.7% which is significantly lower than the adult rate of 8.1%. However, children aged 0-14 represent nearly 15% of AIDS-related deaths every year [6]. There is also a striking difference between adults and children; while 92% of adults 15 years and over were on ART in 2023, only 58% of HIV-positive children 0-14 were on treatment [6]. In particular, adherence and coverage should be strengthened among children in poor settings. Intervention with timely ART gives the best chance for a child to enjoy decades of good health following treatment, and early diagnosis is a very valuable factor.

Importance of Antiretroviral Therapy (ART) and Consequences of Poor Adherence:

ART has significantly transformed management of HIV infection, thereby lessening both morbidity and mortality associated with it. A person living with HIV, including a child, depends on ART to minimize the viral load, strengthen the immune system, and reduce the risk of opportunistic infections [7]. Achieving and maintaining viral suppression requires a patient to take at least 95% of the prescribed ART dosage [8]. with this high level of adherence, the efficacy of ART against the virus is maximized, which improves the quality of life for the patient and prevents the further progression of the disease [7, 9].

Factors Contributing to Poor ART Adherence among Children under Five

Poor adherence to ART among children under five years of age is a complex issue influenced by numerous interrelated factors. These factors largely fall into the categories of child-related, caregiver-related, health system-related, and socio-economic. An understanding of these determinants must be taken into account while giving shape to interventions meant to promote adherence and to achieve better treatment results in this weak segment of population.

Child-Related Factors:

The issue of ART adherence is more pressing in children due to their complete dependency on caregivers for drug administration. A child's age and stage of development affect their ability to understand the importance of medication, which may lead to refusal or resistance. For instance, a study highlighted that children under five present a unique adherence challenge as they rely entirely on their caregivers [10].
In general, adverse drug effects such as nausea, headaches, and abdominal discomfort can be distressing for a child and may contribute to non-adherence. Another concern related to treatment in children is the unpleasant taste of some ART formulations, which can discourage them from taking the medication [7]. The presence of comorbidities, such as tuberculosis, also increases the risk of non-adherence—possibly due to the increased pill burden or side effects [20, 21].

Caregiver-Related Factors

Given the complete dependence of young children on their caregivers, several caregiver-related factors are critical to ensuring adherence to antiretroviral therapy (ART). The literature has examined how knowledge, attitudes, behaviour, and emotional well-being of the carergivers influences treatment outcomes. Non-adherence is sometimes attributed to forgetfulness, disorganized routines, or low health literacy. In some cases carergivers do not fully understand how important strict adherence schedules are or the long-term consequences of missed or double doses [12]. Other barriers include psychosocial stress, depression, other mental health conditions, or limited caregiving capacity. food insecurity, socioeconomic constraints and social support might limit the capacity of a caregiver to prioritise clinic visits or everyday medication administration. Another hindrance would be stigma concerning HIV infection as it might have encouraged caregivers to avoid openly discussing the child's condition or hide the medications, starting medication irregularly or outrightly missing out [13]. Moreover, the quality of the caregiver–child relationship is a contributing factor. Several studies have found higher adherence rates among biological parents compared to foster carers or institutional caregivers [13].

Given these complex dynamics, interventions aimed at improving ART adherence must include **caregiver education, psychosocial support, and strategies to reduce stigma and economic hardship**.

Socio-economic related factors:

Socioeconomic conditions ensure the ability of caregivers to assure that their young children maintain ART adherence at all times. **Poverty**, transport scarcity, and food insecurity often become the impediments to attending clinics regularly and administrating medicine on time. **House hold Food insecurity**, especially at moderate to severe levels, has been correlated with levels of non-adherence [11]. Side effects may occur in children who take ARTs on an empty stomach and hence discourage the caregivers from ensuring the continuation of the medication. Others also see **rural residence** contributing to non-adherence due to the distances to health facilities and support services [14]

Poor adherence is also caused by **cultural beliefs and practices of traditional or alternative medicine**, whereby some caregivers stop ART for herbal remedies, especially when encouraged by community norms or religious beliefs [15]. These challenges are worsened by unemployment, caregiver stress, and social exclusion, all of which threaten to disrupt daily schedules and lower treatment consistency.

Health system related factors:

Health system weakenesses impact ART adherence of children below five by creating structural barriers to access and continuities of the provision of care. Among the chief challenges is the long distance to the health facilities, especially for the rural people, which increase travel time and transport costs for care givers. This often causes caregivers to miss appointments or interruptions in treatment. Long waiting times at clinics and overburdened health workers can also discourage caregivers from attending follow-up visits or engaging in adherence counseling [16].

Another hindrance to the process is frequent stock-outs of pediatric ART formulations, which compel caregivers to return multiple times or risk running out of medication entirely. If the proper dose or formulation is not available, caregivers might be told to use the wrong dose, thus putting children at risk of being under- or overdosed. Also, limited counseling and follow-up services during busy or understaffed clinic hours hamper caregivers' ability to learn ART administration, side effect management, and how to maintain adherence through disruptions due to incidents such as illness or travel. Occasionally, there arose some bad attitudes by providers, stigma, or lack of privacy during consultations discourage open communication between caregivers and clinic staff, further reducing adherence support [17].

To improve adherence among under-five children, health systems need to address these operational gaps, ensuring drug supply, caregiver-friendly services, and adherence counseling, as well as follow-up mechanisms.
Hence, realizing optimal ART adherence for children below five years is troublesome-yet-important work. Down from multi-factorial under the umbrellas of child-related, caregiver-related, regimen-related, and socio-economic/structural-related factors, this dynamic becomes frequented by barriers to adherence. As the outcomes of poor adherence are drug resistance, treatment failures, and the increase in morbidity and mortality in the already vulnerable population, it is pertinent to realize the depth in the contributing factors toward drawing and applying an intervention. This proposal aims to contribute toward further
exploring these factors to provide insights that can steer the way for target strategies to enforce and improve ART adherence for the improvement of the health and well-being of young children living with HIV.

Rationale:

Pediatric HIV and ART for children are explicitly stated as national priorities for Malawi. The National AIDS Commission (NAC) and Ministry of Health (MOH) policy documents give importance to providing services that could prevent ,diagnose and get improved treatment outcomes for children living with HIV [25, 26]. Good adherence to ART in children under five years is pertinent to fulfill these national health objectives.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) has been instrumental in supporting pediatric HIV programs in Malawi while improving early infant diagnosis, treatment access, and adherence support interventions. The experiences of EGPAF have shown that caregiver-based approaches and community involvement are crucial to resolving adherence barriers that young children living with HIV in Malawi face [27].

Poor adherence to ART is still greatly concerning for this population, despite national attempts and institutional contributions, such as the ones made by EGPAF. Young children rely on caregivers for administering medication, and several factors hinder adherence, including the taste of the medicine,

caregivers' knowledge and mental health, access to health services, and socio-economic status .Since pediatric HIV is still considered a national policy priority, this study intends to identify and analyze factors that influence ART adherence among less-than-five-year-old children attending Queen Elizabeth Central Hospital. The study will provide critical data to initiate context-based interventions to improve adherence to this treatment and hence the health outcomes of these vulnerable groups.

Objectives

Our main objective is to identify various factors that contribute to poor adherence to ART among under five children attending Queen Elizabeth hospital

Our specific objectives:

1. To assess the level of ART adherence among HIV-positive children under five at Queen Elizabeth Central Hospital, Malawi.
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5. ~~To assess the relationship between socioeconomic factors (e.g., access to health care, transportation) and ART adherence.~~
5. To assess the impact of socioeconomic factors on ART adherence

Methodology

Study design:

This will be a **quantitative, cross-sectional study** conducted at Queen Elizabeth Central Hospital in Malawi. The study will assess the relationship between child-related, caregiver-related, health system–related and socioeconomic factors and antiretroviral therapy (ART) adherence among HIV-positive children under five years of age.

Study location:

This study will be conducted at the Lighthouse Clinic, located within Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi. QECH is the largest referral hospital in southern Malawi and a major teaching institution for the University Of Malawi College Of Medicine. It serves a large and diverse population from both urban and rural areas.

The Lighthouse Clinic is a specialized center within QECH that provides comprehensive HIV care and treatment services, including pediatric antiretroviral therapy (ART). The clinic plays a key role in the management of HIV-positive patients, including children under the age of five, making it a suitable and relevant setting for this study. Its established ART program, structured follow-up system, and experienced healthcare staff provide an ideal environment for investigating factors influencing ART adherence in young children.

Study population:

The study population will comprise **HIV-positive children under the age of five**—defined as children aged **0 to 59 months** age [22] who are receiving antiretroviral therapy (ART) at the Lighthouse Clinic within Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi. In addition, their primary caregivers will also be included, as they are the key informants regarding the child's treatment adherence and related factors.

These children are part of the pediatric ART program and are routinely followed up at the Lighthouse Clinic for HIV care and treatment services. Caregivers are typically responsible for medication administration and clinic attendance, making their input essential for understanding factors influencing ART adherence in this age group.

Inclusion Criteria

Participants will be included in the study if they meet the following conditions:

1- HIV-positive children aged 0–59 months.

2- Receiving ART at Lighthouse Clinic, QECH.

3- On ART for ≥6 months.

4- Accompanied by a primary caregiver aged ≥18 years who has been caring for the child for at least one month.

Exclusion Criteria

Participants will be excluded if:

~~1. The child has been on ART for less than six months.~~
~~2. The child is not accompanied by a caregiver who meets the inclusion criteria.~~
~~3. The caregiver is unable or unwilling to provide consent.~~
~~4. The caregiver is cognitively impaired, intoxicated, or otherwise unable to provide reliable responses during the interview.~~
1. 1. The child is critically ill or requires urgent medical care on the day of the interview (e.g., severe respiratory distress, seizures, unconsciousness).
2. 2. The caregiver is unable to participate comfortably, for example due to emotional distress, fatigue, or urgent personal matters.
3. 3. The caregiver is intoxicated, cognitively impaired, or otherwise unable to provide reliable responses.
4. 4. The person accompanying the child is not the primary caregiver (e.g., a neighbor, relative, or friend who does not administer the ART medication).
5. 5. Essential medical records needed to assess adherence are missing or incomplete, making it impossible to determine adherence.

Sampling Procedure

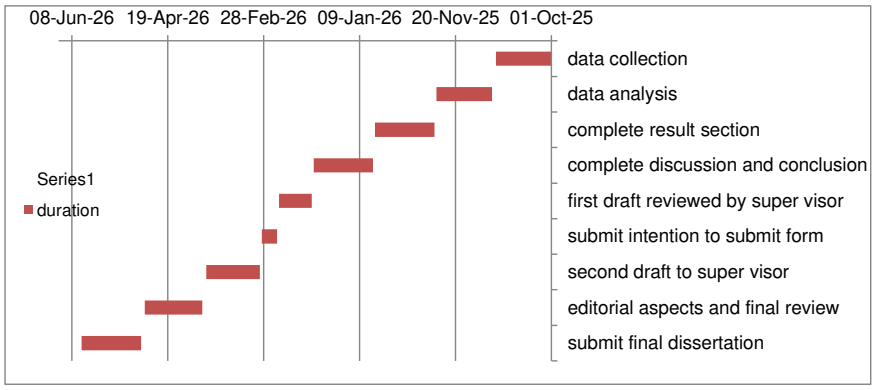
A systematic random sampling method will be used to select eligible caregiver-child pairs from the ART register at Lighthouse Clinic, Queen Elizabeth Central Hospital. The clinic maintains a regularly updated list of HIV-positive children attending ART services, which will serve as the sampling frame.
On each clinic day during the data collection period, a sampling interval (k) will be calculated by dividing the estimated number of eligible children expected to attend during that period by the required sample size. The first participant will be selected randomly among the first few eligible cases using a simple lottery method, and subsequent participants will be selected at every kth interval until the daily target is achieved.
If a selected caregiver-child pair does not meet the inclusion criteria or declines to participate, the next eligible pair in sequence will be selected.

This method ensures that each eligible child has an equal and unbiased chance of being selected, while maintaining logistical feasibility in a busy clinic setting

Study period:

The study will be conducted over a period of nine months, from 1st October 2025 to 30th June 2026. The timeline covers all stages of the research process, including proposal finalisation, ethical clearance, pretesting of tools, data collection, analysis, and report writing.

A detailed breakdown of the activities is shown in the Gantt chart below:



This schedule ensures that adequate time is allocated to each phase of the research to maintain quality, meet academic requirements, and ensure timely completion.

Study Sample Size

A recent meta-analysis reported an overall ART adherence rate of 76.2% among children in Eastern and Southern Africa [18].
Using Cochran's formula with a 95% confidence level (Z = 1.96), 5% margin of error (d = 0.05), and p = 0.762, the initial sample size is 278.
Applying finite population correction for approximately 200 eligible children at the Lighthouse Clinic yields n ≈ 117.
Accounting for a 10% non-response rate, the final target sample size is 129 caregiver-child pairs.

The sample size for this study was determined using Cochran's formula for estimating sample size for proportions:

$n_o = (Z^2 \times p \times (1 - p)) / d^2$

Where:

- n_o = initial sample size
- Z = standard normal deviate at 95% confidence level = 1.96

- p = estimated adherence rate = 0.762 (76.2%) based on recent findings in Eastern and Southern Africa [18]
- d = desired margin of error = 0.05

Substituting the values:

$n_o = (1.96^2 \times 0.762 \times (1 - 0.762)) / 0.05^2$
$n_o = (3.8416 \times 0.762 \times 0.238) / 0.0025$
$n_o \approx 0.6943 / 0.0025 \approx 278$

Given that the total number of eligible HIV-positive children under five receiving ART at Lighthouse Clinic is approximately 200, the finite population correction (FPC) was applied:

$n = n_o / [1 + (n_o - 1) / N]$
$n = 278 / [1 + (277 / 200)] = 278 / (1 + 1.385) = 278 / 2.385 \approx 117$

To account for a potential 10% non-response rate, the final sample size is:

$117 \times 1.1 \approx 129$ caregiver-child pair

Data Collection Procedures

Data will be collected through interviewer-administered electronic questionnaires using the KoBoToolbox platform from eligible caregivers [19]. Trained research assistants will ask the questions verbally in the local language (Chichewa) and enter responses directly into an electronic data collection tool using tablets. This approach ensures inclusivity for caregivers with low literacy while maintaining data accuracy and reducing manual entry errors.

The questionnaire will be structured to capture a wide range of variables, including:

- **Child-related factors**: age, sex, ART regimen, duration on ART, palatability of medication, medication side effect, and comorbid conditions.
- **Caregiver-related factors**: age, sex, education level, marital status, relationship to child, knowledge of ART, belief in ART effectiveness, HIV disclosure status, stigmatization, and forgetfulness,
- **Socioeconomic factors**: household income, caregiver employment status, food security, housing conditions, and transportation cost.

- **Health system factors**: waiting time, drug availability and access to health facility.

  In addition to the caregiver interviews, **relevant clinical information** (such as ART start date, current regimen, most recent weight, and appointment attendance history) will be extracted from the child's **medical file** using an **electronic data abstraction form** developed specifically for this study.

The study tool will be **pretested** in a similar setting to ensure **clarity, cultural relevance, and reliability** before actual data collection begins.

Measurement of ART Adherence:

ART adherence will be assessed using the following two methods:

1. Visual Analogue Scale (VAS)

Caregivers will be asked to estimate the percentage of ART doses their child took in the past 30 days using a Visual Analogue Scale. The scale ranges from 0% (no doses taken) to 100% (all doses taken). The caregiver will be guided to mark a point on the line that best represents their child's medication intake. A VAS score of less than 95% will be considered indicative of non-adherence.

2. pill count

One of the methods used to assess adherence is the pill count approach. For this study, adherence will also be measured using data extracted from the electronic medical record (EMR), where adherence is routinely calculated based on pill counts. This involves determining the number of tablets remaining at the time of the clinic visit and comparing it to the expected number of tablets the patient should have if doses were taken as prescribed.

The adherence percentage will be calculated using the formula:

$$\text{Adherence (\%)} = \left(\frac{\text{Number of tablets expected to be taken} - \text{Number of tablets remaining}}{\text{Number of tablets expected to be taken}} \right) \times 100$$

Children with adherence levels below 95% will be classified as non-adherent

Data Management/ Analysis

All data will be collected electronically using KoBoToolbox on password-protected tablets and uploaded daily to a secure cloud server. Data will be reviewed regularly for completeness, consistency, and accuracy by the study supervisor.

Data collection forms will be anonymous and identified only by a unique study identification number assigned to each participant. Clinical information will be extracted from the child's medical records, including care and greatment (CTC) cards, case notes, and the electronic medical record system, depending on the documentation used at the facility. For participants with indicators of poor adherence, caregivers will be asked follow-up questions to explore the reasons behind non-adherence, such as forgetfulness, transportation issues, medication side effects, or lack of food.

To ensure confidentiality, all final datasets will be stored securely and backed up regularly. Only authorized research staff will have access to the data.

Statistical analysis:

The data will be processed and analyzed using Stata version 17. Throughout the data cleaning phase, rigorous quality control measures will be employed to maintain data integrity. Descriptive statistics will summarize the study variables, using averages and measures of variability for continuous data, and counts with percentages for categorical data. Findings will be displayed using appropriate visual tools such as tables, graphs, and charts.

Adherence to ART will be computed and classified into adherent (≥95%) and non-adherent (<95%) groups. To examine relationships between adherence and potential influencing factors, bivariate analyses will be conducted employing Chi-square tests or Fisher's exact test when necessary. The strength of associations will be expressed using odds ratios (ORs).

Variables with a p-value less than 0.2 during bivariate analysis will be further examined in a multivariable logistic regression model to determine independent predictors of non-adherence. Variables with an adjusted odds ratio (AOR) significant at the 0.05 level, along with their 95% confidence intervals, will be considered statistically meaningful.

Presentation of Results

The results will be comprehensively reported in a structured format and prepared for submission to a peer-reviewed journal. Statistical analyses will be conducted to assess the relationship between ART non-adherence and selected independent variables. Findings will be presented in tables, accompanied by narrative descriptions and interpretations. Where appropriate, data will also be visually summarized using graphs and charts to enhance understanding

Dissemination of Results

The findings of this study will be disseminated to various stakeholders to ensure that the knowledge generated contributes to improving ART adherence among children. Thereafter, findings will be shared at national scientific forums such as the College of Medicine Research Dissemination Day, and where possible, at international conferences. A written summary of the findings will be submitted to the local paediatric department at QECH and to the College of Medicine Research and Ethics Committee (COMREC). Finally, the study will be prepared for publication in a peer-reviewed open-access journal to ensure wider dissemination and contribution to global knowledge on paediatric ART adherence.

Ethical Considerations

Ethical approval to conduct this study will be obtained from the College of Medicine Research and Ethics Committee (COMREC). Permission will also be sought from the management of Queen Elizabeth Central Hospital (QECH) and the Lighthouse Clinic, where the study will be conducted.

Participants will be informed that they have the right to withdraw from the study at any point without any consequence to the care they or their child receives at the clinic. Monetary incentives will not be provided to avoid undue influence or coercion that may compromise voluntary participation. However, light refreshments such as bottled water, juice, or biscuits may be offered as a gesture of appreciation for the caregivers' time and participation.

Possible constraints

Several challenges may be encountered during the implementation of this study:

1. **Caregiver Literacy and Understanding**
   Some caregivers may have limited literacy, which could affect their ability to understand the study tools or consent forms. To address this, data collection tools will be administered orally in a language the caregivers understand, and trained research assistants will assist with clarifying questions.
2. **Social Desirability Bias**
   Caregivers may provide answers they believe are expected or acceptable, especially regarding adherence behavior. This may affect the accuracy of self-reported data. To minimize this, interviews will be conducted in a non-judgmental, private environment to encourage honest responses.
3. **Incomplete or Inaccurate Medical Records**
   The quality of ART adherence data may be limited by incomplete or inconsistent documentation in patient records. The research team will cross-check multiple sources (e.g., pharmacy refill logs and clinical notes) where possible.
4. **Time Constraints of Caregivers**
   Caregivers may have limited time to participate in interviews due to other responsibilities. To reduce this burden, interviews will be kept as brief as possible without compromising data quality, and conducted during their routine clinic visits.
5. **Resource Limitations**
   Budget constraints may affect the number of data collectors, availability of digital tools, or logistics. Efficient planning and seeking in-kind support from the facility will help address these challenges.

Capacity Building

This study will contribute to capacity building in several ways. It will provide training opportunities for research assistants and healthcare staff involved in data collection, enhancing their skills in quantitative research methods, ethical research conduct, and use of electronic data collection tools such as KoBoToolbox. The findings will be shared with Lighthouse Clinic healthcare providers and management to improve their understanding of factors affecting ART adherence in children, supporting evidence-based practice.
Additionally, the research process will strengthen collaboration between Kamuzu University of Health Sciences and Queen Elizabeth Central Hospital, fostering an environment conducive to future research and continuous professional development in paediatric HIV care.

Study Requirements

To successfully conduct this study, the following resources and conditions are required:

- **Ethical Approval and Permissions:** Approval from the College of Medicine Research and Ethics Committee (COMREC), and permission from the management of Queen Elizabeth Central Hospital (QECH) and Lighthouse Clinic.
- **Trained Research Team:** A team of trained data collectors proficient in administering interviewer-led electronic questionnaires and handling sensitive data.
- **Data Collection Tools:** Access to electronic data collection platforms such as KoBoToolbox, tablets or smartphones for data entry, and paper forms for backup.
- **Logistical Support:** Transportation for the research team to and from Lighthouse Clinic, and provision of light refreshments for participants.
- **Financial Resources:** Funding to cover personnel costs, data collection materials, data management software, and dissemination activities.
- **Collaboration and Support:** Cooperation from Lighthouse Clinic staff and caregivers for smooth recruitment and data collection.
- **Time Allocation:** Adequate time for training, data collection (September 2024 to June 2025), data analysis, and report writing.

Training for Study Staff

All study staff, including data collectors and supervisors, will undergo comprehensive training before the commencement of data collection. The training will cover the following key areas:

- **Study Objectives and Protocol:** Understanding the aims, research questions, and methodology of the study to ensure consistency and quality in data collection.
- **Ethical Considerations:** Emphasizing confidentiality, informed consent procedures, and respectful interaction with participants.
- **Data Collection Tools:** Hands-on training in administering the electronic questionnaires using KoBoToolbox, including troubleshooting common technical issues.
- **Interview Techniques:** Developing skills in conducting interviewer-administered surveys, managing sensitive topics, and minimizing social desirability bias.
- **Data Management:** Proper handling, storage, and transmission of data to ensure accuracy and security.

Budget & Justification of Budget

The budget for this study has been carefully estimated to cover all essential components required for successful completion. The main cost categories include personnel, data collection, materials and supplies, transport, communication, and dissemination of findings. Below is an itemized budget estimate:

Item	Description	Quantity	Unit Cost (MWK)	Total Cost (MWK)	Total Cost (USD)
Personnel	Research assistant stipend	3 months	50,000	150,000	84
	Data collectors (2 persons, 10 days)	20 days	20,000	400,000	224
Training	Training workshop for data collectors	1 session	180,000	180,000	100
	Printing questionnaires,	Lump sum	90,000	90,000	50

Data Collection Materials	consent forms, stationery				
	Digital devices (tablets or phones for data entry)	2 units	135000	270000	150
Transport	Travel to/from QECH study sites (fuel, transport)	15 trips	20,000	300,000	168
Communication	Mobile airtime, internet data	Lump sum	50000	50000	28
Data Analysis	Stata version(17) consultation fees	Lump sum	100,000	100,000	56
Dissemination	Printing final report, workshops, conference fees	Lump sum	100,000	100,000	56
Contingency (10%)	To cover unexpected expenses	Lump sum	—	358000	200
TOTAL				**1,998,000**	**1,116**

Note: USD amounts are approximate, based on an exchange rate of 1 USD ≈ 1,800 MWK.

References:

1. World Health Organization. (2024). HIV/AIDS Fact Sheet. Retrieved from https://www.who.int/news-room/fact-sheets/detail/hiv-aids
2. Wikipedia: HIV adult prevalence rate
3. Matola BW, Mapahla L, Nyasulu JCY. Malawi's progress towards UNAIDS 95-95-95 fast-track targets: who is lagging? African J AIDS Res. 2025;5906(May).
4. ICAP at Columbia University. (2023). Malawi Population-based HIV Impact Assessment (MPHIA) 2022–2023 Summary Sheet. Retrieved from https://phia.icap.columbia.edu

5. UNAIDS. Africa's children deserve better: Accelerating action to end AIDS in children. [Internet]. Geneva: UNAIDS; 2024 Jun 14 [cited 2025 Jul 3]. Available from: https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2024/june/20240614_day-african-child
6. World Education Inc./Bantwana Initiative. Strengthening pediatric case finding and improving HIV treatment outcomes for OVC in Malawi: APA Technical Brief [Internet]. Blantyre: Bantwana Initiative; 2020 [cited 2025 Jul 3]. Available from: https://bantwana.org/wp-content/uploads/2022/07/APA-OVC-Tech-Brief-July20-forPRINTING.pdf
7. U.S. Department of Health and Human Services. Adherence to antiretroviral therapy among children and adolescents living with HIV [Internet]. Washington (DC): HIV.gov; [updated 2023 Nov; cited 2025 Jul 3]. Available from: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/adherence-antiretroviral-therapy-children-and-adolescents-living-hiv
8. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach [Internet]. Geneva: WHO; 2016 [cited 2025 Jul 3]. Available from: https://www.who.int/publications/i/item/9789241549684
9. Tadese BK, Hennessy F, Salmon P, et al. Adherence to antiretroviral therapy and its association with quality of life among people with HIV in the United States. Aids Care-psychological and Socio-medical Aspects of Aids/hiv 2024; 1–13.
10. Tong, P. D., Atuhairwe, C., & Taremwa, I. M. (2020). Differential Self-Reported Determinants to Antiretroviral Therapy Adherence: Findings from Caregivers of Children Under Five Years Living with Human Immunodeficiency Virus Infection Attending Al-Sabah Hospital, South Sudan. HIV/AIDS - Research and Palliative Care, 12, 175 –186.
11. Ssanyu JN, Nakafeero M, Nuwaha F. Multi-measure assessment of adherence to antiretroviral therapy among children under five years living with HIV in Jinja, Uganda. BMC Public Health 2020; 20: 1–10.
12. Vreeman RC, Wiehe SE, Pearce EC, Nyandiko WM. A systematic review of pediatric adherence to antiretroviral therapy in low- and middle-income countries. Pediatr Infect Dis J. 2008;27(8):686–691

13. Getahun BG, Hebo H, Kura Z. Children's adherence to antiretroviral therapy and associated factors: multicenter cross-sectional study. HIV AIDS (Auckl). 2023;15:231–241.
14. Clinical Non-Adherence and Its Associated Factors Among HIV-Positive Pediatric Patients Attending HIV Care in South Gondar Zone Public Health Facilities, Northwest Ethiopia, 2021. 2022; 14: 23–32.
15. Lubinga SJ, Kintu A, Atuhaire J, Asiimwe S. Concomitant herbal medicine and antiretroviral therapy (ART) use among HIV patients in Western Uganda: A cross-sectional analysis of magnitude and patterns. Afr Health Sci. 2012;12(1):1–9.
16. Chikwari CD, Ferrand RA, Simms V. Barriers to HIV care and treatment in children and adolescents: A qualitative study from Zimbabwe. PLoS One. 2019;14(2):e0210736.
17. Bemelmans M, Baert S, Goemaere E, et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. Trop Med Int Health. 2014;19(8):968–977.
18. Gebremichael B, Derseh L, Alemayehu M. Adherence to antiretroviral therapy among children in Eastern and Southern Africa: A systematic review and meta-analysis. PLoS One. 2023;18(3):e0312529. doi:10.1371/journal.pone.0312529
19. 13.Harvard Humanitarian Initiative . KoBoToolbox. Cambridge: Harvard Humanitarian Initiative; 2019. [Google Scholar]
20. Gemechu GB, Hebo H, Kura Z. Children's adherence to antiretroviral therapy and associated factors: multicenter cross-sectional study. HIV AIDS (Auckl). 2023 Jul 21;15:423–434. doi:10.2147/HIV.S407105. PMID: 37497118; PMCID: PMC10368110.
21. Mussa FM, Massawe HP, Bhalloo H, Moledina S, Assenga E. Magnitude and associated factors of anti-retroviral therapy adherence among children attending HIV care and treatment clinics in Dar es Salaam, Tanzania. PLoS One. 2022 Sep 30;17(9):e0275420. doi:10.1371/journal.pone.0275420. PMID: 36178915; PMCID: PMC9524636.
22. UNICEF. Levels & Trends in Child Mortality: Report 2021. Estimates developed by the UN Inter-agency Group for Child Mortality Estimation. New York: United Nations Children's Fund; 2021.
23. Alemu GG, Yirsaw BG, Tesfie TK, Yismaw GA, Abuhay HW, Alemayehu MA, et al. Adherence to antiretroviral therapy and its associated factors among children living with HIV in Eastern and Southern Africa: A

systematic review and meta-analysis. PLOS ONE. 2025 Jan 6;20(1):e0312529.

24. Kayange M, Mopamboli P, Ogbonna G, Jumbe V. Barriers and Facilitators to PrEP Uptake and Adherence among Adolescent Girls and Young Women Attending Family Planning Clinics in Mulanje District, Malawi: A Qualitative Study. 2025 Jan 23;
25. National AIDS Commission. Malawi National Strategic Plan for HIV and AIDS 2020–2025. Lilongwe: NAC; 2020.
26. Ministry of Health. Malawi Guidelines for Clinical Management of HIV in Children and Adults. Lilongwe: MoH; 2022.
27. Elizabeth Glaser Pediatric AIDS Foundation. Malawi Program Overview. EGPAF; 2023. Available from: https://www.pedaids.org/where-we-work/malawi/

COMREC INTRODUCTION LETTER (FINAL FORMATTED VERSION)

Date: 9 December 2025

To:
The Chairperson
College of Medicine Research and Ethics Committee (COMREC)
Kamuzu University of Health Sciences

From:
Ms. Tagwa Elmahi
Kamuzu University of Health Sciences

RE: RESPONSE TO COMREC QUERIES FOR PROTOCOL P.10/25-1848

Dear Prof. Eric Umar,

Thank you for reviewing my research protocol titled "Factors contributing to poor adherence to Antiretroviral Therapy (ART) among children under five years at Lighthouse Clinic, Queen Elizabeth Central Hospital." I appreciate the guidance provided by the committee and have revised the proposal based on the comments received.

1. Specific Objectives 4 and 5 were outside the scope of the broad objective

The broad objective has been maintained as originally written. However, Specific Objectives 4 and 5 have been revised so that they now fully align with the broad objective.

The revised objectives are:

- Revised Specific Objective 4:
  To examine the influence of health system–related factors on ART adherence.

- Revised Specific Objective 5:
  To assess the impact of socioeconomic factors on ART adherence.

These revisions ensure that all specific objectives clearly relate to factors contributing to poor ART adherence among children under five.

2. Exclusion criteria were not appropriate

The exclusion criteria have been revised to reflect practical and ethical considerations, rather than simply the opposite of the inclusion criteria. The updated exclusion criteria now include:

1. The child is critically ill or requires urgent medical care on the day of the interview (e.g., severe respiratory distress, seizures, unconsciousness).

2. The caregiver is unable to participate comfortably, for example due to emotional distress, fatigue, or urgent personal matters.

3. The caregiver is intoxicated, cognitively impaired, or otherwise unable to provide reliable responses.

4. The person accompanying the child is not the primary caregiver (e.g., a neighbor, relative, or friend who does not administer the ART medication).

5. Essential medical records needed to assess adherence are missing or incomplete, making it impossible to determine adherence.

3. Provision of consent incorrectly included as an inclusion/exclusion criterion

All references to provision of consent have been removed from the inclusion and exclusion criteria. Consent is now addressed solely within the Ethical Considerations section in accordance with COMREC requirements.

Documents Submitted

1. This introduction letter detailing all revisions
2. Revised protocol with tracked changes
3. Clean version of the revised protocol

Thank you once again for the constructive feedback. I kindly request expedited re-review of my revised submission.

Yours sincerely,
Ms. Tagwa Elmahi
Kamuzu University of Health Sciences
Phone: 098 203 2224

KAMUZU UNIVERSITY
OF HEALTH SCIENCES

Study Title

Factors contributing to poor adherence to ART among under five children

Investigators

Principal Investigator

Full Name: Tagwa Elmaleeh Mugadam Elmahi
Qualifications: BPharm (Omdurman Islamic University), MPH Candidate
Academic Title: Postgraduate Student
Institutional Affiliation: Department of Public Health, Kamuzu University of Health Sciences (KUHeS)
Role: Principal Investigator – responsible for study design, ethical approval, data collection, analysis, and report writing.

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Institution Under Whose Umbrella the Research Will Be Conducted

- Kamuzu University of Health Sciences (KUHeS)
- Queen Elizabeth Central Hospital (QECH)

Contents

List of Abbreviations

COM	- College of Medicine
COMREC	- College of Medicine Research Ethics Committee
QECH	– Queen Elizabeth Central Hospital
AIDS	_ Acquired Immunodeficiency Syndrome
HIV	_ Human Immunodeficiency Virus
ART	_ Antiretroviral Therapy
NAC	_ National AIDs commission
MOH	_Ministry of health
EGPAF	_Elizabeth Glaser Pediatric AIDs Foundation
CTC	_Care and Treatment Cards

Executive summary

Type of research study

This study is quantitative cross sectional descriptive study designed to identify key factors contributing to poor adherence to ART among under five.

The problem

The HIV/AIDS epidemic continues to strain Malawi's healthcare system while affecting children at unequal rates. The population of children under five years living with HIV constitutes a group facing extreme morbidity and mortality risks. Antiretroviral therapy (ART) transformed HIV into a chronic manageable condition yet young children's poor ART adherence still disrupts treatment success. The lack of proper adherence leads to virological failure while promoting disease progression and the emergence of drug-resistant HIV strains which threaten individual and public health [23]. Numerous age-related and situational challenges make ART adherence difficult for children under five, including caregiver reliance for medication delivery, unpleasant drug taste, intricate dosing schedules, and common infections like diarrhea that disrupt drug absorption [23] . The combination of caregiver-related elements including stigma and poverty along with caregiver mental health issues and misunderstanding of HIV treatment creates additional barriers to consistent adherence [24]

Current Pediatric HIV programs in Malawi and similar low-income settings have primarily concentrated their efforts on starting ART treatments and decreasing initial death rates. These essential efforts have been critical yet research shows a significant gap in understanding why young children under five struggle with ART adherence. The majority of adherence interventions apply broad methods

intended for older children and adults which may fail to address specific factors affecting this younger demographic [23] .

Objectives

Our main objective is to identify various factors that contribute to poor adherence to ART among under five children attending Queen Elizabeth hospital.

Our specific objectives:

1. To assess the level of ART adherence among HIV-positive children under five at Queen Elizabeth Central Hospital, Malawi.
2. To examine the association between child-related factors (e.g., age, comorbidities, medication palatability) and ART adherence.
3. To determine the influence of caregiver-related factors (e.g., caregiver age, education level) on ART adherence.
4. To examine the influence of health system factors on ART adherence.
5. To assess the impact of socioeconomic factors on ART adherence.

Methods

We will conduct a quantitative cross-sectional descriptive study using secondary data from patient records at the Lighthouse Clinic, Queen Elizabeth Central Hospital. The study will be conducted in association with with Lighthouse Clinic team.

The data extraction will be carried out in collaboration with the Lighthouse Clinic team and trained research assistants to ensure accuracy and completeness of extraction. This data collection will take place in october 2025. This study will look at the record of children under five years living with HIV on ART to measure non-adherence level.

We will use systematic random sampling to select eligible records of children aged under 5 receiving ART at Lighthouse Clinic. Data on caregivers, children, socioeconomic factors, and health system will be collected using structured and pre-tested questionnaire. Trainings will be held for all data collectors before data collection is commenced

Expected findings and dissemination

We will expect that a mixture of factors, including child factors, caregiver-related factors, socio-economic and health system influences, will be found to contribute to poor adherence to antiretroviral treatment (ART) in children under five years. Possible contributing factors might include the lack of caregiver knowledge, economic difficulties, stigma, bitterness of drugs, and healthcare system-related barriers such as stock-outs or long distances to health facilities.

We will expect that the analysis will identify some socio-demographic factors (like care giver educational level, household income, and HIV disclosure status) associated with poor adherence to ART. The findings will help propose interventions that target these factors in order to improve ART adherence among these populations.

After completion of the study we will complete our analysis and will disseminate results to stakeholders in Malawi including those based at QECH and to COMREC, and at international conferences. Ultimately, we will publish our results in open-access journals to share our results widely.

Background

With the introduction of ART, life for people living with and affected by HIV/AIDS improved considerably, as it made the HIV infection into a manageable chronic condition. However, all ART is adherence-dependent, and any poor level of adherence will precipitate resistance, treatment failure, and increased mortality. This issue has become especially dangerous in children under five years due to physiological, developmental, and social factors. This background reviews the burden of pediatric HIV, underscores the importance of ART, and examines barriers to adherence faced by this vulnerable group.

Global Burden of HIV/AIDS and Pediatric HIV

Attention has been paid to prevention, testing, and treatment of HIV/AIDS; however, it remains a significant public health challenge on a global scale. Forecast estimates suggest that by end of 2023, 39.9 million people will be living with HIV, with 65% of these resided in the WHO African Region [1].

People living with HIV in Malawi is about 1.64 million, which puts Malawi among the most affected countries with a skewed burden among women and children [2,4]. Children still lag behind adults in HIV diagnosis, ART initiation, and viral suppression in Malawi. Currently, over 1.3 million children (aged 0–14) living with HIV in sub-Saharan Africa [5].In Malawi the HIV prevalence rate among children is 0.7% which is significantly lower than the adult rate of 8.1%. However, children aged 0-14 represent nearly 15% of AIDS-related deaths every year [6]. There is also a striking difference between adults and children; while 92% of adults 15 years and over were on ART in 2023, only 58% of HIV-positive children 0-14 were on treatment [6]. In particular, adherence and coverage should be strengthened among children in poor settings. Intervention with timely ART gives the best chance for a child to enjoy decades of good health following treatment, and early diagnosis is a very valuable factor.

Importance of Antiretroviral Therapy (ART) and Consequences of Poor Adherence:

ART has significantly transformed management of HIV infection, thereby lessening both morbidity and mortality associated with it. A person living with HIV, including a child, depends on ART to minimize the viral load, strengthen the immune system, and reduce the risk of opportunistic infections [7]. Achieving and maintaining viral suppression requires a patient to take at least 95% of the prescribed ART dosage [8]. with this high level of adherence, the efficacy of ART against the virus is maximized, which improves the quality of life for the patient and prevents the further progression of the disease [7, 9].

Factors Contributing to Poor ART Adherence among Children under Five

Poor adherence to ART among children under five years of age is a complex issue influenced by numerous interrelated factors. These factors largely fall into the categories of child-related, caregiver-related, health system-related, and socio-economic. An understanding of these determinants must be taken into account while giving shape to interventions meant to promote adherence and to achieve better treatment results in this weak segment of population.

Child-Related Factors:

The issue of ART adherence is more pressing in children due to their complete dependency on caregivers for drug administration. A child's age and stage of development affect their ability to understand the importance of medication,

which may lead to refusal or resistance. For instance, a study highlighted that children under five present a unique adherence challenge as they rely entirely on their caregivers [10].
In general, adverse drug effects such as nausea, headaches, and abdominal discomfort can be distressing for a child and may contribute to non-adherence. Another concern related to treatment in children is the unpleasant taste of some ART formulations, which can discourage them from taking the medication [7]. The presence of comorbidities, such as tuberculosis, also increases the risk of non-adherence—possibly due to the increased pill burden or side effects [20, 21].

Caregiver-Related Factors

Given the complete dependence of young children on their caregivers, several caregiver-related factors are critical to ensuring adherence to antiretroviral therapy (ART). The literature has examined how knowledge, attitudes, behaviour, and emotional well-being of the carergivers influences treatment outcomes. Non-adherence is sometimes attributed to forgetfulness, disorganized routines, or low health literacy. In some cases carergivers do not fully understand how important strict adherence schedules are or the long-term consequences of missed or double doses [12]. Other barriers include psychosocial stress, depression, other mental health conditions, or limited caregiving capacity. food insecurity, socioeconomic constraints and social support might limit the capacity of a caregiver to prioritise clinic visits or everyday medication administration. Another hindrance would be stigma concerning HIV infection as it might have encouraged caregivers to avoid openly discussing the child's condition or hide the medications, starting medication irregularly or outrightly missing out [13]. Moreover, the quality of the caregiver–child relationship is a contributing factor. Several studies have found higher adherence rates among biological parents compared to foster carers or institutional caregivers [13].

Given these complex dynamics, interventions aimed at improving ART adherence must include **caregiver education, psychosocial support, and strategies to reduce stigma and economic hardship**.

Socio-economic related factors:

Socioeconomic conditions ensure the ability of caregivers to assure that their young children maintain ART adherence at all times. **Poverty**, transport

scarcity, and food insecurity often become the impediments to attending clinics regularly and administrating medicine on time. **House hold Food insecurity**, especially at moderate to severe levels, has been correlated with levels of non-adherence [11]. Side effects may occur in children who take ARTs on an empty stomach and hence discourage the caregivers from ensuring the continuation of the medication. Others also see **rural residence** contributing to non-adherence due to the distances to health facilities and support services [14]

Poor adherence is also caused by **cultural beliefs and practices of traditional or alternative medicine**, whereby some caregivers stop ART for herbal remedies, especially when encouraged by community norms or religious beliefs [15]. These challenges are worsened by unemployment, caregiver stress, and social exclusion, all of which threaten to disrupt daily schedules and lower treatment consistency.

Health system related factors:

Health system weakenesses impact ART adherence of children below five by creating structural barriers to access and continuities of the provision of care. Among the chief challenges is the long distance to the health facilities, especially for the rural people, which increase travel time and transport costs for care givers. This often causes caregivers to miss appointments or interruptions in treatment. Long waiting times at clinics and overburdened health workers can also discourage caregivers from attending follow-up visits or engaging in adherence counseling [16].

Another hindrance to the process is frequent stock-outs of pediatric ART formulations, which compel caregivers to return multiple times or risk running out of medication entirely. If the proper dose or formulation is not available, caregivers might be told to use the wrong dose, thus putting children at risk of being under- or overdosed. Also, limited counseling and follow-up services during busy or understaffed clinic hours hamper caregivers' ability to learn ART administration, side effect management, and how to maintain adherence through disruptions due to incidents such as illness or travel. Occasionally, there arose some bad attitudes by providers, stigma, or lack of privacy during consultations discourage open communication between caregivers and clinic staff, further reducing adherence support [17].

To improve adherence among under-five children, health systems need to address these operational gaps, ensuring drug supply, caregiver-friendly services, and adherence counseling, as well as follow-up mechanisms.
Hence, realizing optimal ART adherence for children below five years is troublesome-yet-important work. Down from multi-factorial under the umbrellas of child-related, caregiver-related, regimen-related, and socio-economic/structural-related factors, this dynamic becomes frequented by barriers to adherence. As the outcomes of poor adherence are drug resistance, treatment failures, and the increase in morbidity and mortality in the already vulnerable population, it is pertinent to realize the depth in the contributing factors toward drawing and applying an intervention. This proposal aims to contribute toward further
exploring these factors to provide insights that can steer the way for target strategies to enforce and improve ART adherence for the improvement of the health and well-being of young children living with HIV.

Rationale:

Pediatric HIV and ART for children are explicitly stated as national priorities for Malawi. The National AIDS Commission (NAC) and Ministry of Health (MOH) policy documents give importance to providing services that could prevent ,diagnose and get improved treatment outcomes for children living with HIV [25, 26]. Good adherence to ART in children under five years is pertinent to fulfill these national health objectives.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) has been instrumental in supporting pediatric HIV programs in Malawi while improving early infant diagnosis, treatment access, and adherence support interventions. The experiences of EGPAF have shown that caregiver-based approaches and community involvement are crucial to resolving adherence barriers that young children living with HIV in Malawi face [27].

Poor adherence to ART is still greatly concerning for this population, despite national attempts and institutional contributions, such as the ones made by EGPAF. Young children rely on caregivers for administering medication, and several factors hinder adherence, including the taste of the medicine,

caregivers' knowledge and mental health, access to health services, and socio-economic status .Since pediatric HIV is still considered a national policy priority, this study intends to identify and analyze factors that influence ART adherence among less-than-five-year-old children attending Queen Elizabeth Central Hospital. The study will provide critical data to initiate context-based interventions to improve adherence to this treatment and hence the health outcomes of these vulnerable groups.

Objectives

Our main objective is to identify various factors that contribute to poor adherence to ART among under five children attending Queen Elizabeth hospital
Our specific objectives:

1. To assess the level of ART adherence among HIV-positive children under five at Queen Elizabeth Central Hospital, Malawi.
2. To examine the association between child-related factors (e.g., age, comorbidities, medication palatability) and ART adherence.
3. To determine the influence of caregiver-related factors (e.g., caregiver age, education level) on ART adherence.
4. To examine the influence of health system factors on ART adherence.
5. To assess the impact of socioeconomic factors on ART adherence

Methodology

Study design:
This will be a **quantitative, cross-sectional study** conducted at Queen Elizabeth Central Hospital in Malawi. The study will assess the relationship between child-related, caregiver-related, health system–related and socioeconomic factors and antiretroviral therapy (ART) adherence among HIV-positive children under five years of age.

Study location:

This study will be conducted at the Lighthouse Clinic, located within Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi. QECH is the largest referral hospital in southern Malawi and a major teaching institution for the University Of Malawi College Of Medicine. It serves a large and diverse population from both urban and rural areas.

The Lighthouse Clinic is a specialized center within QECH that provides comprehensive HIV care and treatment services, including pediatric antiretroviral therapy (ART). The clinic plays a key role in the management of HIV-positive patients, including children under the age of five, making it a suitable and relevant setting for this study. Its established ART program, structured follow-up system, and experienced healthcare staff provide an ideal environment for investigating factors influencing ART adherence in young children.

Study population:

The study population will comprise **HIV-positive children under the age of five**—defined as children aged **0 to 59 months** age [22] who are receiving antiretroviral therapy (ART) at the Lighthouse Clinic within Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi. In addition, their primary caregivers will also be included, as they are the key informants regarding the child's treatment adherence and related factors.

These children are part of the pediatric ART program and are routinely followed up at the Lighthouse Clinic for HIV care and treatment services. Caregivers are typically responsible for medication administration and clinic attendance, making their input essential for understanding factors influencing ART adherence in this age group.

Inclusion Criteria

Participants will be included in the study if they meet the following conditions:

1- HIV-positive children aged 0–59 months.
2- Receiving ART at Lighthouse Clinic, QECH.
3- On ART for ≥6 months.
4- Accompanied by a primary caregiver aged ≥18 years who has been caring for the child for at least one month.

Exclusion Criteria

Participants will be excluded if:

1. The child is critically ill or requires urgent medical care on the day of the interview (e.g., severe respiratory distress, seizures, unconsciousness).

2. The caregiver is unable to participate comfortably, for example due to emotional distress, fatigue, or urgent personal matters.
3. The caregiver is intoxicated, cognitively impaired, or otherwise unable to provide reliable responses.
4. The person accompanying the child is not the primary caregiver (e.g., a neighbor, relative, or friend who does not administer the ART medication).
5. Essential medical records needed to assess adherence are missing or incomplete, making it impossible to determine adherence.

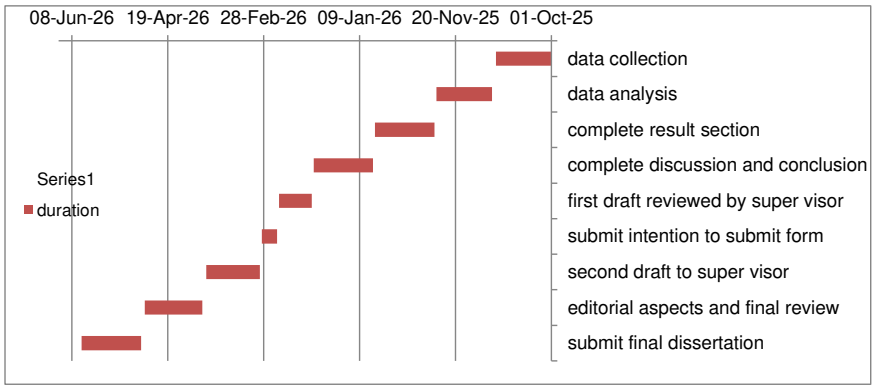
Sampling Procedure

A systematic random sampling method will be used to select eligible caregiver-child pairs from the ART register at Lighthouse Clinic, Queen Elizabeth Central Hospital. The clinic maintains a regularly updated list of HIV-positive children attending ART services, which will serve as the sampling frame.
On each clinic day during the data collection period, a sampling interval (k) will be calculated by dividing the estimated number of eligible children expected to attend during that period by the required sample size. The first participant will be selected randomly among the first few eligible cases using a simple lottery method, and subsequent participants will be selected at every kth interval until the daily target is achieved.
If a selected caregiver-child pair does not meet the inclusion criteria or declines to participate, the next eligible pair in sequence will be selected.
This method ensures that each eligible child has an equal and unbiased chance of being selected, while maintaining logistical feasibility in a busy clinic setting

Study period:

The study will be conducted over a period of nine months, from 1st October 2025 to 30th June 2026. The timeline covers all stages of the research process, including proposal finalisation, ethical clearance, pretesting of tools, data collection, analysis, and report writing.

A detailed breakdown of the activities is shown in the Gantt chart below:



This schedule ensures that adequate time is allocated to each phase of the research to maintain quality, meet academic requirements, and ensure timely completion.

Study Sample Size

A recent meta-analysis reported an overall ART adherence rate of 76.2% among children in Eastern and Southern Africa [18].
Using Cochran's formula with a 95% confidence level (Z = 1.96), 5% margin of error (d = 0.05), and p = 0.762, the initial sample size is 278.
Applying finite population correction for approximately 200 eligible children at the Lighthouse Clinic yields n ≈ 117.
Accounting for a 10% non-response rate, the final target sample size is 129 caregiver-child pairs.

The sample size for this study was determined using Cochran's formula for estimating sample size for proportions:

$n_o = (Z^2 \times p \times (1 - p)) / d^2$

Where:

- n_o = initial sample size
- Z = standard normal deviate at 95% confidence level = 1.96

- p = estimated adherence rate = 0.762 (76.2%) based on recent findings in Eastern and Southern Africa [18]
- d = desired margin of error = 0.05

Substituting the values:

$n_o = (1.96^2 \times 0.762 \times (1 - 0.762)) / 0.05^2$
$n_o = (3.8416 \times 0.762 \times 0.238) / 0.0025$
$n_o \approx 0.6943 / 0.0025 \approx 278$

Given that the total number of eligible HIV-positive children under five receiving ART at Lighthouse Clinic is approximately 200, the finite population correction (FPC) was applied:

$n = n_o / [1 + (n_o - 1) / N]$
$n = 278 / [1 + (277 / 200)] = 278 / (1 + 1.385) = 278 / 2.385 \approx 117$

To account for a potential 10% non-response rate, the final sample size is:

$117 \times 1.1 \approx 129$ caregiver-child pair

Data Collection Procedures

Data will be collected through interviewer-administered electronic questionnaires using the KoBoToolbox platform from eligible caregivers [19]. Trained research assistants will ask the questions verbally in the local language (Chichewa) and enter responses directly into an electronic data collection tool using tablets. This approach ensures inclusivity for caregivers with low literacy while maintaining data accuracy and reducing manual entry errors.

The questionnaire will be structured to capture a wide range of variables, including:

- **Child-related factors**: age, sex, ART regimen, duration on ART, palatability of medication, medication side effect, and comorbid conditions.
- **Caregiver-related factors**: age, sex, education level, marital status, relationship to child, knowledge of ART, belief in ART effectiveness, HIV disclosure status, stigmatization, and forgetfulness,
- **Socioeconomic factors**: household income, caregiver employment status, food security, housing conditions, and transportation cost.

- **Health system factors**: waiting time, drug availability and access to health facility.

  In addition to the caregiver interviews, **relevant clinical information** (such as ART start date, current regimen, most recent weight, and appointment attendance history) will be extracted from the child's **medical file** using an **electronic data abstraction form** developed specifically for this study.

The study tool will be **pretested** in a similar setting to ensure **clarity, cultural relevance, and reliability** before actual data collection begins.

Measurement of ART Adherence:

ART adherence will be assessed using the following two methods:

1. Visual Analogue Scale (VAS)

Caregivers will be asked to estimate the percentage of ART doses their child took in the past 30 days using a Visual Analogue Scale. The scale ranges from 0% (no doses taken) to 100% (all doses taken). The caregiver will be guided to mark a point on the line that best represents their child's medication intake. A VAS score of less than 95% will be considered indicative of non-adherence.

2. pill count

One of the methods used to assess adherence is the pill count approach. For this study, adherence will also be measured using data extracted from the electronic medical record (EMR), where adherence is routinely calculated based on pill counts. This involves determining the number of tablets remaining at the time of the clinic visit and comparing it to the expected number of tablets the patient should have if doses were taken as prescribed.

The adherence percentage will be calculated using the formula:

$$\text{Adherence (\%)} = \left(\frac{\text{Number of tablets expected to be taken} - \text{Number of tablets remaining}}{\text{Number of tablets expected to be taken}} \right) \times 100$$

Children with adherence levels below 95% will be classified as non-adherent

Data Management/ Analysis

All data will be collected electronically using KoBoToolbox on password-protected tablets and uploaded daily to a secure cloud server. Data will be reviewed regularly for completeness, consistency, and accuracy by the study supervisor.

Data collection forms will be anonymous and identified only by a unique study identification number assigned to each participant. Clinical information will be extracted from the child's medical records, including care and greatment (CTC) cards, case notes, and the electronic medical record system, depending on the documentation used at the facility. For participants with indicators of poor adherence, caregivers will be asked follow-up questions to explore the reasons behind non-adherence, such as forgetfulness, transportation issues, medication side effects, or lack of food.

To ensure confidentiality, all final datasets will be stored securely and backed up regularly. Only authorized research staff will have access to the data.

Statistical analysis:

The data will be processed and analyzed using Stata version 17. Throughout the data cleaning phase, rigorous quality control measures will be employed to maintain data integrity. Descriptive statistics will summarize the study variables, using averages and measures of variability for continuous data, and counts with percentages for categorical data. Findings will be displayed using appropriate visual tools such as tables, graphs, and charts.

Adherence to ART will be computed and classified into adherent (≥95%) and non-adherent (<95%) groups. To examine relationships between adherence and potential influencing factors, bivariate analyses will be conducted employing Chi-square tests or Fisher's exact test when necessary. The strength of associations will be expressed using odds ratios (ORs).

Variables with a p-value less than 0.2 during bivariate analysis will be further examined in a multivariable logistic regression model to determine independent predictors of non-adherence. Variables with an adjusted odds ratio (AOR) significant at the 0.05 level, along with their 95% confidence intervals, will be considered statistically meaningful.

Presentation of Results

The results will be comprehensively reported in a structured format and prepared for submission to a peer-reviewed journal. Statistical analyses will be conducted to assess the relationship between ART non-adherence and selected independent variables. Findings will be presented in tables, accompanied by narrative descriptions and interpretations. Where appropriate, data will also be visually summarized using graphs and charts to enhance understanding

Dissemination of Results

The findings of this study will be disseminated to various stakeholders to ensure that the knowledge generated contributes to improving ART adherence among children. Thereafter, findings will be shared at national scientific forums such as the College of Medicine Research Dissemination Day, and where possible, at international conferences. A written summary of the findings will be submitted to the local paediatric department at QECH and to the College of Medicine Research and Ethics Committee (COMREC). Finally, the study will be prepared for publication in a peer-reviewed open-access journal to ensure wider dissemination and contribution to global knowledge on paediatric ART adherence.

Ethical Considerations

Ethical approval to conduct this study will be obtained from the College of Medicine Research and Ethics Committee (COMREC). Permission will also be sought from the management of Queen Elizabeth Central Hospital (QECH) and the Lighthouse Clinic, where the study will be conducted.

Participants will be informed that they have the right to withdraw from the study at any point without any consequence to the care they or their child receives at the clinic. Monetary incentives will not be provided to avoid undue influence or coercion that may compromise voluntary participation. However, light refreshments such as bottled water, juice, or biscuits may be offered as a gesture of appreciation for the caregivers' time and participation.

Possible constraints

Several challenges may be encountered during the implementation of this study:

1. **Caregiver Literacy and Understanding**
   Some caregivers may have limited literacy, which could affect their ability to understand the study tools or consent forms. To address this, data collection tools will be administered orally in a language the caregivers understand, and trained research assistants will assist with clarifying questions.
2. **Social Desirability Bias**
   Caregivers may provide answers they believe are expected or acceptable, especially regarding adherence behavior. This may affect the accuracy of self-reported data. To minimize this, interviews will be conducted in a non-judgmental, private environment to encourage honest responses.
3. **Incomplete or Inaccurate Medical Records**
   The quality of ART adherence data may be limited by incomplete or inconsistent documentation in patient records. The research team will cross-check multiple sources (e.g., pharmacy refill logs and clinical notes) where possible.
4. **Time Constraints of Caregivers**
   Caregivers may have limited time to participate in interviews due to other responsibilities. To reduce this burden, interviews will be kept as brief as possible without compromising data quality, and conducted during their routine clinic visits.
5. **Resource Limitations**
   Budget constraints may affect the number of data collectors, availability of digital tools, or logistics. Efficient planning and seeking in-kind support from the facility will help address these challenges.

Capacity Building

This study will contribute to capacity building in several ways. It will provide training opportunities for research assistants and healthcare staff involved in data collection, enhancing their skills in quantitative research methods, ethical research conduct, and use of electronic data collection tools such as KoBoToolbox. The findings will be shared with Lighthouse Clinic healthcare providers and management to improve their understanding of factors affecting ART adherence in children, supporting evidence-based practice.
Additionally, the research process will strengthen collaboration between Kamuzu University of Health Sciences and Queen Elizabeth Central Hospital, fostering an environment conducive to future research and continuous professional development in paediatric HIV care.

Study Requirements

To successfully conduct this study, the following resources and conditions are required:

- **Ethical Approval and Permissions:** Approval from the College of Medicine Research and Ethics Committee (COMREC), and permission from the management of Queen Elizabeth Central Hospital (QECH) and Lighthouse Clinic.
- **Trained Research Team:** A team of trained data collectors proficient in administering interviewer-led electronic questionnaires and handling sensitive data.
- **Data Collection Tools:** Access to electronic data collection platforms such as KoBoToolbox, tablets or smartphones for data entry, and paper forms for backup.
- **Logistical Support:** Transportation for the research team to and from Lighthouse Clinic, and provision of light refreshments for participants.
- **Financial Resources:** Funding to cover personnel costs, data collection materials, data management software, and dissemination activities.
- **Collaboration and Support:** Cooperation from Lighthouse Clinic staff and caregivers for smooth recruitment and data collection.
- **Time Allocation:** Adequate time for training, data collection (September 2024 to June 2025), data analysis, and report writing.

Training for Study Staff

All study staff, including data collectors and supervisors, will undergo comprehensive training before the commencement of data collection. The training will cover the following key areas:

- **Study Objectives and Protocol:** Understanding the aims, research questions, and methodology of the study to ensure consistency and quality in data collection.
- **Ethical Considerations:** Emphasizing confidentiality, informed consent procedures, and respectful interaction with participants.
- **Data Collection Tools:** Hands-on training in administering the electronic questionnaires using KoBoToolbox, including troubleshooting common technical issues.
- **Interview Techniques:** Developing skills in conducting interviewer-administered surveys, managing sensitive topics, and minimizing social desirability bias.
- **Data Management:** Proper handling, storage, and transmission of data to ensure accuracy and security.

Budget & Justification of Budget

The budget for this study has been carefully estimated to cover all essential components required for successful completion. The main cost categories include personnel, data collection, materials and supplies, transport, communication, and dissemination of findings. Below is an itemized budget estimate:

Item	Description	Quantity	Unit Cost (MWK)	Total Cost (MWK)	Total Cost (USD)
Personnel	Research assistant stipend	3 months	50,000	150,000	84
	Data collectors (2 persons, 10 days)	20 days	20,000	400,000	224
Training	Training workshop for data collectors	1 session	180,000	180,000	100
	Printing questionnaires,	Lump sum	90,000	90,000	50

Data Collection Materials	consent forms, stationery				
	Digital devices (tablets or phones for data entry)	2 units	135000	270000	150
Transport	Travel to/from QECH study sites (fuel, transport)	15 trips	20,000	300,000	168
Communication	Mobile airtime, internet data	Lump sum	50000	50000	28
Data Analysis	Stata version(17) consultation fees	Lump sum	100,000	100,000	56
Dissemination	Printing final report, workshops, conference fees	Lump sum	100,000	100,000	56
Contingency (10%)	To cover unexpected expenses	Lump sum	—	358000	200
TOTAL				**1,998,000**	**1,116**

Note: USD amounts are approximate, based on an exchange rate of 1 USD ≈ 1,800 MWK.

References:

1. World Health Organization. (2024). HIV/AIDS Fact Sheet. Retrieved from https://www.who.int/news-room/fact-sheets/detail/hiv-aids
2. Wikipedia: HIV adult prevalence rate
3. Matola BW, Mapahla L, Nyasulu JCY. Malawi's progress towards UNAIDS 95-95-95 fast-track targets: who is lagging? African J AIDS Res. 2025;5906(May).
4. ICAP at Columbia University. (2023). Malawi Population-based HIV Impact Assessment (MPHIA) 2022–2023 Summary Sheet. Retrieved from https://phia.icap.columbia.edu

5. UNAIDS. Africa's children deserve better: Accelerating action to end AIDS in children. [Internet]. Geneva: UNAIDS; 2024 Jun 14 [cited 2025 Jul 3]. Available from: https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2024/june/20240614_day-african-child
6. World Education Inc./Bantwana Initiative. Strengthening pediatric case finding and improving HIV treatment outcomes for OVC in Malawi: APA Technical Brief [Internet]. Blantyre: Bantwana Initiative; 2020 [cited 2025 Jul 3]. Available from: https://bantwana.org/wp-content/uploads/2022/07/APA-OVC-Tech-Brief-July20-forPRINTING.pdf
7. U.S. Department of Health and Human Services. Adherence to antiretroviral therapy among children and adolescents living with HIV [Internet]. Washington (DC): HIV.gov; [updated 2023 Nov; cited 2025 Jul 3]. Available from: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/adherence-antiretroviral-therapy-children-and-adolescents-living-hiv
8. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach [Internet]. Geneva: WHO; 2016 [cited 2025 Jul 3]. Available from: https://www.who.int/publications/i/item/9789241549684
9. Tadese BK, Hennessy F, Salmon P, et al. Adherence to antiretroviral therapy and its association with quality of life among people with HIV in the United States. Aids Care-psychological and Socio-medical Aspects of Aids/hiv 2024; 1–13.
10. Tong, P. D., Atuhairwe, C., & Taremwa, I. M. (2020). Differential Self-Reported Determinants to Antiretroviral Therapy Adherence: Findings from Caregivers of Children Under Five Years Living with Human Immunodeficiency Virus Infection Attending Al-Sabah Hospital, South Sudan. HIV/AIDS - Research and Palliative Care, 12, 175 –186.
11. Ssanyu JN, Nakafeero M, Nuwaha F. Multi-measure assessment of adherence to antiretroviral therapy among children under five years living with HIV in Jinja, Uganda. BMC Public Health 2020; 20: 1–10.
12. Vreeman RC, Wiehe SE, Pearce EC, Nyandiko WM. A systematic review of pediatric adherence to antiretroviral therapy in low- and middle-income countries. Pediatr Infect Dis J. 2008;27(8):686–691

13. Getahun BG, Hebo H, Kura Z. Children's adherence to antiretroviral therapy and associated factors: multicenter cross-sectional study. HIV AIDS (Auckl). 2023;15:231–241.
14. Clinical Non-Adherence and Its Associated Factors Among HIV-Positive Pediatric Patients Attending HIV Care in South Gondar Zone Public Health Facilities, Northwest Ethiopia, 2021. 2022; 14: 23–32.
15. Lubinga SJ, Kintu A, Atuhaire J, Asiimwe S. Concomitant herbal medicine and antiretroviral therapy (ART) use among HIV patients in Western Uganda: A cross-sectional analysis of magnitude and patterns. Afr Health Sci. 2012;12(1):1–9.
16. Chikwari CD, Ferrand RA, Simms V. Barriers to HIV care and treatment in children and adolescents: A qualitative study from Zimbabwe. PLoS One. 2019;14(2):e0210736.
17. Bemelmans M, Baert S, Goemaere E, et al. Community-supported models of care for people on HIV treatment in sub-Saharan Africa. Trop Med Int Health. 2014;19(8):968–977.
18. Gebremichael B, Derseh L, Alemayehu M. Adherence to antiretroviral therapy among children in Eastern and Southern Africa: A systematic review and meta-analysis. PLoS One. 2023;18(3):e0312529. doi:10.1371/journal.pone.0312529
19. 13.Harvard Humanitarian Initiative . KoBoToolbox. Cambridge: Harvard Humanitarian Initiative; 2019. [Google Scholar]
20. Gemechu GB, Hebo H, Kura Z. Children's adherence to antiretroviral therapy and associated factors: multicenter cross-sectional study. HIV AIDS (Auckl). 2023 Jul 21;15:423–434. doi:10.2147/HIV.S407105. PMID: 37497118; PMCID: PMC10368110.
21. Mussa FM, Massawe HP, Bhalloo H, Moledina S, Assenga E. Magnitude and associated factors of anti-retroviral therapy adherence among children attending HIV care and treatment clinics in Dar es Salaam, Tanzania. PLoS One. 2022 Sep 30;17(9):e0275420. doi:10.1371/journal.pone.0275420. PMID: 36178915; PMCID: PMC9524636.
22. UNICEF. Levels & Trends in Child Mortality: Report 2021. Estimates developed by the UN Inter-agency Group for Child Mortality Estimation. New York: United Nations Children's Fund; 2021.
23. Alemu GG, Yirsaw BG, Tesfie TK, Yismaw GA, Abuhay HW, Alemayehu MA, et al. Adherence to antiretroviral therapy and its associated factors among children living with HIV in Eastern and Southern Africa: A

systematic review and meta-analysis. PLOS ONE. 2025 Jan 6;20(1):e0312529.

24. Kayange M, Mopamboli P, Ogbonna G, Jumbe V. Barriers and Facilitators to PrEP Uptake and Adherence among Adolescent Girls and Young Women Attending Family Planning Clinics in Mulanje District, Malawi: A Qualitative Study. 2025 Jan 23;
25. National AIDS Commission. Malawi National Strategic Plan for HIV and AIDS 2020–2025. Lilongwe: NAC; 2020.
26. Ministry of Health. Malawi Guidelines for Clinical Management of HIV in Children and Adults. Lilongwe: MoH; 2022.
27. Elizabeth Glaser Pediatric AIDS Foundation. Malawi Program Overview. EGPAF; 2023. Available from: https://www.pedaids.org/where-we-work/malawi/

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Bill to: **Ms. Tagwa Elmahi** **KUHES** **tagwamaleeh2014@gmail.com** **+265 982 03 22 24**	Invoice #	P.10/25-1848
	Date	**02/01/2026**

ITEMs	DESCRIPTION	AMOUNT
Research Submission Approval	10% Overhead fee	**$0.1**

TOTAL	$0.1

Account Name	College of Medicine Research Admin Account
Account Number	697672
Bank Details	National Bank Of Malawi
Branch	Chichiri
Swift	NBMAMWMW003