OUTCOME EVALUATION OF COMPLIANCE TO EARLY INFANT DIAGNOSIS OF HIV TESTING PROTOCOL AMONG HIV EXPOSED CHILDREN IN REGIONAL REFERRAL HOSPITALS, DAR ES SALAAM, TANZANIA

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By

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A dissertation Submitted in (Partial) Fulfillment of the requirement for the degree of Masters of Science in Project Management, Monitoring and Evaluation in Health of Muhimbili University of Health an Allied Sciences

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CERTIFICCATION

The undersigned certify that they have read and hereby recommended for acceptance to Muhimbili University of Health and Allied Sciences a dissertation report entitled "**Outcome Evaluation of compliance to Early infant diagnosis of HIV testing protocol among HIV exposed children in regional referral hospitals, Dar es salaam, Tanzania,"** in partial fulfilment of the requirements for the degree of Masters of Science in Project Management, Monitoring and Evaluation in Health of Muhimbili University of Health an Allied Sciences.

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DECLARATION AND COPYRIGHT

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

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DEDICATION

I dedicate this work to my lovely Father (Yamungu Mustapha), my lovely sister Sada Yamungu, and my precious family (Husband Hashim Yatera), children Naesh Hashim and Zayn Hashim) for your infinity love, support in prayers, morally and materially. Thank you so much and always keep in mind that GOD is always with us and there is no easy thing but with GOD's grace and he makes difficulties easy whenever he wills to do so.

ABSTRACT

Background: **Background**: After birth, all HIV-exposed children aged 0-18 months are eligible to receive a series of HIV tests as per the early infant diagnosis (EID) protocol recommendations to rule out their HIV infection status as early as possible. However, early infant diagnosis (EID) of HIV testing remains a challenge owing to guidelines compliance, though evidence is inconclusive. This study therefore, evaluated the compliance to EID of HIV testing protocol among HIV exposed children aged 0-18 months, and its associated factors. The results will inform policies and practices on the implementation status of EID of HIV testing protocol in Tanzania and countries with similar contexts.

Methods: A cross section method using quantitative approach was used to gather data from 288 pairs of HIV infected mother and HIV exposed children (observation unit). They were selected using convenient sampling techniques from the regional referral hospitals. Data was collected using standardized questionnaire containing health provider compliance questions, compliance to EID of HIV testing implementation questions, social demographic data of the mother, maternal factors, and health facility factors to the respective participants. The outcome variable of interest was compliance to EID of HIV implementation protocol. Data analysis was conducted using descriptive statistics, bivariate and multivariate logistic regression analysis to address the research objectives.

Results: Only 72.6% of mothers living with HIV complied to the EID of HIV testing protocol, although a significant majority (83.3%) of health workers were well-acquainted with the EID of HIV testing protocol and utilize it consistently during daily routine implementation. Mothers on antiretroviral therapy for at least two years were more likely to adhere to EID HIV testing compared to their peers with less duration (AOR=2.28, 95% CI: 1.05-4.95). Moreover, those who resided at least 5km from the health facility were twice more likely to adhere to this recommendation (AOR=1.97, 95% CI: 1.04-3.73). Perceived benefits of EID for HIV (AOR =2.57 (95% CI: 1.26-5.24) and less average time spent to receive EID services (AOR= 3.20, 95% CI: 1.48-6.88) were also associated with compliance to EID services.

Conclusion and recommendations: Although a significant proportion of health workers are well-acquainted with EID protocols for HIV testing in Dar es salaam, Tanzania; only seven in ten of mothers living with HIV complied to the EID of HIV testing protocol for their exposed children. Improving this crucial HIV elimination intervention can be achieved with tailored interventions targeting immediately diagnosed mothers or those on ART for a shorter period, providing services closer to where they live, improving counseling on EID, and improve efficiency in service provision to cut down waiting time.

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ABBREVIATIONS

ART	Antiretroviral treatment
CTC	Care and treatment center
DBS	Dried blood sample
DED	District executive director
DHIS	District health information system
DNA	Deoxyribonucleic Acid
EID	Early infant diagnosis
eMTCT	Elimination of Mother to Child Transmission
HCW	Health care workers
HEI	HIV exposed infants
HIV	Human Immunodeficiency virus
MoH	Ministy of Health
MUHAS	Muhimbili University of Health and Allied Sciences
NAAT	Nucleic Acid Amplification test
NAT	Nucleic Acid Testing
PCR	Polymerase Chain Reaction
PMTCT	Prevention of Mother to Child Transmission
RAS	Regional Administrative Secretary
TACAIDS	Tanzania Commission for AIDS
TB	Tuberculosis
UNAIDS	United Nation Programme on HIV& AIDS
WHO	World Health Organization

DEFINITION OF TERMS

Early infant diagnosis: is defined as HIV testing among HIV exposed children aged 0-18 months (virological tests using polymerase chain reaction tests before 72 hours after birth for highly exposed infants, at 4 to 6weeks , at 9months and serological testing at 15months or 3 months after stopping breastfeeding and 18months) (1).

HIV exposed children: these include infants and children aged 0-18 months who are born or taken care by HIV positive mother/caretakers (2).

Dried blood sample: is the collection of whole blood from HIV exposed infants or child by pricking the heel, toe, or finger with a lancet and there after placed on filter paper and dried then later transported to the laboratory for HIV polymerase chain reaction testing (1,3).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Early infant diagnosis of HIV remains important public concern and its negative impact remains challenging particularly in the resource limited countries, despite the progress that has been made in the fight against it (4,5). It is the leading cause of infant mortality in the resource limited countries (5). Every single day in the year 2021, there were approximately 850 children who became infected with HIV and approximately 301 children who died globally as a result of AIDS-related causes (6). The main reason for this is a lack of adequate access to HIV prevention, care, and treatment services (6,7).

All HIV exposed infant and children 0-18 months are eligible to receive HIV test as early as possible after birth though immediate test depending on exposure status (8). This intervention has originated from the forth prong of the global plan or component of the comprehensive PMTCT Programme endorsed by the WHO and UNICEF(5,9,10). For HIV exposed infants and children to access EID of HIV testing, there should be adequate participation of the mother in accessing and utilizing prevention of mother to child transmission (PMTCT) services(11). Several maternal interventions (PMTCT) are being implemented, among these interventions includes Option B+. This is a global plan of the four pronged approaches which all aim at ART initiation among positive pregnant women with their babies as early as possible since the day were diagnosed to be HIV positive regardless CD4 count or clinical stage (10,12,13). If PMTCT intervention services are not provided and accessed adequately and timely as required, HEI and children are at risk of acquiring HIV infection where by 15-30% for non-breastfeeding and 20-45% for breastfeeding of which this is responsible for over 90% of the infection (4).

Global implementation goal agenda of the " start free, Stay free, AIDS free framework" aims to provide a road map to end HIV/ AIDS as a public health threat by 2030 (4). Despite the

implementation of this goal agenda , in 2017 there were 180000 new HIV infection in children (5).

The global trend of performance in infant HIV diagnosis and treatment in low- and middle-income countries were 1.59 million tests (2018) and 1.63 million tests (2019) this indicates a slight increase in the number of infants tested but persistent gaps in access and uptake, this translates to an estimated coverage of only about 60%(14). Despite these efforts, morbidity and mortality among infants remain unacceptably high, with over 160,000 infants acquiring HIV and over 100,000 dying from AIDS-related causes with only 50% acquiring the EID test within the first 2 months of life(14). HIV testing among these children globally is challenging mostly to resource constrained countries (4), In sub-Saharan Africa, only 39% of HEI receive HIV tests within the first two months of life (13). Tanzania EID of HIV testing coverage is still challenging as in 2018 EID of HIV testing rate drops from 64% at a second month to 32% at 18 months (15). In 2019, EID coverage was 72% at 2 month as it is below the national target (80%) and global target (90%) (4). Failure to attain the recommended target is associated with poor tracking of HEI less than two months of age for DBS testing, skilled staff turnover, long turnaround time for DBS results, low mother infant pair retention, mobility of pregnant women to seek for support for delivery and post-partum period (16).

EID of HIV testing has been recommended to be integrated into different points of service delivery (17,18). This can be achieved with the presence of clear national standard guidelines and testing algorithm or protocol, monitoring and evaluation systems, identification of the HIV exposed children, retention in care, health provider selection and trainings, ongoing supervision and quality improvement, laboratory practices, sample transport and results return, forecasting and supply chain management, linkage of HIV infected children to antiretroviral therapy, community engagement (3). The presence, use and integration of clear and standard EID of HIV testing national guideline and testing algorithm (protocol) is essential as it helps healthcare provider to adequately implement EID of HIV testing among HEI and children at each required clinic visit (2).

Tanzania, Prevention of Mother-to-Child Transmission (PMTCT) services are seamlessly integrated within Reproductive and Child Health (RCH) clinics (2). This integration ensures that every health facility catering to a minimum of 30 pregnant women annually is mandated to conduct Early Infant Diagnosis (EID) of HIV testing for HIV-exposed children aged 0-18 months (2,19). This requirement is in accordance with the standardized guidelines outlined in the national HIV/AIDS protocol (2).

The integration of EID of HIV testing within clinics in previous studies is acceptable, feasible (20), accessible (21) and efficient in identifying HIV exposed children and enhancing maximum EID of HIV testing coverage (22). Compliance implementation to EID of HIV testing protocol integrated within RCH clinics to facilitate eMTCT has not been evaluated to inform policies and practices in the country.

EID OF HIV TESTING GUIDELINE.

When the protocol started globally and in Tanzania

In the 1990s, various initiatives were introduced globally to reduce HIV transmission. The concept of early infant diagnosis emerged in the 2000s, following a meeting hosted by the WHO and CDC in Entebbe in May 2006. This meeting led to a consensus statement on the use of early infant diagnosis assays and identified areas needing further research. It also agreed on the effectiveness of dried blood spot (DBS) specimens for making HIV testing more accessible to children(23)

PMTCT Program in Tanzania has evolved through three phases: pilot (2000-2004), scale-up (2004-2010), and elimination (2011-present). The elimination phase has been guided by three strategic plans, with eMTCT Plan I (2011-2015) aiming to achieve virtual elimination of vertical HIV transmission(15).

The early HIV infant diagnosis services in Tanzania started in 2008 at the National Public Health Laboratory (NPHL). To meet increasing demand, the Ministry of Health expanded these services to three zonal hospital laboratories in 2009-2011. In 2015-2016, EID testing was further expanded to eight hospitals. To improve accessibility, the Ministry of Health advocated for the use of DBS samples for testing at conventional labs(15).

Objective of the guideline ; To contribute to the 13th WHO Global Programme of Work- Triple-Billion initiative, specifically under Global Public Health Goods 1.1.2, and align with the objective of meeting the Sustainable Development Goal 3 of ending AIDS by 2030 (14).

The guideline implementors; these are primarily intended for national HIV program managers and policymakers. However, they will also be of interest to a wider audience, including national HIV treatment and prevention advisory boards, national TB and HIV program managers, maternal, newborn, and child health program managers, sexual and reproductive health program managers, clinicians, health service providers, national laboratory service managers, people living with HIV, key population networks and organizations, community-led and community-based organizations and service providers, and international and bilateral agencies providing financial and technical support to HIV programs in resource-limited settings(14) .

Expected outcomes of the Guideline is to achieve total elimination of mother to child transmission through early identification and timely testing of all the HIV exposed children. And for those infected to early be initiation on ART treatment and care to improve their health outcomes.

1.2 Problem Statement

Generally, efforts have been made to improve compliance to EID of HIV testing protocol. However, evidence on its evaluation remains unavailable in Tanzania and settings of similar contexts, with most of EID tests trend information available for 2months and 18 months tests: the rate of early detection testing fall from 64% at 2 months in 2018 to just 32% at 18 months, while in 2019, the rate is slightly better at 72% at 2 months, yet still falls below both the national target

of 80% and the global target of 90% (1,3,5,19,25,26). While Infants born to HIV positive mothers are at a higher risk of being infected with HIV, the risk is about 15-30% for non-breastfeeding and 20-45% for breastfeeding of which this is responsible for over 90% of the infection (4) (26). The diagnosis of HIV at an early stage in Children is essential to ensure adequate healthy living for the child as well as access to antiretroviral therapy (ART)(25,27).

Tanzania has made progress to improve compliance to EID of HIV testing protocol through integrating eMTCT services within RCH clinics (2) (26). Despite the progress, evaluation of compliance to EID of HIV testing implementation of such integration into the system in the country has not been done so that it can inform the best practices or utilization of protocol for EID of HIV testing. Therefore, this study aimed at evaluating the compliance to early infant diagnosis of HIV testing protocol among HIV exposed children within at regional referral hospitals in Dar es salaam, Tanzania.

1.3 Conceptual Framework

With reference to Donabedian model described above, this study structure, process, outcome and an addition of the balancing measures are considered as the main component of this framework and as well all depend on each other so as to provide an effective suit of measure which will help to evaluate and put an emphasis in improving the standards of a deliverable (28).

The attainment of maximum compliance to EID of HIV testing protocol requires structure component of which includes place where EID service is being conducted, health providers responsible to perform EID services (24,29). In the process component, implementation of EID of HIV testing is done following standard process or procedure (EID of HIV testing protocol) that involves firstly the identification of HIV exposed children at a certain point of care, then test them for HIV following the standard protocol and the finally dissemination of the results to the parent as early as possible not later than 4 weeks (27). If the process will be followed as required, then this will enhance the attainment of the desired outcome which in this study is compliance to EID of HIV testing protocol (25). The presence of the balancing measure component of which in this study is represented by predisposing factor (social demographic, maternal and health system factors). These factors are responsible in adequately influencing the outcome as they can enhance

the process either positively or negatively so, they should be studied as well to show the relationship between them and how they influence the outcome variable (compliance to EID of HIV testing protocol) (21,29).

In this Take into consideration the "compliance to EID of HIV testing guide" as the outcome variable of interest diagram, the existing relationship between the study variables is shown by the blue arrows.

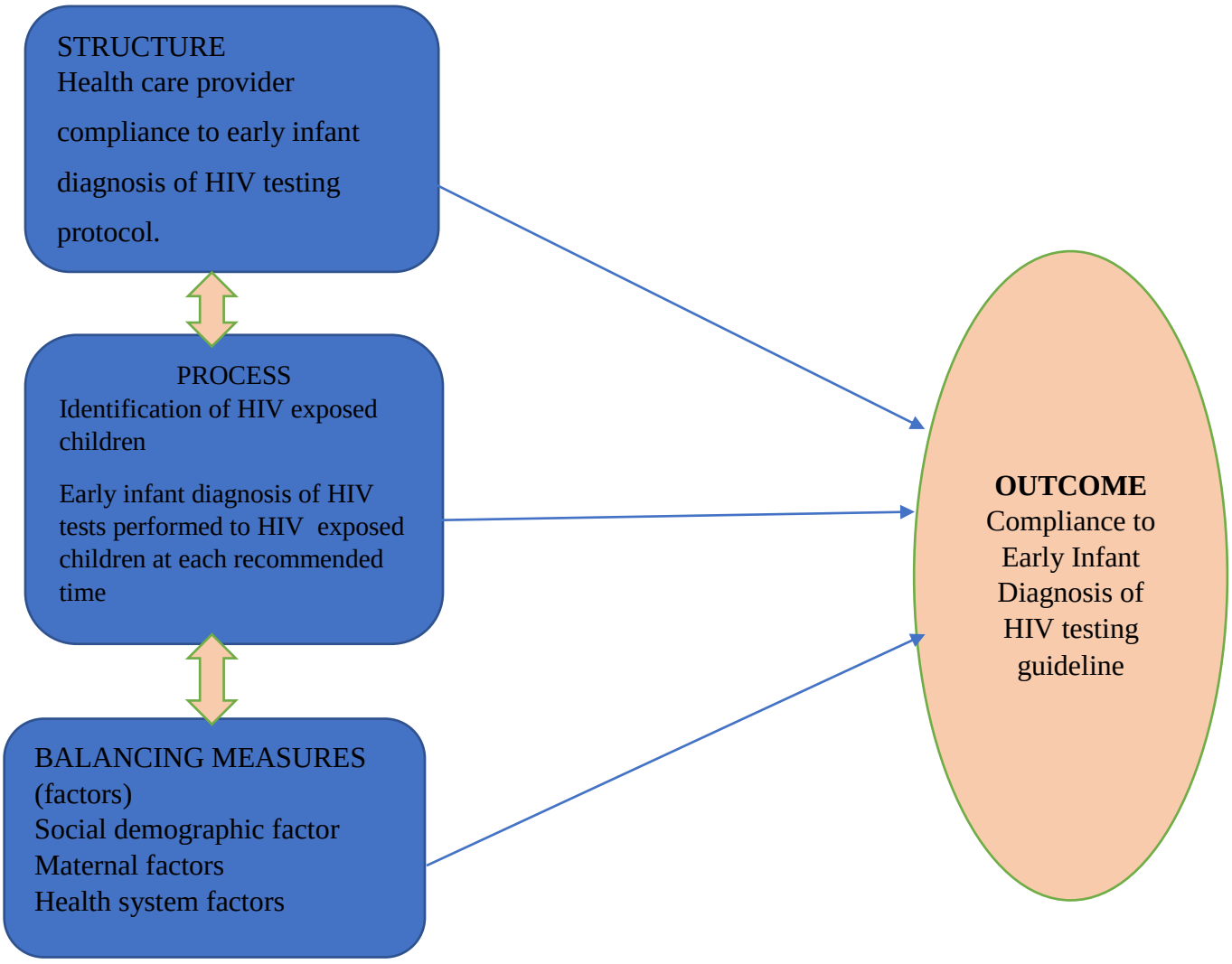


FIGURE 1: CONCEPTUAL FRAMEWORK

1.4 Rationale of the study

The purpose of the study is to state the general EID compliance state of the protocol and as well to particularly identify the compliance state of each recommended HIV tests (at birth, 4-6weeks, 9months, 15months and 18 months). The study findings are expected to add EID compliance literature as less information is available. More so, the findings will be useful in strengthening efforts and proposing effective and adequate strategies for EID of HIV testing protocol integration and implementation among HIV exposed children aged 0-18 months. They are further expected to provide guidance and alarm towards adhering and enhancing factors of EID of HIV testing as it as well evaluated factors that facilitate and are associated with EID of HIV testing implementation.

1.5 Research Questions

1.5.1 Broad research question

To what extent is early infant diagnosis of HIV testing protocol complied among HIV exposed children in regional referral hospitals in Dar es salaam?

1.5.2 Specific research questions

1. To what extent are early infant diagnosis of HIV tests being performed to HIV exposed children as per EID of HIV testing protocol in regional referral hospitals in Dar es Salaam?
2. To what extent do health providers comply to early infant diagnosis of HIV testing protocol among HIV exposed children in regional referral hospitals in Dar es salaam?
3. What are the factors associated with the compliance to early infant diagnosis of HIV testing protocol among HIV exposed children in regional referral hospitals in Dar es salaam?

1.6 Research objectives

1.6.1 Broad objective

To evaluate the extent at which early infant diagnosis of HIV testing protocol is compiled among HIV exposed children in regional referral hospitals in Dar es salaam.

1.6.2 Specific objective

1. To determine the extent of performance of early infant diagnosis of HIV tests among HIV exposed children as per EID of HIV testing protocol in regional referral hospitals in Dar es salaam.
2. To determine the extent at which health providers comply to early infant diagnosis of HIV testing protocol among HIV exposed children in regional referral hospitals in Dar es salaam.
3. To examine the factors associated with the compliance to early infant diagnosis of HIV testing protocol among HIV exposed children in regional referral hospitals in Dar es salaam.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview

To prevent infants from HIV infection, prevention of mother to child transmission programs are wide implemented for woman of reproductive age (30). Strengthening PMTCT programs provided promising result where by 1.4 million HIV infections among exposed infant were prevented between 2010 to 2018 though much has to be done to prevent infant infections especially in postnatal period and breastfeeding where there is poor engagement for women to seek PMTCT care (30). The number of newly HIV infected children is unacceptably high where by 438 children acquired HIV everyday world wide and 1.7 million children around aged 14 years and below living with HIV, 54% of them are in ART (31).

2.2 Compliance to early infant diagnosis of HIV testing protocol

Identification for HEI and children is still low as in 54 reporting countries only 15%(10-28%) of children born to HIV infected women received EID within two month of life (32). Due to limited facilities for diagnosis of HIV infections in Latin America and Caribbean necessities to send DBS sample overseas for processing hence forth many children can be missed to be identified as HIV exposed (33). In USA the identification of HEI results to effective EID implementation at around six weeks of age, 83% which was improved follow-up post-partum through phone call to women with exposed infants (29).

The implementation of routine EID in South Africa has shown a significant increase in the diagnosis of infant infected with HIV in comparison with the use of targeted EID to high risk infants diagnosis of HIV infected infants 86% vs 21% (34). In Ethiopia 90 (71%) infants and children exposed to HIV were identified (35). In Uganda one-year EID implementation study show that there is increase of the implementation 53.6% of the baseline which was the finding of one year before the study to 86.3% of the study participants by the 14 weeks of age. However

whole population showed 68.5% of EID implementation. This increase of EID of implementation was equivalent to significant incremental increase of 20.5% for year review (36).

The accessibility to EID services ranges from 43% to 57.1% among the HEI and children in Tanzania whereby there is still a big population of HEI and children still not accessing EID services and are not yet identified (21). Other area like Mbeya, Tanga and Kilimanjaro in Tanzania have found higher average proportional of EID implementation of 83% with increase from 72% in 2009 to 97.8% in 2011 (37).

DBS collection still among HEI and children is still not done as recommended as less than 47%of the HEI received EID services at less or equal to 8weeks of age, with more than half received EID services after 8 weeks or missed the opportunity of EID services in Myanmar (8). The median age for sample collection for DBS is 8weeks (38) with 72.2% of HIV exposed infants sample for DBS collected within 8 weeks of age (39).

EID implementation through DBS collection in USA at around six week of age was 83% which was improved follow-up post-partum through phone call to women with exposed infants (29).In Sub Saharan Africa the proportional of HEIs who received EID within 2 months of age of life ranges from 3 to 58%, which is still far below the 80% recommended level by WHO. EID services still not available in more than 30% of health facilities in most sub-Saharan Africa countries(19). In Kenya findings shows that the median age for HIV diagnosis to be 3month of age. However two-third equivalent to 66.5% of infant presented late in comparison to the recommendation(40).

More than half (51%) of the HEI and children receive EID at the age of 4 to 6 weeks of age in Tanzania which is below the target, all HEI and children have a right and should have DBS test at every recommended time (21). In other area of Tanzania the median age for first EID was significantly higher from the recommended time of 4 to 6weeks where the median age at first EID testing was 8.57 weeks at Mbeya, 7.95 weeks at Tanga while it was only in Kilimanjaro region where the median age was 5.6 weeks of age as its recommended (37).

The median turnaround time from the time of sample collection to time results were received by mother still is a challenge which results to long waiting time for results for example in Myanmar it was 7(4-12) weeks (8). Missed opportunities for EID of HIV in rural North-Central region in Nigeria has a quite higher turnaround time for DBS sample processing as 77.4% (199/254) of results were ready at the laboratory for disseminations at minimum of 3months up to 28 month (39).

The median turnaround time from blood draw to caregiver results receipt in Lesotho was 76.5days at birth and 63 days at six weeks where by HEI tested at birth were one month younger when their caregiver received EID results than those who tested at six weeks(41)**.** In Tanzania the turnaround time for EID results found to range from 2.7 weeks in Mbeya region to 7.0 weeks at Kilimanjaro region (37).

Generally, there is an improvement in the identification, EID of HIV testing and provision of EID results of HIV exposed children. Despite that, still there is miss identification of the HIV exposed children in the following visits after 2months testing which results to not receiving other recommended tests hence non-compliance to EID testing protocol. More so, from the above review most of the available information is only EID implementation within 2 months, missing to show the whole performance trend of all the recommended tests as per EID protocol. There forth, this study's aim is to evaluate the EID implementation compliance as per the recommended protocol.

2.3 Health provider's compliance to early infant diagnosis of HIV testing protocol among HIV exposed children.

Failure to adhere to EID interventions undermine the effort of PMTCT, research done to sub-Saharan Africa reviled that despite of high prevalence of pediatric HIV also health providers are facing challenges in providing HIV services to pediatrics as guidelines recommended, this is due to inadequate knowledge caused by lack of pediatric HIV training which rise the concern of Health workers' compliance to EID of HIV testing(43). Health worker's compliance to VL test

and guideline it reaches 80% which is below target of 95%, other contributing factors include inadequate tools and delay return of tests (44). This study's aim also was to evaluate the current status of health care provider competence to compliance in implementing EID services with regard to knowledge, utilization and familiarization of the protocol to facilitate the targeted compliance.

2.4 Factors associated with compliance to early infant diagnosis of HIV testing protocol.

2.4.1 Social demographic factors

These individual socio-demographic characteristics have a positive or negative influence in accessibility and acceptance of EID services. Negative influence such as guardian with low formal education, religious beliefs of parents/guardian, mothers being unemployed, lack of paternal support to mother, geographical locations, inadequate awareness of HIV control and prevention services, poor adherence to prevention of mother to child transmission services lack of general knowledge of HIV transmission, stigma and discrimination, inadequate human resource for health, weak infrastructure, inadequate supplies of laboratory materials and late feedback of HIV test results (19). More so parents/guardian having higher formal educations and having good knowledge on the HIV influenced positively EID of HIV implementations (21).

2.4.2 Maternal factors

These factors influence positively or negatively EID of HIV testing performance as required. Negative influence include the mother's HIV status not known and not being on ART before pregnancy as well as distance from the PCR facility (8). In Kenya maternal ANC non-attendance, new maternal HIV diagnosis and lack of maternal antiretroviral therapy (ART) was shown to be statistically significant predictor of late presentation for testing for EID (40). Failure to know the HIV status of the mother at conception and failure to take sample at the appropriate age had negative influence early infant diagnosis of HIV implementations as parents/guardian having higher formal educations and having good knowledge on the HIV influenced positively EID of HIV implementations(21).

2.4.3 **Health system factors associated with compliance to early infant diagnosis of HIV testing protocol.**

These are factors facilitates or hinder the delivery and uptake of EID of HIV of which include inadequate skilled staffs for sample collection, non-reliable transport of collected samples to the reference laboratory for analysis, long turnaround time for results and frequent PCR machine breakdown, adequate knowledge of HCW on EID, availability of DBS cards found to facilitates EID services delivery hindered EID services delivery (42). Other factors that are associated with low EID coverage include low mother-infant pair retention, mobility of pregnant women to seek support for delivery and post-partum period, skilled staff turnover, long turn-around times for dried blood spots (DBS) results, and poor tracing of HIV exposed infants (HEI) Less than two months of age for DBS testing(16). More so, in order to attain maximum coverage of EID services in clinics the following criteria should be present and fulfilled adequately, key elements to facilitate EID within clinics ;Clear national guidelines and testing algorithm, Monitoring and evaluation systems, Identification of HIV-exposed infants, Retention in care, Healthcare provider selection and training, Ongoing supervision and quality improvement, Laboratory practices, Sample transport and results return, Forecasting and supply chain management, Linkage of HIV-infected infants to antiretroviral therapy, Community engagement (3).

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

This study deployed pre and post outcome evaluation which adopted cross-sectional study design using a quantitative approach. This design measured the outcome and exposures at the same time (45,46).

3.2 Study area

The study was conducted at Amana, Temeke, and Mwananyamala regional referral hospitals in Dar es salaam region. These are the only regional referral hospitals found in three major municipal councils in Dar es Salaam region which are Ilala, Temeke, and Kinondoni respectively. They serve a population of about 4.3 million people (47). These regional referral hospitals provide wide range of health care services such as obstetrics and gynecology, internal medicine, pediatrics, surgery, dentistry, ophthalmology, orphanage unit as well as reproductive and child health clinic comprised of immunization services and comprehensive HIV services for both children and adults. They were purposively selected because they offer HIV diagnosis, treatment and supportive care to a large population to both children and adults. Also, from unpublished data from District Health Information System 2 (DHIS 2) indicates that majority (>70%) of HIV exposed children reported at these selected hospitals for eMTCT services.

3.3 Study population

The study population for this research comprised 288 pairs of mothers living with HIV alongside their HIV exposed children and six health care workers two from each facility. These study population were conveniently chosen from the Reproductive and Child Health (RCH) within regional referral hospitals situated in Dar es Salaam, Tanzania. The selection process focused on mother-infant pairs who participated in the Early Infant Diagnosis (EID) program in between May 2022 and May 2023 within the designated healthcare facilities. This time frame was selected to ensure that the infants who had completed the 18-month EID recommended timeline (4,27,48).

The selection of health care workers considered the provider serving the unit for at least 1 year or more to ensure long term experience in providing the EID services.

2.5 Inclusion and exclusion criteria

All HIV positive women with their HIV exposed children who had graduated EID of HIV testing within May 2022 to May 2023 and two health workers present and attending children for RCH and immunization clinics at data collection period as per study requirement. HIV negative women, non-HIV exposed children, HIV exposed children who had not graduated EID of HIV testing within the study period were direct excluded from the analysis and health workers not providing services in RCH and immunization clinic were excluded from this study.

3.5 Sampling procedure

The sampling procedure for this study involved the purposive selection of three regional referral hospitals renowned for providing comprehensive HIV diagnosis, treatment, and care services to a substantial population, encompassing both children and adults. RCH clinics were conveniently selected as this unit contained the targeted population. To ensure a representative sample, a probability proportional to size sampling approach was adopted, where the number of participants required from each site was calculated based on its population of HIV-exposed children, as obtained from the DHIS 2 database.

Within each selected facility, participants were chosen using a systematic random sampling method, specifically targeting pairs of HIV-exposed children and their respective mothers attending the RCH clinic. The sampling interval (Kth) was determined using the formula Kth = N/n, where N represented the total monthly attendance of clients (pairs of HIV-exposed children and caregivers) at the reproductive and child health (RCH) and immunization clinic, and denoted the predetermined sample size for the study. For instance, based on available records, there were approximately 861 HIV-exposed children attending the RCH clinic per month, while the estimated sample size for the study was 288. Hence, the sampling interval was calculated as K = 861/288, indicating that every third individual on the list was included until the desired sample size was reached.

3.6 Sample size

The sample size was calculated through approach based on precision rate and confidence level using single proportion formula for finite population by Kothar CR, 2008 second revised edition (49).

$$\boldsymbol{n = \frac{z^2.p.q.N}{\varepsilon^2(N-1) + z^2.p.q}}$$

Whereby;

n= estimated sample size (individual to be included in the study i.e pair of HIV exposed infants/children and their mother/caretakers/caregivers);

N= total pair of HIV exposed infants/children and their mother/caretakers/care givers from the selected study sites per month (N=861);

z= standard normal distribution at 95% confidence interval (z=1.96)

ε = the margin of error (5%);

p= the proportion of HEIs who complete the EID of HIV from the previous study on adherence to HEIS in Uganda 45% (p=0.45) (50);

q= proportion of HEIs who had no compliance with EID of HIV (1-p =1-0.17=0.83).

The calculation gave a minimum sample size of 260. When adjusting for non-response rate of 10%, total sample size was 288 pair of HEIs and their mother/caretakers. In this study, the actual data collected reached 288 participants which is a pair of mother and her HIV exposed child.

The distribution by referral hospital was attained using probability proportional to size sampling approach which considered population of HIV-exposed children as obtained from the DHIS 2 database. Amana, Mwananyamala and Temeke referral hospitals HIV exposed children population as per DHIS2 was 231,241,389 their proportion sample size was 0.2682, 0.2799, 0.4518 and sample size for each hospital was 77, 81,130 respectively.

3.7 Study variables

Dependent or outcome variable

The outcome variable of interest for this study was compliance to EID of HIV testing protocol. Compliance refers to the act of adhering to rules, regulations, guidelines, or standards set forth by a particular authority or organization. In the context of this study, compliance specifically pertains to adherence to the Early Infant Diagnosis (EID) of HIV testing protocol i.e to follow all the recommendations outlined in the standard implementation guide for EID of HIV testing. This includes completing all necessary testing as prescribed i.e attending appointments to undergo the required tests. One is considered non-compliant when they fail to fulfill all the recommendations outlined in the EID of HIV testing protocol. This could include missing tests, or not following through with recommended treatments.

The compliance is addressed to mothers with HIV-exposed infants, as they are responsible for ensuring that their infants receive the necessary testing and follow-up care as per the protocol. The source of the compliance tool is the standard implementation guide for EID of HIV testing described by World Health Organization (4). This guide provides detailed instructions and recommendations for healthcare providers and caregivers on how to conduct HIV testing for infants and follow-up care procedures.

Independent variables

These were the factors that influence EID of HIV testing implementation among HIV exposed infants and children of which include; social demographic and maternal factors and health system factors.

Social Demographic Variables:

The age of participants was measured in years, categorized into distinct groups: 15-24, 25-29, 30-39, and 40-49. This classification was adapted from the Tanzania Demographic and Health Survey questionnaire (TDHS) (51), a widely recognized and utilized survey tool. Understanding the influence of participant age on Early Infant Diagnosis (EID) of HIV testing protocols among HIV exposed children is crucial for tailoring interventions effectively.

Participants' marital statuses were classified into three categories: never married, married/living together, or divorced/separated/widowed. This classification was derived from the TDHS questionnaire (51), a validated instrument used in national surveys. The marital statuses provided insights into the social context affecting healthcare utilization among HIV-exposed children.

Participants' educational backgrounds were categorized into various levels, ranging from no education to secondary education and beyond. Education plays a significant role in shaping health-seeking behaviors, making this variable essential for understanding disparities in access to EID services. This variable was gathered to elucidate the association between educational attainment and EID utilization, drawing from the TDHS questionnaire (51).

Participants' occupation was assessed based on the following categories ‘not employed, permanent employment, temporary employment, and others. This classification, obtained from the TDHS questionnaire(51), provides valuable insights into the influence of occupational factors on EID accessibility. Understanding how occupation intersects with healthcare utilization can inform targeted interventions to improve EID uptake among different occupational groups.

Participants' roles within the household were considered, encompassing categories such as head of the family, husband/wife, child, and others. This information, derived from the TDHS questionnaire (51), offers valuable insights into household dynamics affecting EID access. Household structure and dynamics can significantly impact healthcare decision-making, making this variable crucial for understanding EID utilization.

Distance from attending health facilities, participants were grouped based on the proximity of their residences to health facilities, distinguishing between those within 5km and those beyond. This categorization, sourced from the TDHS questionnaire (51), allows for the evaluation of how distance impacts EID accessibility. Proximity to health facilities is a critical determinant of healthcare utilization, particularly for services like EID testing, making this variable essential for identifying geographical barriers to access

Maternal Factors:

HIV Status was measured using a question adopted from TDHS (51). Maternal HIV status was categorized as positive or negative, allowing for an examination of how maternal HIV status influences EID utilization as indicated by the TDHS.

For the ART Use, the status of mothers being on antiretroviral therapy (ART) or not was assessed to understand its relationship with EID uptake. ART usage is a critical factor influencing the health-seeking behavior of HIV-positive mothers, making this variable essential for understanding EID utilization patterns within this population. This variable was derived from multiple sources ie in the previous studies conducted in Uganda and Kenya (27,40).

Mothers' duration on ART was categorized into less than 2 years or more than 2 years, providing valuable insights into the association between ART duration and EID engagement, as indicated by the TDHS (51). Understanding how the duration of ART usage impacts EID utilization can inform strategies to improve continuity of care and adherence to testing protocols among HIV-exposed children.

Maternal awareness of EID testing was evaluated to understand the role of knowledge in EID utilization, informed by previous research done in Uganda (27). Adequate knowledge about EID testing is essential for informed decision-making and utilization of healthcare services, making this variable critical for assessing barriers to access and uptake.

The timing of maternal awareness of EID was categorized as before, during, or after pregnancy, was examined to assess its impact on EID uptake, based on previous study done in Boston (48). Timing of awareness may significantly influence maternal engagement with EID services, highlighting the importance of addressing awareness gaps at crucial stages of reproductive health care.

Maternal attitudes toward EID for infants and children, whether positive or negative, were explored to understand their influence on EID engagement, drawing from previous research done in Uganda (27). Maternal attitudes play a crucial role in shaping health-seeking behaviors,

making this variable essential for identifying potential barriers to EID utilization and tailoring interventions accordingly.

Benefits of EID, mothers' perceptions of the benefits of EID were assessed to identify factors driving EID utilization, informed by previous study in Uganda (27). Understanding perceived benefits can inform messaging and educational interventions aimed at promoting EID uptake among HIV-exposed children, emphasizing the importance of early diagnosis and treatment initiation.

Maternal knowledge of the appropriate age for EID testing was examined to understand its association with EID uptake, based on previous research findings in Kapchorwa district (52). Accurate knowledge about the timing of EID testing is essential for timely access to healthcare services, making this variable crucial for identifying knowledge gaps and addressing misconceptions among mothers as done in the study that was conducted in Tanzania(21).

Acceptance to perform EID, maternal acceptance of EID services for their child was evaluated to identify barriers to EID utilization, informed by previous studies in Kenya (40). Understanding factors influencing maternal acceptance can help address barriers and improve uptake of EID services among HIV-exposed children, emphasizing the importance of patient-centered approaches to care delivery.

The HIV status of the child, categorized as positive, negative, or unknown, was assessed to explore its influence on EID utilization, drawing from previous study conducted in Kenya (40). Understanding how the child's HIV status impacts EID uptake can inform tailored interventions to improve access to testing and treatment services among affected children and their families. ART Use Status of the Child was also assessed. Whether the child is on antiretroviral therapy or not was examined to understand its association with EID engagement as in study that was conducted in Tanzania(21).

Disclosure of Child's HIV status, maternal disclosure of the child's HIV status to family members was evaluated to understand its impact on EID utilization. Disclosure can influence healthcare-

seeking behaviors and support networks, making this variable essential for understanding factors affecting EID uptake within families as conducted in a previous research in Kenya (40).

Caregivers' membership in psychosocial support groups was assessed to explore its association with EID utilization. Psychosocial support plays a crucial role in coping with the challenges of HIV/AIDS, highlighting the importance of community-based interventions in promoting EID uptake and retention in care indicated by the TDHS(51). Belonging to Psychosocial Support Group: Maternal membership in psychosocial support groups was assessed to explore its association with EID utilization as conducted in a previous research in Kenya (40).

Perceived advantages of EID for HIV-exposed infants were examined for their potential influence on EID testing protocol (40). Understanding mothers' perceptions of EID benefits can inform messaging and educational interventions aimed at promoting uptake and adherence to testing protocols among HIV-exposed children, emphasizing the importance of addressing perceived barriers to care access as done in a previous research in Kenya (40).

Health System Factors:

EID service cost, the requirement for payment for EID services was assessed to understand the financial barriers to EID utilization. Financial constraints can significantly impact healthcare access, highlighting the importance of addressing affordability concerns to improve uptake of EID testing protocols among HIV-exposed children as done in a previous research in Boston (48).

Linkage of EID Services was also assed. How EID services are linked, whether verbally, through written reports, escorted by healthcare workers, or self-referral, was examined to identify facilitators and barriers to EID access, based on previous studies in Uganda(27). Understanding the mechanisms of service linkage can inform strategies to streamline service delivery and improve access to EID testing among affected populations. The frequency of EID service availability was evaluated to understand its impact on EID utilization.

Adequate service availability is essential for ensuring timely access to testing and treatment services, emphasizing the importance of strengthening healthcare infrastructure to support EID implementation efforts (27).

The frequency of health worker availability for EID services was assessed to identify staffing-related factors influencing EID access, drawing from previous research. Adequate staffing is crucial for ensuring quality service delivery and minimizing wait times, highlighting the importance of workforce capacity building in supporting EID program implementation as in study that was conducted in Tanzania and Uganda (4,27).

The waiting time experienced by mothers for EID services was examined to identify potential barriers to EID utilization classified as long or not based on cut point of one hour. Long wait times can deter individuals from seeking care, emphasizing the importance of efficient service delivery and patient-centered care approaches in improving EID uptake among HIV-exposed children as presented in a study that was conducted in Uganda (27).

The adequacy of counseling received during EID services was assessed to understand the quality of EID service delivery. Effective counseling is essential for informed decision-making and adherence to testing protocols, highlighting the importance of training healthcare providers in patient-centered communication skills as presented in a study that was conducted in Uganda (27).

EID Appointment schedule, whether mothers receive a copy of their EID appointment schedule was evaluated to understand the organization of EID services and its impact on utilization, based on previous research as done in Boston (48). Clear communication and scheduling practices are essential for ensuring continuity of care and adherence to testing protocols, emphasizing the importance of patient engagement and empowerment in EID service delivery.

Follow-up remainders of EID uptake, whether mothers are followed up after EID service uptake was assessed to understand the continuity of care in EID service delivery. This was categorized as yes or no if participant is reminded for follow-up or not. Follow-up reminders facilitate engagement with care services and support retention in EID programs, emphasizing the

importance of comprehensive care coordination in improving health outcomes among HIV-exposed children as done in a previous research in Tanzania (52).

3.8 Data collection method

Data was collected using questionnaire of which contained standardized questions in Kiswahili language. After the facility administration gone through the study purpose and all involved documents, a written document permission was granted to proceed with the conduction of the study. At the RCH units, the identification of the eligible participants was done using their children RCH4 cards and antenatal card of the mother. The eligible HIV positive mother with their HIV exposed children after accepting to participate and consent filling, were provided with the questionnaire to answer the study questions. Compliance to EID of HIV testing protocol was confirmed from CTC data base and CTC2 HEI cards present in HIV positive mother file. More so, two health workers present and attending children at RCH and immunization clinic were interviewed as well on compliance to EID of HIV testing protocol questions.

WHO recommends HIV testing for highly exposed newborns within 72 hours of birth and for less exposed infants between 4 and 6 weeks old. Test results should be provided to parents within 4 weeks of collection (4,24). Rapid communication of positive test results to the mother and child is essential for early ART treatment. HIV exposed children should get another test (virological test) at 9 months old. Serological testing for HIV should be done following HIV serological testing algorithm for adults to all HIV exposed children at 15 months or 3 months after stopping breast feeding and at 18 months to exclude HIV infection to the child. To detect HIV infection in HIV-exposed infants, adding NAT at birth to existing EID testing approaches can be considered.

Investigation tools, validity and reliability issues

The evaluation questions regarding compliances for this study were developed following standard guideline of early infant diagnosis HIV testing (4). Questions regarding associated factors have been developed based on the evidence based protocol for EID of HIV implementation guide for managers (3) and the previous studies on factors associated with adherence to EID in the neighbor country in Uganda (27). To test the reliability of the study tool,

pre-test was conducted among 10% of the expected participants, analyzed and check for the consistent of the responses and no adjustment was made prior actual data collection.

3.9 Data Management and statistical analysis

Data were collected in paper questionnaire and entered in the excel data entry sheet. Checking for completeness and consistency of information filled on the questionnaires was done on daily basis by Principal investigator and the research assistant. Stata software version 18 was used for cleaning and analysis. Descriptive statistics were conducted to describe socio demographic maternal characteristics and health facility related factors.

Bivariate and multivariate logistic regression analysis was used to establish the strength of association between dependent variable and independent variable. Crude Odds Ratio (COR) and Adjusted Odd Ratio (AOR) with 95% Confidence interval of the factors were estimated, while controlling for confounding factors and effect of multiple factors in the model. All variables were checked for multicollinearity before being included in the multivariate model, all tests were two sided and the level of significance was set at 5%.

3.10 Ethical consideration

Ethical approval was obtained from MUHAS Research and Ethics Committee. Permission to collect data in the health facility was granted by Regional Administrative Secretary (RAS) and District Executive Directors (DED) from respective districts in Dar es Salaam Participation in the study was voluntary and a written consent was obtained from the HIV positive mother having HIV exposed child after being introduced in the study and understanding the purpose of the study. The aim, duration and potential benefits of the study were shared to participants before consenting to be involved in the study. Participant were ensured that personal identifying information will not be collected from the study to warrant confidentiality. Every participant on the selected list willingly provided their informed consent, demonstrating a 100% participation rate.

CHAPTER FOUR

4.0 RESULTS

4.1 Enrollment of the eligible participants

In this study, 288 pairs of mothers and their HIV-exposed infants were successfully enrolled from the selected health facilities. All enrolled pairs were included in the final analysis.

More so, a total of 6 health care provider working in the RCH, 2 were recruited from each site Amana, Temeke and Mwananyamala regional referral hospitals.

4.2 Sociodemographic characteristics of the participants

Of 288 participants, the majority of mothers are within the age range of 30-39 years (56.3%, n=162). The participants are predominantly married or living together (55.2%, n=159). In terms of education, primary education is the most prevalent (44.4%, n=128), and the majority are informally employed (61.1%, n=176). A significant portion has been on antiretroviral therapy for at least 2 years (86.8%, n=250). The majority of participants reside at least 5km from the facility (65.3%, n=188), and most children were identified as HIV exposed during pregnancy (71.9%, n=207). Disclosure of HIV status to family members is prevalent (70.1%, n=202), while the majority do not belong to any psychosocial-support group (99.0%, n=285). The distribution of child sex shows a slight female majority (55.2%, n=159), and the majority of children are over 18 months old (91.0%, n=262), (Table 1).

Two health care providers from each health facility, all of them were female and majority 4(66.7%) were aged above 35 years.

Table 1: Sociodemographic characteristics of the participants

Variables	Number	Percentage
Maternal age in years		
15-24	27	9.4
25-29	57	19.8
30-39	162	56.3
40-49	42	14.6
Marital status		
Married or Living together	159	55.2
Divorced	55	19.1
Widowed	4	1.4
Never married or living together	70	24.3
Education level		
Non-formal	14	4.9
Primary	128	44.4
Post primary training	16	5.6
Secondary	51	17.7
College/University	79	27.4
Occupation		
Not employed	31	10.8
Informal employed	176	61.1
Formal employed	81	28.1
Duration on ART		
Less than 2 years	38	13.2
≥2 years	250	86.8

Distance from facility		
Less than 5km	100	34.7
≥5km	188	65.3
When was the children identified as HIV exposed?		
During pregnancy	207	71.9
At labor	16	5.6
At immunization clinic	42	14.6
Another clinic	23	8.0
Disclosed the HIV status to family members		
No	86	29.9
Yes	202	70.1
Belong to any psychosocial-support group		
No	285	99.0
Yes	3	1.0
Sex of the child		
Male	129	44.8
Female	159	55.2
Age of a child		
18 months	26	9.0
>18 months	262	91.0

4.3 Compliance with EID of HIV testing Protocol

In a cohort of 288 HIV exposed infants, a majority 72.6% (n=209) had compliance to the EID of HIV testing protocol, while 27.4% (n=79) did not. Notably, the Conducting of Nucleic Acid Testing (NAT) for HIV-exposed newborns and 4-6 weeks was high, with 97.9% (n=282) receiving the test. The adherence to conducting tests at 9 months and the final diagnostic test at 18 months was also substantial at 95.8%(n=275) and 95.0% (n=268) respectively. However, there were variations in compliance with later tests, such as serological test at 15 months (79.7%, n=228). Overall, most of HIV test results were negative, with percentages ranging from 97.0% to 99.6%, (Table 2).

Table 2: Compliance with EID of HIV testing protocol

Variable	**EID test Yes(done) No (not done)**	**Frequency**	**Percentage**
Overall compliance to EID for HIV (for whom all done appropriately)	No	79	27.4
	Yes	209	72.6
Conduct NAT for HIV exposed newborn	No	6	2.1
	Yes	282	97.9
Conduct NAT at 4 -6 weeks	No	6	2.1
	Yes	282	97.9
Conduct NAT at 9 months (n=287)	No	12	4.2
	Yes	275	95.8
Conduct test at 15months (n=286)	No	58	20.3
	Yes	228	79.7

Did final test at 18 months or after	No	14	5.0
cessation of breast feeding (n=282)	Yes	268	95.0
Result of 1st NAT	Negative	281	97.6
	Missing	7	2.4
Results of 2nd NAT (n=282)	Negative	281	99.6
	Positive	1	0.4
Result of 3rd NAT (n=276)	Negative	275	99.6
	Positive	1	0.4
Results 4th test (n=228)	Negative	223	97.8
	Positive	1	0.4
	Missing	4	1.8
Results Final diagnostic test (n=268)	Negative	260	97.0
	Positive	6	2.2
	Missing	2	0.7

4.4 Healthcare providers' compliance to EID of HIV testing protocol

The findings indicate a high level of familiarity and adherence to the protocol among 6 health care providers interviewed. A significant majority (83.3%) are well-acquainted with the EID of HIV testing protocol, utilizing it consistently during daily routine implementation (83.3%). All respondents employ the protocol to screen for HIV-exposed children, demonstrating a high commitment to its application. The healthcare providers exhibit confidence and comfort in performing screenings (83.3%) and consistently order EID of HIV tests for eligible children.

Additionally, all respondents provide test results to mothers and refer HIV-positive children for Antiretroviral Therapy (ART) initiation at CTC clinics. The findings underline a positive perception of the recommended EID of HIV testing protocol, with a majority finding it very easy to use or follow (66.7%), (Table 3).

Table 3: Healthcare providers' compliance to EID of HIV testing protocol

Variables	Categories	Frequency	Percentage
Familiarity with the EID of HIV testing protocol	Yes	5	83.3
	No	1	16.7
Refer to the EID of HIV testing protocol for reference during EID of HIV testing implementation	All the time	5	83.3
	Sometimes	1	16.7
Use EID of HIV testing protocol to screen for HIV exposed children	Use it all the time	6	100.0
	Don't use it all the time	0	0.0
Comfortability with screening for HIV exposed children with regard to the EID of HIV testing protocol	Very comfortable	5	83.3
	Confident	1	16.7
Perform screening of HIV exposed children at clinic	Yes	6	100.0
	No	0	0.0
Perform EID of HIV testing to all eligible children	Yes	6	100.0
	No	0	0.0

Order for EID of HIV tests to all eligible children	All the time	6	100.0
	No	0	0.0
Provide EID of HIV test results of the HIV exposed children to their mothers	Yes	6	100.0
	No	0	0.0
For HIV positive children, refer them to CTC clinic for ART initiation	Yes	6	100.0
	No	0	0.0
Confident with performing EID of HIV tests to the eligible children	Very comfortable	4	66.7
	Confident	2	33.3
Opinion on the use of the recommended EID of HIV testing protocol	Very easy to use/follow	4	66.7
	Easy to use/follow	2	33.3

4.5Factors associated with Compliance to Protocol of EID for HIV

To examine the factors associated with compliance to protocol of EID for HIV, the study employed bivariate analysis and multivariate analysis. More so, the study used chi square approach to make comparison between categorical independent variables with regard to outcome variable and bivariate logistic regression.

Chi square approach was employed to compare the significance of categorical independent variable with regard to the outcome variable (compliance to EID of HIV testing protocol). Factors that revealed significant with compliance to EID of HIV testing protocol included, the period child identified as HIV exposed (0.034) as those who were identified at labour 81.25% had higher compliance compared to those identified during pregnancy 76.33%, at immunization clinic 59.52% and at another clinic 56.52%. In addition to that perceived benefit of EID testing was significant (0.000) as mothers who knew more than one benefit of EID of HIV testing 79.7%

complied compared to those who knew one benefit 57.14%. More so, EID knowledge was slightly significant (0.06) as those who had adequate EID knowledge 75.34%complied in comparison to those who had inadequate EID knowledge 63.77%. Also, average waiting time to receive EID services (0.003) was significant as those who waited for 1 hour or less 86.11% complied more in comparison with those who waited for more than an hour 68.06% as presented in Table 4 below.

Table 4: Comparison between explanatory variables and compliance to EID of HIV testing

Variable		N	Compliance to EID		
			Freq	Percent	P-value
Age category	15-24 years	27	21	77.78	
	25-29 years	57	41	71.93	
	30-39 years	162	119	73.46	
	40-49 years	42	28	66.67	0.758
Marital status	Married or Living tog	159	117	73.58	
	Divorced/widowed	59	43	72.88	
	Never married or living together	70	49	70.00	0.853
Education level	Non-formal	14	11	78.57	
	Primary	128	96	75.00	
	Post primary training	16	9	56.25	
	Secondary	51	34	66.67	
	College/University	79	59	74.68	0.428
Occupation	Not employed	31	26	83.87	
	Informal employed	176	123	69.89	0.257

	Formal employed	81	60	74.07	
Duration on ART	Less than 2 years	38	24	63.16	
	≥2 years	250	185	74.00	0.163
Distance from facility	Less than 5km	100	67	67.00	
	≥5km	188	142	75.53	0.122
When was the children identified as exposed	During pregnancy	207	158	76.33	
	At labour	16	13	81.25	
	At immunization clinic	42	25	59.52	
	Other clinics	23	13	56.52	0.034
Disclosed HIV status to family members	No	86	57	66.28	
	Yes	202	152	75.25	0.118
Perceived benefits of EID	No	91	52	57.14	
	Yes	197	157	79.70	<0.001
EID knowledge	Inadequate	69	44	63.77	
	Adequate	219	165	75.34	0.060
Waiting time	≤ hour	72	62	86.11	
	More than one hour	216	147	68.06	0.003
Provided with EID counselling	Rarely	6	4	66.67	
	Frequently	282	205	72.7	0.743

Have EID appointment schedule	No	233	168	72.10	
	Yes	55	41	74.55	0.715
Regularly followed-up for EID uptake services	No	8	4	50.00	
	Yes	280	205	73.21	0.147

In the bivariate analysis, the significant factors associated with compliance to EID of HIV testing included, perceived benefits of EID for HIV were significantly associated with compliance as those who knew EID of HIV testing benefits had 2.94 times higher odds of compliance(COR=2.94, 95% CI: 1.71-5.06), time the child was identified as HIV exposed being during labor had 3.33 time higher odds of increased compliance to EID (COR=3.33, 95% CI: 1.02-6.01), the participants who's average waiting time to receive EID service during visits being 1 hour or less had 2.91 higher odds of compliance (COR of 2.91 ,95% CI: 1.41-6.02) (Table 5).

Table 5: Bivariate analysis for the factors associated with compliance to EID of HIV testing protocol

Variables	**COR (95%CI)**	**P-value**
Maternal age		
15-24 years	1.75 (0.58-5.32)	0.324
25-29 years	1.28 (0.54-3.04)	0.574
30-39 years	1.38 (0.67-2.87)	0.383
40-49 years	1	
Marital status		
Married or Living tog	1.19 (0.64-2.22)	0.576
Divorced/widowed	1.15 (0.53-2.48)	0.719
Never married or living together	1	

Education level		
Non-formal	1	
Primary	0.81(0.21-3.12)	0.769
Post primary training	0.35 (0.07-1.76)	0.203
Secondary	0.55 (0.13-2.22)	0.397
College/University	0.80 (0.20-3.18)	0.756
Occupation		
Not employed	1	
Informal employed	0.45 (0.16-1.23)	0.117
Formal employed	0.55 (0.19-1.62)	0.276
Duration on ART		
Less than 2 years	1	
≥2 years	1.66(0.81-3.40)	0.166
Distance from facility		
Less than 5km	1	
≥5km	1.52(0.89-2.59)	0.124
Point at diagnosis		
During pregnancy	2.48(1.02-6.01)	0.044
At labor	3.33(0.7414.97)	0.116
Immunization clinic	1.13(0.40-3.17)	0.814
Another clinic	1	
HIV status disclosure		
No	1	
Yes	1.55(0.89-2.68)	0.120

Perceived benefits of EID		
No	1	
Yes	2.94(1.71-5.06)	0.000
EID Knowledge		
Inadequate	1	0.062
Adequate	1.33(0.88-2.02)	
Waiting time for EID		
≤ hour	2.91(1.41-6.02)	<0.004
More than one hour	1	
EID counselling		
rarely	1	
Frequently	1.33(0.24-7.42)	0.744
EID appointment schedule		
no	1	
Yes	1.13(0.58-2.22)	0.715
Regularly followed for EID		
No	1	
Yes	2.73(0.67-11.21)	0.162

All maternal and health system factors with P value 0.2 or less were further subjected to a multiple logistic regression. Duration on ART for at least 2 years remained a significant predictor of compliance (AOR=2.28, 95% CI: 1.05-4.95, p=0.038), as well as the distance from the facility

being at least 5km away from the facility (AOR=1.97, 95% CI: 1.04-3.73, p=0.038). The perceived benefits of EID for HIV also emerge as a significant factor, with AOR of 2.57 (95% CI: 1.26-5.24, p=0.009), the average waiting time to receive EID service during visits being 1 hour or less remained a significant factor associated with EID compliance, (AOR= 3.20, 95% CI: 1.48-6.88, p=0.003). (Table 6).

Table 6: Multivariate analysis for the factors associated with compliance to EID of HIV testing protocol

Variables	COR (95%CI)	P-value	AOR (95%CI)	P-value
Maternal age				
15-24 years	1.75 (0.58-5.32)	0.324	1.44(0.42-4.90)	0.556
25-29 years	1.28 (0.54-3.04)	0.574	0.95(0.35-2.56)	0.924
30-39 years	1.38 (0.67-2.87)	0.383	1.8(0.48-2.43)	0.844
40-49 years	1			
Marital status				
Married or Living together	1.19 (0.64-2.22)	0.576	1.3(0.69-2.73)	0.364
Divorced/widowed	1.15 (0.53-2.48)	0.719	1.32(0.57-3.04)	0.504
Never married or living together	1			
Education level				
Non-formal	1			
Primary	0.81(0.21-3.12)	0.769	0.87(0.22-3.42)	0.845
Post primary training	0.35 (0.07-1.76)	0.203	0.37(0.06-2.05)	0.257
Secondary	0.55 (0.13-2.22_	0.397	0.62(0.14-2.70)	0.530

College/University	0.80 (0.20-3.18)	0.756	0.87(0.20-3.67)	0.857
Occupation				
Not employed	1			
Informal employed	0.45 (0.16-1.23)	0.117	0.48(0.17-1.37)	0.173
Formal employed	0.55 (0.19-1.62)	0.276	0.56(0.18-1.75)	0.323
Duration on ART				
Less than 2 years	1			
≥2 years	1.66(0.81-3.40)	0.166	2.28(1.05-4.95)	0.038
Distance from facility				
Less than 5km	1			
≥5km	1.52(0.89-2.59)	0.124	1.97(1.04-3.73)	0.038
Point at diagnosis				
During pregnancy	2.48(1.02-6.01)	0.044	2.39(0.82-7.02)	0.112
At labor	3.33(0.7414.97)	0.116	3.29(0.6716.12)	0.142
Immunization clinic	1.13(0.40-3.17)	0.814	1.22(0.42-3.55)	0.715
Another clinic	1			
HIV status disclosure				
No	1			
Yes	1.55(0.89-2.68)	0.120	1.17(0.65-2.11)	0.609
Perceived benefits of EID				
No	1			
Yes	2.94(1.71-5.06)	0.000	2.57(1.26-5.24)	0.009

EID Knowledge				
Inadequate	1	0.062		
Adequate	1.33(0.88-2.02)		1.12(0.56-2.22)	0.757
Waiting time for EID				
≤ 1 hour	2.91(1.41-6.02)	0.004	3.20(1.48-6.88)	0.003
>1 hour	1			
Regularly followed for EID				
No	1			
Yes	2.73(0.67-11.21)	0.162	2.56(0.60-10.99)	0.205

CHAPTER FIVE

5.0 DISCUSSION

5.1 Discussion of the key findings

This study assessed compliance with Early Infant Diagnosis (EID) of HIV testing protocol among 288 pairs of mothers and HIV-exposed infants. Key findings reveal low overall compliance rate of about seventy-three percent still below the recommended global target. Notably, most (97.9%) of the HIV-exposed newborns and children at 4-6 weeks received Nucleic Acid Testing (NAT) exceeding Tanzania target (80%) of and global target (90%), also compliance at the final diagnostic test at 18 months has progressed from 32% (2018) to 95%. The compliance to conducting NAT at 9 months was also substantial at 95.8%. However, there were variations in compliance with later tests, such as test at 15 months being 79.7%. Factors associated with EID compliance of HIV testing included knowing perceived benefits of EID for HIV, Duration on ART for at least 2 years, the distance from the facility being at least 5km, and the average waiting time to receive EID service during visits being one hour or less.

5.2 Compliance with EID of HIV Testing Protocol

The study delves into the compliance rates with the Early Infant Diagnosis (EID) of HIV testing protocol, focusing on all HIV tests conducted to HIV-exposed infants. The findings reveal that approximately seventy three percent of HIV-exposed infants underwent testing in accordance with the EID protocol (2). At 4-6 weeks test, higher compliance is revealed similarly in previous studies in Tanzanian context like Mbeya, Tanga, and Kilimanjaro exhibit higher average proportional of EID of HIV testing at 4-6 months that met the WHO target of eight-percent (8,37) but with low median age of 8 weeks for sample collection, falling short of the recommended timeframe (38). Comparable trends were observed in South Africa (34), Ethiopia (35), and Uganda (36) , where a significant proportion of compliance with EID for HIV testing protocol at 4-6 weeks exceeded eighty percent. Despite the high rate of compliance, HIV testing to HIV exposed infants in many resource-constrained settings particularly sub-Saharan Africa is below the WHO target of eighty percent (18,20). This implies that, mothers with exposed HIV infants still need to be well informed and supported to follow-up system with EID for HIV testing. In

contrast, findings from high-income countries, such as the United States, indicate a higher proportion of compliance with EID for HIV testing among HIV-exposed infants where eighty-three percent of HIV-exposed children undergo HIV testing in accordance with the recommended guidelines (29). This disparity in compliance rates could be attributed to variations in healthcare infrastructure and awareness level.

The regional disparities observed in compliance with EID of HIV among HIV-exposed infants emphasize the necessity for targeted interventions that consider diverse healthcare infrastructures and accessibility. Recognizing these variations is crucial for developing effective strategies to improve compliance rates and ensure timely and accurate HIV testing for exposed infants across different settings.

5.3 Healthcare providers' compliance to EID of HIV testing protocol

The study indicates a positive trend in healthcare providers' compliance with the EID of HIV testing protocol, with eighty-three percent demonstrating familiarity and consistent utilization during routine implementation. This commitment is reflected in the providers' confidence and comfort in performing screenings, regular EID tests and result provision to the mothers. The findings align with previous studies that emphasize the importance of healthcare provider knowledge and commitment to EID services (42). However, the current study differs from previous findings in the turnaround time for receiving EID results. While the current study reports a relatively shorter turnaround time in Tanzania (2.7 weeks to 7.0 weeks), previous studies in Myanmar, Nigeria, and Lesotho highlight significantly longer waiting times, ranging from 7 to 76.5 days (9, 11). These variations suggest that regional differences and healthcare infrastructure play a crucial role in determining the efficiency of EID services. The high compliance among healthcare providers suggests a positive impact on the delivery of EID services. Shorter turnaround times contribute to timely initiation of Antiretroviral Therapy (ART) for HIV-positive children, emphasizing the importance of effective EID protocols in ensuring prompt intervention and care.

Additionally, all respondents provide test results to mothers and refer HIV-positive children for Antiretroviral Therapy (ART) initiation at CTC clinics. The findings underline a positive

perception of the recommended EID of HIV testing protocol, with a majority finding it very easy to use or follow (over sixty-five percent). The median turnaround time from the time of sample collection to time results were received my mother still is a challenge which results to long waiting time for results for example in Myanmar it was ranging between 4 to 12 weeks (8). Missed opportunities for EID of HIV in rural North-Central region in Nigeria has a quite higher turnaround time for DBS sample processing as seventy-seven percent of results were ready at the laboratory for disseminations at minimum of 3 months up to 28 month (39). The median turnaround time from blood draw to caregiver results receipt in Lesotho was 76.5days at birth and 63 days at six weeks where by HEI tested at birth were one month younger when their caregiver received EID results than those who tested at six weeks (41). In Tanzania the turnaround time for EID results found to range from 2.7 weeks in Mbeya region to 7.0 weeks at Kilimanjaro region (37).

Moreover, in order to attain maximum coverage of EID services in clinics the following criteria should be present and fulfilled adequately, key elements to facilitate EID within clinics Clear national guidelines and testing algorithm, Monitoring and evaluation systems, Identification of HIV-exposed infants, Retention in care, Healthcare provider selection and training, Ongoing supervision and quality improvement, Laboratory practices, Sample transport and results return, Forecasting and supply chain management, Linkage of HIV-infected infants to antiretroviral therapy, Community engagement (3).

5.4 Factors Associated with Compliance to Protocol of EID for HIV

The perceived benefits were found as the key factor contributing to compliance with EID of HIV testing protocol for infants exposed to HIV; the recognition of benefits such as early treatment initiation and improved child health outcomes have been described the mothers with HIV exposed as important attributes for attending immunization clinic for EID. This observation resonates with existing research that underscores the pivotal role of perceived benefits in fostering health-seeking behaviors (53,54). To strengthen compliance, interventions should focus on augmenting awareness regarding the advantages of EID, including timely treatment initiation and enhanced overall health outcomes for the child. By emphasizing these benefits, it is plausible

to strengthen the commitment to and engagement with EID protocols, ultimately contributing to improved HIV management among HIV exposed infants.

The duration on antiretroviral therapy (ART) for more than 2 years emerged as a significant predictor of compliance in this study. Mothers in this ART treatment for duration of two or more years are ought to have received several health talks and education sessions with regard to PMTCT services in their clinic visits hence influenced compliance. This finding aligns with previous studies that have emphasized the positive impact of sustained ART on adherence to EID protocols (2,50). In contrast, previous studies conducted in Kenya indicated that maternal ANC non-attendance, new maternal HIV diagnosis, and lack of maternal antiretroviral therapy (ART) were associated with late presentation for EID testing (40). These differences may be attributed to variations in healthcare systems, education levels, or cultural practices.

The distance from the facility being within 5km or more than 5km was associated with compliance to EID of HIV testing for HIV exposed infants, participants who were located more than 5 km were observed to have complied to EID of HIV testing unlike those who were located within 5 km. Higher compliance can be attributed to the persistent stigma surrounding HIV, coupled with prevalent misunderstandings that may dissuade individuals residing farther away from seeking testing services. This phenomenon suggests that individuals may opt for healthcare facilities in closer proximity to their residence to avoid potential stigma associated with HIV. These findings contrast with observations in Kenya, where greater distances were linked to decreased compliance, underscoring the substantial impact of geographical barriers on the timely initiation of EID testing (40). This underlines the need for targeted interventions and accessible healthcare services to mitigate geographical obstacles, ensuring widespread and timely EID testing for HIV-exposed infants.

Average waiting times of one hour or less to receive EID services was found to influence compliance, this encouraged clients to timely reach and seek for EID services as they did not wait long to receive the service. More so, the procedure to collect blood samples from children is not time consuming hence allowing them to quickly resume in their daily life activities. This finding

aligns with previous studies indicating that prolonged waiting times hinder EID compliance (55). However, in contrast to previous studies, which reported that the health system factors influencing EID compliance include inadequate skilled staff for sample collection, unreliable transport of samples, long turnaround times for results, and PCR machine breakdown (42). Adequate knowledge of healthcare workers (HCW) on EID and availability of dried blood spot (DBS) cards facilitate EID services, whereas staff turnover, poor tracing of HIV-exposed infants (HEI), and low retention of mother-infant pairs hinder EID coverage (16). Meeting criteria such as clear national guidelines, monitoring and evaluation systems, identification of HIV-exposed infants, and community engagement are essential for maximizing EID services in clinics (3)..

Addressing issues related to waiting times and appointment scheduling is essential. Furthermore, comprehensive strategies considering the broader healthcare system are crucial to enhance compliance, including improving staff capacity, transport reliability, result turnaround time, and implementing quality assurance measures in PCR machine maintenance. These findings emphasize the need for a multifaceted approach to optimize EID services, ensuring timely diagnosis and intervention for HIV-exposed infants.

5.6 Strengths and weakness of the study

Strengths:

The use of a quantitative approach provided a structured and systematic method for data collection, allowing for a comprehensive analysis of compliance rates. The inclusion of 288 participants enhances the reliability and generalizability of the findings, providing a robust representation of HIV-exposed children within the selected regional referral hospitals. The use of standardized questions developed from established guidelines and protocols and other literature ensured consistency in data collection, reducing the likelihood of bias and enhancing the validity of the study. The study incorporated healthcare provider compliance questions, shedding light on the commitment and familiarity of healthcare professionals with the EID of HIV testing protocol.

Limitations:

Data collection relied on self-reporting from mothers or caretakers, which could be subject to recall bias and social desirability bias, affecting the accuracy of the information gathered. The cross-sectional design captures a snapshot of compliance at a specific time, limiting the ability to establish causation or assess changes in compliance over an extended period. The study focused on regional referral hospitals in Dar es Salaam, Tanzania, which may not fully represent the diversity of healthcare settings in the country, potentially impacting the external validity of the findings.

CHAPTER SIX

6.0 Conclusion and Recommendations.

6.1 Conclusion

More than seven in ten mothers living with HIV complied to the EID of HIV testing protocol as a result, 72.6% of mothers living with HIV fully complied to EID of HIV testing protocol by making sure that their HIV exposed children receive all the recommended tests, this is still below target of 90%, despite that compliance of EID of HIV testing at 2months has progressed from 72% (2019) to 97.9% exceeding Tanzania target (80%) and the global target (90%)(16), also compliance at 18 months has progressed from 32% (2018) to 95%. Factors associated with EID compliance included knowledge on perceived benefits, average waiting time being one or less, mother's longer duration on antiretroviral therapy for at least 2 years, and residing at least 5km distance from the healthcare facility. Healthcare providers exhibited a high level of familiarity and adherence to the protocol, with 83.3% consistently utilizing it in their daily routine implementation.

6.2 Recommendations

For healthcare practices should include; Improving efficiency in EID services, particularly health care providers at PMTCT clinic to reduce waiting times for EID of HIV sample collection and result provision by utilizing time block scheduling to avoid congestions of mothers waiting for EID services at one once, can positively influence compliance rates. Ministry of health and health care providers Implementing educational campaigns to increase awareness about the long-term benefits of EID for HIV and EID of HIV testing knowledge (knowing appropriate time for EID testing for their children) to mothers, caretakers and community at large can improve compliance. More so, MOH providing continuous training and reinforcement for healthcare providers on the importance and nuances of the EID protocol can further enhance compliance.

For future research; Future researchers should consider expanding the geographical scope to include diverse healthcare settings, employing a longitudinal design to assess changes over time and employing a mix of qualitative and quantitative methods to capture a more holistic understanding of compliance determinants.

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APPENDIX I: INFORMED CONSENT (ENGLISH VERSION)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

DIRECTORATE OF RESEARCH AND PUBLICATIONS

MUHAS: INFORMED CONSET

Participant ID No: …….

Greetings! I, ZILABELLA YAMUNGU, I am a student of Muhimbili University of Health and Allied Sciences, MSc in Project Management Monitoring and Evaluation in Health. I am researching the title: "Evaluating compliance to early infant diagnosis of HIV testing protocol among HIV exposed children integrated with in immunization clinics at regional referral hospitals in Dar es salaam".

The aim of the Study: This study aims to Evaluate compliance to early infant diagnosis of HIV testing protocol among HIV exposed children integrated with in immunization clinics at regional referral hospitals in Dar es salaam.

Participation: You are selected because you are one of the participants who is directly meet the criteria for the subject matter of this study. Interviewer-administered questionnaire will be used and privacy will be maintained as much as possible. I hope that you will be willing to share your information with the researcher. If you have questions about this research, please do not hesitate to ask or contact the researcher at any time.

Confidentiality: All information and issues relating to your participation in the study will be treated confidential, no unauthorized person will have access to your information. As soon as this process is complete, the material used will be discarded in a safe way to enhance research confidentiality. Furthermore, to protect confidentiality, your names will not be used in the written copy of the discussion.

Right to refuse or withdraw: It is your choice to participate in this study. Also, you don't have to talk about anything you don't want to and you may end the interview at any time. However, your views are of much importance in this study.

Benefits: There are no direct benefits to you from being in the study, however, your participation in this study will provide useful information for compliance to early infant diagnoses of HIV implementation.

Risks: There will be no harm to you as a result of participation in this study although some questions will be personal which might trigger your emotions, feelings, and worries. The information you give will be used to develop a better approach for appropriate early infant diagnosis of HIV testing strategies among children 18 months and below in Dar es salaam.

Whom to Contact: If you ever have questions about this study you may call, the Chairperson of the (Research and Publications Committee, MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania 255 0222151596.

Declaration: I have read the contents of this form and understand. My questions have been answered. I agree to participate in this study.

Participant's signature _____ Date_____

Signature of the interviewer _____ Date_____

APPENDIX II: INFORMED CONSENT KISWAHILI VERSION

CHUO KIKUU CHA AFYA NA SAYANSI VISHIRIKA MUHIMBILI

KURUGENZI YA UTAFITI NA MACHAPISHO

FOMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI

Kitambulisho cha Mshiriki/Namba ya ushiriki: _____

Salamu! Jina langu ni “ZILABELLA YAMUNGU”, ni mwanafunzi wa Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, MSc katika Ufuatiliaji na Tathmini ya Usimamizi wa Miradi katika Afya. Ninatafiti mada: "Kutathmini uzingatiaji wa utambuzi wa mapema wa itifaki ya upimaji wa VVU kwa watoto wa mwezi 0-18 waliozaliwa na wamama wenye maambukizi ya virus vya ukimwi wanaojumuishwa katika kliniki za chanjo katika hospitali za rufaa za mkoa wa Dar es salaam".

Madhumuni ya Utafiti: Utafiti huu unalenga Kutathmini uzingatiaji wa utambuzi wa mapema wa itifaki ya upimaji wa VVU kwa watoto wa mwezi 0-18 waliozaliwa na wamama wenye maambukizi ya virus vya ukimwi wanaojumuishwa katika kliniki za chanjo katika hospitali za rufaa za mkoa wa Dar es salaam.

Ushiriki: Umechaguliwa kwa sababu wewe ni mmoja wa washiriki ambaye ametimiza moja kwa moja vigezo vya mada ya utafiti huu. Hojaji inayosimamiwa na mhojaji itatumika na faragha itadumishwa kadiri inavyowezekana. Natumai kuwa utakuwa tayari kushiriki maelezo yako na mtafiti. Ikiwa una maswali kuhusu utafiti huu, tafadhali usisite kuuliza au kuwasiliana na mtafiti wakati wowote.

Usiri: Taarifa na masuala yote yanayohusiana na ushiriki wako katika utafiti yatachukuliwa kuwa siri, hakuna mtu ambaye hajaidhinishwa atapata taarifa zako. Punde tu mchakato huu utakapokamilika, nyenzo zitakazotumiwa zitatupwa kwa njia salama ili kuimarisha usiri wa utafiti. Zaidi ya hayo, ili kulinda usiri, majina yako hayatatumika katika nakala iliyoandikwa ya majadiliano.

Haki ya kukataa au kujiondoa: Ni chaguo lako kushiriki katika utafiti huu. Pia, sio lazima kuzungumza juu ya kitu chochote ambacho hutaki na unaweza kumaliza mahojiano wakati wowote. Hata hivyo, maoni yako ni muhimu sana katika utafiti huu.

Manufaa: Hakuna manufaa ya moja kwa moja kwako kutokana na kuwa katika utafiti, hata hivyo, ushiriki wako katika utafiti huu utatoa taarifa muhimu kwa ajili ya kufuata utambuzi wa mapema wa utekelezaji wa upimaji wa VVU kwa watoto wenye umri wa mwezi 0-18.

Hatari: Hakutakuwa na madhara kwako kama matokeo ya kushiriki katika utafiti huu ingawa baadhi ya maswali yatakuwa ya kibinafsi ambayo yanaweza kuibua hisia, hisia na wasiwasi wako.

Mawasiliano: Ukiwahi kuwa na maswali kuhusu utafiti huu unaweza kumpigia simu, Mwenyekiti wa (Kamati ya Utafiti na Machapisho, MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania 255 0222151596).

Tamko: Nimesoma yaliyomo kwenye fomu hii na kuelewa. Maswali yangu yamejibiwa. Ninakubali kushiriki katika utafiti huu.
Sahihi ya mshiriki _____ Tarehe _____
Sahihi mhojaji _____ Tarehe _____

APPENDIX III: QUESTIONNAIRE ENGLISH VERSION

Topic; Evaluating compliance to early infant diagnosis of HIV testing protocol among HIV exposed children integrated with in immunization clinics and the associated factors at regional referral hospitals in Dar es salaam,

QUESTIONNAIRE;

Date of interview	|__|__| |__|__|__| |__|__|__|__| Day Month Year
Write initials of three names of the interviewer	|__|__|__|

SECTION A: COMPLIANCE TO EID OF HIV TESTING PROTOCOL (MoHCDGEC, 2019)

Information concerning the child.

Age in months

Date of birth

Sex a) Male b) Female

Where was the children identified as HIV exposed?

a) During pregnancy
b) at labour
c) at immunization clinics
d) at other clinics (specify)

At what age did the HEI and children test for HIV?

a) 4-6 weeks
b) 9 months
c) 15months
d) 18 months
e) other time of testing …….

Diagnosis status

a) Early
a) Delayed

When were HIV results of the child received?

a) less than 4 week b) above 4 weeks

HIV status

a) Positive ……/..…./…… b) Negative ……/……/… c) Awaits result .. . ...….

SECTION B; COMPLIANCE OF HEALTHCARE PROVIDERS TO EID OF HIV TESTING PROTOCOL.

Are you familiar with the EID of HIV testing protocol?

a) Yes
b) No

How often do you refer to the EID of HIV testing protocol for reference during EID of HIV testing implementation?

a) All the time during daily routine implementation
b) Often
c) Rarely
d) Not at all

Do you use EID of HIV testing protocol to screen for HIV exposed children?

a) I use it all the time
b) I use it often
c) I rarely use it
d) I don't use it at all

How comfortable are you in screening for HIV exposed children with regard to the EID of HIV testing protocol?

a) Very comfortable
b) Confident
c) Slightly confident
d) Not confident

Implementation process

Do you perform screening of HIV exposed children at your clinic?

a) Yes
b) no

Do you perform EID of HIV testing to all eligible children?

a) Yes
b) No

How often do you order for EID of HIV tests to all eligible children?

a) All the time
b) Often times but not always
c) Rarely
d) Not at all

Do you provide EID of HIV test results of the HIV exposed children to their mothers?

a) Yes
b) No

After how long do you provide EID of HIV test results of the HIV exposed children to their mothers?

a) Less than 4 weeks
b) More than 4 weeks
c) Other time specify

For HIV positive children do you refer them to CTC clinic for ART initiation?

a) Yes
b) No

How confident are you upon performing EID of HIV tests to the eligible children?

a) Very comfortable
b) Confident
c) Slightly confident
d) Not confident

What opinion do you have on the use of the recommended EID of HIV testing protocol, I think it is;

a) Very easy to use/follow
b) Easy to use/follow
c) Not easy to use/follow probe; explain

Do you think this intervention integration for EID of HIV testing in immunization clinics is relevant in the implementation of EID of HIV testing among HIV exposed children?

a) Yes
b) No
c) I don’t know

SECTION C: MATERNAL SOCIO-DEMOGRAPHIC INFORMATION .(47)

1.1	Ward	
1.2	Type of residence	a) Urban b) Rural
1.3	Please record the observed gender	a) Male b) Female
1.4	What is your age? (years)	
1.6	Please circle your marital position	a) Never married b) Married/living together c) Divorced \Separated \Cohabiting
1.8	Please indicate your highest level of education?	a) No education b) Primary incomplete c) Primary complete d) Secondary +
1.9	What is your current occupation?	a) Not employed b) Permanent employment c) Temporary employment d) Private employment e) Farmers f) Business g) Livestock keepers h) Others
1.10	What is your status in this household	a) Head of the family/ b) husband/wife c) Child d) Housekeeper e) Relative f) Others

	Distance from facility	a) less than 5km b) ≥ 5km

D: Maternal or care givers factors (8,18,23).

What is your HIV status?	a) positive b) negative
If HIV+, are you on ART?	a) YES b) NO
For how long have you been on ART?	a) Less than 2 years b) ≥2 years
Do you have knowledge of EID of HIV testing?	A) yes B) no
What is the definition of EID of HIV testing?	a) HIV testing in infants and children 18 months and below b) I don't know c) Other definition
When were you aware of EID of HIV testing?	a) before pregnancy b) during pregnancy c) after pregnancy
Do you think it's a good idea to perform EID of infants and children as early as possible?	a) Yes b) no
What is the benefits of EID?	a) know HIV status b) access to ART c) getting counselling d) I don't know
what is the appropriate EID age for EID of HIV testing?	A. at birth B. 4-6 weeks C. 9 months

	D. 3 months after breastfeeding or 15 moths E. D) 18 months
Do you accept to perform EID to the infant or child?	A) yes B) no
Why not accept EID services?	a) fear C) don't know clear benefits b) I don't know
What is your child HIV status?	a) positive b) negative c) I don't know
If POSITIVE, Is your child on ART use?	a) Yes b) no
Have you disclosed the HIV status of the infant or child to your family members?	a) Yes b) no
Do you belong to any psychosocial-support group?	a) yes b) no
Do you think the group has been of help in regard to your health?	a) Yes b) No

E: Health System factors. (22,26,46,50)

Do you pay for EID service?	A) yes B) no;
how were you linked for EID services?	verbally written report escorted by HCW self-referral;
Are EID services available in clinics?	A) always available B) sometimes available;

Are health workers availabile to provide EID of HIV testing?	a) always available b) sometimes available
For how long do you wait (time) to receive EID service?	a) one hour b) ≥hour
Are you provided with EID counseling message?	a) adequate b) inadequate
do you have EID appointment schedule ?	a) have a copy b) not given a copy c) don't know
Are you followed up for EID uptake service?	a) followed up b) not followed up

Thank you

APPENDIX IV: QUESTIONNAIRE KISWAHILI VERSION

Topic; Utafiti wa kutathmini utumiaji fasaha wa muongozo wa upimaji wa virusi vya ukimwi kwa watoto wa miezi 18 na kushuka chini hudumiwa au kulelewa na wazazi au walezi wenye maambukizi ya virusi vya ukimwi katika hospitali za rufaa za Dar es Salaam.

Tarehe ya mahojiani	|__|__| |__|__|__| |__|__|__|__| Siku mwezi mwaka
Andika kifupisho cha jina la mhojiwa kwa kuandika herufi za kwanza za majina yake tu	|__|__|__|

SEHEMU A: Utumiaji fasaha wa muongozo wa upimajibwa virusi vya ukimwi kwa watoto wenye umri wa miezi 18 na kushuka chini.(2)

Taarifa za mtoto. (Zihakikiwe kwenye mifumo ya uhifadhi taarifa mituha na data base)

1. Umri wa mtoto kwa miezi
2. Tarehe ya kuzaliwa
3. Jinsia a) Me b) ke
4. Wapi mtoto aligunduliwa kua yupo kwenye hatari ya kupata maambukizi ya virusi vya ukimwi?

    a) a)wakati wa ujauzito
    b) wakati wa kujifungua
    c) clinic ya chanjo
    d) sehem nyingine

5. Katika umri gani mtoto wako alipata kipimo cha uchunguzi wa maambukizi ya virusi vya ukimwi?

   a) Baada tu yakujifungua
   b) wiki 4-6
   c) miezi 9
   d) miezi 15
   e) miezi 18
   f) mda mwingine …….

6. Hali ya uchunguzi a) mapema b)kwa kuchelewa
7. Ulipokea lini majibu ya kipimo cha mwanao?
   a) chini ya wiki 4 b) baada ya wiki 4
8. Hali ya maambukizi ya mtoto

a) chanya ……/..…./…… b) hasi ……/……/… c) sijui .. . ...….

SECTION B: MATERNAL SOCIO-DEMOGRAPHIC INFORMATION .(47)

1.1	Ward	
1.2	Mahali unapotokea	a)Mjini b)Kijijini
1.3	Nakili jinsia	a)Me b)Ke
1.4	Una umri gani?	
1.6	Hali yako ya ndoa?	a) sijawahi kuolewa b) nimeolewa c)nimeachika \tumetengana \tunaishi tu
1.8	Kiwango chako cha elimu ni kipi?	a) sijasoma b) sijamaliza mafunzo ya shule yamsingi

		c) nimehitimu mafunzo ya shule ya msingi d) nimehitimu sekondari na kuendelea
1.9	Hali yako ya ajira?	a) sijaajiriwa b) ajira ya kudumu c) ajira ya muda d) ajira ya sekta binafsi e) mkulima f) mfanyabiashara g) mfugaji h)zingine
1.10	Uhusiano wako katika familia yako?	a) mkuu wa kaya b) mke / mume c) mtoto d) mfanyakazi wa ndani e) ndugu f)Nyingine taja
	Ni upi umbali kutoka kwako mpaka hospitali?	a) chini ya km 5 b) km 5 na zaidi

C: Maternal or care givers factors (8,18,23)**.**

1. Ni ipi hali yako ya maambukizi?	a) Chanya b) Hasi
Kama ni chanya, umeshaanza kutumia dawa za kupunguza makali ya VVU?	a) Ndio b)Hapan
2. Ni kwamda kani unatumia dawa za kupunguza makali ya VVU toka ulipo	a) chini ya miaka 2 b) miaka 2 na zaidi

gundulika?	
3. Una ufaham wowote kuhusu upimaji wa VVU kwa watoto wenye umri wa miezi 18 na kushuka?	a) ndio b) hapan
4. Nini maana ya upimwaji wa VVU kwa watoto wenye umri wa miezi 18 na kushuka?	a) upimaji mapema wa VVU kwa watoto wenye umri wa miezi 18 na kushuka b) sijui
5. Toka lini ulikua na huu uelewa wa upimaji wa VVU?	a) kabla ya ujauzito b) nikiwa mjamzito c) baada ya kujifungua
6. Unadhani ni wazo zuri kufanya upimaji wa VVU kwa mwanao mapema iwezekanavyo?	a) ndio b) hapana
7. Nini umuhimu wa kufanya kipimo cha VVU mapema kwa mwanao ?	a) kujua hali yake ya maambukizi b) kumuanzishia dawa za kupunguza makali mapema c) kupata ushauri jinsi ya kumkimga mtoto na maambukizi ya VVU d) sijui
8. Ni upi umri sahihi wa kumpima mwanao maambukizi ya VVU?	a) mara tu baada ya kujifungua 4-6 wiki b) miezi 9 c) miezi 15 d) miezi 18 e) sijui
9. Unaruhusu au kukubali mwanao afanyiwe kipimo mapema cha maambukizi ya VVU	a) ndio b) hapana

?	
10. Kwanini hukubali mwanao afanyiwe kipimo mapema cha maambukizi ya VVU?	a) naogopa b) sijui umuhim wa hiko kipimo c) sijui
11. Ni ipi hali ya maambukizi ya mtoto wako?	a) chanya b) hasi c) sijui
12. Kama ni chanya, je mwanao kasha anzishiwa dawa za kupunguza makali ya maambukizi ya VVU?	a) ndio b) hapana
13. Je umewafahamisha familia yako kuhusu hali ya maambukizi ya mtoto wako?	a) ndio b) hapana
14. Je umejiunga na kikundi chochote cha ustawi wa jamii ?	a) ndio b) hapana
Unadhani kikundi hiko kimekua cha msaada kuhusiana na hali yako?	a) ndio b) hapana

D: Health System factors. (22,26,46,50)

1. Unalipia huduma ya upimaji wa maambukizi ya VVU kwa mwanao?	a) ndio b) hapana
2. Uliunganishwaje katika huduma ya upimaji mapema wa maambukizi ya VVU kwa mwanao?	a) niliambiwa kwa mdomo b) niliambiwa wa maandishi c) nilipelekwa na mhudumu wa afya d) nilijipeleka mwenyew

3. Je huduma hio ya upimaji wa maambukizi ya VVU hupatikana kila unapompeleka mtoto kwaajili ya kipimo?	a) ndio mda wote hupatikana b) haipatikani muda wote
4. Je wahudumu wa afya hua wapo kila uendapo kwaajili ya kipimo cha mwanao?	a) wapo mda wote b) wakati mwingine hawapo
5. Hua unasubiria muda gani mpaka mwanao kuchukuliwa kipimo cha maambukizi ya VVU?	a) saa 1 b) saa 1na zaidi
6. Je hua unapatiwa ushauri na saha kuhusiana na upimaji wa maambukizi ya VVU kwa mwanao?	a) Ndio kwa ufasaha b) hapana sio kwa ufasaha
7. Una ratiba ya miadi ya upimaji wa maambukizi ya VVU kwa mwanao ?	a) nina nakala b) sina nakala c)sijui
8. Je unafatiliwa na unakumbushwa kuja kumleta mwanao kyfanyiwa kipimo cha maambuki ya VVU?	a) ndio nafatiliwa na nakumbushwa b) hapana sifatiliwi na sikumbushwi

Asantee kwa ushiriki wako katika utafiti huu.

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

In reply quote;
Ref. No.DA.282/298/01.C/1611 Date: 03/04/2023

MUHAS-REC-03-2023-1611

MUHAS-REC-04-2023-1611
ZILABELA YAMUNGU
School of Public Health and Social Sciences
MUHAS.

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: EVALUATING COMPLIANCE TO EARLY INFANT DIAGNOSIS OF HIV TESTING PROTOCOL AMONG HIV EXPOSED CHILDREN INTEGRATED WITHIN IMMUNIZATION CLINICS AT REGIONAL REFERRAL HOSPITALS IN DAR ES SALAAM, TANZANIA.

Reference is made to the above heading.

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

APPROVAL DATE: 03/04/2023
EXPIRATION DATE OF APPROVAL: 02/04/2024

STUDY DESCRIPTION:
Purpose:
To evaluate the compliance to early infant diagnosis of HIV testing protocol integrated with in immunization clinics and the associated factors among HIV exposed children inregional referral hospitals in Dar es salaam, Tanzania.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014597.pdf and in the MUHAS archives.

The PI is required to:

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

Dr. Kasusu Nyamuryekung'e,
Chairman, MUHAS Research and Ethics Committee

Cc; Director, Directorate of Postgraduate Studies.

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.848/2020

04th April, 2023

The Executive Director,
Temeke Regional Referral Hospital,
P.O. Box 32823,
DAR ES SALAAM

Re: INTRODUCTION LETTER

The bearer of this letter is Zilabela Yamunugu (HD/MUH/T.848/2020), a student at Muhimbili University of Health and Allied Sciences (MUHAS) " pursuing MSc. Project Management Monitoring Evaluation in Health.

As part of her studies she intends to do a study titled: "***Evaluating Compliance to Early Infant Diagnosis of HIV Testing Protocol Among HIV Exposed Childen intergrated Within Immuization Clinics at Regional Referral Hospitals in Dar es Salaam, Tanzania.***

The research has been approved by the Chairman of University Senate.

Kindly provide her the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c. Zilabela Yamunugu

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam; Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

DAR ES SALAAM REGION
ADDRESS: "HEALTH"
PHONE: 022 – 2861903
IN REPLY PLEASE QUOTE
REF. NO. MOHCDGEC/ARRH/R.1/VOL XIII/34

AMANA REGIONAL REFERRAL HOSPITAL
P.O. BOX. 25411
DAR ES SALAAM.

24/05/2023

Director – Postgraduates Studies,
MUHAS,
P. O. Box 65001,
DAR ES SALAAM.

Re: PERMISSION FOR DATA COLLECT

Refer to your letter dated 4th April, 2023 which requested us to allow Zilabala Yamungu to conduct research and collect data in our institution

We are here to acknowledge your request with the following conditions, that she must submit the results of her researchafter completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.

Dr. Rose Ntambuto

For: MEDICAL OFFICER INCHARGE
AMANA REGIONAL REFERRAL HOSPITAL

MEDICAL OFFICER I/C
AMANA REGIONAL REFERRAL HOSPITAL
P. O. Box 25411
DAR ES SALAAM

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

Telephone Address:

Telephone: 022-2760500

Mwananyamala Regional
Referral Hospital,
P.O.Box 61665
Dar es Salaam.

RE: NO.: MA. 239/240/01/78 **DATE:** 10th May, 2023

Director,
Postgraduate Studies,
MUHAS,
P.O.BOX 65001,
Dar es Salaam.

RE: ZILABELA YAMUNUGU TO CONDUCT HER RESEARCH IN MWANANYAMALA REGIONAL REFERRAL HOSPITAL

The captioned subject refers

2. May you be informed that your prescribed request for your bonafide student **Zilabela Yamunugu** to conduct her Research in our Institution through your letter referred **No. HD/MUH/T.848/2020 dated 04th April, 2023**, is asserted.

3. The Institution charges **50,000/=**, as a Research fee. The payments are to be made upon reporting.

4. May she report to the Administration and HR department head for further instruction.

Thanks.

Dr. Praygod Lekasio
RESEARCH COORDINATOR
FOR: MEDICAL OFFICER INCHARGE
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Student - **Zilabela Yamunugu**

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Baruapepe:temekerh@afya.go.tz,S.L.P 45232 Dar es Salaam,Simu 0222856007

Kumb. Na. TRRH/RSC/9/9/77 **Tarehe: 24/04/2023**

Ndg. Zilabela Yamunugu
Muhimbili University of Health and Allied Sciences (MUHAS)
School of Pharmacy,
S.L.P 65001,
DAR ES SALAAM.

YAH: OMBI LA KUFANYA UTAFITI "EVALUATING COMPLIANCE TO EARLY INFANT DIAGNOSIS OF HIV TESTING PROTOCOL AMONG HIV EXPOSED CHILDREN INTERGRATED WITHIN IMMUNIZATION CLINICS AT REGIONAL REFERRAL HOSPITALS IN DAR ES SALAAM TANZANIA" (RESEARCH)

Tafadhali husika na somo tajwa hapo juu.

Nimepokea barua yako ya tarehe 04 Aprili, 2023 kuhusu ombi lako la kufanya Utafiti (Research) katika Taasisi yetu, kuhusu **"Evaluating Compliance to Early infant Diagnosis of HIV Testing Protocol Among HIV Exposed Children intergrated within immunization clinics at Regional Referral Hospitals in Dar es Salaam Tanzania".**

Ombi lako limekubaliwa, utatakiwa kulipa ada ya utafiti kiasi cha **Tshs. 50,000/=** Hivyo wasiliana na mhasibu wa mapato wa Hospitali **Ndg. Lusajo Nsajigwa** kwa namba **0717 959495** ili akupatie control Number kwa ajili ya malipo ya ada hii ili uweze kuruhusiwa kufanya utafiti.

Asante kwa ushirikiano.

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Nakala: **(HOD – CTC.)** - ***Tafadhali hakikisha taarifa ya utafiti inabaki hospitalini***

EVALUATING COMPLIANCE TO EARLY INFANT DIAGNOSIS OF HIV TESTING PROTOCOL AMONG HIV EXPOSED CHILDREN IN REGIONAL REFERRAL HOSPITALS, DAR ES SALAAM, TANZANIA.

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