



**College of Medicine**

**Acceptability of Integrating HIV Early Infant Diagnosis (EID) into under-five outreach  
immunization clinics in Lilongwe rural areas in Malawi**

**By**

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## **Certificate of Approval**

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## **Declaration**

I Mphatso Makanda hereby declare that this dissertation is my original work and has not been presented for any other awards at the University of Malawi or any other University.

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March, 2020

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### **Abstract**

Human Immunodeficiency Virus (HIV) disease progresses quickly in children. Without treatment, 50% of the children living with HIV die before 2 years of age. Hence, HIV exposed infants are recommended to have an Early Infant Diagnosis (EID) at 4-6 weeks of age. This is so that infected children are identified and started on treatment timely. However, it has been observed that 29% of HIV exposed infants receive EID test late in Malawi. Hence, there is need to identify better strategies to increase EID testing rates at 6 weeks.

**Objectives:** This study aimed at assessing acceptability of integrating EID into under-five outreach immunization clinics in Lilongwe rural areas among mothers of under-five children.

**Methods:** This was an observational, analytical, cross sectional study. It used quantitative study methods to answer the researched question. A questionnaire was used to collect data from study participants. The data was analyzed using Stata version 14.

**Results:** We enrolled 100 mothers in the study regardless of their HIV status. Almost all of them (99%) indicated that the integration of EID in immunization clinics is important. The majority of them (96%) also indicated that they would accept their infants to have an HIV EID test at outreach immunization clinics. Availability of HIV test providers was reported to be the number one facilitator of the integration and it was seconded by the availability of infrastructures at the immunization clinics. The study also found out that unavailability of HIV testing providers have the greatest potential of hindering the integration of HIV EID in immunization clinics seconded by unavailability of shelter at the outreach immunization clinics.

**Conclusion:** Integration of HIV early infant diagnosis into under-five outreach immunization clinics of Lilongwe rural areas is acceptable among mothers of under-five children. The integration can aid in increasing EID test rates of HIV exposed infants at 6 weeks of age.

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## Abbreviations/Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral therapy
DBS	Dried Blood Spot
DHMT	District health management team
DNA	Deoxyribonucleic acid
EID	Early infant diagnosis
EPI	Expanded program on immunizations
HAS	Health surveillance assistant
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
MTCT	Mother- to-child transmission
NAR	Net attendance ratio
PCR	Polymerase Chain Reaction
MPHIA	Malawi Population-Based HIV Impact Assessment

## **Chapter 1 : Introduction**

### **1.1 Background**

Human Immunodeficiency Virus (HIV) related disease is still a major cause of morbidity and mortality in low-income countries despite the efforts and many interventions [1]. In 2016, it was estimated that 1.8 million children aged between 0 to 14 years were living with HIV worldwide and 87% of them live in sub-Saharan Africa [2]. An estimated 150 000 children were newly infected with HIV globally and 85% of them occur in sub-Saharan Africa [2]. The global estimated number of these children dying of AIDS related causes was at 110 000 and 86% of them happen in sub-Saharan Africa [2]. However, just half of the 1.8 million children (aged 0-14 years) living with HIV were on Anti-retroviral treatment and that treatment initiation in sub-Saharan Africa only starts on average at nearly 4 years of age [3]. In 2016, Malawi had an estimated HIV prevalence of 1.5% among children aged between 0 to 14 years [4]. By the end of 2015, only 49% of children living with HIV were receiving Anti-retroviral treatment [5]. This indicates that there is an urgent need to identify and implement strategies that would increase the number of children initiating timely Anti-Retroviral Therapy (ART).

The main mode of HIV transmission among children, worldwide and particularly in sub-Saharan Africa, is through mother-to-child transmission (MTCT) [6]. HIV progresses quickly in children hence children aged 0 to 4 years living with HIV face the highest risk of AIDS-related death compared with all other age groups [2]. Therefore, conducting HIV EID test by dried blood spot (DBS) on infants born to HIV positive women by six weeks of age is a critical intervention to reduce early infant morbidity and mortality. Without treatment, half of the children living with HIV die before the age of two [7]. In the age when the tools and knowledge are at hand to

prevent and treat HIV infection in children, new infections and deaths among this age group reflect a collective failure to prioritize children, including an inability to implement and adapt new science and solutions to unique needs of children so that they can survive and thrive [2]. The AIDS response must focus on solutions to identify better strategies to increase EID in HIV exposed children which is the extremely vulnerable population.

## **1.2 Statement of the problem**

The World Health Organizations (WHO), as well as Malawi's Ministry of Health (MoH) recommends that infants known to be exposed to HIV should have an EID at 4-6 weeks of age or at the earliest opportunity for infants seen after 4-6 weeks [8]. WHO recommends that, at least 80% of infants born to women living with HIV should receive an HIV EID test within two months of age. The current Malawi EID program targets at 85% of HIV exposed infants to receive HIV EID test within 2 months of age [9]. It is estimated that HIV testing at this time (4-6 weeks of age) will identify more than 95% of infants infected intra and peripartum [8]. Delaying testing beyond this time, delays diagnosis and put HIV infected infants at risk of disease progression and death [8]. In Malawi, most of the HIV exposed infants do not get the infant HIV EID test within the recommended 4-6 weeks period. The 2015/16 Malawi Population-Based HIV Impact Assessment (MPHIA) survey found that among children born to HIV-positive mothers aged 15-49 years who gave birth during the three years preceding the survey, only 49% received an infant HIV EID test before 2 months of age, 29% between 2 and 12 months of age and the rest received later or not at all [4]. Integrated HIV program report of January to March 2018 reported that, of all dried blood spot (DBS) results dispatched from all Deoxyribonucleic acid (DNA)-Polymerase Chain Reaction (PCR) laboratories in the first quarter of 2018, 65% of them were

from infants under 2 months old at the time of sample collection, 25% from infant between 2 to 5 months old, 7% from infants between 6 to 11 months old, 1% from infants between 12 to 17 months old and less than 1% were from infants 18 months old or older than that [10]. This shows that there is a need to increase early diagnosis of HIV infection in infants within two months of age, which is essential to ensure their survival. In addition to that, it shows the need to find new or better strategies to improve timely diagnosis in this population.

In Malawi, there are limited entry points for HIV EID testing for infants. Early infant diagnosis services are offered at a facility level only and not on a community level. Dried blood spot sample collection for HIV EID testing happens in HIV Testing Services (HTS) rooms and at HIV clinic where women take their antiretroviral drugs. However, it has been observed that there is need to increase the coverage of EID testing for HIV [4]. Several system-level interventions have been proposed to increase points of entry to testing and one of them is putting additional point of entry to testing such as immunization clinics [4].

In Malawi, under-five outreach Immunization clinics are under EPI program and are conducted at a community level. They are done at monthly bases. Health surveillance assistants (HSAs) are the ones who manage these clinics. EPI program is one of the successful programs in the Ministry of Health with a high coverage of more than 90% [11]. The typical EPI services offered at under-five outreach immunization clinics include infant weighing, and vaccination. Other health programs have taken advantage of the high attendance and coverage of EPI to enhance their services. These are services like administration of Albendazole (de-worming drugs),

Vitamin A supplements and treated bed nets. HIV EID services are not offered at under-five outreach immunization clinics. Integration of HIV EID services in under-five immunization clinics is one of the suggested strategies to increase HIV EID testing

The schedule of under-five immunizations in Malawi is in such a way that, the first dose of the second vaccine pentavalent (diphtheria, pertussis and tetanus) in infants is done at 6 weeks which is the same time recommended for HIV EID testing in HIV exposed infants. In 2015/2016 year, first dose of pentavalent vaccine was received by 97% of Malawian children [11]. Therefore, if a visit for the first dose of pentavalent vaccination is also utilized for HIV DBS sample collection in HIV exposed infants, that could mean, meeting more infants. In addition to that, it could also mean reducing the number of hospital appointments of the mothers, saving their time, as well as accessing the mothers while they access immunization services.

### **1.3 Literature review**

Studies have been conducted concerning acceptability of integrating HIV early infant diagnosis in under-five immunization clinics both globally and even in Malawi. In consideration to that, we reviewed already existing literature related to our research topic and the research objectives. This was done in order to know what has already been done related to the topic, how it has been done and to identify gaps that need to be addressed.

#### **1.3.1 Information sources**

Medical Literature Library of Medicine (MEDLINE) databases were accessed through PubMed and Google Scholar. This was conducted with an aim of searching for studies reporting primary

data on acceptability of integrating HIV early infant diagnosis services in under-five immunization clinics.

### **1.3.2 Search strategy**

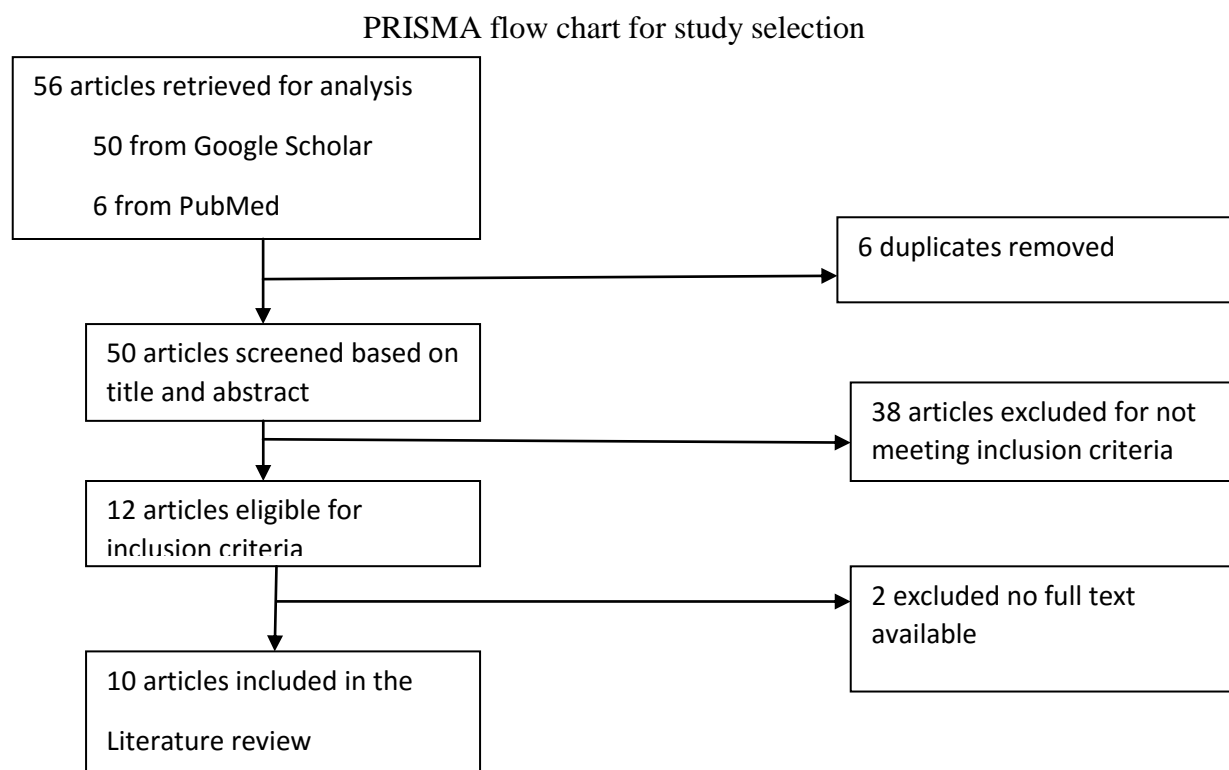
Acceptance, HIV, AIDS, EID, integration, under-five and immunization clinics were the words that were used to search for studies which were included in this literature review.

### **1.3.3 Inclusion criteria**

We included all studies that were relevant to the researched topic and in line with the study objectives. Studies that we included were the ones that have been conducted from 2009 to 2019 because they contain latest information regarding the integration of HIV early infant diagnosis into under-five immunization clinics. We only included studies that were in English language and full text was also available for free.

### **1.3.4 Exclusion criteria**

We excluded all studies that were irrelevant to our research topic and its objectives. We also excluded studies that were not conducted from 2009 to 2019 because they do not contain latest information regarding our research topic. Studies which were not in English language and whose full text was not available for free or could not be found were also excluded from this literature review. (Refer Figure 1)



**Figure 1: PRISMA flow diagram for study selection**

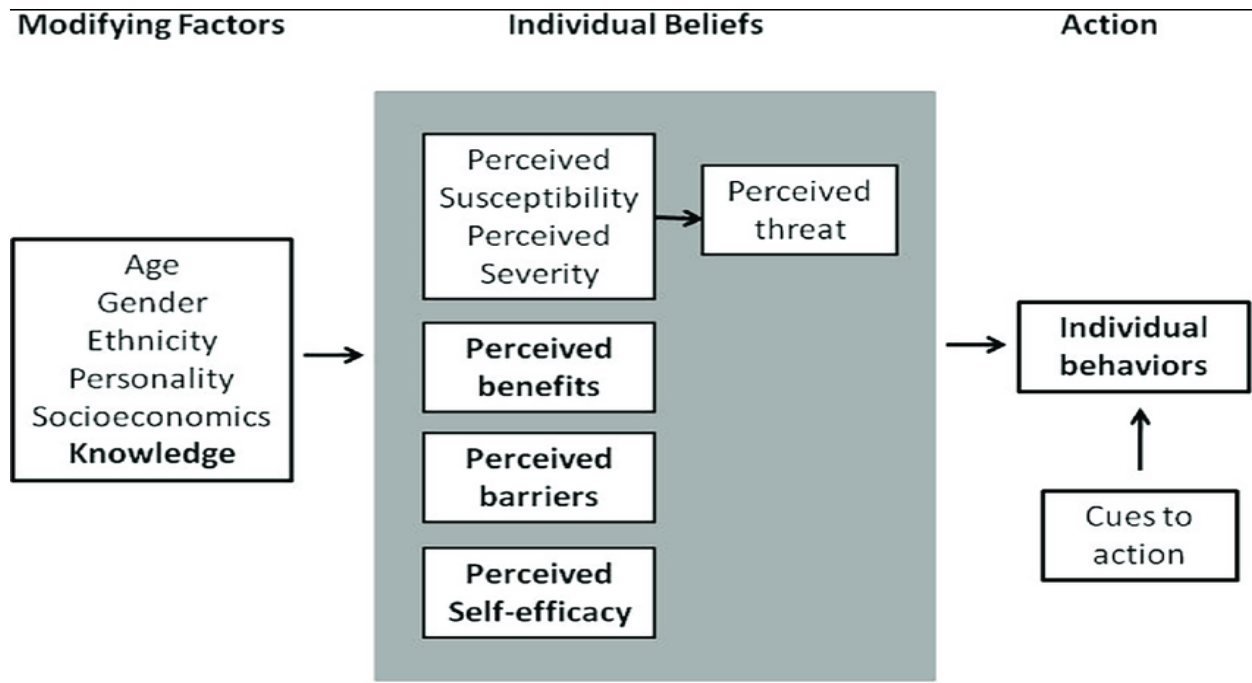
### 1.3.5 Conceptual framework

The study used Health Belief Model (HBM) in its theoretical framework. HBM is a behavior change theory which helps understand individuals and communities that you work with. HBM explain the factors promoting and inhibiting change at the individual, community and societal levels. HBM contains concepts that predict why people will accept a public health intervention. For instance, why would people prevent a disease, screen for a disease or to control illness conditions? The model has four concepts which are perceived susceptibility, perceived severity, perceived benefit and perceived barrier [12].

Perceived susceptibility refers to beliefs about the likelihood of getting a disease or condition. For instance, an HIV positive woman must believe that there is a possibility of her transmitting HIV to her infant if she does not follow Prevention of Mother-to-Child Transmission (PMTCT) guidelines. Perceived severity refers to the feelings about the seriousness of contracting an illness or of leaving it untreated and that include evaluations of both medical and clinical consequences. The clinical consequences could be death, disability, and pain and possible social consequences such as effects of the conditions on work, family life, and social relations. The combination of susceptibility and severity is taken as perceived threat [12].

Perceived benefit is another concept of HBM. This is when an individual believes that the recommended actions to deal with the problem are beneficial. These are other non-health-related perceptions, such as the financial savings related to accepting a public health intervention (e.g. HIV EID test at an immunization clinic). The fourth concept of HBM is perceived barriers. This concept refers to the time when an individual makes a kind of non-conscious cost-benefit analysis by weighing if the benefit of taking an action outweighs the costs or barriers [12]. (Refer Figure 2)

## Concepts of health belief model



**Figure 2: conceptual elements of Health Belief Model**

This study has borrowed the HBM logic that feeling that something is important is sufficient motivation to make an individual change a health behavior or accept a public health intervention. If mothers perceive that there is a like hood of them transmitting HIV to their infants (when HIV positive), and that HIV can kill their infants if there is no early diagnosis and treatment. In addition to that, if they perceive that early diagnosis and treatment of HIV in children is life saving, and that the intervention is time and cost efficiency since it is happening at a community level. Then the mothers would accept the integrated services and bring children for EID in the face of other barriers.

### **1.3.6 Global perspective**

Most HIV- infected children in Africa still present with severe symptoms and some die before they have an opportunity to start ART or even Cotrimoxazole prophylaxis [13]. Early identification of HIV-positive infants and provision of ART are critical to improve infant survival. It is estimated that early mortality in HIV exposed infants can be reduced by 76% if ART is initiated in good time (6-12 wks) [14]. Early diagnosis of HIV exposed infants is still a challenge in many Global Plan countries [15]. It is estimated that only half of all HIV exposed infants in Global Plan countries receive an EID test in the first two months of life [15]. Different approaches have been suggested to enhance the rates of testing at 6 weeks. One of the suggested strategies is to offer EID during routine infant immunization visits since vaccination coverage is substantially higher than EID coverage [4,11] Research have been conducted to find out whether integration of HIV EID services with EPI services can be acceptable to population. Some of the studies focused on knowing whether the integration of HIV EID services with EPI could result in increase in HIV EID testing rates without decreasing the immunization uptake. This section shall discuss findings from studies done related to the researched topic.

Nigel Rollins et al. conducted a study in KwaZulu Natal in South Africa. The study aimed at determining the acceptability and feasibility of universal HIV testing of 6-week infants attending immunization clinics to achieve early diagnosis of HIV and referral for HIV treatment and care services. Every infant who attended immunization clinic was screened for HIV. The results showed that the screening process identified more HIV exposed infants. Their findings show that mothers received the integration of HIV testing and EPI services positively as they perceived the integration as an opportunity to learn about the infant's HIV status [16].

The use of routine immunization visits to identify and follow-up HIV exposed infants was also evaluated in Tanzania by Goodson et al. More HIV exposed infants, HIV infected infants and HIV infected mothers were identified; however decrease in the uptake of vaccines was noted. Mother especially those from the rural areas, expressed fear of HIV-related stigma because of perceived inadequate privacy during HIV testing [17]. Shaffiq Essajee et al. also reported that mechanisms to track mothers and HIV exposed infants who do not return for testing are weak. Hence, infants who are not brought for testing at 6 weeks are lost to follow-up or be brought for testing after the first two months. That is too late for optimal initiation of treatment and prevention of early mortality among HIV-infected infants [15]. Insufficiency and stock outs of laboratory reagents have been indicated also to contribute to low late of EID in sub-Saharan Africa [15, 18]. Low education, maternal unemployment, religious belief and lack of knowledge of HIV transmission were also identified to have contributed to low EID testing [18].

Wang, et al. studied whether integration of HIV EID in under-five immunization clinics would increase infant and post partum maternal testing rates without harming immunization uptake. This was a cluster randomized trial. Women expressed positive opinions about HIV testing in that study. The women recognize the importance of knowing their HIV status as knowledge that would enable them to take better care of themselves and their children. They also find out that HIV testing reagents supply reinforcement can also increase HIV testing rates without affecting immunization uptake [19, 20].

A qualitative assessment of the integration of HIV services with infant routine immunization visit was done by Wallace, et al in Tanzania. Service providers and mothers who took part in the study believed that the integration of HIV services and EPI services was beneficial. Mothers viewed the integration of HIV services and EIP services as cost and time saving since fewer facility visits would be required to receive both HIV services and immunization services. On the other hand, concerns were raised from both mothers and the service providers. Mothers complained long queues for the integrated services that resulted in long waiting time and that confidentiality of services delivered were compromised. Community stigma was also among some of the concerns raised by the mothers affecting the integration of the two services. Service providers complained that the health visits were long due to the integration of the services [21].

### **1.3.7 Malawian perspective**

In Malawi, only one study which was found to have been conducted on this topic. This study was conducted in Lilongwe at Bwaila District Hospital and Kamuzu Central Hospital. The study was evaluating outcome of integrating EID services into immunization clinics compared to the delivery of EID at general pediatric outpatient clinic. It also looked at feasibility for providers and acceptability for caregivers of PCR for eligible infants. The results showed superior uptake and outcome of HIV EID services at an immunization clinic compared to EID at general pediatric clinic. EID at immunization clinic enrolled more infants and at younger ages. The results also showed that, it was more feasible for providers and more acceptable for caregivers[22]. This study took place at a well structured static health facility that offers immunization daily. It was also conducted in urban setting where only 15% of Malawians live and their net attendance ratio (NAR) of secondary school education is at 41% compared to rural

area where NAR of secondary school education is at 13% [23]. There is still no information regarding acceptability of integrated services of HIV EID and under-five immunization in the rural areas in Malawi.

### **1.3.8 Summary of literature review**

From the studies that we reviewed, it has been shown that the integration of HIV EID testing services in immunization clinics can help in identifying more HIV exposed infants and can increase EID testing rates at 6 weeks. Availability of HIV testing supplies has also been revealed to be one of the factors that could help increase HIV EID testing rates. The studies have also revealed that mothers perceive the integration of HIV EID and immunization services positively as time and cost saving. Service providers also viewed the integration of HIV EID services and EPI services as an opportunity to identify more HIV exposed infants in time. Privacy and confidentiality, community stigma related to HIV and long waiting times were concerns related to integration of HIV EID services and EPI services which need consideration.

### **1.4 Justification of the study**

Although there have been suggestions to integrate EID in immunization clinics, data are limited on the acceptability of this approach by mothers who live in rural areas of Malawi. A study was done on this topic in Lilongwe urban, specifically at Kamuzu Central and Bwaila District Hospitals. This study evaluated the integration of EID testing into an immunization clinic compared to the current standard of EID testing at an under-five clinic. It also assessed acceptability of EID at an immunization clinic. The study found out that integrating EID in immunization clinics it is more feasible for providers and more acceptable for caregivers and it

enrolls more infants into EID at younger ages [22]. However, this study took place at a well structured static health facility that offers immunization daily. It was also conducted in urban setting where only 15% of Malawians live and their net attendance ratio (NAR) of secondary school education is at 41% compared to rural area where NAR of secondary school education is at 13% [23]. Studies have shown that education make people think and view things differently [24].

An under-five immunization outreach clinic is done once a month, at a community level and in rural setting. Outreach clinic are normally conducted in areas that are very far from a health facility. The main purpose for such clinics is to bring EPI services close to people and ensuring that every child has access to them. In Malawi, the majority of under-five clinics are conducted as outreach clinics. For example Lilongwe district has only 57 static under-five immunization clinics and 348 under-five immunization outreach clinics. This implies that we have more under-five immunization outreach clinics than under-five immunization static clinics. However, there is no information on the acceptability or feasibility of integration of EID services in under-five immunization outreach clinics in Malawi. In addition to that, there is evidence that more than 30% of HIV exposed children test late [4]. Therefore, there was a need to find acceptable strategies to improve timeliness and coverage of EID in Malawi. Hence, this study assessed acceptability of integrating HIV EID among mothers attending under-five immunization outreach clinics in Lilongwe rural areas. If this strategy can be accepted and implemented it has a potential to reach more children by bringing services closer to the people.

## **1.5 Objectives of the study**

### **1.5.1 Broad objective**

To assess acceptability of integrating HIV early infant diagnosis (EID) into under-five immunization outreach clinics in Lilongwe rural areas among mothers/caregivers of under-five children.

### **1.5.2 Specific objectives of the study**

1. To assess the proportion of mothers who perceive integration of HIV early infant diagnosis into under-five outreach immunization clinics as being important.
2. To determine the percentage of mothers who would accept their infants to be tested for HIV EID at under-five outreach immunization clinics.
3. To identify factors which are viewed to be hindrance or facilitating the integration of HIV EID into under-five outreach immunization clinics among mothers of under-five children.

### **1.5.3 Hypothesis**

Integrating HIV EID into under-five immunization outreach clinic in Lilongwe rural areas among mothers/caregivers of under-five children is acceptable

## **Chapter 2 : Research methodology**

### **2.1 Type of the research study**

This was an observational, analytical, cross section study which employed quantitative study methodology to answer the researched question.

### **2.2 Study place**

The study was conducted at Chimalame, Sendwe, Sonkhwe and Gwande outreach immunization clinics of Lilongwe rural areas (refer Appendix 6: Map of study Areas).

Chimalame is an outreach immunization clinic of M'bang'ombe 2 health centre, Sendwe is an outreach immunization clinic of Malembo Health Centre, while Sonkhwe is an outreach immunization clinic of Nanthenje Health Centre and Gwande is an outreach immunization clinic of Mitundu Health Centre

M'bang'ombe 2 and Malembo Health Centres were selected from the 41 rural health centers of Lilongwe district because they are hard to reach. These health centers are approximately 80km away the district health office. Nanthenje and Mitundu Health Centers were selected from the 41 rural health centers of Lilongwe district because of their high workloads. . The total monthly attendance of under-five immunization clinics of Mitundu Health Centre and Nanthenje Health Centre are estimated to be at 1000 and 1200 infants respectively.

M'bang'ombe health facility has six outreach immunization clinics, Malembo health facility has ten outreach immunization clinics while Nanthenje health facility has also seven outreach

immunization clinics and Mitundu health centre has eight outreach immunization clinics. We use simple random sampling method to select Chimbaleme, Sendwe, Sonkhwe and Gwande outreach immunization clinics from these facilities.

### **2.2.1 Simple random sampling method**

In simple random sampling method, each and every member of the study population has an equal chance of being selected into the sample. For instance, we listed down all the names of under-five outreach immunization clinics for Malembo Health Center. Each name was then transferred on a separate piece of paper and then the paper was folded to make sure that nobody sees what's on that paper. This was done to avoid selection bias. The folded papers were then placed in a hat and mixed. We then randomly select one paper from the hat and this was Sendwe under-five outreach immunization clinic. This method was applied when selecting an under-five outreach immunization clinic from the rest of the health facilities

### **2.3 Study population**

Our study subjects were mothers who came with their under-five children to attend outreach immunization clinics of Chimbaleme, Sendwe, Sonkhwe and Gwande and regardless of their HIV status.

### **2.4 Study period**

The study took place from February 2018 to July 2019. This is from proposal development up to the analysis of the results (refer to the appendix 4).

## 2.5 Sample size

A similar kind of study was done in Lilongwe, Malawi. The study was looking at acceptability of mothers/caregivers for their infants to have an HIV EID testing at an under-five immunization clinic. That study was done in urban setting and at static clinics. The study found acceptance of mothers/caregivers to be at 93% [15]. Therefore, using the formula  $n = Z^2 (P) (1-p)/m^2$ , this study used the acceptability of 93% for caregivers from that previous study to find the sample size of this study.

$$n = Z^2 (p) (1-p)/m^2$$

Where; n is sample size

Z is from normal distribution

p is the proportion of caregivers who accepted in the previous study

m is marginal error

Therefore,  $n = (1.96)^2 (93.0) (1 - 93.0) / (0.05)^2$

$$n = 99.998 = 100$$

All mothers who came with their under-five children to outreach immunization clinics were eligible for the study regardless of their HIV status. We used convenient sampling method to enroll the mothers into the study. This is to say, every mother who came with his/her under-five child to the outreach immunization clinic and was willing to join the study, was enrolled into the study until the sample size was reached. We sought consent from all eligible mothers using written consent forms before enrolling them into the study. For the mothers who did not know how to write, a witness, who was not part of the study staff, was sought to sign the consent form

on their behalf. We sampled an equal number of 25 mothers from each of the 4 study site in order to come up with 100 mothers required for this study.

## **2.6 Data collection**

### **2.6.1 Pilot- testing**

We oriented four research assistants about the research project and trained them on how to collect data. Manual data collecting tools (questionnaire forms) were used to collect data from the study participants (mothers). The questionnaire was first piloted on non- study participants (mothers). The questionnaire was then finalized by incorporating the changes recommended during the pilot test.

### **2.6.2 Actual data collection**

The research assistants were starting with a sensitization talk (refer appendix 2) to the mothers who came with their children to under-five immunization outreach clinics as they were waiting to receive health care. The research assistants screened for eligible participants for the study and offered them an opportunity to participate in the study. Eligible participants who consented were asked to remain after receiving health care for a maximum of 30 minutes. The basic demographic characteristic of the study participants was obtained. Data was also collected concerning HIV status of mothers who come with their children to under-five immunization clinics both reported and from the records. Data collectors also collected data from mothers regarding their views on the integration of HIV early infant diagnosis in under-five immunization outreach clinics, anticipated challenges and acceptance of integrated services. (Refer to appendix-1).

## **2.7 Data management and analysis**

Data collected using a questionnaire was entered in Microsoft Excel, thoroughly cleaned and exported to STATA version 14 for analysis. The data was protected with a password to ensure that it's not tampered with, which may affect its validity. Descriptive statistics (univariate analysis) was done on socio-demographic data in order to summarize the data set quantitatively which was used to make inferences with other predictor variables. Bivariate analysis was done employing chi-square test of association to assess the relationship between acceptance of infant HIV EID and socio-demographic factors. A multinomial logistic regression (MLR) was performed to establish with certainty the factors that hinder or facilitate integration of HIV EID into under-five outreach immunization clinics among mothers of under-five children.

## **2.8 Limitations**

The study only involved mothers and not health care service providers who might have a different view about the EID and EPI integration. We used convenience sampling method, whereby we included all those mothers who were available at the immunization clinic, who were willing and also able to participate in the study. Hence, our sample may not be representative of the true population. We might also have limited responses for barriers and facilitators of the integration of EID and EPI. This might be the case because we did not give the mothers a choice to say what they think about the integration but rather we only gave them a list of barriers/facilitators to choose one.

## **2.9 Ethical consideration**

The investigator asked for an authorization from district health office for the conduction of the study. Written informed consent was used to ask for consent from potential study participants

(refer appendix 2). Study participants were given all the information about the study, after they have understood all aspects of the study, they were asked to sign or put finger print on the form to indicate acceptance. The potential study participants were informed that they had a right to refuse to participate in the study without losing their health care benefits. After enrollment into the study, they also had a right to withdrawal any time without losing their health care benefits. The investigator sought for ethical approval from College of Medicine Research and Ethics Committee (COMREC) before data collection of the study (refer Appendix 5: Certificate of Ethics Approval).

The research assistants administered questionnaires to mothers, who came with their children to the under-five outreach immunization rural clinics and had consented to take part in the study. This was done after they have received health services and it only took approximately 30 minutes.

## Chapter 3 : Results

### 3.1 Demographic composition of study participants

A total of 100 mothers were interviewed using a structured questionnaire. The interviewed mothers had a mean age of 25, median of 24 with an inter-quartile range of 6.5. The mothers were equally sampled 25 (25%) from each of the 4 study sites. The majority of them, 87 out of 100 (87%) were married or living together with their spouse. This was followed by those that were widowed who were 9 out of 100 (9%). The highest educational level attended by the majority of the mothers 84 out of 100 (84%) was primary school and they survive on farming 89 out of 100 (89%). The nearest health facility to all the interviewed mothers was more than 5km away from their respective homes. (Refer **Error! Reference source not found.**)

**Table 1: Demographic characteristics of the study participants (mothers)**

Variable	Under-five outreach immunization study site			Totals	
	Chimbalame	Sendwe	Sonkhwe	Gwande	
	n=25 n(%)	n=25 n(%)	n=25 n(%)	n=25 n(%)	N=100 N(%)
<b>Age of mother</b>					
15-19	2 (8)	0 (0)	3(12)	5(20)	10(10)
20-24	12(48)	13(52)	12(48)	10(40)	47(47)
25-34	9 (36)	6 (24)	10(40)	9(36)	34(34)
35-44	2 (8)	6 (24)	0(0)	1(4)	9(9)
<b>Education Level</b>					
None	0 (0)	5 (20)	0 (0)	2(8)	7(7)
Primary	18(72)	15(60)	22(88)	22(88)	77(77)
Secondary	5 (20)	4 (16)	3(12)	1(4)	13(13)
Tertiary Education	2 (8)	1 (4)	0 (0)	0(0)	3(3)
<b>Marital Status</b>					
Married	23(92)	21(84)	22(88)	21(84)	87(87)
Divorced/Separated	2 (8)	1 (4)	1 (4)	0 (0)	4 (4)
Widowed	0 (0)	3(12)	2 (8)	4 (16)	9 (9)
<b>Occupation</b>					
Farming	24(96)	20(80)	23(92)	22 (88)	89(89)
Employed	0 (0)	4(16)	1 (4)	2 (8)	7(7)
None	1(4)	1(4)	1 (4)	1 (4)	4(4)

### 3.2 Demographics of the children who took part in this study

A total of 100 children were involved in the study. These children were equally drawn 25 (25%) from each of the 4 study sites. The children had a mean age of 13 months, median of 10 with an inter-quartile range of 13 months. A total of 56(56%) of these 100 children were females and 42 (44%) were males. The study found out that 90(90%) out of these 100 children born at a health facility. These were followed by 9(9%) out of the 100 that were born at traditional birth attendants. All of the children who were involved in the study were brought to the immunization clinic by their own mothers. (Refer **Error! Reference source not found.**)

**Table 2: Demographic characteristics of the children who participated in the study**

Variable	Rural outreach immunization clinic study site				Total N=100 N (%)
	Chimbalame n=25 n (%)	Sendwe n=25 n (%)	Sonkhwe n=25 n (%)	Gwande n=25 n (%)	
Child gender					
Male	12 (48)	6 (24)	12 (48)	14 (56)	44 (44)
Female	13 (52)	19 (76)	13 (52)	11 (44)	56 (56)
Age (months)					
Median	7	10	14	10	10
IQR	13	12	14	12	12
Place of birth					
H/C	20 (80)	24 (96)	25 (100)	21 (84)	90 (90)
TBAs	4 (16)	1 (4)	0 (0)	4 (16)	9 (9)
Home	1 (4)	0 (0)	0 (0)	0 (0)	1 (1)
Relationship to caregiver					
Mother	25 (100)	25 (100)	25 (100)	25 (100)	100(100)

\*TBAs – Traditional birth attendants

\*H/C- Health centre

\*IQR- inter-quartile range

### 3.3 HIV information of the mothers and the children

The study has found out that 96 (96%) mothers out of the 100 mothers, who took part in this study, have ever had an HIV test before. The remaining 4(4%) mothers out of the 100 mothers, who participated in the study, have never had a chance to have an HIV test before. According to their HIV test results, 6(6.25%) of the mothers out the 96 mothers were HIV positive and 90(93.8) of them were HIV negative. (Refer **Error! Reference source not found.**).

**Table 3: HIV information of mothers and children who participated in the study**

Variable	Rural outreach immunization clinic study site				Total
	Chimbalame	Sendwe	Sonkhwe	Gwande	
	n=25 n (%)	n=25 n (%)	n=25 n (%)	n=25 n (%)	
Mother ever tested for HIV					
Yes	24 (96)	24 (96)	25 (100)	23 (92)	96 (96)
No	1 (4)	1 (4)	0 (0)	2 (8)	4 (4)
Mother HIV status					
Positive	2 (8)	2 (8)	1 (4)	1 (4)	6 (6)
Negative	22 (88)	22 (88)	24 (96)	22 (88)	90 (94)
Unknown	1 (4)	1 (4)	0 (0)	2 (8)	4 (4)

### 3.4 HIV information of the children involved in the study

Out of the 100(100%) children that were involved in the study, 6(6%) were HIV exposed children. Out of the 6(100%) children who were HIV exposed, 5(83.3%) were tested for HIV and 1(16.7%) was never tested for HIV. An HIV exposed child who never had an HIV test before, was at 15months of age during data collection period of this study. Out of the 5(100%) HIV exposed children that have tested for HIV, 4(80%) of them the results were verified in their health passport and 1(20%) out of the 5(100%) the results were verbally communicated by the

mother. The HIV exposed child whose HIV test result was verbally communicated was HIV negative.

### **3.5 Importance and acceptance of the mothers to EID and EPI integration in outreach immunization clinics in Lilongwe rural areas**

Out of the 100 mothers that took part in the study, 99(99%) of them perceived the integration of EID into outreach immunization clinics as very important. The majority of mothers 96 (96%) from a total of 100 mothers also said they would allow their children to have an HIV test at an outreach immunization clinic. The percentage of mothers who would accept their infants to be tested for HIV EID was further disaggregated by various demographic characteristics to find out which groups were more willing than others to have their infants tested for HIV EID. In addition to that, a Chi-square test was performed in order to check if there existed any association between a mother's willingness to have their infant tested for HIV EID and the different demographic factors as well as other non-demographic factors.

Results showed that 90% of the mothers aged 15-19years would accept their infants to be tested for HIV EID at under-five outreach immunization clinics and 97.70% of the married mothers would also accept to have their infants tested. In terms of education, 94.81% of mothers with primary education would accept testing of their infants while 5.19% of the mothers with the same level of education would not accept to have their infants tested for HIV EID at under-five outreach immunization clinics. Furthermore, at least 98% of the mothers who were comfortable with the idea of HIV EID at the under-five immunization clinics said that they would accept that

their infants be tested for HIV EID while only three mothers would accept that their infants be tested despite being not comfortable with the tests at the outreach immunization clinics.

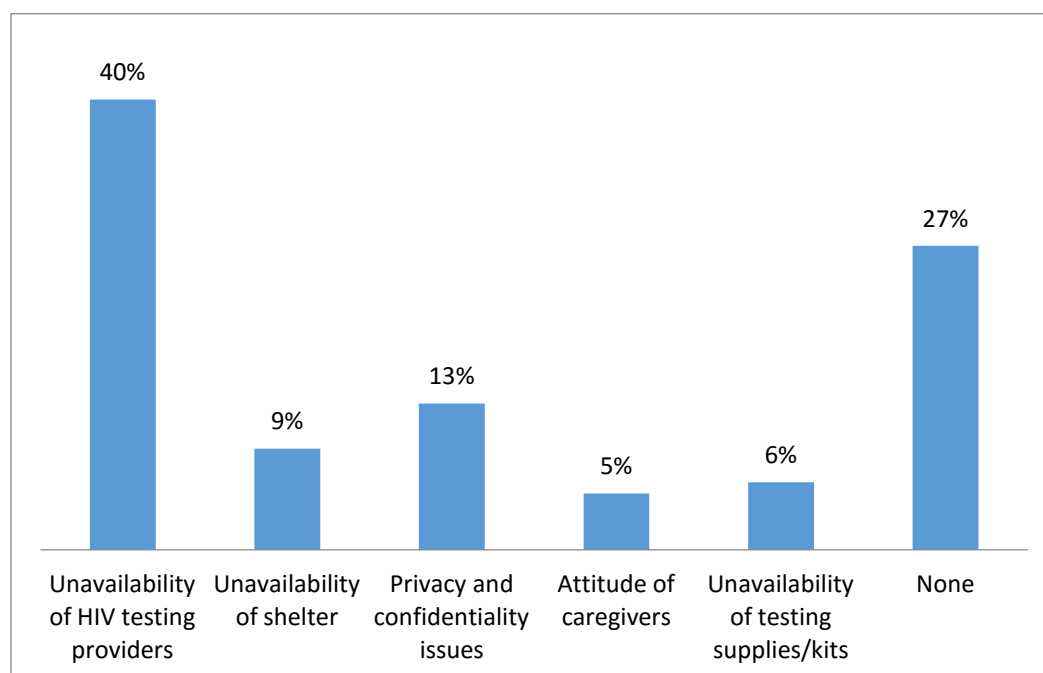
In terms of the association between the mothers' acceptance for their infants to be tested for HIV EID at an outreach immunization clinic and other variables, marital status, comfortability with tests and belief that HIV EID can reduce risk of death in HIV exposed infants, were found to be associated with the mothers accepting that their infant be tested for HIV EID at an under-five outreach immunization clinics with p values less than 0.05, (0.014, <0.01 and 0.031 respectively for the three variables). (Refer Table 4)

**Table 4: Association between the mothers' acceptance for HIV EID at immunization clinic with other variables**

	Acceptance of infant HIV EID		P-Value
	Yes n (%)	No n (%)	
<b>Age</b>			
15-19years	9(90)	1(10)	<b>0.331</b>
20-24years	44(93.62)	3(6.38)	
25-34years	34(100)	0	
35-44years	9(100)	0	
<b>Marital Status</b>			
Married	85(97.70)	2(2.30)	<b>0.014</b>
Divorced/Separated	4(100)	0	
Widowed	7(77.78)	2(22.22)	
<b>Level of Education</b>			
None	7(100)	0	<b>0.742</b>
Primary	73(94.81)	4(5.19)	
Secondary	13(100)	0	
Higher	3(100)	0	
<b>Comfortability with test</b>			
Agree	96(98.97)	1(1.03)	<b>&lt;0.01</b>
Disagree	3(100)	0	
<b>Belief that HIV EID can reduce risk</b>			
Strongly agree	66(97.06)	2(2.94)	<b>0.031</b>
Agree	28(96.55)	1(3.45)	
Don't know	2(66.67)	1(33.33)	

### 3.6 Factors that could hinder the EID and EIP integration in rural outreach immunization clinics in Lilongwe

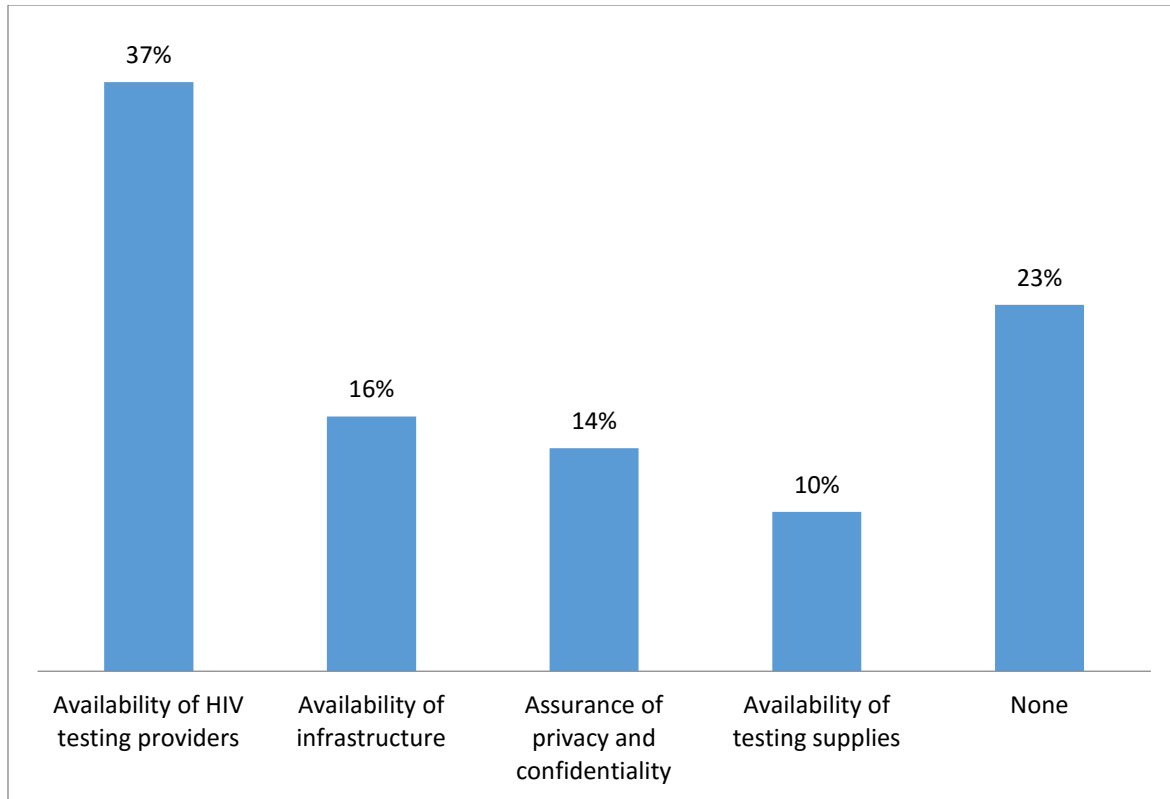
The mothers were asked to choose at least one factor that they view could hinder the integration of EID into immunization clinics from the list which was on the questionnaire. The majority of mothers (40%) indicated that unavailability of HIV testing providers during the immunization clinics has a potential to hinder the integration, this was followed by 27(27%) out of 100 mothers who did not indicate anything to have potential of hindering the integration. Refer to Figure 3.



**Figure 3: Perception of mothers on what factors may hinder uptake of HIV EID integration in rural outreach immunization clinics in Lilongwe**

### 3.7 Factors that would facilitate the integration of EID into EPI

Most mothers indicated that availability of HIV testing providers (37%) may facilitate the process. However, there were also a large percentage of mothers (23%) that indicated that none of the factors highlighted by the researcher may facilitate the process (Refer Figure 4)



**Figure 4: Perception of mothers on what factors may facilitate the uptake of HIV EID integration in rural outreach immunization clinics in Lilongwe**

### **3.8 Association between integration of HIV EID into under-five outreach immunization clinics and various factors**

Firstly, a chi-square test of association was performed in order to check for any association between integration of HIV EID into under-five outreach immunization clinics and various factors. (Refer Table 5). From the table, it can be seen that occupation of the mother, infant's birth place, a belief that HIV EID reduces risk of death in infants and inconveniences brought about by integration were associated with the integration with p-values less than 0.005.

**Table 5: Association between integration of HIV EID into under-five immunization clinics with other factors**

<b>Factor</b>	<b>p-value</b>
Age	0.550
Occupation	0.014
Educational level	0.212
Marital Status	0.564
Inconveniences brought by integration	0.015
Comfortability with test	0.137
Belief of risk reduction	0.006
Birth place	0.005

A multinomial logistic regression (MLR) was then fitted to the data to identify factors that would hinder or facilitate integration of HIV EID into under-five outreach immunization clinics among mothers of under-five children. For the factors that hinder integration of HIV EID, a likelihood ratio chi-square of 72.23 with a p-value = 0.0061 (Refer Table 5) indicated that the model as a whole fit significantly better than a model with no predictors.

A p-value of 0.052 indicated that the perception of infants' risk of dying is reduced when there is early infant diagnosis was almost a significant factor in explaining the integration of HIV EID into under-five immunization clinics given shelter availability. The odds of integrating HIV EID into under-five immunization clinics given an availability of shelter at the clinics were three

times higher for the mothers who believed that HIV EID and treatment would reduce the infants' risk of dying. The 95% confidence interval (0.9896, 2.0704) however included a 1 which meant that there was no significant difference in odds of HIV EID integration for mothers who believed that the integration would reduce risk of dying for the infants and those that believed not.

Taking into account an availability of testing kits at outreach immunization clinics would increase the odds of HIV EID integration by about 90% if moving from lowest level of education to the highest educational level with a (0.0099, 1.0545) confidence interval. The CI however indicated that the different levels of education for mothers did not bring any difference in the odds of the integration. A p-value of 0.055 showed that education is almost significant in the integration of HIV EID into under-five immunization clinics.

Given that none of the given factors under the facilitating/hindering factors are in operation, other inconveniences such as confidentiality issues, breach of privacy issue and long periods of waiting were significant in explaining integration of HIV EID at outreach immunization clinics with a p-value of 0.027. The odds of integration being hindered were at least two times higher in presence of these inconveniences as compared to when the inconveniences were not available. The 95% CI (1.121, 6.967) did not include a 1 which indicated that there was indeed a significant difference in odds of HIV EID integration in the presence of various inconveniences to the mothers (Refer Table 6).

**Table 6: Multinomial Logistic Regression Model results**

<b>Factor</b>	<b>Co-efficient</b>	<b>Z</b>	<b>P&gt;  z </b>	<b>95% CI</b>
Risk of death reduced	1.3769	1.95	0.052	-.0105-2.7644
Education Level	-2.2806	-1.92	0.055	-4.6144-.0531
Inconveniences	1.0278	2.21	0.027	.1144-1.9412

## **Chapter 4 : Discussion of the key findings**

### **4.1 Discussion of the key findings**

The results from this study have shown that the majority of the mothers (99%) perceived the integration of HIV EID into under-five immunization clinics as important. This is similar to the findings of a study done in KwaZulu Natal in South Africa by Nigel Rollins et al and the findings of a study done by Wang, et al. in Zambia [16, 20]. In case of this study, the reason could be that this integration of HIV EID and EPI services shall be happening at a community level compared to the current EID mode of service delivery in Malawi whereby EID services are only offered at a health facility level. This shall mean bringing EID services close to the mothers hence saving their time and cost since this study has also revealed that the distance to the nearest health facility for all the mothers is more than 5 kilometers away from their homes.

This study has also found out that 96% of the mothers could accept HIV testing of their infants at an under-five immunization clinic. This is in support of what Mccollum ED et al. found in their study done in urban areas of Lilongwe, Malawi [22]. In this study, education was not found to be associated with the mothers' acceptance to receive HIV EID and EPI integrated service as expected. It was expected that the higher the level of education a mother attended is the higher her acceptance level to receive public health interventions such as integration of HIV EID in under-five outreach immunization clinics [15]. Instead, mothers' acceptance to receive integrated services of HIV EID and EPI on an outreach immunization clinic was associated with a belief that HIV EID reduces the risk of death in HIV exposed infants ( $p\text{-value}=0.031$ ) . This finding is in support of the Health Belief Model (HBM). HBM is one of the behavior change model which

predicts why people will take action to prevent, screen for or to control illness conditions. With HBM, a feeling that an individual is susceptible to a certain condition it is sufficient motivation to take an action in the face of other barriers and not education [12].

This study has also found out that availability of HIV testing providers was the number one reported factor to have a potential of facilitating the integration. This is different to what Wang, et al. found. In their study, HIV testing reagents supply reinforcement was found to have a potential of facilitating the integration of HIV EID and EPI services [20]. This could be attributed to the different study design used in the two studies and also different study settings.

This study has also found out that unavailability of HIV testing providers has a potential of hindering the integration of HIV EID and services. This is different to what Bwana et al found [18]. They found out that low education, maternal unemployment, religious belief and lack of knowledge of HIV transmission were contributed to low EID testing. This could be attributed to the different study settings and study design.

The results of this study found out that 6(6%) children out of the 100(100%) who were involved in this study were HIV exposed infants. These HIV exposed infants were suppose to receive an HIV EID test by 6 weeks of age according to Ministry of Health PMTCT guidelines. From the results, it is revealed that it is only 5(83.3%) HIV exposed infants out of the 6(100%) HIV exposed infants that had received the HIV EID test but one never had HIV EID test. The HIV exposed infant who never had HIV EID test was at the age of 15 months by the time this study

was being conducted. This means that the optimal age (6 weeks) for HIV EID test had already passed without this child getting the HIV EID test. This delay in HIV diagnosis puts the infant at risk of disease progression and death if is already infected [8]. This finding is in support of the MPHIA 2015/16 survey findings that most HIV exposed infants (29%) in Malawi receive HIV EID test late or not at all. The delay in diagnosis of this child might have been attributed to the long distances from home to the nearest health facility where HIV EID services are provided. As the study has also revealed the nearest health facility to all mothers who participated in this study is more than 5 kilometers away from their respective homes. The integration of HIV EID in outreach immunization clinics could help cut these long distances short and also save time and costs.

The study results have shown that one HIV exposed infant who has never had an HIV test up to 15 months was identified. This is in support of the findings from a study done in Malawi in this area by Eric D. McCollum et al. and Nigel Rollins et al. in KwaZulu Natal South Africa [2, 5]. However, Nigel Rollins et al. used HIV test as a screening test in their study whereby they were testing every infant at the under-five clinic which is not cost efficiency. Testing HIV exposed children only can be ideal for Malawi.

The HIV test results of one of the HIV exposed children were communicated verbally. The verbal reported results can be a source of information bias. The mothers might have failed to recall the child's last HIV test result or deliberately giving fake result biasing the results of the study towards their specific concerns.

The study only involved mothers and not health care service providers who might have a different view about the EID and EPI integration. The study also used convenience sampling method, whereby it included all those mothers who were available at the immunization clinic and who were willing to participate in the study. As a result HIV negative mothers were over represented in the selection process as compared to the population HIV prevalence basing the results towards their specific concerns. We might also have limited responses for the potential barriers and facilitators of the integration of EID and EPI by giving the mothers closed ended questions. Mothers were not given an opportunity to say what they think about the integration but rather we only gave them a list of potential barriers/facilitators to choose one.

## **Chapter 5 : Conclusion and recommendation**

### **5.1 Conclusion**

From the findings of this study, we have seen that the study identified one HIV exposed infant who never had EID up to 15 months. For all the mothers who participated in the study, their nearest health facility where they could access HIV EID services was more than 5 kilometers away from their homes. The 96% of the mother viewed the integration as important and 99% indicated to would have accepted the HIV test at immunization clinics.

With the above findings, we can conclude to say that, the integration of HIV EID and EPI services has a potential of identifying more exposed infants and at their young age. The integration would result in saving time and cost for the mothers. Mothers have shown to be willing to have HIV EID and EPI integrated services at under-five immunization clinics. We also conclude that there is no difference in the acceptance of HIV EID and under-five immunization clinics in the urban and rural settings.

The study found out that integrating HIV early infant diagnosis services into rural outreach immunization clinic was acceptable among mother who brought their under-five children in the selected outreach immunization clinics. However, key challenges like availability of HIV test providers and privacy and confidentiality issues to be assessed and monitored.

## **5.2 Recommendation**

From the results of this study, it has been found that some HIV exposed infants are still receiving EID test rate or not at all. The study has also revealed that in rural areas women travel long distances in order to access EID services at a health facility. We have seen that the integration of HIV EID in immunization clinics has a potential of increasing EID testing rates at 6 week. The results have also shown the willingness of mothers to receive HIV EID and EPI integrated services. We therefore recommend the government of Malawi, policy makers and managers in the health system to consider enforcing provision of EID services at the community level in immunization clinics.

This study aimed at quantitative assessment of the acceptability of HIV EID at an under-five immunization clinic in the rural areas of Lilongwe. We therefore recommend other researcher who may have interest in the same area to also consider including qualitative assessment in order to get a deeper understanding of the matter.

This study was only interested to know the acceptability of HIV EID integration among mother who came with their children to under-five immunization clinics. We therefore recommend other researchers to also consider assessing the acceptability of this integration among health care providers.

We used convenient sampling method whereby we enrolled all mothers who were available at the immunization clinics. This ended up over-representing HIV negative mothers. We therefore

recommend other researchers to also try other sampling methods as they are conducting similar studies.

The focus of this study was mainly on assessing how mothers who bring their under-five children to immunization clinics would receive the integration of HIV EID in immunization clinics. Therefore, the study did not involve actual sample collection which is a process that might have its own challenges as well. Hence we recommend other researcher to do studies that involves the actual sample collection and see if that can be acceptable as well.

## References

- [1] World Health Organization (WHO). The top 10 causes of death n.d. <http://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death> (accessed August 13, 2018).
- [2] United Nations Children's Fund, For Every Child, End AIDS – Seventh Stocktaking Report, UNICEF, New York, December 2016. doi:ISBN: 978-92-806-4861-4.
- [3] UNAIDS, President's Emergency Plan for AIDS Relief (PEPFAR) and Partners (2016) Start Free, Stay Free, Aids Free: a Super-Fast-Track Framework for Ending Aids Among Children, Adolescents and Young Women By 2020 2016.
- [4] Ministry of Health, Malawi. Malawi Population-based HIV Impact Assessment (MPHIA) 2015-16: First Report. Lilongwe, Ministry of Health. November 2017.
- [5] UNAIDS. HIV and AIDS in South Africa Groups most affected by HIV in South Africa. Avert 2018:1–14.
- [6] UNAIDS. Progress Report on the Global Plan towards the elimination of new infections among children by 2015 and keeping their mothers alive, 2014
- [7] (KNBS) KNB of S, (MOH) M of H, National AIDS Control Council (NACC), (KEMRI) KMRI, Development NC for P and development (NCPD), N KWJ, et al. WHO child growth standards. Lancet 2014;371:204. doi:JC2502/1/E.
- [8] World Health Organization. Report of the WHO Technical Reference Group, Paediatric HIV/ART Care Guideline Group Meeting WHO Headquarters, Geneva, Switzerland 10-11 April

2008 2008:1–41.

- [9] World Health Organization. Guidance on Global Scale-Up of the Prevention of Mother-Child Transmission of HIV: Towards universal access for women , infants and young children and eliminating HIV and AIDS among children 2007:1–40.
- [10] Ministry of Health:HIV Unit.Malawi integrated HIV report, first quarter 2018 n.d.
- [11] National Statistical Office (NSO) [Malawi] and ICF. 2017. *Malawi Demographic and Health Survey 2015-16*.Zomba, Malawi, and Rockville, Maryland, USA. NSO and ICF.
- [12] Health behavior and health education: theory, research, and practice. Jossey-Bass. 2008.
- [13] Rollins N, Mzolo S, Moodley T, Esterhuizen T, Rooyen HV. Universal HIV testing of infants at immunization clinics : an acceptable and feasible approach for early infant diagnosis in high HIV prevalence settings. 2009;(February):1851–1857.
- [14 ] Violari A, Cotton MF, Gibb DM, Babiker AG, Steyn J, Madhi SA, et al. Early Antiretroviral Therapy and Mortality among HIV-Infected Infants. *N Engl J Med*. 2008 Nov 20;359(21):2233–44.
- [15] Essajee S, Bhairavabhotla R, Penazzato M, Kiragu K, Jani I, Carmona S, et al. Scale-up of Early Infant HIV Diagnosis and Improving Access to Pediatric HIV Care in Global Plan Countries. *JAIDS J Acquir Immune Defic Syndr* 2017;75:S51–8. doi:10.1097/QAI.0000000000001319
- [16] Rollins N, Mzolo S, Moodley T, Esterhuizen T, Rooyen HV. Universal HIV testing of infants at immunization clinics : an acceptable and feasible approach for early infant diagnosis in high HIV prevalence settings. 2009;(February):1851–1857.

- [17] Goodson JL, Finkbeiner T, Davis NL, Lyimo D, Rwebembera A, Swartzendruber AL, et al. Evaluation of using routine infant immunization visits to identify and follow-up HIV-exposed infants and their mothers in Tanzania. *J Acquir Immune Defic Syndr* 2013;63:9–15. doi:10.1097/QAI.0b013e31828a3e3f
- [18] Bwana VM, Frimpong C, Simulundu E, Mfinanga SG, Mboera LEG, Michelo C. Accessibility of services for early infant diagnosis of human immunodeficiency virus in Sub-Saharan Africa: A systematic review. *Tanzania Journal of Health Research*. 2016;18(3):1–18.
- [19] Province S. measuring the impact of reinforced integration of infant hiv testing and immunization services evidence from a 3de evaluation in 2014:2014–5. doi:10.1371/journal.pone.0141455.http.
- [20] Wang PC, Mwango A, Moberley S, Brockman BJ, Connor AL, Kalesha-Masumbu P, et al. A Cluster Randomised Trial on the Impact of Integrating Early Infant HIV Diagnosis with the Expanded Programme on Immunization on Immunization and HIV Testing Rates in Rural Health Facilities in Southern Zambia. *PLoS ONE*. 2015;10(10): e0141455. doi:10.1371/journal.pone.0141455
- [21] Wallace A, Kimambo S, Dafrossa L, Rusibamayila N, Rwebembera A, Songoro J, Arthur G, Luman E, Finkbeiner T, Goodson JL. Qualitative assessment of the integration of HIV services with infant routine immunization visits in Tanzania. *J Acquir Immune Defic Syndr*. 2014 May 1;66(1):e8-e14. doi: 10.1097/QAI.0000000000000078. PubMed PMID: 24326602; PubMed Central PMCID: PMC4663663.

- [22] Mccollum ED, Johnson DC, Chasela CS, Linias D, Kazembe PN, Chb MB, et al. Superior Uptake and Outcomes of Early Infant Diagnosis of HIV Services at an "Under-Five" General Pediatric Clinic in Malawi. *J Acquir Immune Defic Syndr*, 2012;60(4)
- [23] National Statistical Office. Population and Housing Census 2008. *Natl Stat Off* 2008:1–23. doi:10.1016/j.jtcvs.2012.11.079.
- [24] J.Klein, The Relationship between Level of Academic Education and Reversible and Irreversible Processes of Probability Decision-Making . Springer .1999;37(4)323-339. <https://www.jstor.org/stable/3447957> REFERENCES Linked references ar 2018;37:323–

## Appendix 1: Questionnaire of the study

Acceptability of HIV EID integration into under-five immunization outreach clinics  
questionnaire

English version

Name of the interviewer.....Signature..... Date.....

Demography of the mother

1. Name of under-five immunization outreach clinic?

- Chimbalame (0)
- Sendwe(1)
- Sonkhwe (2)
- Gwande (3)

2. Gender of caregiver?

- Male (0)
- Female(1)

3. How old are you?.....

4. What is your current marital status?

- Married/living together (0)
- Divorced/separated(1)
- Widowed (2)
- Never married/never lived together(3)

5. What is the highest educational level attended?

- Never attended (0)

- Preschool (1)
- Primary education(2)
- Secondary education(3)
- Higher education(4)

6. What do you do for a living?

- Farming(0)
- Self-employed/skilled(1)
- Salaried government(2)
- Salaried private sector(3)
- None(4)

**Demography of the child**

7. Is the child male or female?

- Female (0)
- Male (1)

8. How old is the child?.....

9. Place of birth of the child.....

- Health facility (0)
- Tradition birth attendants(1)
- Home(2)

10. Relationship of the child to you (caregiver)?

- Mother(0)
- Aunt(1)

- Sister(2)
- Grandmother(3)
- Dad(4)
- No relationship (5)

11. How far is your nearest health facility?

- Less than 1km(0)
- 1 km(1)
- 2 km(2)
- 5 km(3)
- More than 5km(4)

**General HIV information**

12. Have you ever had an HIV test?

- Yes(0)
- No(1)

13. If yes and you are comfortable to share the results, what where the results?

- Positive(0)
- Negative(1)

14. Has the child ever had an HIV test?

- Yes(0)
- No(1)

15. If yes and you are comfortable to share, what where the results?

- Positive (0)

- Negative(1)

16. Do you have any records to verify?

- Yes (0)
- No (1)

17. Do you believe that HIV can be transmitted from mother to child?

- Yes (0)
- No (1)

18. Do you believe an HIV positive mother can bear an HIV negative child if she adheres to all Medical advice?

- Yes (0)
- No(1)

**Determining the percentage of mothers who would accept their infants to be taken a blood samples for HIV EID at under-five immunization outreach clinics.**

19. Would you allow health workers to test your child for HIV at an under-five immunization outreach clinic?

- Yes (0)
- No (1)

20. I am comfortable for my child to have an HIV test at an under-five immunization outreach clinic.

- Strongly agree(0)
- Agree(1)
- Disagree(2)

- Strongly disagree(3)

**Assessing if mothers/caregivers perceive integration of HIV early infant diagnosis into under-five immunization outreach clinics as being important**

21. Do you believe that availability of HIV test at an under-five immunization outreach clinic is important?

- Yes (0)
- No (1)

22. Do you believe that for infants who born with HIV, without early diagnosis and treatment are at high risk of death?

- Yes (0)
- No(1)

23. Do you believe that the risk of death in infant born to HIV positive mothers can be reduced with early diagnosis and treatment?

- Strongly agree(0)
- Agree(1)
- Disagree(2)
- Strongly disagree(3)
- I don't know(4)

**Identifying factors that are viewed to be hindrance or facilitating the integration of HIV EID into under-five immunization outreach clinics.**

24. I believe that factors that would hinder integration of HIV EID into under-five immunization outreach clinics are (choose all applicable):

- Unavailability of HIV testing providers(0)
- unavailability of shelter(1)
- Privacy and confidentiality issues(2)
- Attitude of caregivers(3)
- Unavailability of testing supplies/kits(4)
- None(

25. Inconveniences that would be brought about by the integration are

- Long waiting(0)
- Breach of privacy(1)
- Breach of confidentiality(2)
- None (3)

26. Factors that would facilitate the integration of HIV EID into under-five immunization outreach clinics are:

- Availability of HIV testing providers.(0)
- Availability of infrastructure (1)
- Assurance of private and confidentiality(2)
- Availability of testing supplies(3)
- None(4)

## **Appendix 2: Consent to participate in a Research study Informed consent form for Screening and Enrolling of mothers/caregiver**

### **English version**

**Title of study:** Acceptability of integrating HIV Early Infant Diagnosis (EID) into under-five immunization outreach clinics of Lilongwe rural areas.

**Investigator:** Mphatso Makanda

**Address:** Kamuzu Central Hospital, Post office box 149, Lilongwe

**Email address:** [Mphatso6@gmail.com](mailto:Mphatso6@gmail.com)

**Source of funding:** Self-sponsored

**Study contact telephone number:** 0888 789 984

**Study contact email:** mphasto6@gmail.com

### **Introduction**

You are being asked to enroll in the study mentioned above which involves research. This research involves mothers/caregivers who come to under-five immunization outreach clinic with children. The person in-charge of the study is Mphatso Makanda and this is a self-sponsored study.

Before you decide whether or not to participate in this study, you should know the purpose of the study, the risks and benefits of the study to you and what is expected of you. The study staff will discuss this with you. They will answer all questions that you may have about the study. After the study has been explained to you and you have understood, you can then decide whether to participate or not to participate in the study. When you understood everything about the study,

and you accept to participate in the study, you will be asked to sign to give consent or put a mark. You will be offered a copy to keep.

You have to note the following things:

- ◁ Taking part in this study is voluntary
- ◁ You can decide not to take part in the study, or to leave at any time without losing your benefits to receive health care
- ◁ If you do not want to take part in the study, you can enter another study in the future if it is available and if you will be eligible

### **Purpose**

The purpose for this study is to obtain information that will help the investigator to understand whether it would be possible to conduct an implementation research in future to assess whether integrating HIV early infant diagnosis into under-five immunization outreach clinics can increase proportion of HIV exposed infants tested before two months as per Malawi Ministry of Health's recommendation. This study will recruit 100 mothers who come with children to under-five immunization outreach clinics.

### **Procedure**

If you are eligible and you have accepted to take part in this study, study staff shall ask you some questions that would help the investigator to determine your acceptability to the integration of HIV early infant diagnosis into under-five immunization outreach clinics. This shall take a maximum of 30 minutes and the study staff shall keep this information as confidential as possible.

### **Risk or other issues**

There is no significant risk associated with participating in this study as this study only involves asking questions and nothing more. The study staff shall ensure that all your information provided shall be kept as confidential as possible.

### **Potential benefit**

You may not receive any benefit from this study. However, the knowledge that will be obtained from this study could help others in the future.

### **Reimbursement**

You are not going to be paid for participating in this study.

### **New findings**

You will be told any new findings from this study that might make you change your mind about to still remaining in this study.

### **Reason why you could be withdrawn from the study without your consent**

The study has been cancelled by the Malawi Ministry of Health or other ethics organization monitoring the study.

### **Participating for another reason**

You don't have to participate in this study if you don't want to. If you are not enrolled into the study you will not lose any benefits of your standard health care.

### **Cost**

You will not pay any costs for participating in this study

### **Confidentiality**

The study staff will keep all your information as confidential as possible. You will only be identified by a number on most study forms. None of your personal information will be released without your written permission. You will not be identified in any publications from this study. Your information can be reviewed by the College of Medicine Research and Ethics Committee.

**Research related injury**

There is no injury associated with participating in this study as this study only involves asking questions.

**Individuals to contact for problems or questions**

If you have any question related to the study or if you have problems as a result of participating in this study, you should contact Mphatso Makanda at 0888 789 984, Kamuzu Central Hospital, Post Office Box149, Lilongwe

**STATEMENT OF CONSENT**

I have read (or someone has read and explained to me) this consent form. I understand the purpose of the research study and the risks and benefits as described in this written summary. I agree voluntarily to join this study.

\_\_\_\_\_ I agree to participate in this study

\_\_\_\_\_ I do not agree to participate in this study

\_\_\_\_\_

Caregiver's Name (print)	Caregiver's Signature or Thumb Print	Date
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For those placing thumb print **only**: I confirm that the participant who states that her/his name is \_\_\_\_\_ has placed her thumbprint on this consent form of her own free will on this day: \_\_\_\_\_.

_____	_____	_____
Name of witness	Witness' Signature	Date

### **Appendix 3: Sensitization script**

#### **English version**

#### **Brief introduction**

I would like to welcome you all who have come with children to under-five immunization outreach clinic today. As you are waiting to receive health care, we just wanted to take advantage and let you know that there is a research study which is taking place here. The research study is about acceptability of integrating HIV early infant diagnosis (EID) into under-five immunization outreach clinics and it involves mothers who have come to under-five immunization outreach clinic. This is an academic research and the principal investigator is Mphatso Makanda, a College of Medicine Public Health Student. After you have received the health care, research assistants will be approaching you to ask you if you are interested to join the study. Thank you.

### Appendix 4: Study period

#### Work-plan

Activity	Feb-Mar 2018	April 2018	May-Jun 2018	July –Sept 2018	Oct 2018	Nov-Dec 2018	Jan -Feb 2019	Mar-April 2019	May 2019
Literature review									
Topic identification & formulation of objectives									
Proposal development									
Submission & approval									
Pretesting Questionnaire									
Data collection									
Data analysis									
Report preparation									
Dissemination of results									

## Appendix 5: Certificate of Ethics Approval



### CERTIFICATE OF ETHICS APPROVAL

This is to certify that the College of Medicine Research and Ethics Committee (COMREC) has reviewed and approved a study entitled:

P.10/18/2486 - Acceptability of integrating HIV Early Infant Diagnosis (EID) into under-five immunization outreach clinics in Lilongwe rural areas. Version 1.0 by Mphatso Makanda

On 24-Oct-18

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

A handwritten signature in blue ink, appearing to read "YB Mlombe".

Dr. YB. Mlombe - Chairperson (COMREC)

24-Oct-18

Date

## Appendix 6: Map of study Areas

