RETENTION OF HIV-EXPOSED INFANTS IN CARE AND ITS INFLUENCING FACTORS IN MBEYA AND SONGWE REGIONS: A RETROSPECTIVE STUDY

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By

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A Dissertation Submitted in (Partial) Fulfilment 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 they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **"Retention of HIV-exposed infants in care and its influencing factors in Mbeya and Songwe regions: a retrospective study",** in (partial) fulfillment of the requirements for the Master of Public Health of Muhimbili University of Health and Allied Sciences.

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DECLARATION AND COPYRIGHT

I **Raphael Mwalyaje Edom**, declare that this **dissertation** is my original work and that it has not 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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DEDICATION

This dissertation is dedicated to my parents; Father Edom Mwalyaje and Mother Kissa Inyekule and My wife Jackline Mligo and my Son Adrian. I love you all

ABSTRACT

Background: The retention of HIV-exposed infants in care programs is critical for preventing mother-to-child transmission and ensuring timely diagnosis and early initiation of treatment among the HIV exposed infants.

Objectives: This retrospective study examines the retention of HIV-exposed infants and asses the influencing factors in the Mbeya and Songwe regions of Tanzania.

Methodology: The retrospective study involved data extracted from the study database and Mothers locator's forms collected from mothers enrolled in the LIFE study from 2019 to 2022 in 14 health facilities in Mbeya and Songwe regions. Key variables included maternal HIV status, maternal HIV disclosure status, maternal age, maternal education, maternal timing of HIV diagnosis, distance to healthcare facilities and socio-economic factors.

Results: The study results show 85% of the infants were retained in PMTCT care at 18 months follow up. The odds of being retained in PMTCT were higher in older compared to younger mothers. Also, odds of retention of HIV exposed infants were high in mothers with secondary education or higher compared to the mothers with primary education.

Conclusions: Findings from this study show that a large proportion of HIV exposed infants were retained in PMTCT care at month 18 follow up in Mbeya and Songwe regions. The retention of HIV exposed infants is influenced by multidimensional factors such as maternal sociodemographic factors and health facilities accessibility factors. Efforts should focus on strengthening health services based on maternal needs and follow-up mechanisms at the health facility level to ensure timely diagnosis of HIV and enhance the engagement of HIV-exposed infants in care throughout the PMTCT continuum.

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ABBREVIATIONS

AIDs	Acquired immunodeficiency syndrome
ANC	Antenatal clinic
ART	Antiretroviral Therapy
HEI	HIV Exposed Infant
HIV	Human immunodeficiency Virus
MOH	Ministry of Health
NIMR	National Institute for Medical Research
PMTCT	Prevention of Mother to Child Transmission of HIV
UNAIDS	Joint United Nations Programme on HIV/AIDS
VHT	Vertical HIV transmission
WHO	World Health Organization

DEFINITION OF KEY TERMS

Prevention of Mother to child transmission means providing care and support for women living with HIV during pregnancy, delivery, and the postpartum period to improve Mother's health and prevent the transmission of HIV from the mother to her baby.(1)

Retention in care the person enrolled in HIV care routinely attends these services in accordance with their needs.(2)

Vertical HIV transmission occurs when a woman living with HIV pass HIV infection to her baby.(3)

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

For decades, Human Immune-deficiency Virus (HIV) has remained a public health threat despite the substantial progress being made toward meeting the ambitious goal to end HIV infection globally by 2030. (4) In 2022, the World Health Organization (WHO) reported approximately 39 million people were living with HIV worldwide and 1.5 million were children aged less than 15 years. The UNAIDS report shows a progressive decline in HIV infection among children from 2.5 million in 2010 to 1.5 million in 2022. (5) However, global reports from 2022 showed that among 1.3 million individuals who were newly infected, 8.7% of these were children. (6) Each year, approximately 1.3 million women living with HIV become pregnant, and an estimated 1.3 million babies are born with mothers living with HIV each year. (7)

Vertical HIV transmission (VHT), when infants and children acquire HIV from their mothers during pregnancy, birth, or breastfeeding, accounts for 90% of all HIV infections among children worldwide. (8). Only 80% of pregnant and breastfeeding mothers have access to antiretroviral therapy (ART) to prevent vertical HIV transmission (VHT). (9) The risk of VHT among mothers living with HIV not on ART is higher during breastfeeding 5-20 percent compared to 5-10 percent and 10-15 percent during pregnancy and labour, respectively. In 2022, breastfeeding alone accounted for about 42 percent of new HIV infections among vertically infected newborns. (10) Furthermore, the UNAIDS 2023 report highlighted those 660,000 children are among the 9.2 million people living with HIV who are not on lifesaving ART globally (11). In 2022, the annual PMTCT report of Tanzania show the Mbeya region is one among the regions with high prevalence of HIV the prevalence of 6.4% among the pregnant and breastfeeding women furthermore the report shows that the prevalence of VHT is 6.5%, the VHT among HIV-exposed infants (HEI) much higher than the <5% global target, moreover the report shows the risk of VHT increases during breastfeeding to approximately 7% percent at the

end of breastfeeding.(12) Prevention of mother to child transmission (PMTCT) interventions such as early HIV diagnosis, initiation to lifelong ART , provision of prophylactics at birth and Early infants diagnosis have the potential to decrease VHT up to less than 5%.(13) and prevent morbidity and mortality among mothers and their HEIs if effectively implemented and utilized.(14) The WHO Recommends all HEIs receive an early infant diagnosis (EID) test for HIV by 4-6 weeks of age. A conditional recommendation for EID at birth, provided countries have successfully implemented strong 4-6-week EID programs, is also provided. Tanzania has adopted a risk-based approach to birth EID, testing newborns at high-risk of VHT based on maternal criteria including 1) HIV viral load >50 copies/ml in the past four weeks, 2) not receiving ART, 3) on ART <4 weeks without a suppressed HIV viral load <50 copies/ml, or 4) incident HIV infection identified at delivery. (15).

Due to their dependence on their mother/caregiver to access care, HEIs are the most disengaged group in PMTCT interventions. Accessibility and retention to care is low which increases the risk of VHT and poor health outcomes among HEIs. (16) A study from Malawi show less than 80 percent of HEIs were retained to care at the end of 18 months. Apangu et al., 2019 In Tanzania, utilization of PMTCT services among HEIs is well below the recommended target.(17) Infants born to mothers living with HIV have high mortality in the first months of life.(18) Early initiation of infant HIV prophylactics and retaining babies to PMTCT care has a significance impact on the survival and overall health of HEIs (20,(19). Despite the benefits evidenced in various studies toward a HIV free generation, the retention of HEIs on PMTCT care in Tanzania is not sufficient to realize this goal. (20)

1.2 Problem Statement and Justification

Option B+ provides an opportunity for all pregnant and breastfeeding mothers to receive lifelong ART, which lowers the risk of VHT to less than 5% when effectively utilized (21). Since the implementation of Option B+ for PMTCT, the intervention has significantly reduced the risk of VHT among HEIs, according to PMTCT annual report the prevalence of VHT has declines to 6.5% in 2022 from 11% in 2021. (22) Retention of HEIs to PMTCT interventions is critically important to move towards the goal of eliminating VHT in Tanzania (18). Insufficient data are available on the factors that influence the retention of HEIs to PMTCT care in Tanzania including in Mbeya and Songwe regions, but other studies have suggested that maternal socio-behavioral factors, socioeconomic, geographic location, and accessibility to the health facilities are important. (18, 24,). This study helped to determine the factors influencing retention of HEIs to PMTCT care in the Mbeya and Songwe regions of Tanzania. Further, the knowledge from this study will contribute to the development of interventions to improve retention in care by understanding the needs of different groups of mothers and their babies accessing PMTCT care and designing more personalized PMTCT care options.

1.3 Conceptual framework

The retention of HIV-exposed Mother-infants in care is an important step for ensuring timely diagnosis and appropriate treatment initiation for HEI also provide an opportunity for maternal supportive services to mitigate the risk of HIV transmission and improve long-term infants' health outcomes.

The conceptual framework was developed on the basis of Socio-Ecological Model.(22)Socio-ecological model is made up of domains such as Individual factors like age, disclosure of HIV status, peer and family domain e.g. Partner support, poverty, the community domain e.g. economic access, and environment domain like accessibility of health facilities, level of health facility.(23) The socio ecological model suggests that these factors are influencers of the maternal or caregiver's preference in PMTCT interventions uptake. The socio-ecological model, which considers individual, interpersonal, community, and societal factors influencing health behaviors hence they determine maternal or caregiver's retention in PMTCT care(24)

The conceptual framework for this study is based on the Socio-Ecological Model (SEM), which provides a comprehensive approach to understanding the factors influencing the retention of HIV-exposed infants (HEIs) in PMTCT care. The Socio ecological model is composed of multiple domains that highlight different levels of influence on maternal or caregiver engagement with PMTCT interventions:

Individual Factors: This level considers personal characteristics such as age, disclosure of HIV status, and other behaviors that may affect a mother's decision to remain in PMTCT care.

Interpersonal Factors: This domain includes the influence of partners, peers, and family support, which are crucial for a mother's continued participation in PMTCT care. For instance, partner support or family encouragement can have a direct impact on adherence and retention in care.

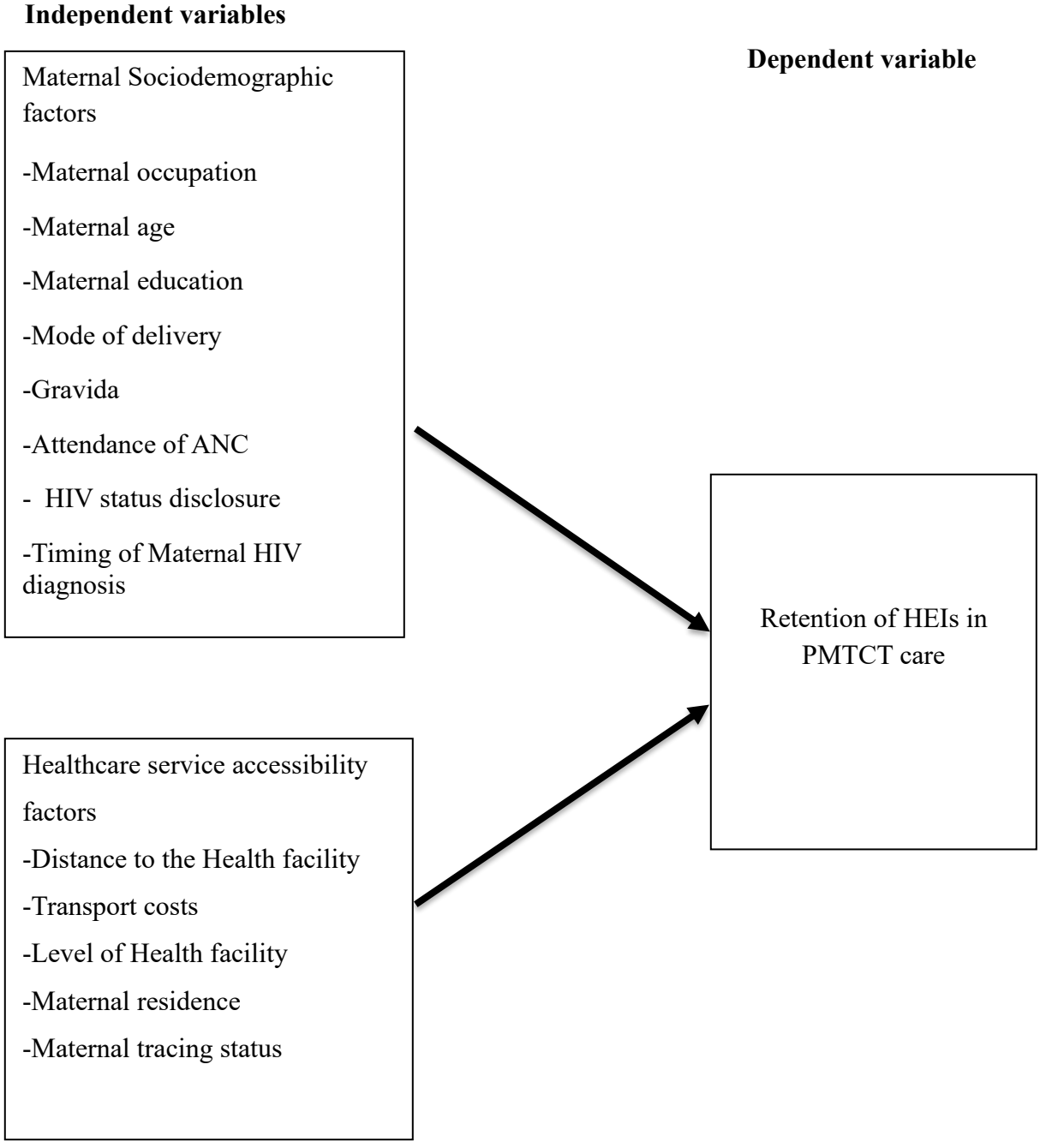
Community Factors: The community context, including socioeconomic factors such as economic access and cultural norms, plays a significant role in shaping attitudes towards

PMTCT care. Community awareness and collective support are essential for reducing stigma and encouraging retention.

Environmental Factors: Accessibility to health facilities, including the geographic proximity, quality of health services, and level of healthcare facilities, also significantly affects retention in PMTCT care. These environmental determinants can either facilitate or act as barriers to effective uptake of PMTCT services.

By incorporating these domains, the Socio-Ecological Model helps to explain how a combination of individual, interpersonal, community, and environmental factors influences the retention of HEIs to PMTCT interventions. Understanding these factors provides insight into why some mothers or caregivers may disengage from care and helps identify areas for targeted interventions to enhance retention rates in the Mbeya and Songwe regions. The model underscores the importance of a multi-level approach to improving maternal and caregiver retention in PMTCT care, addressing not only individual but also broader social determinants of health.

Figure 1.2.1 Conceptual framework



1.4 Rationale

The research findings added valuable knowledge to the existing literature on factors influencing the retention of HIV-exposed infants (HEIs) in PMTCT care. Tanzania, like other sub-Saharan countries with a high HIV burden, experiences suboptimal retention in PMTCT interventions for HEIs. Optimal utilization of PMTCT services among HEIs is crucial as it offers the opportunity to prevent morbidity and mortality through timely early infant diagnosis (EID), early ART initiation, and ongoing monitoring of growth and development. Therefore, the findings from this study are important for improving PMTCT practices and can directly inform clinical practice by guiding healthcare providers in implementing evidence-based interventions to enhance retention rates among HIV-exposed infants.

1.5 Research questions

1.5.1 Main research question

What is the proportion of HEIs retained in PMTCT care and factors associated with retention in Mbeya and Songwe regions?

1.5.2 Specific research questions

1. What is the proportion of HEIs retained at PMTCT care at 18 months in Mbeya and Songwe regions?
2. What is the association between maternal socio demographic characteristics and retention of HEIs to care?
3. What is the association between healthcare accessibility and retention at PMTCT care among the of HEIs in Mbeya and Songwe regions?

1.6 Objectives of the study

1.6.1 Main objective of the study

To determine the proportion of HEIs retention at PMTCT care and factors associated with retention in Mbeya and Songwe regions.

1.6.2 Specific objective of the study

1. To determine the proportion of HEIs retained at PMTCT care at 18 months in Mbeya and Songwe regions
2. To determine the association between maternal socio-demographic characteristics and retention of HEIs in PMTCT care in Mbeya and Songwe regions
3. To determine the association between healthcare accessibility and retention of HEIs in PMTCT care in Mbeya and Songwe regions

CHAPTER TWO

2.0 LITERATURE REVIEW

The retention of HIV-exposed infants in healthcare systems is a critical aspect of preventing mother-to-child transmission (PMTCT) and ensuring the well-being of infants at risk throughout the breastfeeding period. Several studies have explored the factors influencing the retention of HIV-exposed infants in various settings.

2.1 Maternal Socio demographic factors

One of the most common factors affecting retention is the Socio demographic factor such as accessibility of healthcare services. Limited access to healthcare facilities(13), especially in resource-constrained areas, can hinder regular follow-up appointments and necessary interventions. (18,28) Additionally, long travel distances and associated transportation costs may contribute to missed scheduled appointments, emphasizing the need for decentralized and community-based care basing on the maternal needs. (25). Furthermore, socio-economic factors such as maternal income can impact the retention of HIV-exposed infants. Families facing economic hardships may struggle to prioritize healthcare visits, this is highlighting the importance of addressing socioeconomical factors and financial support. In addition, in a prospective cohort study conducted in Tanzania highlighted that mother with older age had better retention in PMTCT care than young mothers. This is evidence that age is an important factor in developing age-specific interventions to improve service uptake. (30,(26)

2.2 Maternal Education level

Maternal education interplay between the chance of retaining the mother to care this is evidenced in a study conducted in Ethiopia that show as higher the maternal education gets higher level the high chance of retaining the mother to care. (27). Education empowerment among Women living with HIV can increase the retention of the mother to PMTCT interventions. To ensure the survival of HIV exposed infants, effective utilization of Prevention of mother to child transmission of HIV interventions is key. Maternal education level plays an

important role toward the maternal health seeking behavior. Data from a study conducted in Malawi shows mothers with higher education level are more likely to be retained in PMTCT care compared to mothers with low education level attained.(28)

2.3 Timing of maternal HIV diagnosis

Timing of maternal HIV diagnosis is important to the acceptance and retention in PMTCT interventions that is whether the mother was diagnosed before pregnancy, during pregnancy and during. Mothers who diagnosed before pregnancy may already have established healthcare routine hence can have an influence in retention of the mother in care post-delivery moreover might have differently influenced the retention compared to mothers who diagnosed during pregnancy and during delivery.(29) A study conducted in Tanzania by Anna at el highlighted the need for intervention to increased retention post-delivery among early ART initiated mothers to ensure maximum uptake of PMTCT services.(30) Findings from the existing literature provide valuable insights into the potential effects of various factors that influence the retention of HEIs in care throughout the continuum of care however there remains a notable gap in understanding the long-term retention of HEIs in PMTCT care and influencing factors specifically within the Mbeya and Songwe regions. While some studies have highlighted on enrollment rates, few have talked about the factors that contribute to long term retention of HEIs in PMTCT continuum of care beyond the first few months postpartum. Addressing this gap is essential for developing targeted interventions and policy recommendations aimed at improving long term retention rates and health outcomes for this disengaged population in Mbeya and Songwe regions.

2.4 Maternal HIV Status Disclosure

Maternal HIV status disclosure to partners, and family is an important aspect in retaining the breastfeeding mothers in PMTCT care. A retrospective cross-sectional study conducted in Ethiopia documented that mother who disclosed their HIV status were retained more than the one who never disclosed.(31) This might be due to the support from the family members who

knows the Maternal HIV status, although HIV disclosure remain low as evidenced by studies conducted in Tanzania**.** (30,32)

2.5 Adherence to ANC appointments

Antenatal appointments among pregnant women are vital because they provide an opportunity for both the mother and her unborn child a chance to health checkups including Maternal HIV status determination (33). During pregnancy for overall maternal and unborn baby health. (34) early booking to antenatal clinic can significantly influence the retention of breastfeeding mothers living with HIV in PMTCT care. (35)

2.6 Maternal tracing to attend scheduled clinics visits

Tracing the mother to her and her baby PMTCT intervention visit remain as an active reminder to an effective utilization of PMTCT intervention for the wellbeing of the HEI. Data from A systematic review study conducted in nine countries including Tanzania show that phone reminders to the breastfeeding mothers remain as an important aspect to improve maternal retention in PMTCT care. (36)

CHAPTER THREE

3.0 METHODS AND MATERIALS

3.1 Study Design

It was a retrospective cohort study involved data collected from 14 health facilities in Mbeya and Songwe regions during the implementation, enrollment and data collection of the cluster-randomized LIFE study project from 2019 to 2022. LIFE Study is a short title for Neonatal HIV early infant diagnosis (EID) versus standard of care EID – Long term Impact on inFant hEalth: a feasibility study of point-of care testing at birth versus at 6 weeks of age, on the uptake of ART and infant prophylaxis, and on rates of infant survival, morbidity and retention in care

The LIFE study evaluated the benefits of HIV testing in neonates born to HIV-infected mothers in Tanzania and Mozambique. It used and assessed novel point-of-care diagnostic systems that provided neonatal HIV test results within 2 hours.

The study aimed to evaluate whether HIV testing at birth, followed by immediate neonatal HIV treatment initiation, would result in reduced infant sickness, HIV progression, or mortality compared to the current standard procedure of testing at 6 weeks after delivery. This evaluation included a cost-effectiveness analysis to inform national HIV programs in developing their guidelines

The study also aimed to evaluate whether point-of-care viral load testing in mothers at birth could identify high-risk scenarios for HIV transmission from mother to child. This approach was intended to lead to enhanced prophylactic treatments for HIV-exposed infants, with the hypothesis that point-of-care viral load monitoring at birth would result in lower transmission rates. The study was conducted at 28 maternity health facilities in Tanzania and Mozambique, with half of the sites randomized to provide point-of-care birth HIV testing for infants and maternal viral load testing, while the other half followed the current standard of care—infant HIV testing at 6 weeks, without point-of-care viral load monitoring at birth for mothers.

The study was conducted in public health settings, with some objectives focusing on the successful provision of modern HIV treatments to infants, the feasibility of HIV testing and treatment procedures for nurses and midwives, and whether these procedures could be implemented in a timely manner. It also included a basic research component to investigate how HIV spreads in the bodies of infected infants, and whether early diagnosis and treatment could reduce the spread of HIV in their cells.

HIV-infected pregnant women and their exposed infants were recruited at maternity clinics in Mozambique and Tanzania. Assuming a 4% mother-to-child transmission (MTCT) rate by week 6 and a difference in combined HIV-infected infant outcomes of 14% in Arm A versus 30% in Arm B, the study aimed to enroll at least 224 HIV-infected infants (112 per arm) from both countries into the follow-up phase, resulting in a total recruitment of 6,000 mother-child pairs (3,000 per arm), accounting for an estimated 5% loss to follow-up. Additionally, 400 HIV-exposed infants from both countries were enrolled after week 12 into a long-term follow-up phase to investigate MTCT rates and associated risks until the study concluded after the cessation of breastfeeding.

In the LIFE study, half of the health facilities offered birth plus 4–6-week EID and half offered only 4–6-week EID.

The LIFE study was conducted in Tanzania and Mozambique, involving 28 public health facilities.

Recruitment and Inclusion: HIV-positive pregnant women were recruited at their obstetric health facility. Informed consent and eligibility assessments were conducted either before or within 72 hours (3 days) after delivery. Maternal antiretroviral therapy (ART) history, obstetric details, and infant birth outcome information were collected. All mothers underwent phlebotomy for CD4 count, with HIV viral load assessments conducted for those in Arm A undergoing immediate point-of-care (PoC) viral load testing. For mothers in Arm B, plasma samples were stored for retrospective viral load assessments at centralized study laboratories. Based on ART history, obstetric information, and viral load data, criteria for high-risk mother-

to-child transmission (MTCT) were assessed. Mothers not on ART were started on treatment, and those with viral loads ≥1000 copies/mL received enhanced ART counseling and were referred to HIV treatment services for repeated follow-up testing to confirm virological failure and initiate ART changes as per national guidelines.

All HIV exposed infants with negative birth PoC EID test results (Arm A) and all infants in Arm B will receive PNP or ePNP according to national guidelines. Infants who are considered high risk for MTCT will receive ePNP. Infant with discordant HIV PoC results in Arm A (first PoC test positive, second test negative) will initiate PNP or ePNP according to national guidelines, but immediate confirmatory HIV testing will be performed at the centralized laboratory.

Between weeks 4-8 and week 12 follow-up, all HIV-infected infants underwent history and physical examination. Infants in Arm B, as well as all previously HIV-negative infants in Arm A, underwent HIV EID testing with PoC where available. ART was initiated immediately in confirmed HIV-infected infants by nurses or through referral to paediatric HIV services. Prior to ART initiation, infant phlebotomy was performed for baseline safety laboratory tests (haematology, biochemistry), plasma viral loads, and biorepositories. Infants already on ART also received phlebotomy for follow-up safety laboratory tests (haematology, biochemistry) and plasma viral loads. Infant ART adherence and any problems related to ART administration were assessed from the mothers, and information on infant prophylactic ARV regimens was obtained. In cases of suspected virological failure or insufficient treatment response, re-enforced adherence counselling and training on administering infant ART were provided to the mothers, with consideration of genotypic drug resistance analysis from stored samples if available. Mothers were assessed at each visit regarding their ART status, adherence, and infant feeding practices. For mothers whose infants were newly tested positive via HIV PoC, blood and breast milk samples were collected for HIVRNA assessment, CD4 count, and biorepositories for extended viral analysis. All mothers received viral load testing at week 12, and all viral load results were communicated.

The main objectives of the study were to determine if PoC EID at birth and at weeks 4-6 postpartum (Arm A) provided better clinical outcomes for HIV-infected infants compared to PoC EID only at weeks 4-6. This involved a test-and-treat strategy for all infants diagnosed HIV-positive at early birth, followed by the collection of clinical outcome data.

The study was funded by the European & Developing Countries Clinical Trials Partnership (EDCTP). Recruitment began in the first quarter of 2019 and continued until January 2022. The follow-up period for all mother-infant pairs was 12 weeks after birth, extending to 18 months for HIV-infected infants and for a subset of HIV-exposed infants included in the long-term follow-up.

Mother-infant pairs were enrolled at delivery and followed for up to 18 months. Data from approximately 192 mother-infant pairs living in the Mbeya and Songwe regions were extracted from the LIFE study database (Open Clinica) for this secondary analysis.

3.2 Study area

The Mbeya and Songwe regions are among 26 regions of Tanzania mainland located in the Southern highland part of Tanzania, 830 Km and 923 KM from Dar es salaam, respectively. According to the 2022 population and household census, approximately 2,343,754 and 1,344,687 people reside in the Mbeya and Songwe regions, respectively (37). Mbeya and Songwe region are among the regions with high HIV prevalence of 9.6% and 6%, respectively (38). Mbeya region is comprised of 7 districts, Busokelo, Chunya, Kyela, Mbarali, Mbeya City, Mbeya Rural, and Rungwe. and the Songwe region comprises of four districts namely Mbozi, Momba, Ileje and Songwe (Mkwajuni), with a total area of approximately 27,598.9 km^2.

Description of 14 health facilities involved in the implementation of Life study

The study sites (Health facilities) were selected based on the previous year MTCT rates. 14 Health facilities involved in the study were Ruanda health center, Kiwanja Mpaka health centre, Igawilo health center, Chimala hospital, Tukuyu District hospital, Igogwe hospital, Itete Hospital, Chunya district hospital, Chalangwa health Centre/Mwambani hospital, Mtanila health centre, Ilembo health center and Inyala health centre/Mbarali District hospital in Mbeya

region and Tunduma health center/Iyula Health Centre, Vwawa district hospital in Songwe region. Closest health facilities involved in the study were Kiwanja Mpaka health centre, Ruanda health centre and Igawilo health centres located with Mbeya city council while the furthest was Mtanila health Centre located 184 KM from Mbeya City.

3.3 Power calculation

The study involved a total of 192 participants who were enrolled and subjected to long term follow up. We used the STATA statistical software to determine the power of the study under the following assumption; the sample size of 192, 95% level of confidence, 50 % rate of non-retention by the end of 18 months of follow-up and hazard ratio of 1.86 among those who disclose their HIV status which was reported as a factor associated with retention to care (39). With this assumption the sample size of 192 participants will have 87 % power to answer our research objectives.

3.4 Data source

This study utilized existing data collected during the LIFE study. The LIFE study was clinical research aimed at Neonatal HIV early infant diagnosis (EID) versus standard of care EID – Long term impact on infant health.(40) The primary objective was to establish the clinical impact of PoC EID for infants and neonates at birth and weeks 4-8, combined with nurse-initiated, physician-supported immediate ART initiation for HIV-infected neonates, compared to SoC on primary and secondary endpoints. Combined clinical outcomes included mortality, morbidity (WHO Stage 2 or above disease, severe infant medical conditions), hospitalization, toxicity (Grade 3 or above laboratory abnormality), and poor antiretroviral treatment response. Demographic information collected from mothers at baseline, as well as retention status of infants at 18 months, was extracted from the Open Clinica study database. Information on mothers' or caregivers' distance to the health facility was extracted from locator forms, which were used during the study for phone calls and home tracing of participants.

3.4.1 Inclusion Criteria

1. Data of mother-infant pairs enrolled in the LIFE Study at 14 health facilities in Mbeya and Songwe regions of Tanzania
2. Data of Mother-infants pairs enrolled in long-term follow-up phase of the LIFE study

3.4.2 Exclusion criteria

Data of mother-infant pairs not enrolled for long term follow-up phase of up to 18 months.

3.5 Variables

3.5.1 Dependent Variable

Retention) for HIV-exposed babies in PMTCT care at 18 months (yes/no). The primary outcome of the study was the proportional of HIV exposed infants retained in PMTCT care at 18 months follow up.

3.5.2 Independent Variables

- Maternal age,
- Maternal education,
- Healthcare accessibility/Distance to health facility (km)
- Maternal HIV status disclosure
- Timing of maternal HIV diagnosis
- Tracing status (phone call or physical home tracing needed for a visit attendance)
- Antenatal care attendance
- Gravida
- Maternal occupation
- Transport costs to health facility
- Residence type (Rural and urban)
- Early infant diagnosis (EID)
- Level of health facility
- Mode of delivery (Spontaneous vagina delivery or Caesarian section).

3.6 Investigation tools and validity and reliability

The parent study employed Case report forms for data collection from Mother-Infant's pair. These Case report forms with structured questions to gather information from participants, Case report forms were tested for validity and reliability during the pilot studies by ensuring they capture the information intended consistently across different respondents.

3.7 Data analysis plan

Data was analyzed using Stata SE version 14. Categorical variables were summarized using counts and percentages while continuous variables were summarized using mean and standard deviation (SD) and median and interquartile ranges (IQR). Logistic regression models were used to test for association between independent variables and retention of infants in PMTCT care, odds ratios and 95% confidence intervals are reported.

3.8 Data management

Secondary data were extracted from OpenClinica using predefined data extraction checklist based on the study objectives. All data sets were provided with a unique participant identification number to protect participant confidentiality. The extracted data were validated for completeness and accuracy before any analysis.

3.9 Ethical approval

All ethical approval were obtained from Muhimbili University of Health and Allied Sciences research ethics committee with reference number DA.282/298/01.C/2335 dated 13th Jun 2024. Permission to Access and use of data of Mother-Infants pairs in this dissertation was granted from National Institute for Medical Research (NIMR). Regarding to participants, there is no participant who will be identified by name or any other identifier moreover data of each participant will be identified through the assigned identification numbers for confidentiality and protection of participant privacy.

Since the study did not involve direct contact with the participants therefore informed consent waivers was requested for this study from MUHAS Institutional review body.

CHAPTER FOUR

4.0 ANALYSIS AND SUMMARY OF RESULTS AND FINDINGS

4.1 Baseline information about the mothers

The study involved 192 mothers with diverse sociodemographic characteristics, as detailed in Table 4.1.1 below.

Table 4.1.1 Baseline characteristics about the mothers

	Number N (%)
Age (years)	
Mean (SD)	30.78 (0.45)
Education	
None	26(13.5%)
Primary school	132(68.8%)
Secondary school or higher	34(17.7%)
HIV disclosure status	
Yes	155(85.6%)
Time since HIV diagnosis (weeks)	
Median [Min, Max]	75.5 (0.143-729)
Antenatal care attendance	
Incomplete (<3 visits)	105(54.7%)
Complete (3 visits)	87(45.3%)
Gravida (number of pregnancies including current one)	
Median [Min, Max]	3.31(1,10)
Distance to health facility (km)	
Median [Min, Max]	9.24(1,100)
Transportation costs (Tsh)	
Median [Min, Max]	2150(0, 10000)
Residence	
Urban	70(36.3%)
Semi urban	68(34.4%)
Rural	56(29.2%)
Occupation	

Peasants	138(72.3%)
Small Business	39(20.2%)
Housewife	4(2%)
Tailor	4(2%)
Community Health worker	2(1%)
Hairdresser	2(1%)
Teacher	2(1%)
Nurse	1(0.5%)

From **Table 4.1.1**. Above the findings show that, the mean age of the mothers was 30.78 years (SD 0.45). Regarding education, 26 (13.5%) had no formal education, 132 (68.8%) completed primary school, and 34 (17.7%) had secondary school or higher education. Most mothers, 181 (94.3%), had disclosed their HIV status. The median time since HIV diagnosis was 75.5 weeks, ranging from 0.143 to 729 weeks. Antenatal care attendance was incomplete for 105 (54.7%) mothers and complete for 87 (45.3%). The median number of pregnancies (gravida) was 3.31, with a range of 1 to 10. The median distance to the health facility was 9.24 km, with a range from 1 to 100 km, and the median transportation cost was 2150 Tsh, ranging from 0 to 10,000 Tsh. In terms of residence, 135 (70.7%) lived in rural areas, while 56 (29.3%) lived in urban areas. Occupation-wise, 138 (72.3%) were peasants, 39 (20.2%) were engaged in small business, 4 (2%) were housewives, 4 (2%) were tailors, 2 (1%) were community health workers, 2 (1%) were hairdressers, 2 (1%) were teachers, and 1 (0.5%) was a nurse.

4.2 Proportion of HIV exposed infants retained in care at 18 months follow up visit

The proportion of HIV-exposed infants retained in care at the 18-month follow-up visit refers to the percentage of these infants who continue to receive PMTCT care over the recommended time.

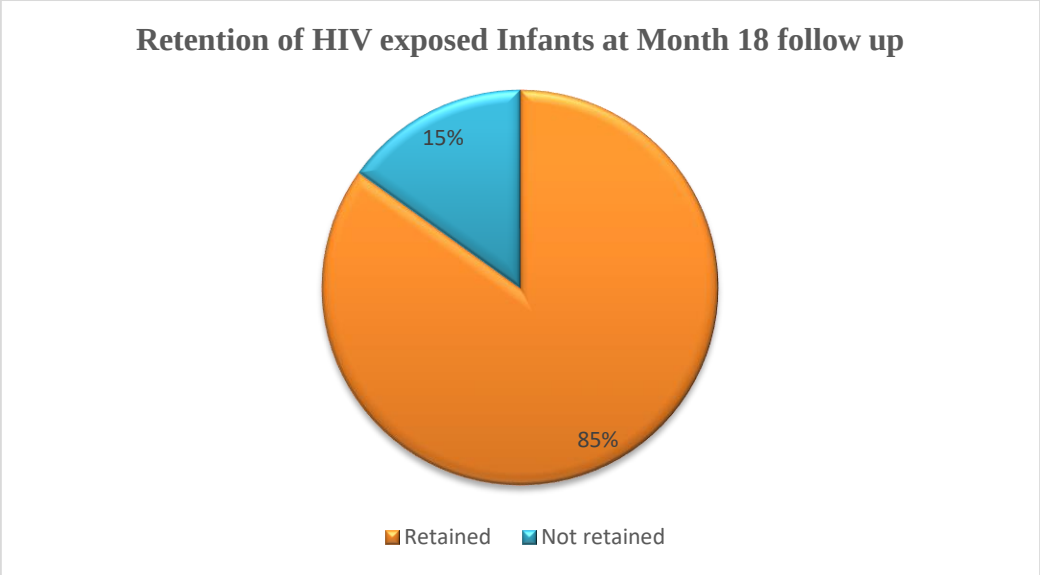


Figure 4.2.1 Distribution of the HIV exposed infants by 18 months follow up visit

From figure 4.2.1 The findings show that 85% of HIV-exposed infants were retained in PMTCT care, while 15% were not retained in PMTCT care at the 18-month follow-up.

4.3 Maternal sociodemographic factors associated with retention of HEIs in PMTCT care in Mbeya and Songwe regions

Table 4.3.1. shows that, the proportion of infants retained in PMTCT care at 18 months follow up among mothers aged between 25-34years old was higher (874%) than among mothers age 18-24years (76.6%). Additionally, 85.6% of mothers of infants retained to care had disclosed their HIV status and 72.7% of mothers of infants retained in PMTCT care at 18 month follow up didn't disclosed their HIV status. Infants whose mothers had secondary or higher level of education had an increased odds of being retained in PMTCT care compared to infants whose mothers had no education. However, the association was not statistically significant (Adj OR=2.09: 95% CI=0.27-16.15). 87.0% of infants retained in PMTCT care at months 18 their mothers resided in the urban and 82.1% and 85.7% resided in the semi urban and rural settings respectively. At 18 months, 87.0% of infants retained in PMTCT care had mothers residing in urban areas, 82.1% had mothers in semi-urban areas, and 85.7% had mothers in rural areas.

Table 4.3.1 Multivariate logistic regression analysis of maternal sociodemographic factors associated with retention of HEIs in PMTCT care in Mbeya and Songwe regions

Variable	**Retained N (%)**	**Crude OR**	**P-Value**	**AdjOR**	**P-Value**
Age group					
18-24 yrs	35(76.6)	Reference		Reference	
25-34 yrs	83(87.4)	1.78(0.69-4.60	0.24	2.69(0.89-8.06)	0.08
35-44 yrs	45(84.9)	1.45(0.51-4.13)	0.49	1.95(0.62-6.15)	0.25
Disclosure of HIV status					
Yes	155(85.6)	Reference		Reference	
No	8(72.7)	0.45(0.11-1.79)	0.26	0.299(0.061-1.46)	0.14
Education level					
None	23(88.5)	Reference		Reference	
Primary Education	108(81.8)	0.59(0.16-2.11)	0.42	0.47(0.12-1.82)	0.27
Secondary Education or higher	29(93.6)	1.89(0.29-12.28)	0.50	2.09(0.27-16.15)	0.48
Residence					
Urban	60(87.0)	Reference		Reference	
Semi urban	55(82.1)	0.69(0.27-1.76)	0.43	0.99(0.29-3.27)	0.98
Rural	48(85.7)	0.90(0.32-2.57)	0.20	1.29(0.368-4.55)	0.69

4.4 Health services accessibility related factors associated with retention of HEIs in PMTCT care in Mbeya and Songwe regions

Findings from table 4.4.1 show that higher retention (90.6%) were observed in health centers compared to hospitals (82%) However, the association was not statistically significant (AdjOR=1.84 95% CI 0.49-6.98). Furthermore, 85.7% (AdjOR: 0.89 (0.24-3.23) and 81.2% AdjOR: 0.60 (0.11-3.20) of infants retained were living at distance from health facilities (11-20) km and greater than 20km respectively and 77.6% AdjOR: 0.46 (0.15-1.39) of infants retained in PMTCT care transport costs were from 1001-2000 Tsh retention decreased to mothers who spent 2000 Tsh and above as transport costs every visit to health facility.

Table 4.4.1 Multivariate logistic regression analysis of health services accessibility related factors associated with retention of HEIs in PMTCT care in Mbeya and Songwe regions

Variable	Retained N (%)	Crude OR	P-Value	AdjOR	P-Value
Health Facility Level					
Health Center	58(90.6)	2.11(0.82-5.49)	0.12	1.84(0.49-6.98)	0.37
Hospital	105(82)	Reference		reference	
Distance from Health Facility (Km)					
0-10	120(85.1)	Reference		Reference	
11-20	30(85.7)	1.05(0.37-3.013)	0.92	0.89(0.24-3.23)	0.86
>20	13(81.2)	0.76(0.20-2.89)	0.69	0.60(0.11-3.20)	
Transport costs (Tsh)					
0-1000	65(90.3)	Reference		Reference	
1001-2000	45(77.6)	0.37(0.14-1.01)	0.05	0.46(0.15-1.39)	0.17
2000 and above	53(85.5)	0.63(0.22-1.82)	0.40	0.77(0.18-3.27)	0.72

Findings from table 4.4.1 show that among 85% of the Mother-infants retained in PMTCT care, higher retention (90.6%) % (AdjOR1.84 95% CI 0.49-6.98) were observed in health centers compared to hospitals (82%), 85.7% (AdjOR: 0.89 (0.24-3.23) and 81.2% AdjOR: 0.60 (0.11-3.20) of Mother-infants retained were living at distance from health facilities 11-20 km and greater than 20km respectively and 77.6% AdjOR: 0.46 (0.15-1.39) of Mother-infants retained in PMTCT care transport costs were from 1001-2000 Tsh retention decreased to mothers who spent 2000 Tsh and above as transport costs every visit to health facility.

CHAPTER FIVE

5.0 DISCUSSION

The reported retention rate of 85% from this study indicates a better retention of HIV exposed infants in PMTCT care, which is a beneficial outcome, the reported results show higher retention than 40.7% HEI retention reported in the annual PMTCT report of 2022. The study results are slightly similar to the study that was conducted in Uganda and similar to the study in Ethiopia reported a 78.7% and 86.3% retention rate respectively.(35)(41), the study in Ethiopia found an 86.3% retention rate for HIV-exposed infants, which closely aligns with the 85.1% retention rate observed in the current study. This suggests that similar strategies and interventions might be effective across different contexts in attaining high retention rates. But the study results are contrary to the study in sub-Saharan Africa and Brazil which found that infant retention at two years did not exceed 60% (42). This can be explained by the difference in the sociodemographic and accessibility of health facilities however retention of HIV exposed infants is important to prevent morbidity and mortality in this population.(43)

The association between maternal socio demographic characteristics and retention of HEIs in care

Infants whose mothers were in the older age groups (25-34 and 35-44 years) have higher odds of retention compared to those in the 18-24 years group. These results are similar to the results from a study in Uganda reported that shows infants of younger mothers had low chance to be retained in PMTCT care compared to older mothers (35) This can be due to the fact that younger mothers face greater challenges in understanding the importance of PMTCT Continuum of Care. However, this result reminds on the importance of targeted intervention based on the maternal needs.

HIV exposed Infants of mothers who did not disclose their HIV status had lower odds of retention compared to those who disclosed their HIV status, but the difference is not statistically significant. Maternal disclosure of HIV status might help in building the social support with

maternal peers hence improves maternal adherence to seeking PMTCT services for their HIV exposed infants. Individuals with primary education have lower odds of retention, while those with secondary education have higher odds compared to those with no education. (44)However, neither finding is statistically significant. Additionally, mothers residing in rural or remote areas often face logistical barriers that hinder their ability to maintain continuous PMTCT care for their infants. Addressing these sociodemographic factors through targeted interventions can improve retention rates of HEIs in PMTCT programs, ensuring better health outcomes for their HIV exposed infants.

Semi-urban and rural residents have lower crude odds of retention compared to urban residents, but these differences are not significant. Adjusted odds show almost no difference for semi-urban residents and slightly higher odds for rural residents, neither of which are significant similarly to the results in a systematic review conducted by Astawesegn at al identified place of residence as an important factor to retention of HIV exposed infants.(45,46)

Association between healthcare accessibility and retention in PMTCT care among the of HEIs in Mbeya and Songwe regions

Patients from health centers have higher odds of retention compared to those from hospitals, but the association is not statistically significant. Patients with transport costs of 1001-2000 Tsh have lower odds of retention compared to those with costs of 0-1000 Tsh, with the crude OR approaching statistical significance (p=0.05). However, the adjusted odds ratio is not significant. Patients with transport costs above 2000 Tsh. also have lower odds of retention, but this finding is not statistically significant. The odds of retention were high for patients attending health centers compared to hospitals. Although it was not statistically significant, but the findings suggest health centers might provide more accessible services. Distance from the health facility shows no significant effect on retention of HIV exposed infants in PMTCT services. Patients living more than 20 km away have slightly lower retention odds, indicating potential accessibility challenges, but these findings are not statistically significant.(47) Higher transport costs (1001-2000Tsh) are associated with lower retention, with the crude OR approaching

significance. This suggests that higher costs may be a barrier to retention, although the adjusted analysis does not confirm this statistically.(46)

There is a trend toward higher retention in health centres compared to hospitals. This could be due to better service delivery due to low workload and accessibility at health centers. Health services accessibility remain a central parameter in the retention of HIV exposed infants in care and factors such as distance to health centers, affordability of transport, and health facilities levels are important to ensure retention of HIV exposed infants in PMTCT care.(48)Having a better understanding of the association between health facility accessibility and retention in PMTCT programs is critical for developing strategies to enhance services based on maternal needs and thereafter improve maternal and HIV exposed infants' health outcomes and ultimately achieve the ambitious goal of eliminating mother-to-child transmission.

5.1 Study Limitations

More meaningful results would have been produced if the scope of the study was extended to more health facilities and other aspects of care provision among the HIV exposed infants for one to get a better understanding on the factors influencing retention of HIV exposed infants in care.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The study investigated the proportion of HIV-exposed infants retained in PMTCT care at the 18-month follow-up period. The findings indicate that the retention rate of HIV-exposed infants in the PMTCT continuum of care at 18 months in the Mbeya and Songwe regions was 85%. While this retention rate is below the recommended national target of 90%, it is still a significant achievement. The findings suggests that factors such as age, HIV status disclosure, education level, and residence might influence retention rates. Although none of the variables analyzed show a statistically significant impact on retention, as all p-values are greater than 0.05. However, the adjusted odds ratios suggest potential trends that might be worth in future studies with a larger sample size. Higher retention odds in health centres compared to hospitals, but not statistically significant. The findings above ssuggests that higher transport costs might be associated with lower retention, but this was not statistically significant.

6.2 Recommendation

Strengthen follow-up mechanisms at health facility level

It is very important to establish tracking and clinic visits reminder mechanisms that ensure optimal engagement with mothers and their HIV exposed infants. Regular reminders and phone calls can be used to remind mothers of upcoming clinic appointments and the importance of continued PMTCT care. Training healthcare workers in follow-up techniques is also essential to enhance patient engagement and retention in PMTCT care.

Integrates community testing approach to increase HEID coverage

Integrating a community testing approach

The existing guidelines should be updated to involve community testing to increase the HIV testing coverage among HIV exposed infants can be a beneficial strategy. This will help to

minimize resources lost by the mothers every time they access care but also will increase the accessibility of health care services for HIV exposed infants.

Areas for further research

Opportunity for prospective cohort studies focusing on different aspects of retention can provide valuable insights into the motivating factors that contribute to retaining HIV exposed infants in PMTCT care in various contexts, such as in health services delivery context, social, or community context and maternal related factors context. These studies can include both quantitative and qualitative components to offer a comprehensive understanding for the motivating factors.

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APPENDICES

Appendix I: Data extraction checklist

DATA EXTRACTION CHECKLIST
TITTLE: Retention of HIV-exposed Infants in care and its influencing factors in Mbeya and Songwe regions. A retrospective Study.
PID:

1. Demographics		
1.1.	Date of maternal birth	|__|__| . |__|__|__| . |__|__|__|__| D D M M M Y Y Y Y
1.2.	Education	[ ] None [ ] Primary school [ ] Secondary school [ ] post-secondary education
1.3	Marital status	Single [ ] Married [ ] Widowed [ ] Cohobating [ ]
1.4	Place of residence	
1.5	Type of residence	1.Rural [ ] 2.Urban [ ]
1.6	Distance (KM) from health facility	1.<15KM [ ] 2.15-30KM [ ] 3.31-45KM [ ] 4.>60KM [ ]
1.7	Transport costs to health facilities	1.<3,000 Tsh 2.3,000-5,000 Tsh 3.>5,000<10,000 Tsh 4.>10,000 Tsh
1.8	Maternal Occupation	1.Farmer/Peasant [ ] 2.Teacher [ ] 3.Small business [ ] 4.Housewife [ ] 5. Others……

2. HIV history and treatment		
2.1.	Date of maternal HIV diagnosis	|__|__| . |__|__|__| . |__|__|__|__| D D M M M Y Y Y Y or ☐ Not known
2.2	Is mother currently taking ART	
2.3.	Has the mother disclosed her HIV status to her family	[ ]1 Yes [ ]2 No
2.4	Who is disclosed to	

DATA EXTRACTION CHECKLIST

TITTLE: Retention of HIV-exposed Infants in care and its influencing factors in Mbeya and Songwe regions. A retrospective Study.

PID:

3. Pregnancy and delivery information			
3.1.	Attendance of Antenatal Care (ANC):	☐1 Yes ☐2 No	first trimester (week 1 to 12)
		☐1 Yes ☐2 No	second trimester (week 13 to 27)
		☐1 Yes ☐2 No	third trimester (week 28 to 42)
3.2	Place of delivery	1.District hospital [ ] 2.Health center [ ]	
3.3	Mode of delivery	1.Spontaneous vaginal delivery [ ] 2.Cesarean section [ ] 3.Others	
3.4	Gravida	[ ]	

18 months visit status

4.1	Date of 18 months visit attendance	[ ][ ].[ ][ ][ ].[ ][ ][ ][ ] DD.MMM.YYYY
4.2	Tracing was done to attend this visit	1 Yes [ ] 2 No [ ]

Name of the Data collector..... Signature.....
Date.....

Appendix II: Data use Permission letter

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

In reply please quote:

Ref. No: NIMR/PF.465 /16 01 March 2024

Rafael M. Edom,
NIMR Mbeya,
P.O. Box 2410,
MBEYA.

u.f.s: H.o.D TB and Emerging Diseases,
NIMR Mbeya,
P.O. Box 2410,
MBEYA.

Permission to use LIFE study data granted LTM 01 Mar. 2024

RE: PERMISSION TO USE LIFE STUDY DATA

Reference is made to your letter dated 16th February 2024 regarding the above subject.

2. Permission has been granted to use LIFE study data on retention of mother-infant pair on long-term follow-up of up to 18 months for your Masters Dissertation.

3. Permission is granted on the understanding that you will adhere to ethical guidelines, and confidentiality, not disclose or share any sensitive information beyond the scope of the study, and also that you will seek necessary approval from relevant bodies for the conduct of the study.

Yours sincerely,

Dr. Bariki Mtafya
Ag. CENTER MANAGER

NIMR Mbeya Medical Research Centre P. O. Box 2410 Tel: +255-25-2503384 +255-25-2502239 Fax: +255-25-2503134 Mbeya

All official correspondences should be addressed to the Director General

Headquarters: 3 Barack Obama Drive, P.O. Box 9653, 11101 Dar es Salaam, Tanzania,
Phone: +255222121400, Email: info@nimr.or.tz, Website: www.nimr.or.tz

NIMR Amani P.O. Box 81 Muheza, Tanga Tanzania Email: amani@nimr.or.tz

NIMR Dodoma Benjamin Mkapa Hospital P.O. Box 605 41110 Dodoma, Tanzania Email: dodoma@nimr.or.tz

NIMR Mbeya Hospital Hill Rd P.O. Box 2410, Mbeya, Tanzania Email: nimr.mbeya@nimr.or.tz

NIMR Muhimbili P.O. Box 3420 Dar es Salaam, Tanzania Email: muhimbili@nimr.or.tz

NIMR Mwanza P.O. Box 1462 Mwanza Tanzania Email: mwanza@nimr.or.tz

NIMR Ngorongoro P.O. Box 514 UDA River, Arusha Tanzania Email: ngorongoro@nimr.or.tz

NIMR Tabora P.O. Box 482 Tabora Tanzania Email: tabora@nimr.or.tz

NIMR Tanga P.O. Box 5004 Tanga Tanzania Email: tanga@nimr.or.tz

Appendix III: National health research ethics committee approval letter -2019-2020

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: nimrethics@gmail.com

Ministry of Health, Community Development, Gender, Elderly & Children
University of Dodoma, College of Business Studies and Law
Building No. 11
P.O. Box 743
40478 Dodoma

NIMR/HQ/R.8a/Vol. IX/3071

25th April, 2019

Dr. Issa Sabi
NIMR-Mbeya Medical Research Centre
P.O. Box 2410
Mbeya

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Neonatal HIV early infant diagnosis (EID) – long term impact on infant health: a feasibility study of point-of care testing at birth versus at 6 weeks of age, on the uptake of ART and infant prophylaxis and on rates of infant survival, morbidity and retention in care (Sabi I. et al), has been granted ethical clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails 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).
5. Sites: Mbeya, Songwe and Njombe regions.

Approval is valid for one year: 25th April 2019 to 24th April 2020.

Name: Prof. Yunus Daud Mgaya

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Prof. Muhammad Bakari Kambi

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY & CHILDREN

CC: Director, Health Services -TAMISEMI, Dodoma
RMO of Mbeya, Songwe and Njombe regions
DMO/DED of respective districts

Appendix IV: National health research ethics committee approval letter -2020-2021

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
Email: ethics@nimr.or.tz

Ministry of Health, Community Development, Gender, Elderly &Children
University of Dodoma, College of Business Studies and Law
Building No. 11
P.O. Box 743
40478 Dodoma

NIMR/HQ/R.8c/Vol. I /1446

25th March 2020

Dr. Issa Sabi
NIMR-Mbeya Medical Research Centre
P.O. Box 2410
Mbeya

RE: APPROVAL FOR EXTENSION OF ETHICAL CLEARANCE

This letter is to confirm that your application for extension on the already approved proposal: Neonatal HIV early infant diagnosis (EID) versus standard of care EID – Long term Impact on infant health: a feasibility study of point-of care testing at birth versus at 6 weeks of age, on the uptake of ART and infant prophylaxis and on rates of infant survival, morbidity and retention in care (Sabi I et al) has been approved.

The extension approval is based on the progress report dated 21st February, 2020 on the project, Ref. NIMR/HQ/R.8a/Vol. IX/3071, dated 25th April, 2019. Extension approval is valid until 24th April, 2021.

The Principal Investigator must ensure that other conditions of approval remain as per ethical clearance letter. The PI should ensure that progress and final reports are submitted in a timely manner.

Name: Prof. Yunus Daud Mgaya

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Prof. Muhammad Bakari Kambi

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY & CHILDREN

Appendix V: National health research ethics committee approval letter 2021-2022

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: ethics@nimr.or.tz

Permanent Secretary
Ministry of Health
Government City Mtumba,
Health Road
P.O. Box 743
40478 Dodoma

28 April, 2022

NIMR/HQ/R.8c/Vol. I/2021

Dr. Issa Sabi
National Institute for Medical Research
Mbeya Medical Research Centre
P O Box 2410
Mbeya

RE: APPROVAL FOR EXTENSION OF ETHICAL CLEARANCE

This letter is to confirm that your application for extension on the already approved proposal: **Neonatal HIV early infant diagnosis (EID) versus standard of care EID – long term impact on infant health (LIFE): a feasibility study of point-of care testing at birth versus at 6 weeks of age, on the uptake of ART and infant prophylaxis, and on rates of infant survival, morbidity and retention in care (Sabi I. et al.),** has been approved.

The extension approval is based on the progress report dated (25/03/2022) on the project, Ref. NIMR/HQ/R.8a/Vol. IX/3071, dated Date (25/04/2019). Extension approval is valid until 24 April, 2023.

The Principal Investigator must ensure that other conditions of approval remain as per ethical clearance letter. The PI should ensure that progress and final reports are submitted in a timely manner.

Name: Prof. Yunus Daud Mgaya

Signature
CHAIR PERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Dr. Aifello Wedson Sichalwe

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH

Appendix VI: Mbeya medical research ethics committee approval letter- 2019-2020

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

Cable Referral Hospital
Telephone: 2503456/2503351
Fax 2503577
Email: info@mzrh.go.tz

MBEYA ZONAL REFERRAL HOSPITAL
P. O. BOX 419
MBEYA

18th January 2019

Ref N: SZEC-2439/R.A/V.1/05

Dr. Issa Sabi,
NIMR-MMRC,
P. O. Box 2410,
Mbeya - Tanzania.

RE: **Request for Ethical Clearance for Protocol LIFE "Neonatal HIV early infant diagnosis versus standard of care EID-long term impact on infant health. A feasibility study of point of care testing at birth versus at 6 weeks of age on the uptake of ART and infant prophylaxis and on rates of infant survival, morbidity and retention in care"; version 1.1 date December 2018**

The above mentioned subject is concerned.

I would like to inform you that, the Mbeya Medical Research and Ethics Committee received and reviewed your protocol. The Committee has granted Ethical Clearance of the above mentioned study for the period of one year, from **15th January 2019** to **14th January 2020**.

This Ethical Clearance approval bears the following specifications;
1. To comply with approved study protocol procedures, and at all times you are responsible for ethical conducts of your research;
2. You must notify the Mbeya Medical Research and Ethics Committee in writing regarding any alteration or deviation to the protocol;
3. To submit progress reports to the Committee every six months;
4. If the research has been completed, abandoned, discontinued or not completed for any reason you are required to submit a final report to the Committee;
5. The approval is given for one year from 15th January 2019 to 14th January 2020, and if you are unable to complete your research within the one year validation period you will be required to write to Mbeya Medical Research and Ethics Committee to request for an extension;
6. You must notify immediately the Mbeya Medical Research and Ethics Committee of any adverse event and/or unforeseen events that might affect continued ethical acceptability of the research.

Sincerely,

Executive Director
Mbeya Zonal Consultant Hospital
P.O. Box 419
Mbeya, Tanzania

Dr. Godlove F. Mbwanji
Chairman
Mbeya Medical Research and Ethics Review Committee.

Dr. Ruby D. Mcharo
Secretary

cc: The Chairman; National Health Research Ethics Review Committee; P.O.Box 9653, Dar es Salaam.
cc: RMO - Mbeya.

All Communication should be addressed to the Chairman, Mbeya Medical Research and Ethics Committee

Appendix VII: Mbeya medical research ethics committee approval letter -2020-2021

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

Cable Referral Hospital
Telephone: 2503456/2503351
Fax 2503577
Email: info@mzrh.go.tz

MBEYA ZONAL REFERRAL HOSPITAL
P. O. BOX 419
MBEYA

14 January 2020

Ref No: *SZEC-2439/R.E/V.1/26*

Dr. Nyanda E. Ntinginya,
Principal Investigator,
P.O. Box 2410,
Mbeya - Tanzania.

RE: Request for extension of Ethical Clearance for Protocol LIFE; "Neonatal HIV early infant diagnosis versus standard of care EID-long term impact on infant health. A feasibility study of point of care testing at birth versus at 6 weeks of age on the uptake of ART and infant prophylaxis and on rates of infant survival, morbidity and retention in care"; version 2.0 date February 2019

Reference is made to the aforementioned subject.

The Mbeya Medical Research and Ethics Committee received your progress report and request for Ethical clearance extension for the above mentioned approved protocol.

I would like to inform you that, the Committee has extended Ethical Clearance of the above mentioned study protocol to continue with study related procedures for the period of one year, from **15th January 2020 to 14th January 2021.**

Please note that other Ethical Clearance specifications and conditions remain the same as per the previous approval dated 08th January 2019, *Ref No. SZEC-2439/R.A/V.1/05*

Sincerely,

Executive Director
Mbeya Zonal Consultant Hospital
P.O. Box 419
Mbeya, Tanzania

.....
Dr. Godlove F. Mbwanji, *MD, MMED*
Chairman
Mbeya Medical Research and Ethics review Committee.

cc: The Chairman; National Health Research Ethics Review Committee; P.O.Box 9653, Dar es Salaam.

cc: RMO - Mbeya.

All Communication should be addressed to the Chairman, Mbeya Medical Research and Ethics Committee

Appendix VIII: Mbeya medical research ethics committee 2021-2022

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

Cable Referral Hospital
Telephone: 2503456/2503351
Fax 2503577
Email: info@mzrh.go.tz

MBEYA ZONAL REFERRAL HOSPITAL
P. O. BOX 419
MBEYA

15th January 2021

Ref No: *SZEC-2439/R.E/V.1/57*

Dr. Nyanda E. Ntinginya,
Principal Investigator,
P.O. Box 2410,
Mbeya - Tanzania.

RE: Request for extension of Ethical Clearance for Protocol LIFE; "Neonatal HIV early infant diagnosis versus standard of care EID-long term impact on infant health. A feasibility study of point of care testing at birth versus at 6 weeks of age on the uptake of ART and infant prophylaxis and on rates of infant survival, morbidity and retention in care"; version 2.0 date February 2019

Reference is made to the aforementioned subject.

The Mbeya Medical Research and Ethics Committee received your progress report and request for Ethical clearance extension for the above mentioned approved protocol.

I would like to inform you that, the Committee has extended Ethical Clearance of the above mentioned study protocol to continue with study related procedures for the period of one year, from **15th January 2021** to **14th January 2022.**

Please note that other Ethical Clearance specifications and conditions remain the same as per the previous approval dated 08th January 2019, *Ref No. SZEC-2439/R.A/V.1/05*

Sincerely,

Executive Director
Mbeya Zonal Consultant Hospital
P.O Box 419
Mbeya, Tanzania

.....
Dr. Godlove F. Mbwanji, *MD, MMED*
CHAIRMAN
Mbeya Medical Research and Ethics review Committee.

cc: RMO - Mbeya.