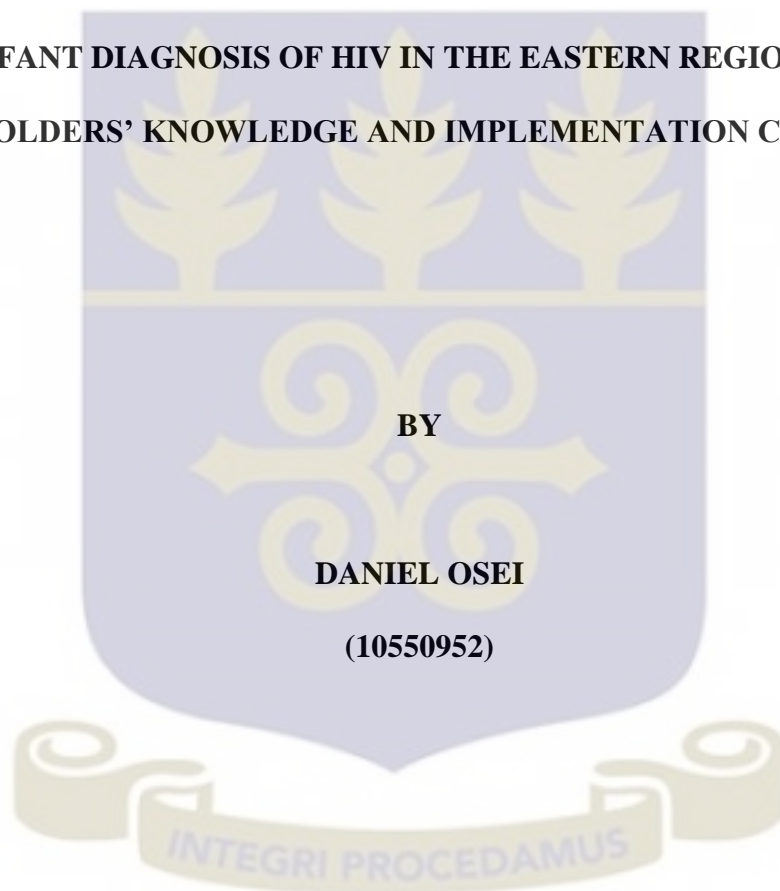


**SCHOOL OF PUBLIC HEALTH  
COLLEGE OF HEALTH SCIENCES  
UNIVERSITY OF GHANA, LEGON**

**EARLY INFANT DIAGNOSIS OF HIV IN THE EASTERN REGION OF GHANA:  
STAKEHOLDERS' KNOWLEDGE AND IMPLEMENTATION CHALLENGES**



**BY**

**DANIEL OSEI**

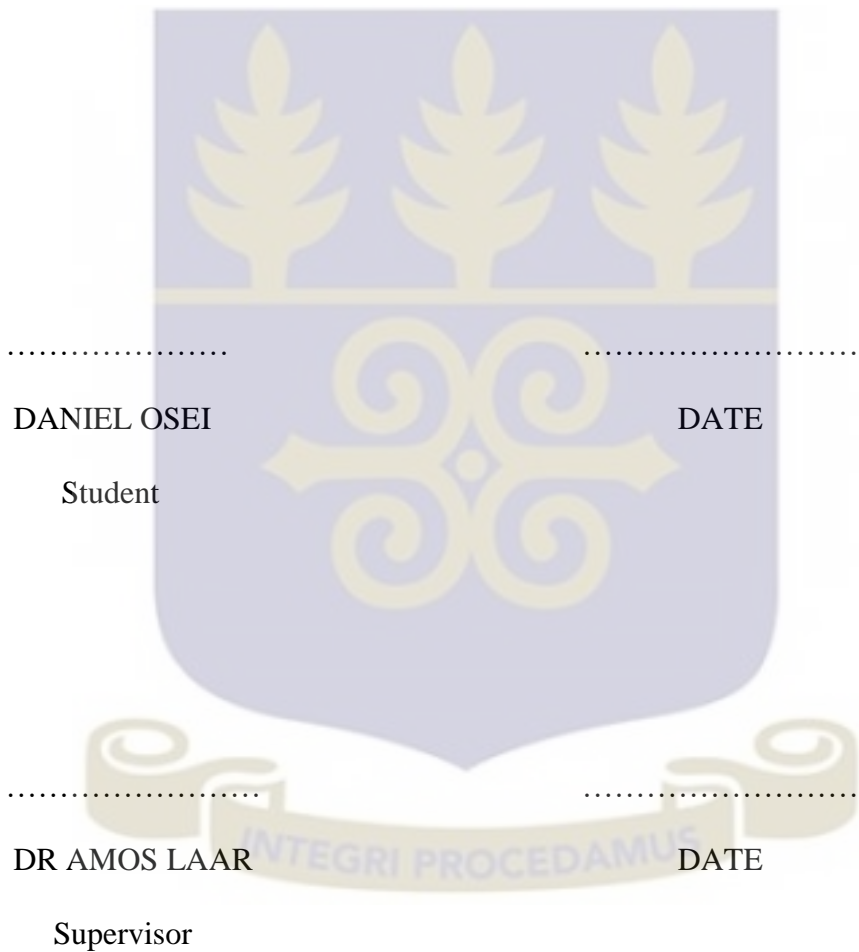
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**THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA,  
LEGON IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE  
AWARD OF MASTER OF PUBLIC HEALTH (MPH) DEGREE**

**JULY 2016**

## DECLARATION

I, DANIEL OSEI, the author of this dissertation, do hereby declare that, except for references to existing literature which have been duly acknowledged, this dissertation is the result of my original research, done under the supervision of my academic supervisor. I further declare that this work, either in part or in whole, has not been presented elsewhere for any other degree.



## **DEDICATION**

This work is dedicated to all HIV Care Workers in Ghana. You are doing a great job for Mother Ghana – bringing hope to the hopeless. Keep up the good work.

The work is also dedicated to all HIV positive pregnant women and mothers. An HIV-free generation is possible. Just believe!



## ACKNOWLEDGEMENT

My endless appreciation goes to the Almighty God, whose abundant grace has seen me to the successful completion of this work as a climax to the MPH course.

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## ABSTRACT

### Background

Infants who acquire HIV infection vertically experience rapid deterioration, usually leading to death. Early initiation of ART can reverse this trend. The WHO therefore recommends virological HIV testing in all exposed infants by six weeks, and if positive, promptly initiate ART. Despite the implementation of early infant testing in Ghana, coverage among eligible infants remains low and infants are tested late, resulting in erosion of possible benefits.

### Study Objectives

This study was therefore designed to assess the performance of EID, assess service providers' and caregivers' knowledge about EID, and document the challenges these stakeholders face in the implementation of EID in the Eastern region of Ghana.

### Methods

The study was a mixed methods research conducted at the Eastern Regional Hospital and St. Martin de Porres Hospital. A desk review of EID tests done in the facilities was conducted to determine the proportion of eligible infants who tested, age at testing and turn-around times for results delivery between 2013 and 2015. In-depth interviews were conducted with the stakeholders to assess their knowledge and find out the challenges they faced in the provision of EID services.

### Results

Only 27.6% of eligible infants were tested for EID. Median age of infants at the time of testing was 9.4 weeks and were over 7 months old before the results reached their EID sites. HIV positive infants would, therefore, have deteriorated before life-saving ART could be initiated. Service providers had adequate knowledge about EID but only laboratory technicians collected and processed DBS samples. Caregivers showed mixed levels of

knowledge about EID. Provider related barriers identified were delays in sample transportation, sample testing and result delivery; frequent breakdown of equipment and shortage of supplies; and high workload for few, poorly motivated staff. Caregiver related challenges were incorrect phone numbers and addresses; financial constraints; non-disclosure and denial of HIV status.



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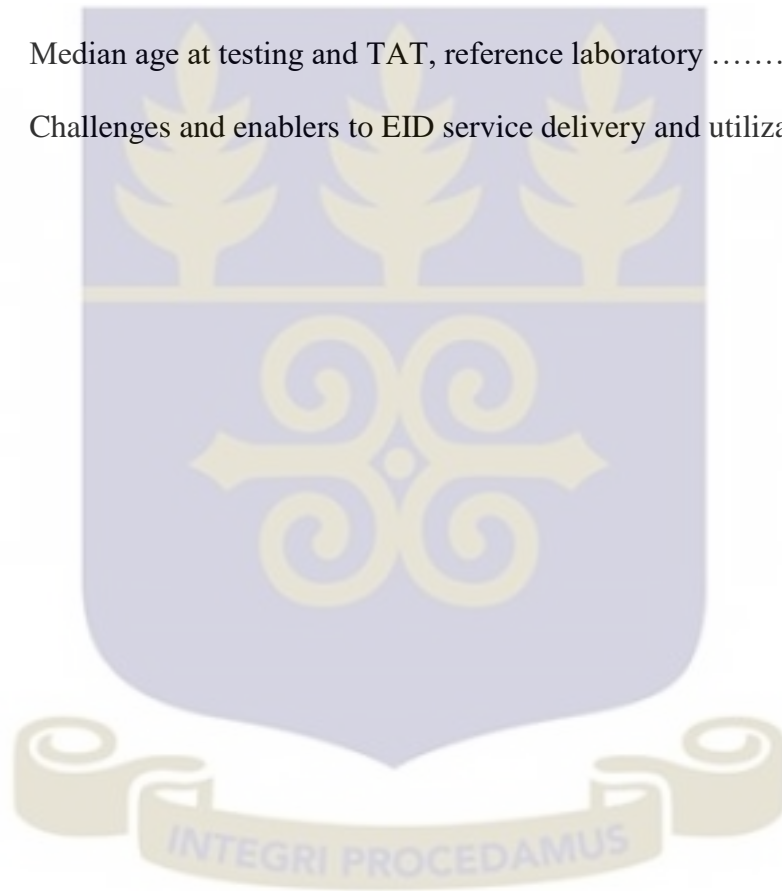
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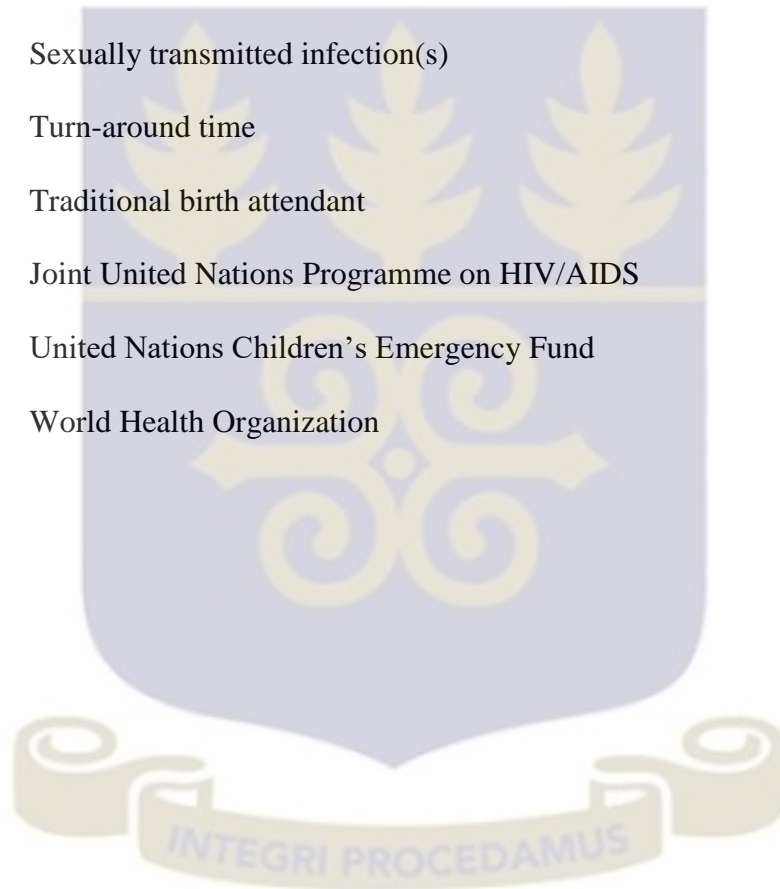
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## LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal clinic
ART	Antiretroviral therapy
ARV	Antiretroviral
BMS	Biomedical Scientist
CHER	Children with HIV Early Antiretroviral Therapy (Trial)
CHN	Community health nurse
CHPS	Community-based Health Planning and Services
CI	Confidence interval
DBS	Dried blood spot
DNA	Deoxyribonucleic acid
EID	Early infant diagnosis
EMTCT	Elimination of mother-to-child transmission
EPI	Expanded Programme on Immunization
GAC	Ghana AIDS Commission
GHS	Ghana Health Service
HIV	Human Immunodeficiency Virus
IDIs	In-depth interviews
IQR	Interquartile range
MCH	Maternal and child health
MO	Medical Officer
MOH	Ministry of Health
MTCT	Mother-to-child transmission
NACP	National AIDS/STI Control Programme

OPD	Out-patient department
PCR	Polymerase chain reaction
PA	Physician Assistant
PI	Principal Investigator
PMTCT	Prevention of mother-to-child transmission
PNC	Post-natal care
RNA	Ribonucleic acid
STI	Sexually transmitted infection(s)
TAT	Turn-around time
TBA	Traditional birth attendant
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organization



## DEFINITION OF TERMS

1. **Antiretroviral therapy:** The use of at least three antiretroviral drugs to maximally suppress HIV replication and stop disease progression in HIV infected persons.
2. **Caregiver:** An HIV positive mother or a person responsible for the upbringing of an HIV exposed infant
3. **Dried blood spot:** Blood specimens collected onto filter paper and air-dried. The spots are later reconstituted into liquid form before conducting the DNA PCR test.
4. **Early infant diagnosis:** The determination of the HIV status of an HIV-exposed infant, using recommended virological assays, preferably between 4-6 weeks of birth
5. **HIV-exposed infant:** Any infant born to an HIV positive mother or any infant whose mother's HIV status cannot be determined and has tested positive to an HIV serological test before attaining 18 months of age
6. **Sero-reversion:** The point in time when specific antibodies that were previously detectable in the blood of an individual are cleared from the blood such that those antibodies are no longer detectable
7. **Service Provider:** A healthcare personnel involved in the provision of EID services to clients
8. **Turn-around time:** The time it takes for a service to be delivered (i.e. when a request for the service is made and when the service is actually received)
9. **Vertical transmission of HIV:** The infection of a child with HIV that occurs before or in the process of delivery or through breastfeeding of the infant. The mother is the source of the infection.

## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 BACKGROUND

The Human Immunodeficiency Virus (HIV) has infected millions of people worldwide, especially in sub-Saharan Africa. In 2014, the number of people living with HIV worldwide was estimated at 36.9 million (UNAIDS, 2015). Two million people were estimated to have been newly infected with HIV in 2014. Sub-Saharan Africa alone accounted for 66% of all the new infections in 2014. The number of new infections that occurred in children in 2014 was estimated at 220,000 (UNAIDS, 2015). About ninety percent of the infections in children are acquired in the pre-partum period, during labour and breastfeeding (WHO, 2010). Such infections are termed mother-to-child transmission (MTCT) of HIV, sometimes also referred to as vertical transmission of HIV.

For infants who acquire HIV vertically before or during labour, the disease progresses very rapidly in the first few months of life and in most cases, this rapid disease progression leads to infant mortality (Bourne et al., 2009). Early initiation of anti-retroviral therapy (ART) in these children has been sufficiently shown to halt and reverse this trend (Goetghebuer et al., 2009; Tukei et al., 2013; Violari et al., 2008). A test to confirm the HIV status of these infants is a necessary prerequisite for the timely initiation of life-saving ART (WHO, 2010).

Early infant diagnosis (EID) involves the virological determination of the HIV status of HIV-exposed infants at 4-6 weeks of age or at the earliest possible opportunity thereafter. In infants that undergo virological testing, World Health Organization (WHO) recommends that, an HIV deoxyribonucleic acid (DNA) assay be conducted on whole blood or dried blood spot (DBS). Alternatively, an HIV (ribonucleic acid) RNA assay be conducted on plasma or DBS, or ultra-sensitive p24 antigen on plasma or DBS (WHO, 2010).

EID can also be used as an effective tool for the routine evaluation of prevention of mother-to-child transmission (PMTCT) programmes in resource-limited settings, especially in sub-Saharan Africa (Temgoua et al., 2015). EID results of infants are compared with various PMTCT interventions employed by their mothers to assess effectiveness of the interventions.

Though Ghana published its guidelines and protocol on EID in 2009 (GHS, WHO, NACP, & UNICEF, 2009) and has been implementing the programme since then, available data suggest that less than 25% of infants expected to test are actually tested (GHS, 2015).

This study, therefore, sought to assess the performance of EID and document the knowledge of service providers and caregivers of HIV-exposed infants in EID. The study also explored challenges on the part of service providers and caregivers that hinder the smooth implementation of the EID programme. Recommendations have been made towards improvements in the delivery and utilization of this service by all stakeholders.

## **1.2 STATEMENT OF THE PROBLEM**

Millions of people all over the world are infected with or affected by HIV, the virus that causes acquired immune deficiency syndrome (AIDS) (UNAIDS, 2015). New HIV infections in children have been at its highest levels in sub-Saharan Africa. Out of a global estimate of 220,000 new infections in children in 2014, about 190,000 (86%) occurred in sub-Saharan Africa (UNAIDS, 2015).

The situation is not much different in Ghana, where 7,812 new infections were estimated to have occurred in 2013. Out of this number, over thirty percent (2,248) occurred in children between the ages of 0 and 14. Eighty percent of the new infections in children occurred in infants below 12 months (NACP & GHS, 2014), giving a strong indication of mother-to-

child transmission. An earlier WHO estimate put the proportion of new infections in children occurring as a result of MTCT at ninety percent, with almost eighty percent occurring in the antenatal period and/or during labour (WHO, 2010).

The course of disease progression in infants who acquire HIV through vertical transmission is rapid in the early months of the infant's life, often leading to death (Bourne et al., 2009). In order to prevent these outcomes, early initiation of anti-retroviral therapy in these infants has been strongly recommended since it has been shown to improve morbidity and reduce mortality (Goetghebuer et al., 2009; Tukei et al., 2013; Violari et al., 2008).

On the basis of these and other findings, the WHO made recommendation on early confirmation of HIV status of HIV-exposed infants and prompt initiation of ART in those who are found to be infected (WHO, 2010). Despite the implementation of these recommendations in member countries, the WHO reports that, "among reporting countries in 2012, only one-third of infants born to HIV-infected mothers received a virological HIV test within the first two months of life" (WHO, 2015, p. 3).

In Ghana, available data suggest low coverage of EID services in HIV-exposed infants in the country. In 2014, DNA polymerase chain reaction (PCR) tests were conducted for only 24% of infants born to HIV positive mothers. Half of this number tested at six weeks of age (GHS, 2015). In the Eastern region, where prevalence of HIV among antenatal clinic (ANC) clients is highest in the country (NACP & GHS, 2015), the situation is even worse. Eighteen percent of exposed infants received a DNA PCR test, with only ten percent testing at six weeks (GHS, 2015).

In spite of the low coverage of such a critical service as EID in the country, review of literature did not reveal any published study in Ghana which documented EID coverage levels and explored the barriers to delivery and utilization of the service. Laar, Amankwa,

& Asiedu (2014) reported on challenges faced by clients and providers of PMTCT in four hospitals in Accra, with some focus on infant feeding practises. They did not, however, research into EID. In the absence of such scientific literature in Ghana, it was difficult for policy makers and managers of HIV care programmes to appreciate the challenges associated with the implementation of EID services in the country. The documentation of such challenges was required to inform policy and corrective measures that should be implemented in order to improve performance of EID and early initiation of ART in HIV positive infants.

This study set out to review service data on EID coverage and explore the challenges faced by clients and providers of EID services. Recommendations have been made towards an improvement in the delivery of this vital service to HIV-exposed infants and their caregivers.

### 1.3 CONCEPTUAL FRAMEWORK

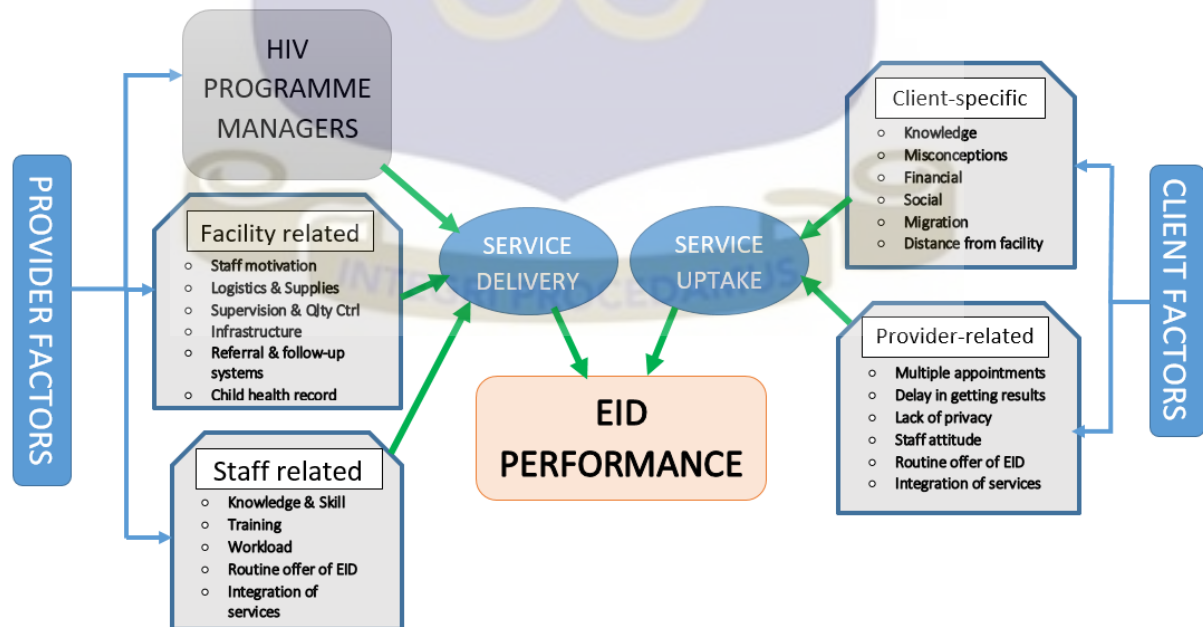


Fig 1.1 Conceptual framework of stakeholders' challenges in implementing EID in Ghana

Source: Conceived by author after reviewing literature on the subject.

Two broad sets of challenges influence performance of EID; provider factors and client factors. The provider factors include programme level issues, health facility related challenges and staff related challenges. The client factors are client-specific and provider-related challenges

The adequacy of infrastructure and equipment affects the ability of the health facilities to deliver services to the satisfaction of clients. The availability of CD4 and PCR machines, as well as laboratories and counselling rooms that will offer adequate privacy to clients, improve service delivery (Cherutich, Inwani, Nduati, & Mbori-Ngacha, 2008; Creek et al., 2007). Frequent shortage of essential supplies have been widely reported to affect the ability of facilities to deliver EID and other services to clients (Chatterjee et al., 2011; Hassan et al., 2012; Laar et al., 2014; Penazzato et al., 2014). Other logistical issues such as availability of robust mechanisms for transporting samples have also affected service delivery (Cherutich et al., 2008; Creek et al., 2007).

It has been documented that regular supervision of sites and personnel in addition to quality control of testing processes ensure high standards of services for clients (Creek et al., 2007; Dube et al., 2012; Penazzato et al., 2014). Such supervision have also ensured rational use and proper stock management of usually scarce supplies (Cherutich et al., 2008; Ciaranello et al., 2011; Hanna, Siromany, Annamalai, Karunaianantham, & Swaminathan, 2015).

Motivation of staff providing EID services, mostly as an additional duty to their usual roles, has been reported to improve service delivery (Finocchiaro-Kessler et al., 2015; Laar et al., 2014). Many EID staff have reported increased workload as a barrier to delivery of services (Laar et al., 2014). Adequate follow up systems that identify HIV-exposed infants and refer them for testing have improved EID coverage (Cherutich et al., 2008; Dube et al., 2012). Additionally, routine offer of provider-initiated testing and counselling services has been

lacking in many settings (Asafo-Agyei, Antwi, & Nguah, 2013; Penazzato et al., 2014; WHO, 2010).

Knowledge of staff on EID and PMTCT has been reported to be inadequate in some studies (Hassan et al., 2012; Laar et al., 2014). Such inadequate levels of staff knowledge have been attributed to lack of training opportunities and absence of or non-adherence to local and international guidelines concerning these services (Cherutich et al., 2008; Creek et al., 2007; Laar et al., 2014).

Utilization of services are influenced by client-specific factors and provider-related factors. Knowledge of mothers about EID has been reported to be inadequate. Mothers exhibited gross misconceptions about vertical transmission of HIV and the need to conduct early tests for their infants (Adeniyi, Thomson, Goon, & Ajayi, 2015; Dube et al., 2012; Hassan et al., 2012). Some mothers have missed EID for their infants as a result of their own social and emotional challenges. Denial, stigma and fear of disclosure have prevented some of these mothers from utilizing the service, even when it is available (Hassan et al., 2012).

Financial challenges have prevented some clients from accessing vital services for their infants. Transportation has been reported as a major cost to many mothers (Hassan et al., 2012; Laar et al., 2014; Penazzato et al., 2014). Some infants have missed their EID tests because their mothers have migrated to other communities to seek greener pastures during the farming season. Decentralization of services has been suggested as a means of overcoming this financial challenge (Chatterjee et al., 2011; Hassan et al., 2012).

Mothers in some settings have been given multiple appointments to receive ART/PMTCT, postnatal care (PNC), maternal and child health (MCH), expanded programme on immunizations (EPI) and EID services at different times, and sometimes, at different service sites. This has resulted in low utilization of some of these services (Chatterjee et al., 2011;

Cherutich et al., 2008; Hassan et al., 2012). Integration of these services have been proposed as a means of improving access of services to clients.

Some clients have used lack of privacy as a reason for not seeking certain services in health facilities (Laar et al., 2014). Others have implicated the delays in the delivery of results and improper attitude of staff towards them as reasons why they have shunned certain essential services of health facilities (Creek et al., 2007; Dube et al., 2012; Hassan et al., 2012).

These provider and client factors influence EID service delivery and utilization respectively. Service delivery and utilization directly affects performance of EID services.

#### **1.4 JUSTIFICATION OF THE STUDY**

The introduction of EID of HIV in Ghana has brought with it a unique lifeline to infants who get infected with the virus before or during delivery. In Ghana, the HIV status of these infants can be determined as early as six weeks after delivery. Once HIV infection is confirmed through DNA PCR testing, life-saving ART can then be initiated in these infants.

However, a large proportion of these infants are inadvertently denied the opportunity to be enrolled into clinical HIV care due to the low coverage of EID services in the country (GHS, 2015). This study, which sought to give voice to the various stakeholders in the implementation of EID in Ghana, was a necessary step in documenting the barriers to adequate coverage of the service. The study has also served as a scientific basis for the recommendations that have been made towards the improvement of the delivery and utilization of EID services throughout the country.

The Eastern Regional Hospital, Koforidua and the St. Martin de Porres Hospital, Agormanya, were chosen for the study because of the high ANC prevalence of HIV at these sites (NACP & GHS, 2015). The high number of HIV positive mothers at these facilities

allowed for wide variation among potential participants and brought out different perspectives from the mothers.

## **1.5 OBJECTIVES OF THE STUDY**

### **1.5.1 General Objective**

The objective of this study was to document stakeholders' knowledge and challenges associated with the implementation of EID of HIV in the Eastern region of Ghana.

### **1.5.2 Specific Objectives**

1. To assess the performance of EID in the Eastern region of Ghana
2. To assess knowledge and skills of service providers about EID of HIV
3. To explore provider related factors that affect the delivery and utilization of EID services in the region
4. To assess awareness and knowledge of HIV-positive mothers about EID of HIV
5. To explore caregiver related factors in relation to the utilization of EID services in the region

## **1.6 RESEARCH QUESTIONS**

The following research questions were asked in order to achieve the study objectives above:

1. What is the performance of EID in the Eastern region of Ghana?
2. What knowledge and skills do service providers have about EID of HIV?
3. What provider related factors affect the delivery and utilization of EID services in the region?
4. What knowledge do HIV-positive mothers have about EID of HIV?
5. What are caregiver related factors influence the utilization of EID services in the region?

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

This review of literature was conducted by searching for words and phrases such as “early infant diagnosis”, “infants”, “EID”, “HIV”, “challenges”, “barriers”, “facilitators”, “disease progression”, “implementation” and “Ghana” from the search engines PubMed, ScienceDirect, Google Scholar and Google. The Boolean operators “AND” and “OR” were used to broaden or restrict the search. References cited in retrieved articles were also followed up and used where they were found relevant. National and international guidelines were also consulted.

### 2.1 DISEASE PROGRESSION IN HIV INFECTED INFANTS

Infants who acquire HIV vertically before or around the time of delivery experience rapid disease progression. In many instances, this rapid disease progression leads to death (WHO, 2010).

In a pooled analysis of individual data from seven randomized MTCT intervention clinical trials conducted in sub-Saharan Africa (Newell et al., 2004), it was established that mortality was significantly higher in infected children of HIV positive mothers than uninfected children. By twelve months of age, mortality rates in infected and uninfected children were 35.2% and 4.9% respectively. By the time the children reached two years of age, death rates had risen to 52.5% for infected children and 7.6% in uninfected children. These results and conclusions were reached after 45805 child months of follow-up that started with 3468 children born to HIV positive mothers (Newell et al., 2004).

The results above were later confirmed in a South African study (Bourne et al., 2009) that reviewed data on causes of post-neonatal deaths among children under five years of age

over a five-year period. The analysis showed an early peak of deaths between 2–3 months of age for HIV-related causes. There was no such peak seen with causes that were not HIV related. The study concluded that there was a peak in early infant mortality for HIV positive infants between 2–3 months that was caused by HIV/AIDS (Bourne et al., 2009).

Another study conducted at the Korle Bu Teaching Hospital in Ghana (Kwara, Shah, & Renner, 2010) reviewed outcomes of hospital admissions in HIV-infected children. The study found pneumonia, gastro-enteritis, tuberculosis, malnutrition and malaria as major causes of admission. About 13% of the 76 children that were included in the study died on admission, while 50% of the children stayed longer than seven days on admission (Kwara et al., 2010).

In a systematic review of 21 studies conducted across the globe, Sherr, Croome, Castaneda, Bradshaw, & Romero (2014) assessed the developmental challenges in HIV infected children with a focus on cognitive development. The studies reviewed employed different tools for the measurement of cognitive development, namely the Bayley Scales of Infant Development, the Snijders–Oomen Nonverbal Intelligence Test, the Wide Range Achievement Test, the Wechsler Scales, the Child Behaviour Checklist, the Griffiths Scales and Rossetti Infant–Toddler Language Scale. Other functioning tests and neurological examinations as well as anthropometric measures were also employed to arrive at conclusions (Sherr et al., 2014). Over 80% of the studies reviewed showed that “HIV was associated with some form of detrimental effect on cognitive development, across a wide range of different measures”. The developmental issues measured were language, cognitive and executive functioning, global (mental and motor) development and behavioural challenges (Sherr et al., 2014)

## **2.2 EFFECT OF EARLY ART ON PROGRESSION OF HIV IN INFANTS**

It has been shown in many studies that the trend of rapid disease progression described above can be halted, and in most instances, reversed with early initiation of ART.

The children with HIV early antiretroviral therapy (CHER) study (Violari et al., 2008) was a randomized open-label trial conducted at two centres in South Africa. Six to twelve-week old HIV positive infants were randomly assigned to receive early ART or deferred until they qualified under existing WHO guidelines for ART initiation. The infants were assessed at regular intervals for HIV-related clinical events, adherence, toxicity, immune response (CD4 count and CD4 percent), full blood counts and liver function. It was concluded that infant mortality and disease progression were reduced by 76% and 75% respectively with early HIV diagnosis and ART (Violari et al., 2008).

In another study involving 210 HIV positive children drawn from eleven European countries (Goetghebuer et al., 2009), risk of developing AIDS or death was evaluated by whether the infant started ART early (before three months of age) or later. It was found that, at twelve months of age, the risk of AIDS/death was 1.6% for early starters and 11.7% for late starters. At age five, the risks were 4.6% and 21.5% respectively. These results led to the conclusion that in vertically infected infants, early initiation of ART is associated with significant decrease in progression to AIDS and/or death (Goetghebuer et al., 2009).

In a prospective cohort study conducted in Uganda (Tukei et al., 2013), 84 HIV infected infants were started on ART and 78 out of the number completed six months of therapy. After the six months, 71.8% of the infants achieved virologic suppression, with the cumulative probability of achieving virologic suppression after twelve months of therapy being 83.1%. Immunologic assays showed a significant increase in mean CD4 percent from

baseline of 23% to 30% after six months of treatment. This further increased to a mean of 36% after twelve months of treatment (Tukey et al., 2013)

A secondary data analysis of anthropometric variations in HIV positive children in South Africa who were started on ART at different ages revealed benefits of early initiation of ART (Shiau et al., 2013). Weight, height and head circumference were measured over 48 months of therapy for children who started ART below six months, between six to twelve months, and between 12 to 24 months of age. After 12 months of therapy, children who were initiated on ART below 6 months achieved more rapid improvements in weight, height and head circumference for age scores than those that were started on ART at older ages. Shiau et al. (2013) thus concluded that, “initiation of ART before 6 months of age results in more rapid growth recovery in children infected with HIV” (p. 1138).

In the systematic review by Sherr et al. (2014) on the developmental challenges in HIV infected children, a few of the studies reviewed looked at the effect of ART on cognitive outcome. Higher CD4 counts at the time of ART initiation and duration of treatment were found to be associated with improved attention control and memory function.

### **2.3 WHY ANTIBODY TESTING IS INAPPROPRIATE FOR INFANTS**

In adults and older children, HIV is diagnosed with inexpensive HIV antibody tests which are readily available, even in resource-limited settings. The antibody tests are possible because, antibodies against HIV are present in essentially all of such persons living with HIV infection (Read, 2007). In younger children, however, these antibody tests are ineffective due to the presence of passively transferred maternal HIV antibodies in infants’ blood (Penazzato et al., 2014; Read, 2007). These maternal antibodies, which are indistinguishable from infants own antibodies produced in response to the presence of HIV

infection, persist in the blood of HIV exposed infants for up to 18 months and, in some instances, longer (Gutierrez et al., 2012; Penazzato et al., 2014). A positive HIV antibody test in an infant, therefore, can only be useful in determining the HIV exposure status of an infant for whom the mother's HIV status is unknown (Read, 2007).

In a cohort study conducted to assess the effects of ART on sero-reversion of HIV exposed but uninfected infants in the United States, Gutierrez et al. (2012) found that, with the advent of ART for HIV positive pregnant women, the median time for sero-reversion of such infants had increased from 9.4, 10.3 and 10.9 months in the pre-ART era to 13.9 months. Fourteen percent of these infants had still not sero-reverted after 18 months while 4.3% sero-reverted after 21 months. These results imply that, for antibody testing to be useful in confirming HIV infection in a child, clinicians would need to wait till the child reaches, at least, 18 months of age (Gutierrez et al., 2012).

Virological assays have, therefore, become the gold standard for early diagnosis of HIV infection in exposed infants since they detect viral nucleic acids (Penazzato et al., 2014; WHO, 2010, 2015). An evaluation of virologic methods for early detection of HIV in Cameroon – a low middle income country – found that the test performance of the HIV p24 antigen ELISA by Perkin Elmer, Roche Amplicor HIV DNA PCR and the Abbott Realtime HIV assay was 100% in correctly identifying positive cases (Torimiro et al., 2013).

## **2.4 GUIDELINES ON THE DIAGNOSIS OF HIV IN INFANTS**

### **2.4.1 WHO Recommendations**

On the bases of the above and other findings involving HIV infected infants, the WHO Recommendations on the Diagnosis of HIV Infection in Infants and Children was published in 2010 (WHO, 2010). The document contains thirteen (13) key recommendations as well

as information on laboratory methods for diagnosing HIV in infants and children. The recommendations include, but not limited to, the following:

- HIV virological testing should be used to diagnose HIV infection in infants and children below 18 months of age.
- In infants and children undergoing virological testing, the following assays and respective specimen types are recommended for use: HIV DNA on whole blood or DBS; HIV RNA on plasma or DBS; ultrasensitive p24 antigen on plasma or DBS.
- All HIV-exposed infants should have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter.
- In infants with an initial positive virological test result, it is recommended that ART be started without delay and, at the same time, a second specimen be collected to confirm the initial positive virological test result. ART should not be delayed while waiting for the results of the confirmatory test since immediate initiation of ART saves lives.
- Test results from virological testing in infants should be returned to the clinic and caregiver as soon as possible, but at the very latest within four weeks of specimen collection. Positive test results should be fast-tracked to the mother-baby pair as soon as possible to enable prompt initiation of ART.
- All infants with unknown or uncertain HIV exposure status, being seen in health facilities at or around birth or at the first postnatal visit or other child health visit, should have their HIV exposure status ascertained.
- Infants with signs or symptoms suggestive of HIV infection should undergo HIV serological testing and, if positive (reactive), virological testing.
- In breastfeeding infants or children, it is recommended that breastfeeding is not discontinued in order to perform any kind of diagnostic HIV test.

- In sick infants in whom HIV infection is being considered as an underlying cause of symptoms and signs, and virological testing is not available, HIV serological testing and use of the clinical algorithm for presumptive clinical diagnosis of HIV infection is recommended.

#### **2.4.2 National Guidelines in Ghana**

In Ghana, guidelines and protocol for early infant HIV diagnosis have been published to regulate implementation of the EID program since 2009 (GHS et al., 2009). The guidelines have been re-emphasized in a more recent publication of National Guidelines for PMTCT of HIV (Ministry of Health Ghana, 2014). The guidelines recommend that, HIV exposed infants undergo early infant diagnosis during the six week PNC visit. For infants who miss this opportunity, testing should be done at the next available opportunity. HIV viral assays (DNA PCR) are conducted on DBS samples collected from the infants. A positive virologic test result at six weeks or older confirms the presence of HIV infection in the infant. A negative PCR test result for non-breastfeeding infants confirms the absence of HIV infection. For a breastfeeding infant, however, an initial negative test must be repeated six weeks after complete cessation of breastfeeding in order to confirm that the child is uninfected (GHS et al., 2009; Ministry of Health Ghana, 2014).

### **2.5 PERFORMANCE OF EID**

#### **2.5.1 Number of Exposed Infants Testing**

Despite the WHO recommendation and its implementation in India in 2010, Hanna, Siromany, Annamalai, Karunaianantham, & Swaminathan (2015) have reported that less than 20% of infants who are eligible for EID in India actually tested. A similar assessment done in Burkina Faso found only 29.4% of HIV exposed infants undergoing a virologic test

on a DBS (Coulibaly et al., 2014). The story was not much different in Uganda where only 30% of HIV-exposed infants were signed up for EID services (Mugasha et al., 2014). In Mozambique, 25% of 443 HIV positive mothers who were receiving care in the PMTCT programme brought their infants to be tested under the EID programme (Cook et al., 2012). The WHO reports that, in spite of the continuous expansion of EID programmes in most member countries, only about 44% of HIV-exposed infants received a virological test in the countries that reported these data in 2013” (WHO, 2014).

There was, however, a departure from this trend in Tanzania. A study conducted in three regions in that country showed that 88.3% of all HIV-exposed infants were tested for HIV between 2009 and 2011 (Chiduo et al., 2013). The proportion increased from 77.2% in 2009 to 97.8% in 2011. A review of the EID programme established in two primary care facilities in Malawi also revealed that, out of 1214 HIV positive women followed up between January 2008 and June 2010, 869 (71.6%) of the women tested their infants for EID (Dube et al., 2012). Forty-nine out of the fifty women who visited the facility after six weeks of delivery but refused infant testing indicated that they needed their spouses’ permission before doing the tests.

### **2.5.2 Age at Testing and Results Turn-Around Time**

Many infants who benefit from the tests are tested much later than the recommended age at testing. This situation, coupled with the long turn-around time (TAT) time for results of the tests to become available, puts infants with positive results at a disadvantage. In a study involving desk review of data in four countries, less than half of all tested infants had their tests conducted before they reached two months of age. TAT for availability of results ranged from an average of 10.4 days in Namibia to 36 days in Uganda (Chatterjee et al., 2011). The median age of a first EID test in Mozambique was 5 months. With a median

TAT of 12.6 weeks for results delivery, infants would be about nine months old before their status are known and a decision made on the need for initiation of ART (Cook et al., 2012). A similar situation has been reported in India, where median age at sampling was four months. In this setting where confirmatory results were carried out for initial positive test, the median age at second sampling for such infants was seven months and median TAT for results delivery was reported at 46 days (Hanna et al., 2015). Infants would, therefore, be above 8 months by the time results are delivered to them.

In a chart review of EID testing services at the Macha HIV clinic in rural Zambia, the median age at first testing for exposed infants was 8.1 weeks (Sutcliffe, Dijk, Hamangaba, Mayani, & Moss, 2014). The median TAT between sample collection and its arrival at the central laboratory in Lusaka for testing was 17 days. Upon arrival at the laboratory, it took a median of 6 days for the tests on the samples to be run and a further 29 days after the tests had been run for the results to arrive at the Macha clinic. The median TAT between arrival of the results at the clinic and its delivery to the caregiver was 45 days. Overall, the median time it took from sample collection to the delivery of results to the caregiver was about 3 months (Sutcliffe et al., 2014).

However, success stories have been reported elsewhere in sub-Saharan Africa. A study assessing the successes and challenges of EID of HIV in three regions in Tanzania reported the median age of infants at first EID testing between 5.6 weeks in Kilimanjaro region to 8.6 weeks in Mbeya region (Chiduo et al., 2013). TAT for delivery of results were 2.7 weeks in Mbeya region, 5.0 weeks in Tango region and 7.0 weeks in Kilimanjaro region. Overall, HIV status of infants in these regions were determined by the time they reached three months of age.

### **2.5.3 Number Receiving Results**

Among the infants who are tested early for HIV, loss to follow-up rates at the point of receiving results were very high. The trends were even more worrying for infants with positive test results who required prompt initiation of ART. Many mothers did not return for results and facilities did not have adequate mechanisms to trace such infants and their mothers to deliver results and enrol them into care (Chatterjee et al., 2011). In Kenya, it was reported that, because there was no results delivery mechanism in place, mothers could only receive results of such tests at their next appointment date, which could be months away (Cherutich et al., 2008). In Malawi, out of 869 mothers who conducted early infant HIV testing for their babies, only 60% returned to the testing sites to receive their results (Dube et al., 2012).

There was, however, an exceptionally high rate of results delivery in Burkina Faso where 97.8% of tested infants received their results through their caregivers (Coulibaly et al., 2014). Similarly high rates were reported in Tanzania where mothers who returned for the test results of their infants ranged from 91% to 99% (Chiduo et al., 2013). Seidenberg et al. (2012) recommends the use of technology such as mobile texting to deliver quickly results.

## **2.6 AWARENESS AND KNOWLEDGE ABOUT EID**

### **2.6.1 HIV Positive Mothers' Awareness/Knowledge about EID**

Many HIV positive mothers have very little or no knowledge about EID of HIV for their exposed infants. They are mostly unaware of the need to test their infants early and the benefits that come with early testing (Hassan et al., 2012). This low level awareness of HIV care services in the community could explain the rejection or low utilization of EID services by many HIV positive mothers. The low level of awareness has also been linked to the level of education in Burkina Faso, where in 2008/2009, only 20.1% of the population had

attended secondary school (Coulibaly et al., 2014). Some mothers and caregivers of HIV-exposed infants in Kenya exhibited very low knowledge of MTCT of HIV and the need for EID. Many caregivers had not heard of EID until their infants were enrolled. For the few of such mothers who had some knowledge, they did not know the types of tests available and the timelines for the various tests to be done (Hassan et al., 2012).

It is therefore necessary for dedicated healthcare staff to educate HIV positive pregnant women especially during the third trimester and during postnatal care on the benefits of PMTCT and EID services. Mugasha et al. (2014) recommended this as an “essential component of the ANC counselling package” (p. 14). Coulibaly et al. (2014) further recommended that male partners of these HIV positive pregnant women and mothers should also be targeted and involved in the education and counselling, since they can offer immense support and encouragement to their partners to fully utilize PMTCT and EID services.

### **2.6.2 Service Providers Knowledge and Practice of EID**

Knowledge of service providers on EID in some settings have been shown to be inadequate (Hassan et al., 2012). A study in Kenya which explored health workers’ knowledge, attitudes and perceptions of the EID process found that some service providers were not sure of the number and type of tests to be conducted in the EID continuum and their timelines. Other providers who knew these information did not know the rationale for the various tests. EID content in PMTCT training programmes were reported by providers as inadequate (Hassan et al., 2012).

A study by Laar et al. (2014) on PMTCT in Ghana reported that nurses and midwives did not have adequate knowledge on infant feeding in the context of HIV, though they were expected to counsel clients on the subject. Opportunities to update their knowledge were absent and in-service training was reported to be largely inadequate (Laar et al., 2014).

Service providers in some testing sites did not know the contents of local guidelines and algorithms on EID and provided EID services without adhering to these guidelines (Adetokunboh & Oluwasanu, 2015). An assessment of 58 facilities in Kenya did not find any copies of national guidelines for HIV testing in the facilities. None of the facilities had any local facility-based policy guidelines or algorithms on HIV counselling and testing of infants and children either (Cherutich et al., 2008).

## **2.7 CHALLENGES IN IMPLEMENTATION OF EID**

### **2.7.1 Geographical Access / Decentralization**

Geographical access to the site of EID service provision has been reported widely as a barrier to adequate utilization of the service by many HIV positive mothers, especially those in rural settings. In many places, the service is not available at the local clinics and the mothers are required to travel from their villages to provincial or district capitals in order to access the service (Cherutich et al., 2008). As a means of improving accessibility of EID to mothers, many countries have subsequently decentralized the service (Chatterjee et al., 2011). This has either taken the form of geographical decentralization or re-organization of the health system to allow DBS samples to be taken and transported to central testing sites. Client referral is thus substituted with sample referral (Adetokunboh & Oluwasanu, 2015; Coulibaly et al., 2014). The integration of point-of-care EID technologies into the health systems of countries will help overcome the challenge of geographical access to services (Bailey, 2015; Urick, 2015)

### **2.7.2 Multiple Appointments for Different Services**

In some settings, HIV positive mothers are referred back and forth between two or more facilities to receive various maternal and child health (MCH) services (Coulibaly et al.,

2014). Even where all the services are delivered at the same site, mothers are required to visit the facility at different times to receive various services including maternal ART, infant ARV prophylaxis, Expanded Programme on Immunizations (EPI) and EID (Chatterjee et al., 2011). The provision of these services at different times and sometimes at different service points hindered linkage of mother-baby pairs to EID services. In many cases, mothers did not attend the various services because of the additional stress and financial implications of such arrangements. Many studies in Africa have thus recommended the integration of EID into routine family planning, PMTCT, MCH, PNC and EPI services. Such integration will ride on the back of childhood first vaccination – which has seen high coverage rates in many countries – to improve EID coverage among eligible infants (Chatterjee et al., 2011; Hassan et al., 2012; Mugasha et al., 2014).

### **2.7.3 Financial Access**

No direct financial charges have been reported to be associated with the delivery of EID services in all the studies reviewed. However, mothers had to bear certain indirect costs in their bid to access the service for their infants. These costs include transportation (especially for multiple appointments and inter-facility referrals) and long waiting times. Long waiting times at the facility can be greatly improved with integration of services, as discussed above (Coulibaly et al., 2014; Hassan et al., 2012; Mugasha et al., 2014). In instances where certain tests are referred to other facilities because of their unavailability at the primary facility, the costs of such tests have deterred some mothers from further seeking any other services (Chatterjee et al., 2011).

Another indirect source of financial challenges comes to the fore when mothers migrate to other places during the farming season for greener pastures. Such migration eventually results in attrition of mother-baby pairs from the EID care programmes (Hassan et al., 2012).

#### **2.7.4 Privacy and Confidentiality**

In Kenya, all laboratory samples referred for testing had client identification tags on the tubes. These tags contained clients' personal information such as name and hospital record number. Such a system increased the chances of unintentional disclosure of clients HIV status to others within the facility (Cherutich et al., 2008). Such limitations to privacy and confidentiality affected linkage to other HIV care services in urban settings in Uganda (Mugasha et al., 2014). In Malawi, the limited privacy in the clinics made it impossible to integrate EID services into EPI clinics as has been recommended by other studies (Dube et al., 2012).

In their study in Ouagadougou hospitals, however, Coulibaly et al. (2014) found that all six district hospitals and two university hospitals that were assessed conformed to the WHO standards on the protection of the privacy of patient test results. In the United States, state and federal laws and regulations regarding HIV testing require “the protection of the privacy of health information” (Read, 2007, p. 1548). The strict adherence to such regulations will improve confidentiality and encourage clients to access services.

#### **2.7.5 Human Resource**

Insufficient number of adequately trained health service staff who are dedicated to the provision of HIV services is a major challenge in many African countries. An assessment of staff in health facilities providing paediatric HIV care in Ouagadougou concluded that number of medical and pharmacy staff were inadequate as compared to WHO standards (Coulibaly et al., 2014). Although the number of nurses was generally adequate, most of them could not collect DBS samples and sample collection was limited to one day in a month. This situation led to high attrition rates of mother-baby pairs from HIV care (Coulibaly et al., 2014). A similar situation has also been reported in Kenya where

laboratory staff numbers were inadequate to combine HIV care duties with other routine tasks. Staff trained in DBS collection were scarce. (Cherutich et al., 2008)

### **2.7.6 Test Supplies and Equipment**

Frequent shortages of laboratory reagents and other supplies for EID testing was a major challenge reported in Burkina Faso and Kenya (Cherutich et al., 2008; Coulibaly et al., 2014). While the cost of such reagents has been cited as a reason for these shortages (Ciaranello et al., 2011; Penazzato et al., 2014), improper stock management and non-adherence to good laboratory practice (Chatterjee et al., 2011) were also found to be major contributing factors. In both countries, as well as in Zimbabwe, a lack of preventive maintenance of the equipment was noted in all health facilities (Cherutich et al., 2008; Coulibaly et al., 2014).

### **2.7.7 Referral for Testing**

Two models of EID service delivery were observed in four countries whose national programmes were analysed by Chatterjee et al. (2011). One model involved the collection of DBS samples at the site's laboratory after exposed infant had been identified and referred from other services within the facility. The other model involved the collection of samples by trained nurses at all service points where exposed infants were identified. Both modules, however, came with peculiar challenges including post-test counselling, exposed infant follow up, delivery of results to service providers and mothers, and the requirement for significant site organization for consumables and registers (Chatterjee et al., 2011).

Within rural sites in Uganda, multi-parous mothers who presented with the third pregnancy were significantly more likely to be linked to EID services after six weeks of delivery. No such difference was seen in urban settings (Mugasha et al., 2014).

In a study assessing 58 facilities in Kenya for their performance in EID service delivery, only six facilities had functional referral and follow-up systems that linked HIV-exposed infants to EID services (Cherutich et al., 2008). None of the facilities had any record that identified HIV exposure status of infants visiting the clinic for other services. Although mothers' ANC cards contained such information, it was rarely transferred to infants record book which would aid easy identification of exposure status and hence referral for testing. Staff at PNC did not make any attempts to ask or check for mothers' HIV status. Systems for transporting samples to central sites for testing were virtually non-existent.

Cherutich et al. (2008) recommended the development of a standard system for identification and follow up of HIV exposed infants. The use of a child welfare card that has HIV exposed information would be a step to facilitate referral of exposed infants to care (Cherutich et al., 2008; Woldesenbet et al., 2015). (Woldesenbet et al., 2015) also recommends the use of electronic medical records to provide PNC nurses access to information on exposed infants.

### **2.7.8 Referral to Care and Treatment**

Analysis of EID programmes in four countries revealed that many facilities did not have adequate referral mechanisms for infants who tested positive into clinical care and subsequent initiation of ART. The referral rates ranged from 22% in Senegal, 37% in Uganda and 38% in Cambodia. These low referral rates and high attrition between testing positive and enrolment on ART occurred despite the location of testing and treatment sites in the same facility, sometimes located in the same unit (Chatterjee et al., 2011).

In a study including 21 sub-Saharan African priority countries, Adetokunboh & Oluwasanu (2015) reported that poor linkage between mother-infant pairs was a major cause of delayed

testing of HIV-exposed infants, which in turn resulted in delays in initiation of ART. In the study conducted in Ouagadougou, some PCR-positive infants were not started on ART mainly because their mothers did not return for their results and service providers could not reach them through their addresses or telephone numbers (Coulibaly et al., 2014). In an EID program review in Malawi, 58% of infants with confirmed HIV infection were started on ART (Dube et al., 2012).

Namibia, however, was an exception where up to 70% of infants receiving positive test results were actually started on ART after referral into clinical care. Based on the experience in Namibia, the authors recommended improvements in the processes for starting ART in PCR-positive infants. A decentralization of ART to MCH and EPI clinics was suggested as a way of improving the enrolment (Chatterjee et al., 2011). In Tanzania, Chiduo et al. (2013) reported that the proportion of HIV infected infants referred to care and treatment centres between 2009 and 2011 was as high as 99.2% for Mbeya region. Tanga region recorded the lowest average referral rate over the period (71.4%), but this rate had increased to more than 95% in 2011 (Chiduo et al., 2013).

### **Summary**

Infants who are vertically infected with HIV face high morbidity and mortality risks which can be averted with early initiation of ART. To be eligible for initiation of ART, HIV exposed infants need to have their HIV status confirmed in the early stages of life. Readily available HIV antibody tests are, however, unsuitable for confirmation of infection in exposed infants due to the presence of maternal antibodies in infants' blood. Viral assays are therefore recommended for confirmation of HIV status in exposed infants. Early infant diagnosis guidelines have been published by the WHO and adapted by various countries, including Ghana.

Despite the implementation of these guidelines in many countries, coverage of EID remains low in many developing countries, with few exceptions. This low coverage has been largely attributed to challenges related to health facilities, service providers and caregivers of HIV exposed infants.

When these challenges are identified in the local setting and appropriately resolved, performance of EID will improve in the country and lead to improved morbidity and mortality for infants vertically infected with HIV.



## CHAPTER THREE

### 3.0 METHODOLOGY

#### 3.1 STUDY SITE AND SETTINGS

The study was conducted at the Eastern Regional Hospital, Koforidua and St. Martin de Porres Hospital, both in the Eastern Region of Ghana. According to the 2010 Population and Housing Census in Ghana, the Eastern region was home to 2,633,154 people, made up of 1,290,539 males and 1,342,615 females. This made it the third most populous region in Ghana after Ashanti and Greater Accra regions respectively. With an annual population growth rate of 2.1%, the 2015 population of the region can be estimated at 2,921,494 (Ghana Statistical Service, 2012).

The Eastern region has consistently recorded the highest regional prevalence of HIV among ANC attendants in Ghana since 2000. In 2014, the prevalence of HIV in the region was recorded at 3.7%, much higher than the national median prevalence of 1.6% (NACP, 2015). This was an indication that a high proportion of HIV-exposed infants needing the EID service were born at these two facilities. The two sites, therefore, served as ideal settings for this study which sought to document the challenges faced by mothers of HIV-exposed infants. The regional hospital was also selected as a site for this study because it serves as the regional testing site for EID in the Eastern region. It afforded the opportunity to document the perspectives of the service providers who conduct the tests.

The choice of these two settings allowed the study to unravel challenges that have existed at different levels of care, which are also present throughout all the ten regions of Ghana. Therefore, until further work is done in the other regions, findings from this study can be used as a basis for effecting changes in all major hospitals in the country that offer the EID service.

### **3.1.1 St Martin De Porres Hospital, Agormanya**

St Martin De Porres Hospital was established in 1946 as a clinic and maternity home by the Rt. Rev. Joseph Oliver Bowers (Bishop Emeritus) of blessed memory. It was eventually granted hospital status by the Ministry of Health in 1997 (St. Martin de Porres Hospital, 2012). It is located at Agormanya which, together with Atua and Nuaso form the Odumase Township – the capital of the Lower Manya Krobo Municipality. The municipality, which was created in 2012 has a total population of 89,246 as of the 2010 population and Housing Census (Ghana Statistical Service, 2014a).

The 89-bed hospital is a member of the National Catholic Health Service and the Christian Health Association of Ghana. Its management is under the supervision of the Koforidua Diocese of the Catholic Church (St. Martin de Porres Hospital, 2012). It is a non-profit hospital offering a full range of health care services including Reproductive and Child Health, Pharmacy, Radiology, Laboratory, Mortuary, Ophthalmology, Oral Health, Mental Health, Surgery, Internal Medicine, Paediatrics, Obstetrics and Gynaecology. Other specialist services available include HIV testing and counselling, PMTCT, ART and clinical care for persons living with HIV/AIDS, Tuberculosis and Leprosy. These services are available to clients on out-patient and in-patient basis (St. Martin de Porres Hospital, 2016).

In 2015, the hospital attended to 76,092 cases at its outpatient department (OPD). The ANC saw 5,607 clients with 1,170 being new registrants. 1,389 supervised deliveries were conducted in the year. The postnatal clinic recorded 1,246 new registrants in the year. All the 1,170 new registrants at the ANC were counselled and tested for HIV as part of the PMTCT programme. Out of this number, 67 pregnant women (representing 5.7%) tested positive for HIV (St. Martin de Porres Hospital, 2016).

The hospital is also an HIV sentinel site with an average HIV prevalence of 8.5% among ANC clients that visited the hospital in 2014. This site has consistently recorded the highest HIV prevalence among ANC clients throughout the country in HIV sentinel surveys (NACP & GHS, 2015). The hospital does not have facilities for DNA PCR testing of HIV-exposed infants. DBS of exposed infants are collected at the facility and transported to the Regional Hospital, Koforidua for testing. Results are transported back to EID service providers of the facility for onward delivery to clients.

### **3.1.2 Eastern Regional Hospital, Koforidua**

The Eastern Regional Hospital was established in 1926 in Koforidua, the capital of the Eastern region (Regional Hospital Koforidua, 2015). The town is also the capital of the New Juaben Municipality with a 2010 population of 183,727 representing 6.9 percent of the Eastern region's total population. The municipality has a large migrant population mainly coming from the Volta, Greater Accra and Ashanti regions contributing 11%, 10% and 9.7% of the migrant population respectively (Ghana Statistical Service, 2014b).

The 340-bed capacity hospital is currently the secondary level referral facility for the region, serving as a major referral point for about eighteen district hospitals in the region. It also doubles as the Municipal Hospital for the New Juaben Municipality. The hospital offers the following services: Internal Medicine including Anti-Retroviral Therapy, Paediatrics, Surgery, Medicine, Dental, Ophthalmology, Physiotherapy, Ear, Nose and Throat, Pharmacy, Laboratory, X-ray, Ultrasound, Catering and Hospitality, Laundry, Mortuary and Primary Healthcare Services. It is a Ghana Health Service facility which is a not-for-profit healthcare organization (Regional Hospital Koforidua, 2015).

In 2014, the hospital attended to 174,106 cases at its OPD, with an average daily OPD attendance estimated at 605. The ANC recorded 5,625 attendants, of which 1,481 were new registrants. A total of 4,881 deliveries were conducted in the year, resulting in the delivery of 5,033 babies. The postnatal clinic also recorded 5,469 attendants. All the new registrants at the ANC were counselled and tested for HIV as part of the PMTCT programme. Of this number, 22 pregnant women tested positive for HIV (Regional Hospital Koforidua, 2015).

The hospital's reference laboratory conducted 132 PCR tests on DBS for EID of HIV in eligible infants. Twenty-two infants, representing 16.7%, tested positive. The hospital is a PMTCT, EID, ART site providing all range of services to persons living with HIV/AIDS (Regional Hospital Koforidua, 2015). It is also an HIV sentinel site with HIV prevalence of 3.5% among ANC clients in 2014 – the second highest prevalence in the region (NACP & GHS, 2015).

## **3.2 STUDY DESIGN AND SUMMARY OF FIELD PROCEDURES**

### **3.2.1 Study Design**

This study was a facility-based mixed methods study which employed both the qualitative and quantitative approaches (Creswell, 2009). For the qualitative aspect of the study, in-depth interviews (IDIs) were employed to explore the knowledge and perspectives of service providers and caregivers on the delivery and utilization of EID services. Interviews were conducted for all eligible mothers who agreed to participate in the study. All eligible service providers were also interviewed for their perspectives and challenges EID implementation.

The quantitative aspect of the study involved a desk review of service data on EID with focus on proportion of eligible infants testing, infant age at testing and TAT for results

delivery to clients. In the facilities, records on all deliveries to HIV positive mothers between January 2013 and December 2015 were extracted. The records of such infants were tracked for the date of birth; the date of sample collection for their EID test – if the tests were done – and the date when result was received at the facility for onward delivery to the caregivers.

At the regional reference laboratory, records on all DBS samples received from January 2013 to December 2015 were collected. Data extracted from each individual entry were date of birth; date of sample collection at EID site; age of infant at the time of sample collection; date of receipt of samples at reference laboratory; date on which tests were conducted; date of collection of results; and the result of the test as in Chiduo et al. (2013). The records extracted represented the total number of infants tested for EID in the Eastern region over the period.

### **3.2.2 Study Subjects**

Two main groups of respondents – HIV-positive mothers and EID service providers – were interviewed for their perspectives on EID.

### **3.2.3 Sampling**

Caregivers were sampled by using the purposive sampling method (Lund Research Ltd, 2012; Tongco, 2007). Under this method, mothers were selected using the maximum variation technique (Al-Busaidi, 2008) to ensure the inclusion of mothers who had tested their infants and those who had not tested their infants. All eligible mothers who visited the ART centres at the study sites during the data collection period were offered the opportunity to participate. A conscious effort was also made to reach all other eligible mothers through their telephone numbers and addresses available at the study sites.

For service providers, the entire population of eligible health workers involved in EID were interviewed in order to get varied views from different categories of workers.

### **3.2.4 Inclusion and Exclusion Criteria**

#### **Inclusion Criteria:**

All HIV positive mothers with infants aged six months or less at the time of data collection were eligible for selection. In addition to mothers attending ART/PMTCT/EID clinic who were sampled for interview, efforts were made to reach non-attendant mothers who qualified under the inclusion criteria. This was accomplished with the aid of hospital PMTCT and delivery records. Addresses and contact numbers of such mothers were used to reach them. Any HIV negative person who had been acting as the caregiver for an HIV-exposed child for the preceding six months was eligible for selection. All health workers in the facilities who were directly involved in the delivery of the EID service were eligible for selection.

#### **Exclusion Criteria:**

HIV positive mothers whose children were older than six months at the time of data collection were not eligible for selection due to the possibility of recall bias. Health workers who were not directly involved in the delivery of the EID service were not eligible for selection.

### **3.3 PRE-TESTING OF INTERVIEW GUIDES**

The interview guides were pretested at the Nsawam Government Hospital, Nsawam. Similar to the Eastern Regional Hospital and St Martin de Porres Hospital, Nsawam Hospital is an ART/PMTCT/EID site offering a wide range of services to persons living with HIV/AIDS.

The facility also delivers the entire range of services available in a general hospital (Nsawam Government Hospital, 2016).

The purpose of the pre-test was to establish the field procedures to be used for the study. The pre-test also helped in testing the reliability and usefulness of the interview guides. Responses and reactions from respondents served as a basis for fine-tuning the interview guides to make them useful tools for data collection.

### **3.4 DATA COLLECTION TECHNIQUES AND TOOLS**

#### **3.4.1 Techniques**

The principal technique for data collection was IDIs with an interview guide. All eligible mothers who were reachable during the data collection period and were willing to participate in the study were interviewed until data saturation (Mason, 2010) was deemed to have been reached, at which point the interviews will be terminated. All eligible health workers were interviewed for their individual experiences and perspectives on the subject.

The interviews were recorded live while field notes were taken simultaneously. All interviews for service providers were conducted in English. Interviews for caregivers who could not speak English were conducted in Akan. At the end of each day of data collection, the interviews were transcribed and compared with the field notes.

Relevant service records on EID in the selected facilities were captured digitally on site. The records captured were later transferred into a worksheet, cleaned and analysed appropriately.

### **3.4.2 Tools**

The principal tools for this study were interview guides, pretested and refined at a facility similar to the study sites. Separate interview guides (See Appendix 1A and 1B) were used for the two groups of respondents. Other tools that were employed for data collection during this study included digital tape recorders, notepads and pens. A digital camera was used in capturing service records on site. The interviews and service data collection were done over a period of three weeks, from 6<sup>th</sup> to 24<sup>th</sup> June 2016.

### **3.5 QUALITY ASSURANCE**

In order to assure quality of the study and its outcomes, certain measures were enforced throughout the research process. Interview guides were pre-tested to ensure their usefulness for the purpose. Transcript of interviews were written daily and compared with field notes to ensure that every piece of relevant data were captured.

For the review of service data, records were collected from the labour wards, child welfare clinics and the laboratories of the study sites. The data were analysed together to ensure that all eligible infants were accounted for and multiple counting was avoided.

### **3.6 DATA PROCESSING AND ANALYSIS**

The recorded IDIs were transcribed and compared with handwritten field notes to ensure every piece of the data were captured. The data were initially sorted into responses from the different categories of respondents namely mothers caregivers and service providers. For each of the above categories of respondents, the responses (transcript and field notes) were manually analysed using thematic content analysis technique. Themes were developed from the responses of participants to the various questions asked. Alphabets were used to code the various themes and these alphabets were then used to label responses that were closely

related to the respective themes. Responses were then grouped under the various themes and reported appropriately (Adeniyi et al., 2015; Mugasha et al., 2014; Varkevisser, Pathmanathan, & Brownlee, 2003).

At the St Martin de Porres Hospital site, records extracted were used to estimate infant's age at time of sample collection; age at result delivery; and TAT from sample collection to result delivery for each entry. The quantitative data thus collected were analysed with STATA<sup>®</sup> quantitative data analysis software (Version 13.1). The software was used to estimate proportion of eligible infants who tested, the median age of infants at the time of testing and the median TAT for the delivery of results to clients.

At the Regional Hospital Koforidua, where raw data on deliveries by HIV positive women and dates of infant sample collection were not available, the aggregate number of deliveries for the years 2013, 2014 and 2015 were compared with the number of samples received at the regional reference laboratory from the facility during the same period. These data were then used to calculate the proportion of eligible infants that tested during the period.

At the regional reference laboratory, data extracted from each individual entry were date of birth; date of sample collection at EID site; age of infant at the time of sample collection; date of receipt of samples at reference laboratory; date on which tests were conducted; date of collection of results; and the result of the test. Between date of birth; date of sample collection at EID site; and age of infant at the time of sample collection, where one of the three records for a particular infant was absent, the two available records were used to estimate the other. Where more than one of the records were absent, the entry for that infant was considered an invalid entry. Records of children older than 18 months at the time of sampling were also considered invalid entries.

The records extracted for each entry were used to estimate the time between sample collection and sample delivery at reference lab; the time between sample delivery at the lab and testing of sample; and the time from testing of sample to collection of result by EID site. STATA<sup>®</sup> (Version 13.1) was used in analysing the data to determine the median age at sample collection; median TAT for sample delivery to the lab, for testing of sample and for collection of result. Median age of child at the time of result collection and the proportion of infants receiving positive results were also determined using STATA. The proportion of infants who tested and/or received results at specific ages were also determined.

All time related data were processed and analysed in days and reported in weeks, months or years as appropriate.

### **3.7 ETHICAL CONSIDERATIONS**

Approval for this study was first sought from the School of Public Health, University of Ghana, Legon. Further, ethical clearance was sought and obtained from the Ethics Review Committee of the Ghana Health Service. On the field, permission was sought from the heads of the selected facilities through an introductory letter from the School of Public Health before any form of data collection commenced.

#### **Consenting Procedure**

The information sheet (see Appendix 2A) was given to all prospective participants to read. Where a prospective participant was unable to read, the information sheet was read and explained to her in a language she was conversant with and in the presence of a witness. Upon agreement to participate in the study, the participant was asked to sign or thumbprint a consent form (see Appendix 2B). For participants who were unable to read, their witnesses also signed the consent form. Finally, the interviewer seeking the participant's consent also endorsed each consent form.

### **Potential Risks**

Participants in this study were not be exposed to any risks. The interviews were in relation to participants' experiences concerning early HIV diagnosis of HIV-exposed infants.

### **Benefits**

Participants in this study did not enjoy any direct financial benefits. However, findings and recommendations from the study could help improve the delivery and utilization of EID services in the country, which may benefit the participants and other HIV positive women and their infants. Participants who were found not to have conducted EID for their infants were educated on the importance of the test and referred to the appropriate unit of the hospital for counselling and testing.

### **Costs**

Participants will not have to incur any costs for accepting to participate in this study, besides their time.

### **Compensation**

Cash compensation was not paid to participants for consenting to be part of the study. Participants' contribution to this study has, however, been recognized and appreciated. Where participants had to travel from their residence to the health facility in relation to the study, the costs of travel were borne by the researcher.

### **Privacy/Confidentiality**

In order to protect the identity of participants, interviews were conducted at venues that did not expose them to other individuals who may not have known their HIV status. Participants' names were not collected to further ensure anonymity. All information concerning individual subjects have and will continue to remain anonymous and

confidential. All data collected were protected and secured. Access to data was limited to the Principal Investigator (PI) and Academic supervisor.

### **Data Collection, Usage and Storage**

Interviews were recorded and later transcribed in the English language. Data collected were used for research purposes only. To ensure confidentiality, audio tapes were stored in password-protected folders and hard copies were kept under lock and key. Only the researcher and supervisor had access to all forms of data collected. Recordings will be kept for a period of 12 months, by which time all processes relating to this study would have been completed.

### **Right to Refuse or Withdraw**

Participants were informed that participating in the study was entirely voluntary and that they had a right to refuse to participate or withdraw from the study at any time during the interview process. They were also informed of their right to refuse to answer any question(s) which they felt uncomfortable about. All the above rights of participants could have been exercised without suffering any consequences regarding provision of health services.

### **Conflict of interest**

The Principal Investigator declares no conflict of interest with respect to the conduct of this study. Aside transport costs, there was no form of compensation for participants in the study.

### **Contact for Further Information**

The name and telephone number of the principal investigator, academic supervisor and the administrator of the GHS Ethics Review Committee were provided on the information sheet for participants to call for any further clarifications where necessary.

## CHAPTER FOUR

### 4.0 RESULTS

#### 4.1 BACKGROUND ON DATA RETRIEVED AND RESPONDENTS

##### 4.1.1 Background on Data Retrieved

At the St Martin de Porres Hospital, information from 302 HIV-exposed infants were retrieved from the EID service records between January 2013 and December 2015. These included 254 infants delivered at the labour ward of the hospital and 48 others who were tested at the facility. The number is made up of 101 infants in 2013, 106 infants in 2014 and 95 infants in 2015. The records of the mother-infant pairs were followed for testing and delivery of test results. DBS samples were collected from 118 of the 302 exposed infants recorded in the facility.

At the Regional Hospital Koforidua, raw data on deliveries by HIV positive women and dates of infant sample collection were not available for follow up of the mother-infant pairs. Summary reports, however, showed that a total of 324 babies were born to HIV positive mothers between January 2013 and December 2015. This comprised the delivery of 93 HIV exposed infants in 2013, 119 in 2014 and 112 in 2015.

At the regional reference laboratory, a total of 1896 DBS samples were received during the period January 2013 and December 2015. The samples were received from 21 EID sites across the region. The Regional Hospital was the only site in the entire New Juaben municipality that submitted samples for testing during the period. After excluding 44 invalid entries, records of 1852 entries were analysed.

**Table 4.1 DBS samples received at the regional reference laboratory**

Year	2013	2014	2015	Total
Total number of samples received	722	588	586	1896
Number of invalid entries	27	10	7	44
No of valid entries used	695	578	579	1852

#### 4.1.2 Background on Caregivers

A total of nine eligible mothers aged between 28 and 45 years were interviewed. This number was made up of five mothers who had tested their infants and four mothers who had not. All the mothers had three or more children, with the most fertile being a mother of six. None of the predominantly Christian mothers interviewed had attained secondary education. All of them were, however, engaged in some form of trade. With the exception of two mothers (one separated and the other cohabiting), all the mothers were married.

#### 4.1.3 Background on Service Providers

Ten service providers were interviewed and they included one medical officer (MO), two physician assistants (PA), five nurses/midwives and two biomedical scientists (BMS). The two biomedical scientists interviewed included the officer in charge of testing DBS samples at the regional reference laboratory. Three of the nurses interviewed were community health nurses by training whose services were being deployed at the reproductive and child health (RCH) unit of the facilities. Service providers interviewed had been involved with EID in their facilities for an average of three and half years, with the minimum being one year. Five of the service providers were aged above 53 years, with three of them 59 years old or more.

## 4.2 PERFORMANCE OF EID

### 4.2.1 EID Coverage and Positivity Rates

Out of the 254 HIV exposed infants born at the St Martin de Porres Hospital between January 2013 and December 2015, seventy of them, representing 27.6% (95% confidence interval (CI) 22.1% – 33.1%) had been returned to the facility for EID testing at the time of data collection.

**Table 4.2 HIV Deliveries and their EID Tests at St. Martin’s Hospital**

Year	2013	2014	2015	Total
Total number of exposed infants delivered (n)	80	96	78	254
Number of exposed infants who tested (n)	18	32	20	70
Proportion of exposed infants who tested (%)	22.5	33.3	25.6	27.6
(95% confidence interval)	(13.4 – 31.7)	(23.9 – 42.8)	(16.0 – 35.3)	(22.1 – 33.1)

At the Regional Hospital Koforidua, though only 324 exposed babies were delivered over the period, 473 (146.0%) DBS samples had been taken in the facility and submitted to the regional reference laboratory for EID testing.

**Table 4.3 HIV Deliveries and EID Tests at Regional Hospital, Koforidua**

Year	2013	2014	2015	Total
Total number of exposed infants delivered (n)	93	119	112	324
Number of infants who tested (n)	176	160	137	473
Proportion of exposed infants who tested (%)	189.2	134.5	122.3	146.0

Of the 1852 infants whose DBS samples were tested at the reference laboratory, 253 returned a positive test result, representing a crude positivity rate of 13.7% (95% CI 12.1 –

15.2). The positivity rates, stratified by age at sample collection and facility, are shown below in **Table 4.4**

**Table 4.4** Positivity rates of PCR results by age at sample collection and facility

Age at sample collection	Proportion with positive results, by facility			
	SMH*	RHK**	Others	All Facilities
6 weeks or earlier	14.3%	9.3%	11.7%	10.4%
6 weeks – 6 months	15.6%	15.8%	12.1%	13.2%
6 – 12 months	21.7%	15.1%	19.6%	18.7%
12 – 18 months	12.5%	18.4%	13.4%	15.2%
Total	16.4%	14.4%	13.4%	13.7%

\* St Martin's Hospital

\*\* Regional Hospital, Koforidua

#### 4.2.2 Median Age at Testing

Among the 302 exposed infants who tested at the St. Martin's Hospital over the period, the median age at the time of DBS sample collection was 9.4 weeks (interquartile range (IQR) 6.9 – 19.3). See **Table 4.5**.

However, from records at the regional reference laboratory, which represents all tests conducted in the region, median age of infants at the time of DBS sample collection was 11.6 weeks (IQR 6.6 – 26.0). See **Table 4.6**. By the age of six weeks, only 3.8% (95% CI 2.9 – 4.7) of all exposed infants had their DBS samples taken. At three months, 52.8% (95% CI 50.5 – 55.1) of eligible infants had tested. This increased to 74.6% (95% CI 72.6 – 76.6) by six months and by the time eligible infants were a year old 93.9% (95% CI 92.8 – 95.0) of them had tested.

Among the 253 babies who tested positive, 4.0% (95% CI 1.6 – 6.4) of them had their tests done by six weeks, increasing to 41.9% (95% CI 35.8 – 48.0) at three months; 68.4% (95% CI 62.7 – 74.1) at 6 months and 92.5% (95% CI 89.2 – 95.7) by the age of one year.

**Table 4.5 Median age at testing and TAT, St Martin’s Hospital**

Year	2013		2014		2015		Overall (2013 – 2015)	
	median	IQR	median	IQR	median	IQR	median	IQR
Age at testing (weeks)	8.9	6.7 – 15.9	14.3	7.4 – 32.1	7.7	6.7 – 15.9	9.4	6.9 – 19.3
TAT, result collection (weeks) *	16.3	7.7 – 21.9	32.3	19.0 – 46.1	17.6	13.1 – 20.1	19.1	13.0 – 24.3
Age at result collection (weeks)	28.3	20.4 – 33.3	58	43.4 – 63.0	26.7	22.4 – 32.0	30.3	24.4 – 56.1

\* The time it takes between sample collection at EID site and availability/collection of result at EID site

**Table 4.6 Median age at testing and TAT, Regional Reference Laboratory**

Year	2013		2014		2015		Overall (2013 – 2015)	
	median	IQR	median	IQR	median	IQR	median	IQR
Age at testing (weeks)	11.6	7.0 – 26.0	9	6.1 – 21.0	13.3	6.7 – 29.3	11.6	6.6 – 26.0
TAT, sample delivery (weeks) *	1.4	0 – 3.9	2.3	0.3 – 6.2	1	0.1 – 3.0	1.6	0.1 – 4.1
TAT, delivery to testing (weeks) **	3.1	1.4 – 7.9	2.6	1.4 – 26.1	1.6	1.0 – 2.9	2.4	1.1 – 5.3
TAT, result collection (weeks) ***	4.4	2.7 – 9.6	4.9	2.1 – 8.0	2.9	0.9 – 7.7	4.3	1.9 – 8.1
Age at result collection (weeks)	29.9	19.7 – 46.2	37.7	20.7 – 55.1	25.1	14.5 – 40.6	29.6	18.0 – 48.4

\* The time it takes between sample collection at EID site and delivery of the sample at the reference lab

\*\* The time it takes between receipt of sample at reference lab and testing of the sample

\*\*\* The time it takes between testing of sample and collection of result by EID site

### 4.2.3 Median TAT for Result Delivery

Among the 118 infants that had their DBS samples taken at St. Martin’s Hospital, median TAT until result delivery was 19.1 weeks (IQR 13.0 – 24.3). See Table 4.5. At the regional reference laboratory, the TAT was segmented at various points. The median TAT from sample collection at EID site to its delivery at the reference laboratory was 1.6 weeks (IQR 0.1 – 4.1). Median TAT from the time of sample receipt at the reference laboratory till the

time tests were conducted was 2.4 weeks (IQR 1.1 – 5.3). Median TAT from completion of test till collection of results by EID site was 4.3 weeks (IQR 1.9 – 8.1) **See Table 4.6.**

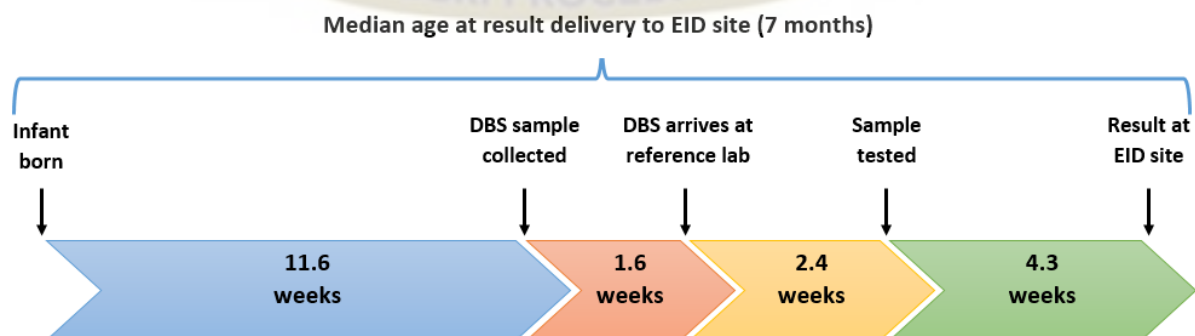
#### 4.2.4 Age at Result Collection/Delivery

Among the infants that tested at the St Martin’s Hospital during the period, median age of the infants at the time of results availability and delivery was 30.3 weeks (IQR 24.4 – 56.1). **See Table 4.5.** At the regional reference laboratory, the median age of infants at the time their results were collected from the laboratory was 29.6 weeks (IQR 18.0 – 48.4). **See Table 4.6.**

By the age of three months, only 13.2% (95% CI 11.6 – 14.8) of all exposed infants that tested had their results ready at EID sites for collection. At four months, 23.2% (95% CI 22.2 – 24.2) of the infants had their results ready for collection at their EID sites. This increased to 42.5% (95% CI 40.2 – 44.8) by six months and by the time the infants were a year old 78.2% (95% CI 76.2 – 80.1) of them had their results available at EID sites.

Fig 4.1 denotes the flow of EID services in the Eastern region of Ghana, showing the median times at which specific services within the EID continuum are delivered.

**Fig 4.1** Flow of EID services in the Eastern region, with median time



Among the 253 infants who tested positive, 13.4% (95% CI 9.2 – 17.6) of them had their test results ready by the time they were three months old, increasing to 21.0% (95% CI 15.9

– 26.0) at four months; 37.6% (95% CI 31.6 – 43.5) at 6 months; and 71.5% (95% CI 66.0 – 77.1) by the age of one year. The oldest age for a child’s result to become available at their EID site for collection was 2.1 years.

Table 4.7 below summarizes the challenges and enablers that were identified by service providers and caregivers as critical to the delivery and utilization of EID services in the Eastern region. The details of these factors are provided in the ensuing sections.

**Table 4.7 Challenges and Enablers to EID Service Delivery and Utilization**

<b>Level</b>	<b>Challenges</b>	<b>Enablers</b>
Provider related	<ul style="list-style-type: none"> <li>Inadequate training</li> <li>Sample collection skills</li> <li>Delay in transporting samples</li> <li>Delay in testing samples</li> <li>Delay in delivering results</li> <li>Frequent breakdown of equipment</li> <li>Frequent stock-out of supplies</li> <li>High workload for few staff</li> <li>Lack of staff motivation</li> </ul>	<ul style="list-style-type: none"> <li>Adequate knowledge</li> <li>On-the-job training</li> <li>Identification of eligible infants</li> <li>Result notification by reference lab</li> <li>Privacy settings in facilities</li> <li>Staff attitudes</li> <li>Supportive Supervision</li> </ul>
Caregiver related	<ul style="list-style-type: none"> <li>Poor knowledge</li> <li>Incorrect phone numbers and addresses</li> <li>Financial constraints</li> <li>Non-disclosure</li> <li>Denial</li> <li>Loss to follow-up</li> </ul>	<ul style="list-style-type: none"> <li>Adequate knowledge</li> <li>Disclosure and support</li> </ul>

### 4.3 SERVICE PROVIDERS' KNOWLEDGE AND SKILLS ON EID

#### 4.3.1 Service Providers' Knowledge

The service providers displayed adequate knowledge on EID especially on the questions of eligibility, type of test conducted, rationale and timelines for testing. All but one of the service providers (SP) correctly indicated that the test was conducted for the infants from six weeks of age. The only one who could not be exact about the timelines said:

*“The children are tested early so that we can put them on appropriate treatment” (SP #6, Midwife)*

The service providers identified the type of test to be conducted for the exposed infants as the polymerase chain reaction (PCR).

*“We do the PCR i.e. polymerase chain reaction, to detect DNA/RNA of the virus” (SP #5, BMS)*

*“DNA PCR is done at six weeks to find out if the child is positive” (SP #8, PA)*

*“I take the dried blood spot for the PCR” (SP #10, Midwife)*

The service providers indicated that, all children who had been born to HIV positive mothers and had attained the age of six weeks or beyond were eligible for the test.

*“The one who needs it (EID) is a child from six weeks whose mother is HIV positive” (SP #3, Nurse)*

*“Babies born to HIV positive mothers are to be tested” (SP #7, MO)*

*“When a child is born to an HIV positive mother, then we take a sample and screen for HIV” (SP #9, BMS)*

*“EID is a diagnosis we make on babies. Those who have been exposed to HIV positive mothers” (SP #10, Midwife)*

The service providers generally indicated that the rationale for early testing of exposed infants is to identify infected infants early enough so as to commence ART. This, they indicated, is done to prevent deterioration of infants' health and eventual death.

*“They are tested early in order to know if the baby is positive or negative to start ART treatment” (SP #4, Nurse)*

*“When you pick the virus early in a child, then you start treating early” (SP #7, MO)*

*“We have to test the children, those at risk because of their mothers’ status, to prevent early death” (SP #8, PA)*

*“... so that we start treatment as early as possible” (SP #9, BMS)*

However, one service provider ascribed the reason for early testing to sero-reversion and cessation of breastfeeding, in addition to the reason of early ART initiation.

*“We need to test the children at six weeks, that’s the time that the antibodies of the mother will go out of the baby. ... so if the mother knows the status at that time, then she will stop breastfeeding ... It has become necessary to do all those tests for them as early as possible so that we can pick those who are positive and know what to do for them” (SP #1, PA)*

#### **4.3.2 Service Providers’ Sample Collection Skills**

Despite, the adequate knowledge displayed on EID, some of the service providers expressed challenges with the skill of collecting and processing the DBS samples.

*“The collection of the sample, if you are not good at it, you can miss the diagnosis” (SP #1, Physician Assistant)*

*“When you are taking the sample and you are shaking, afraid, you feel for the children, you can’t take the sample. It will affect the quality of the sample” (SP #9, BMS)*

Though many of the staff had received training in the skill of sample collection and processing, some nurses lacked the confidence to go through with the process.

*“... we organized a workshop for the district; how samples are taken ... the blood should fill the broken ring on the paper but some of the samples are very small ... on monitoring, we found out that, some of the samples are exposed on the benches for a long period; dust and other things settle on it ... even those that we trained, the samples are not coming from them” (SP #9, BMS)*

Sample collection was mostly left for laboratory technicians, most of whom were able to handle the process.

*“The sample collection, though most of us are able to do it, we still need more hands to support” (SP #5, BMS)*

When asked about their role in EID, three nurses gave essentially the same response:

*“I fill the request form for the mother to send to the lab” (SP #2, #3 & #4, Nurses)*

An exception was the midwife at the regional hospital who collects and processes the DBS samples herself before sending them to the reference laboratory for testing.

*“I take the samples myself, with the DBS papers” (SP #10, Midwife, Regional Hospital)*

### **4.3.3 Training of Service Providers**

Most of the service providers had not attended any EID related trainings in the last two years. Some providers had not attended any trainings since they left school.

*“Since 2014, I have not attended any trainings ... when they call one person for training, it will take a long time before another training comes up” (SP #1, PA)*

*“We went for workshop in Accra some years back, but it’s been a long time” (SP #2, Nurse)*

*“None recent, the last one was in 2010” (SP #7, MO)*

The major approach employed towards transfer of knowledge among EID service providers was internal trainings within the facilities. These took the form of formal in-service trainings and informal on-the-job training of newly appointed staff by experienced providers.

*“... within the facility, those of us who are more experienced, we conduct training for the antenatal nurses, the new ones that come” (SP #1, PA)*

*“I attended internal workshops while at Tema General Hospital in 2011/2012” (SP #8, PA)*

*“Two months ago as a facilitator, we organized a workshop for the district” (SP #9, BMS)*

Many of the providers expressed the need for more regular in-service training to sharpen their knowledge and skills in the provision of EID services.

*“Lots of us need in-service training ... in-service training needs to be carried out all the time for every person who finds herself working at the unit ... we are calling out for more in-service training” (SP #1, PA)*

*“Generally, we need in-service training, so that the interest will be there for people to get involved” (SP #5, BMS)*

*“Regular training is needed ...” (SP #9 BMS)*

#### 4.4 PROVIDER RELATED FACTORS AFFECTING EID

##### 4.4.1 Testing Practices and Processes

At the St Martin's Hospital, eligible infants are identified by nurses and midwives at the RCH unit of the hospital who fill laboratory request forms for the mothers. DBS samples are then taken by the laboratory technicians who later delivers the samples at the reference laboratory when a sufficient number has been collected and/or transportation is available. The laboratory technicians later retrieve the results from the reference laboratory and deliver them to RCH nurses.

*"The ANC identifies the positive mother and follow up when the baby is born and then the baby has to be tested" (SP #7, MO, St Martin's Hospital)*

*"We do the sample collection and send the specimen to the regional hospital for analysis. Then when the result is ready, we go for it" (SP #5, BMS, St Martin's Hospital)*

*"They (laboratory staff) give the results to the antenatal nurse" (SP #1, PA, St Martin's Hospital)*

*"When the results come, the lab technician will bring the results to us here" (SP #2, Nurse, St Martin's Hospital)*

At the regional hospital, the midwife who is the PMTCT coordinator takes care of all HIV positive pregnant women and their children until the children are 18 months old. This midwife collects DBS samples, sends them to the reference laboratory and retrieves the results when they are ready.

*"I'm taking care of the pregnant women so I track them through delivery to testing. I have some of the infant ARV in the fridge, so when they come and they are qualified, I test them" (SP #10, Midwife, Regional Hospital)*

In both facilities, the nurse/midwife then calls the mothers to come for their results and refer those testing positive to dedicated doctors or physician assistants to commence ART.

*"Most of them receive the results when they are coming to weighing. And we call others too" (SP #4, Nurse)*

*"The moment the result came, the nurse called me to come" (MC #8, Mother)*

*... as soon as the results come and it's positive, then you need to start treatment (SP1, PA)*

*“When the child is negative we inform the mothers, if it’s positive, then that one, we refer them to the doctor for treatment (SP #2, Nurse)*

*“If the result is positive, then we have to assess the child and put on treatment” (SP #7, MO)*

*“I enrol them and let them go and show it to the doctor ... and start them on the medications” (SP #10, Midwife)*

Nurses at the St Martin’s Hospital have developed their own means of identifying eligible infants. During the first postnatal visit, they write a special code on the child health record book of all exposed infants at the point of issuing the book. This code prompts them to request for EID testing during subsequent postnatal visits by such infants.

*“So if the mother is positive and she delivers ... we write it ... we have created a column for ourselves in the child welfare card that we will know. So if you see that code number or your friend sees it, she knows that this child is exposed” (SP #2, Nurse)*

*“If the mother is positive, we indicate it on their weighing cards. So as soon as we take the cards, we know that this baby, the mother is positive” (SP #3, Nurse)*

*“When they come for postnatal ... we write it (their exposure status) on the top of the weighing card in order for us to know when they are due for testing” (SP #4, Nurse)*

In spite of this arrangement, some mothers who had visited the postnatal clinic on multiple occasions still did not have their infants tested.

*“I have come for weighing twice, they have never asked me about testing the child” (MC #3, mother of a 3 month old)*

*“I have come for weighing three times but he has not been tested” (MC #6, mother of a 2 month old)*

#### **4.4.2 Delays in the EID Continuum**

Delays at various stages of the EID continuum affect the efficient delivery of services to clients. After DBS samples have been collected at facilities, laboratory personnel need to wait until enough samples are collected and a vehicle is available before the samples can be transported to the regional reference laboratory for testing.

*“The other problem is sending the sample to Koforidua ... if we don't have a car moving to Koforidua then it means that the sample will delay. Sometimes it takes more than 5 days for the sample to go” (SP #1, PA, St Martin's Hospital)*

*“Getting the samples there (reference lab) is also a problem. Normally, we go to Koforidua once in a week, so until the car moves there, you cannot go on your own” (SP #5, BMS, St Martin's Hospital)*

*“Taking just one sample and sending it to Koforidua is not feasible” (SP #7, MO)*

*Most of the samples that come, they delay at the facilities” (SP #9, BMS, Reference Lab)*

Another cause of delays in the continuum is the absence of the minimum number of samples required for one batch of testing and the shortage of test reagents. 22 samples are required for each batch of tests.

*“At times the results delay over there because they have to put many samples together before running the tests” (SP #5, BMS, St Martin's Hospital)*

*“We need 22 sample and two controls to be able to run a batch of tests ... sometimes we can run half, but it's a waste of reagent. The samples don't come in as we need, so we have to wait till we get the 22 ... within two weeks we run the tests, provided the reagents and everything is available” (SP #9, BMS, Regional Reference Lab)*

The last identified cause of delay in the continuum is the delay in the delivery of results – from the reference laboratory to the facility. When the results are ready at the reference laboratory, the officer in charge either calls the facilities or shares the information on a regional 'Whatsapp' platform created for that purpose.

*“After running the tests, how to get the results to them is a problem ... we call them to come for the results. Some come, others too delay. Especially the positive ones, we call them repeatedly” (SP #9, BMS, Regional Reference Lab)*

*“They give us information – we have a platform on Whatsapp – then we will go for the results” (SP #5, BMS, St Martin's Hospital)*

In spite of this arrangement, service providers and clients alike have complained of the delay in receiving their results. The mother of a six-month old baby complains:

*“I tested him at six weeks but I don't have the results yet ... It's about four and half months now” (MC #5, mother)*

The following typifies the frustration of most service providers at the delay in receiving results:

*“The delayed results ... it’s often. The results from Koforidua, it delays. Sometimes three months, six months, you’ll not get the results and the mothers keep asking about their results” (SP #3, Nurse, St Martin’s Hospital)*

#### **4.4.3 Infrastructure, Logistics and Supplies**

Both facilities had settings that provided adequate privacy for their clients. The challenge related to infrastructure, which was identified by providers, involved breakdown and servicing of the equipment used in running the test. A medical officer at the St Martin’s Hospital referred to the breakdown of the machine which ends up delaying results.

*“Sometimes, they send the samples to Koforidua, they say the machine is broken down. The test is always not readily available” (SP #7, MO)*

This was also confirmed by the officer in charge of testing DBS samples at the reference laboratory. He also raised his dissatisfaction with the servicing regime of the equipment.

*“Once in a while we experience breakdown of our machines. But we call Roche, the servicing company for NACP, and they resolve it for us. But regular servicing, they have not come for the past two years” (SP #9, BMS)*

All providers interviewed complained about frequent shortages of various supplies and inputs that are required for smooth delivery of the service. The supplies of concern were DBS cards and test reagents.

*“I think, sometimes, the reagents (at the reference lab) are not available because when they send the sample, it takes a long time before they bring the results back (SP #4, Nurse)*

*“It also depends on the availability of test kits (DBS cards) ... there’s always shortage and these are program supplies that they give freely, so when you go to the store and it’s not there, you can’t go and buy” (SP #7, MO)*

*“The issue of logistics is another area of challenges but that area is controlled by the NACP. They control the reagents, the DBS cards, servicing of our machines ... the distribution of the reagents is based on a push system. We don’t request, they push it on us ... so some of the reagents have expired and cannot be used ... the expiry date of the reagents is too short” (SP #9, BMS)*

One service provider even complained about the shortage of A4 sheets for printing the results at the reference laboratory.

*“At times we have shortages of the DBS paper ... the regional lab seems to have some challenges with logistics like A4 sheets. These should be provided for them” (SP #5, BMS)*

#### **4.4.4 Other Factors**

Other provider-related factors that were identified as affecting delivery and utilization of EID services include number of committed staff and workload, staff attitudes, staff motivation and supportive supervision. Many providers complained about the workload and the number of staff who were committed to play their roles in delivery of the service. They have thus called for additional skilled hands to be engaged to support the work.

*“As for St Martin’s ... the workload is too much for us” (SP #1, PA)*

*“It seems that when I don’t send the samples, nobody makes the effort. Others should volunteer and get involved ... we still need more hands to support (SP #5, BMS)*

*“The CHNs ... are supposed to do a follow up visit. But the inadequate number of staff sometimes makes follow up visits impossible and the commitment on the part of the staff is low” (SP #7, MO)*

*Someone was taking care of the pregnant women and I was responsible for the babies, but when she left ... I had to add it to my duties ... I was working with some two midwives but their interest was not high (SP #10, Midwife, Regional Hospital)*

*“I’m the only person handling the EID. I need a helping hand” (SP #9, BMS, Reference Lab)*

Attitude of EID service providers was generally adjudged by mothers to be very good. Clients had only positive comments to make about the attitudes of HIV care staff towards them.

*“Here, your own character determines how the nurses will treat you. Some (clients) are very disrespectful, insulting the nurses, and they will not look on for you to do that. But for me, they take very good care of me. Even the doctor, he opens up to me” (MC #1, Mother)*

*“The staff don’t have any bad attitudes” (MC #4, Mother)*

*The staff are nice. They pamper us very well. They should continue to do what they are doing – the way they get time for us, even more than the other patients” (MC #7, Mother)*

Some of the providers identified staff motivation as an ingredient that was lacking in their facilities. They encouraged management of the facilities to motivate staff who performed such duties.

*“They should give us motivation for the extra work we are doing” (SP #2, Nurse)*

*“They should motivate us ... once in a while, come and say something that we are doing well” (SP #3, Nurse)*

*“There is already high workload for everybody, so they should motivate the people” (SP #6, Nurse)*

The sites received regular supportive supervisory visits from various officers and institutions at different times of the year. The visitors included NACP, Noguchi Memorial Institute for Medical Research, UNICEF, Global Fund and the Municipal Director of Health Services. The most recent visitors were received two weeks prior to the data collection period.

#### **4.4.5 Emerging Phenomenon**

The midwife at the Regional Hospital, has identified a phenomenon where infants who receive initial positive results continue to meet and sometimes exceed all developmental milestones. Upon repeating the tests, most of such infants have returned with a negative result.

*“For some time, when I do the early test at six weeks, the result I get is sometimes positive. The mothers have been taking their drugs for long and their viral load are sometimes undetectable and CD4 are over 800 – 1000. The children were also growing very well without any signs of infection. So I retested the babies at five months and it was negative. So I’m doing that for many of them and I have records of it (pulls out records to show). I have repeated for some at 9 months and it’s still negative. I’m waiting for 18 months to repeat again” (SP # 10, Midwife, Regional Hospital)*

#### 4.5 CAREGIVERS' KNOWLEDGE ON EID

Four of the nine mothers interviewed displayed sufficient knowledge about the early testing of their infants. They correctly described the rationale for early testing, the appropriate time for the infants to be tested and the type of test that was conducted (mode of sample collection).

*“They need to test early because, maybe it’s in his blood and they want to know ... they did the test at six weeks ... they tried to take from the feet, but it was not possible, so they took it from the fingers” (MC #2, Mother)*

*“They said he should test when he is six weeks old. We test early so that they will know if he has the virus, then they will give him drugs” (MC #7, Mother)*

*“We test them to know if they have the infection, then they can give him drugs. They should test at six weeks ... the blood was taken from the big toe” (MC #8, Mother)*

*We test them so that if he is positive, then we will see how to treat him and if negative then we will take better care of him. The test should be done at six weeks” (MC #9, Mother)*

Some of the mothers also displayed mixed knowledge while others appeared almost clueless about the tests they needed to conduct for their infants.

*“We test so that the child will not get the infection from the mother and if he is positive, then they will give him the drugs so that he will not deteriorate. It should be done at six weeks” (MC #4, Mother)*

*“I don’t want the child to get the disease, that’s why I test. So that I will know if he is negative and it will calm my nerves. They said we should test at six weeks ... the blood sample was taken from the heel onto a paper” (MC #5, Mother)*

*“ ... they will tell you when to breastfeed and when to stop, then they will test the child .. the older child, I did his test at six months. This one is three months old, so I’ll do it on Monday (MC # 1, Mother)*

*“When I wean him off breastmilk, then they will test to see if he has the infection. The other day I was here, they said I should wait till after weaning” (MC #3, Mother)*

All of the mothers claimed to have received their information from various service providers, including nurses at the ANC, midwives at the labour ward and prescribers.

## 4.6 CAREGIVER RELATED FACTORS AFFECTING EID

Most of the clients did not clearly outline their own challenges or those they had encountered with the health system in respect of EID services. Many of the factors enumerated below were gathered from the perspectives of service providers, based on the years of experience they had had with the clients.

### 4.6.1 Contact Numbers and Addresses

Many service providers complained about incorrect phone numbers and untraceable addresses that were provided by the mothers. They indicated that such practices made it difficult for them to follow up on the mothers to come for the testing of their infants or return for their results.

*“The clients give wrong addresses and phone numbers. When you are calling them to come and test, you don’t get them” (SP #3, Nurse)*

*“For the mothers, some don’t have phone numbers and the house numbers they give too, you cannot trace ... some of the calls go through, others do not. If the call does not go through, since the house numbers too are not working, there is nothing else we can do” (SP #4, Nurse)*

*“The telephone numbers that they give are not correct. It is difficult to trace them Clients should give us the right information like telephone numbers and location so that we can follow up” (SP #6, Midwife)*

*“Most of them don’t have contact numbers and correct addresses, so I can’t follow them up. Even the CHN could not follow them up with the addresses they gave ... Some too, they’ll give you the number alright, but at the point that you are calling them, the number can’t go through” (SP #10, Midwife)*

### 4.6.2 Loss to Follow-up

Many mothers and caregivers have been lost to follow-up in the EID continuum for a number of reasons. Some have refused to visit the facilities because of previous multiple visits to access the same service or delays encountered in accessing certain services.

*“ ... and when they come and the result is not in, they go, they won't come again ... sometimes when they call the mothers, they don't want to come, because, 'I come today, you don't even take the sample and you say I should go and come next time'” (SP #1, PA)*

*“ ... you send them to the lab and they send them back that there is no reagent for the child ... some people when you tell them that there is no reagent and they go, they won't come back again” (SP #2, Nurse)*

*“Mothers complain of delay at the lab ... sometimes, some of them bring their forms back that they will go and come but they don't come back. It's because the one who is supposed to take the sample is not around” (SP #4, Nurse)*

One mother complained of visiting the hospital many times for her infant's result, only to be told each time that it was not available.

*“I have been here many times during postnatal. I always ask (for the result) but they say it's not in” (MC #5, Mother)*

Some of the mothers have refused to visit the hospital when their appointments are rescheduled due to shortage of supplies at the facility.

*“Sometimes, there is shortage of drugs and test kits. If they come and it's not there, they won't come again” (SP #6, Midwife)*

*“It also depends on the availability of test kits (DBS cards). And the mothers, when they go, they don't come back” (SP #7, MO)*

Others have been lost to follow-up as a result of their desire to keep their HIV status secret from their peers, and sometimes, service providers.

*“Sometimes, they do complain. Some of them will say 'I know somebody here and maybe the one will know that I am going to do this test or that, so let me come on this day'” (SP #3, Nurse)*

*“Some of them, they are positive and they disappear, sometimes they deliver at home or TBA. When they know that you know their status, they won't come and deliver here” (SP #7, MO)*

Some of the mothers simply disappear from the reach of service providers for no apparent reason.

*“... the mothers are reluctant sometimes to come to the hospital and do the test” (SP #1, PA)*

*“And those who have phones, when the result is in and you call them, not all of them return for the result” (SP #4, Nurse)*

*“Some of them can easily come but they just refuse to come” (SP #10, Midwife)*

#### **4.6.3 Disclosure, Financial and other Support**

Financial challenges faced by caregivers have prevented some of them from accessing the full range of available EID services for their infant. These challenges have caused some caregivers to relocate to remote areas or have made them unable to afford transportation to the hospital.

*“Most of the teenagers are not working and they are impregnated by young boyfriends who are also not working, and their parents are in the villages. So coming to the hospital every time, even the transportation is a problem” (SP #10, Midwife)*

*“Because they cannot afford to feed themselves here, some of them will relocate to the villages” (SP #6, Midwife)*

*“I intended to come here but I did not have money. Even my drugs have run out but I don’t have money to come for refill” (MC #4, Mother)*

*“Sometimes when I don’t have money, I have to borrow and come to the hospital” (MC #8, Mother)*

Many service providers asserted that, mothers’ inability or unwillingness to disclose their HIV status to their partners and/or relatives have hindered their ability to access EID services.

*“Most of the mothers, they’ve not disclosed their status to their husbands and families. After delivery, the relatives will accompany mothers to the hospital for postnatal, so some of the mothers feel they are not safe because their relatives may know what they are coming to do ... some from the peripheries their husbands will ask them ‘you started the ANC here in the village, what are you going to do in Koforidua?’ and since she can’t inform the husband, she just stops coming” (SP #10, Midwife)*

Some of the mothers confirmed this assertion and said that, they were unable to get financial support because of their non-disclosure. Others feared that disclosing their status would rather make them lose any support they were receiving from their partners or relatives.

*“He does not know ... I have not disclosed to anyone. If I tell my mother, she will not accept me. She may refuse to continue taking care of me” (MC #4, Mother)*

*“He does not know. Sometimes when I don’t have money, I have to borrow and come to the hospital” (MC #8, Mother)*

*“I have not told him. I don’t get any support from him. Even if I tell him, he won’t give me anything” (MC #9, Mother)*

Such fears were validated by the experience of one mother who was forced out of her matrimonial home after she disclosed her status to her husband.

*“I told my husband, but he said if I have this disease, then he can’t continue to marry me” (MC #3, Mother)*

A majority of the mothers, however, had disclosed their status to their partners, relatives or both and were receiving support from them.

*“He is aware of everything, and is very supportive. I don’t hide anything from him. He gives us money for everything we need ... I have disclosed to my daughter and she is very supportive. She is always asking if I come for my drugs” (MC #2, Mother)*

*“I have informed my parents. They are the ones who give me money (MC #3, Mother)*

*“I have told him ... he is supportive. While I was pregnant with the other child when they were taking five cedis for the drugs, he would give me twenty cedis to take for four months. He even encourages me to go and get the drugs ... I have not disclosed to anybody else” (MC #5, Mother)*

#### **4.6.4 Emotional Reactions and Denial**

Mothers have expressed various emotions – anxiety, fear, worry, excitement and happiness – at different stages of accessing the EID services. Anxiety was the main emotion exhibited by mothers while awaiting their infants’ results.

*“They are mostly afraid that the children will also become positive, and so, that kind of anxiety is there” (SP #1, PA)*

*“When I became pregnant and they told me my status, it was difficult for me but I gave everything to God” (MC #1, Mother)*

*“I feel anxious about it, I keep thinking about it; maybe it’s positive” (MC #2, Mother)*

*“I was worried during the waiting period” (MC #4, Mother)*

*“I was not feeling happy. But if I get the results and he is negative, then I will be ok” (MC #5, Mother)*

The service providers observed that some mothers have reacted to the news of HIV diagnosis with denial and have refused to access available PMTCT and EID services. These mothers and their infants have usually returned to the facility in clinically worse states.

*“Some say when they go to prayer camps, they tell them that they are not positive. Others say it’s a spiritual disease, which they have been cured” (SP #4, Nurse)*

*“The mothers are sometimes in denial of their HIV status and refuse treatment but return in worse state ... some mothers who come to deliver tell you that the book (ANC card) is missing – in order to conceal their status” (SP #7, MO)*

*“Some of the clients are in denial, the positive ones on treatment sometimes abscond along the line. When they get into stage 3 and 4, that’s when they come back” (SP #8, PA)*

#### **4.6.5 Caregivers’ Evaluation of EID Processes**

When asked about any challenges they faced with the health system while they accessed PMTCT and EID services, the mothers were unanimous in awarding very high marks to the staff and systems in place at the facilities. The following quotes summarize the mothers’ evaluation.

*“They are doing a good job. If not for them, I wouldn’t be alive now. So they should keep up the good work” (MC #4, Mother, St Martin’s Hospital)*

*“The test was done the same day, there were no problems ... I have not had any challenges” (MC #8, Mother, Regional Hospital)*

## CHAPTER FIVE

### 5.0 DISCUSSION

#### 5.1 BACKGROUND ON CAREGIVERS AND SERVICE PROVIDERS

Only nine of the caregivers reached for inclusion in the study accepted to volunteer as participants. During the brief data collection period, only a few eligible caregivers visited the facilities to be approached for possible inclusion. The effort to reach the caregivers through their telephone numbers and addresses also yielded very little positive results. This was due to the incorrect phone numbers and untraceable addresses given by caregivers to their service providers (**Table 4.7**). The generally low educational levels of the caregivers – below high school level – could have contributed to the low levels of knowledge on EID among many of them. Higher educational levels have been associated with better knowledge and acceptance of PMTCT and EID services (Shaffer et al., 2004). Conversely, mothers with lower educational levels – such as those encountered in this study – were more likely to report late for EID testing of their infants (Goggin et al., 2016).

Half of the EID service providers interviewed were aged above 53 years. With the compulsory retirement age at 60 years for such workers in Ghana (Government of Ghana, 2008), they have less than seven years – in some cases, less than a year – to continue providing such services to the ever-increasing number of clients. Considering the inadequate number and frequency of EID training programmes organized by program managers (as asserted by service providers), this situation could constitute a serious challenge to service delivery in the near future.

## 5.2 PERFORMANCE OF EID IN THE EASTERN REGION

The EID coverage among infants delivered at the St Martin de Porres Hospital between January 2013 and December 2015 was 27.6% (95% CI 22.1% – 33.1%). This was coverage was no different, at 95% confidence, from what has been reported in many countries including 29.4% in Burkina Faso ( $p = 0.520$ ), 30% in Uganda ( $p = 0.396$ ) and 25% in Mozambique ( $p = 0.346$ ) (Cook et al., 2012; Coulibaly et al., 2014; Mugasha et al., 2014). At 95 % confidence, this coverage was, however, significantly higher than the 20% reported in India ( $p = 0.0013$ ) (Hanna et al., 2015). It was also found to be significantly lower ( $p < 0.0001$ ) than the 44% coverage reported by the WHO as the overall coverage of EID among HIV-exposed infants in reporting member countries – a coverage level the WHO finds inadequate (WHO, 2014). EID coverage among exposed infants should be targeting such levels as reported in Malawi and Tanzania, where coverage levels of 71.6% and 88.3% respectively have been reported (Chiduo et al., 2013; Dube et al., 2012).

The low coverage recorded in this study can be attributed to frequent stock-out of supplies (DBS cards); porous systems for identification of eligible infants; inadequate outreach and home visits by community health nurses; poor EID knowledge among caregivers; non-disclosure and denial; and incorrect addresses and phone numbers.

The proportion of exposed-infants in the region that were tested positive for HIV was 13.7%. This MTCT rate is significantly higher ( $p < 0.0001$ ) than the expected maximum of 5% MTCT rate of HIV infection among women receiving antiretroviral medications in breastfeeding populations (WHO, UNICEF, UNAIDS, & UNFPA, 2008) as is the case in Ghana (Ministry of Health Ghana, 2014).

At the St Martin's Hospital, median age at the time of sample collection was 9.4 weeks. By the time their EID results are available to them at the facility, they had reached a median

age of 30.3 weeks (above 7 months). For all infants across the region whose samples were tested at the regional reference laboratory, the situation was not much different. The median age at the time of sample collection was 11.6 weeks. By the time samples were tested and results were returned to their respective facilities, the infants had reached a median age of 29.6 weeks (above 7 months). The cumulative median TAT for result delivery to the EID sites was far above the four weeks recommended by the WHO (WHO, 2010). This was similar to the situation in Mozambique and India where median age at testing was reported at 5 months and 4 months respectively. Median age at the time of result availability was reported at 9 months in Mozambique and 8.5 months in India (Cook et al., 2012; Hanna et al., 2015). This situation implies that, these infants who could have been infected during pregnancy or delivery had no opportunity of receiving ART interventions to prevent disease progression. The seriousness of this situation becomes clearer when infants receiving positive test results are considered alone. Among these infants, only 37.6% of them had their results available at their EID sites by the time they were 6 months old. This proportion only increased to 71.5% when they reached 12 months old.

The long turn-around times at various stages of the EID process were explained by DBS transportation challenges resulting in slow inflow of DBS samples; shortage and expiry of test reagents; frequent breakdown of equipment and slow results delivery systems.

The system in Tanzania can serve as a good example for emulation. The median age at testing was reported at a low of 5.6 weeks in the Kilimanjaro region and a high of 8.6 weeks in the Mbeya region (Chiduo et al., 2013). In the three regions studied, the overall median age at the time of result delivery was three months. This gives service providers adequate time to initiate life-saving ART to improve the prognosis of these infants.

### 5.3 SERVICE PROVIDERS KNOWLEDGE AND SKILLS

Unlike in Kenya (Hassan et al., 2012) and other sub-Saharan African countries reviewed (Adetokunboh & Oluwasanu, 2015), where service providers' knowledge about the number and type of tests to be conducted, as well as rationale and timelines for the various tests were largely inadequate, the service providers interviewed in this study exhibited thorough knowledge of these areas of EID. All providers responded correctly to questions of eligibility, number and type of tests, timelines and rationale for testing.

Some of the trained providers (mostly nurses), however did not have the confidence to practise the skill of sample collection and processing at the lower levels of care, including CHPS compounds and health centres. This situation resulted in the regular referral of mother-baby pairs to hospitals for testing. The 146% coverage for EID testing at the regional hospital, coupled with the fact that no other facility in the entire New Juaben municipality submitted DBS samples for testing, is an indication of these referrals. Such referrals have come along with their own challenges on the caregivers, including transportation costs, loss of income, multiple appointments and delays at bigger facilities.

Opportunities for update of knowledge among practising service providers and training of new ones were reported to be few and far between. This agreed with findings by Laar, Amankwa, & Asiedu (2014) that, in-service training among PMTCT service providers (who usually double as EID service providers) were largely inadequate. Laar (2013) also identified absence of guidelines and lack of opportunity to refresh and/or upgrade their knowledge as a major constraint among HIV workers in Ghana. Regular in-service training of providers is critical to sharpen their knowledge and skills in order to improve service delivery.

#### **5.4 PROVIDER RELATED FACTORS AFFECTING EID**

The provider-related factors identified in this study can be divided into facilitators and barriers. Provider-related facilitators of EID included mechanism for identifying of eligible infants; medium of notification of facilities about result availability at the reference laboratory; settings that provide adequate privacy for caregivers; service providers' attitude towards caregivers; and supportive supervision.

Nurses at the St Martin's Hospital had developed an in-house mechanism of identifying exposed infants by writing a special code on the child health record books of such infants. The sight of this code prompts any attending nurse at a postnatal clinic to request EID testing for such infants. At the regional hospital, identification of eligible infants was made easier because one midwife was on the sole schedule of providing all antenatal and postnatal services for HIV positive pregnant women until their babies were 18 months old. The relatively lower turnover of clients meant that, she could relate better at the personal level with these clients and ensure the testing of their infants at the appropriate times.

The use of mobile technology (Whatsapp Group) by the reference laboratory to disseminate information on the availability of test results is a progressive step that must be continued and improved.

Infrastructural settings in both facilities were such that, they ensured caregivers of privacy and confidentiality during their visits to the clinics. Settings that do not adequately ensure privacy and confidentiality have been shown to affect uptake of EID services in Malawi and Uganda (Dube et al., 2012; Mugasha et al., 2014).

Caregivers adjudged the attitudes of service providers as very positive towards them. This was a very important finding considering the positive association between attitude of service providers and service utilization by clients (Laar et al., 2014). Regular supportive

supervisory visits to the EID sites by HIV program managers and other institutions is a factor that can ultimately improve the provision of services to all clients.

Provider-related barriers to EID service provision that were identified included delays at various stages of the continuum; frequent breakdown of equipment; frequent stock-out of EID related supplies; increasing workload for few dedicated staff; and inadequate motivation of service providers.

Service providers identified a delay in transporting DBS samples to the reference laboratory for testing as a challenge. This was due to unavailable vehicles or staff to manage the transport. This delay was evidenced by the median TAT from sample collection till delivery at the reference laboratory, recorded at 11 days (1.6 weeks). A similar review in Zambia (Sutcliffe et al., 2014) showed a median TAT of 17 days for sample transport. Another delay identified was the time it took from arrival of samples at the lab to testing of the samples. The median TAT was recorded at 17 days (2.4 weeks) while the Zambian review reported a TAT of 6 days over this period. Service providers attributed this delay to frequent shortage or expiry of reagents and the slow in-flow of DBS samples from EID sites, since a minimum of 22 samples were required for a batch of tests to be run. The last identified delay was the time it took for test results to reach EID sites for onward delivery to caregivers. A median TAT of 30 days (4.3 weeks) was seen for this process, comparable to the 29 days reported in the Zambian review. Despite the rapid notification of results availability on a social media platform, health facilities have not been able to respond quickly to collect results. A more innovative medium of results delivery must be explored to overcome this challenge, which is the longest single delay identified in this study.

Another major barrier identified in service delivery was the irregular servicing of equipment resulting in their frequent breakdown. Regular shortage of EID supplies such as DBS cards

and test reagents were also identified. As reported in Burkina Faso and Kenya, such shortages and the lack of preventive maintenance of equipment have negative effects on service delivery (Cherutich et al., 2008; Coulibaly et al., 2014).

Finally, inadequate number of staff dedicated to the provision of EID services for the ever-increasing workload was also identified as a challenge by service providers. Coupled with the virtual absence of motivation for these providers by Management of the facilities, this challenge has resulted in the loss of interest by many HIV workers, making the workload even heavier for the few who remain committed. Insufficient numbers of well trained and skilled staff available for the delivery of specialized services have led to high loss to follow-up rates in Burkina Faso and Kenya (Cherutich et al., 2008; Coulibaly et al., 2014).

The emerging phenomenon of false positive results being received for some infants may be attributed to procedural challenges during sample collection and processing. It may also be the result of inadequate quality assurance systems associated with the equipment and/or testing processes. Further studies need to be conducted into this phenomenon to identify the root cause and prescribe practical solutions.

## **5.5 CAREGIVERS' KNOWLEDGE ON EID**

Caregivers' knowledge about EID was mixed in this study. A few of the mothers exhibited adequate knowledge about the EID testing of their exposed infants, with regard to the appropriate time for testing, rationale for early testing and the type of test that was to be conducted. Some of the mothers' knowledge of the EID program was mixed while others did not have any correct information about the tests. All the mothers who displayed adequate knowledge about EID had tested their infants. Conversely, the mothers who had not tested their infants were those who displayed mixed or no knowledge of EID.

Since mothers are the primary caregivers for their infants and make daily decisions about their health and wellbeing, the importance of mothers' knowledge and awareness about such a critical service for their infants cannot be overemphasized. The low level of caregivers' knowledge and awareness about PMTCT and EID have been reported as challenges to service uptake in Kenya and Burkina Faso (Coulibaly et al., 2014; Hassan et al., 2012). Adequate caregiver knowledge about EID is a positive predictor of early enrolment of infants for EID services (Makau, Okwara, & Oyore, 2015).

The PMTCT and EID service providers seem to be putting in a lot of effort to educate their clients on EID, since all the caregivers referred to them as the source of their information. Considering the misinformation exhibited by some of the caregivers, however, service providers need to sharpen their communication skills to ensure that the information they pass on to their clients are well received and understood. Such a new communication approach needs to take cognisance of the educational levels of the audience in order to make a meaningful impact – since none of the mothers interviewed had achieved high school education.

## **5.6 CAREGIVER RELATED FACTORS AFFECTING EID**

A major caregiver related challenge that was identified by service providers was incorrect phone numbers and untraceable addresses supplied by caregivers. The reason behind such actions by caregivers was not known to the service providers, but the phenomenon has proved to be a major hindrance to EID service delivery. When providers realized that particular infants were past due for testing, they tried to reach them through their phone numbers or residential addresses. Similar efforts were made to reach caregivers when infants' results had been received from the reference laboratory. When service providers

were unable to reach caregivers through these mediums, the mother-baby pairs were lost to follow up in the EID continuum.

Another vital issue that was identified in this study was the issue of disclosure and support from partners and relatives. Service providers generally regarded mothers' non-disclosure of their HIV status to their partners and/or relatives as a barrier to smooth utilization of services. The mothers, however, showed mixed views. While some agreed with the service providers that disclosure had facilitated their ability to continue receiving HIV care for themselves and their infants, others had fears and real experiences of the negative consequences of disclosure. Some feared that disclosing their status to their partners or relatives would cause them to lose any support they were hitherto receiving from these persons. One woman had been forced to leave her matrimonial home after she disclosed her status to her husband.

Literature abounds with views and conclusions that support the service providers' assertion that disclosure of HIV status to partners and significant others is a major facilitator for retention in care while non-disclosure represents a barrier (Adeniyi et al., 2015; Adetokunboh & Oluwasanu, 2015; du Plessis et al., 2015; Hassan et al., 2012; Mugasha et al., 2014; Shaffer et al., 2004). In the light of some caregivers' fears and experiences with disclosure, the services of experienced counsellors should be made available to mothers during the process of disclosure in order to prevent or minimize any negative effects of the disclosure on the mothers and their infants.

Caregivers also faced various forms of financial constraints which limited their ability to access EID and other services for themselves and their infants. The inability to earn a decent living in towns and cities have forced some mothers to relocate to remote villages where such services are unavailable. Others have found it difficult to afford the costs of

transportation to health facilities, especially when multiple appointments are scheduled for the same or similar services. Studies in many parts of Africa (Coulibaly et al., 2014; Hassan et al., 2012; Mugasha et al., 2014) have reported similar impact of such financial challenges on utilization of services by HIV positive mothers.

Many mother-baby pairs have been lost to follow up for a variety of reasons ranging from denial of their HIV status; desire to keep their HIV status from their peers and some service providers; and multiple appointments to access same or similar services. Such multiple appointments have been occasioned as a result of shortage of tests supplies or non-availability of test results on scheduled dates. Chatterjee et al. (2011) reported that multiple visits to sites was a major barrier to access and utilization of services.

## **5.7 STRENGTHS AND LIMITATIONS OF THE STUDY**

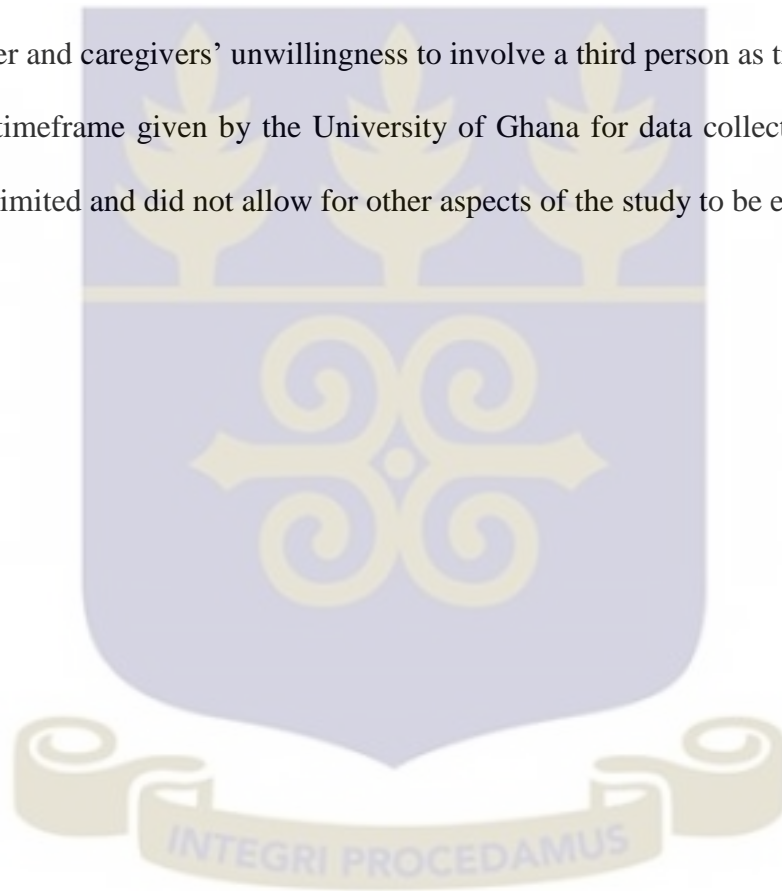
A major strength of this study is that, it is the first of its kind to review the performance and challenges of early infant diagnosis since the service was rolled out in Ghana. The combination of a desk review of EID performance and qualitative interviews of stakeholders helped to better understand the underlying causes of the poor performance of certain EID indicators in the country.

The study, however, had the following limitations

1. The use of focussed group discussions may have been a better data collection technique to elicit more comprehensive views from the mothers and caregivers. However, strong privacy and confidentiality concerns associated with HIV did not allow for such a technique to be employed.
2. Poor addressing system in the communities did not allow for home tracing of many eligible mothers. Wrong phone numbers provided by some clients to their health

service providers made it impossible to reach and include many eligible caregivers in the study.

3. Facility records did not always indicate the dates of result delivery to clients. Therefore, the only dates that could be used for analysis were the dates on which results from the reference laboratory reached the facilities for subsequent collection by caregivers.
4. The interviewer was unable to reach and interview some caregivers due to language barrier and caregivers' unwillingness to involve a third person as translator.
5. The timeframe given by the University of Ghana for data collection and analysis was limited and did not allow for other aspects of the study to be explored.



## CHAPTER SIX

### 6.0 CONCLUSIONS AND RECOMMENDATIONS

#### 6.1 CONCLUSIONS

The performance of EID in the Eastern region was assessed. EID coverage among eligible infants at the St Martin de Porres Hospital between January 2013 and December 2015 was 27.6% (95% CI 22.1% – 33.1%). The median age at the time of sample collection for all infants tested in the region during the period was 11.6 weeks (IQR 6.6 – 26.0). Median TAT from sample collection to delivery at the reference laboratory was 1.6 weeks (IQR 0.1 – 4.1) and that for delivery of sample to time of testing was 2.4 weeks (IQR 1.1 – 5.3). Median TAT for test completion to result collection by EID site was 4.3 weeks (IQR 1.9 – 8.1). By the time results reach the EID site, infants had reached a median age of 29.6 weeks (IQR 18.0 – 48.4).

Service providers had adequate knowledge about EID, with regards to eligibility, type of test conducted, rationale and timelines for testing. Though many had been trained, laboratory technicians were the only group that regularly collected and processed DBS samples. Caregivers' knowledge about EID in respect of timing, rationale for testing and type of tests conducted were mixed. While some exhibited very good knowledge, others were almost clueless about the tests.

Provider related challenges of EID identified were delays (in transporting samples, testing samples and delivering results to EID sites), frequent breakdown of equipment and shortage of supplies, high workload for few staff and lack of staff motivation. Provider-related facilitators were adequate staff knowledge, on-the-job training, mechanism of identifying eligible infants, privacy settings in facilities, staff attitudes towards clients and supportive supervision.

Caregiver related challenges identified were poor knowledge about EID, provision of incorrect phone numbers and addresses, financial constraints, non-disclosure of HIV status to significant others, denial of HIV status and loss to follow-up. Caregiver related facilitators were adequate knowledge about EID and disclosure of HIV status to significant others.



## 6.2 RECOMMENDATIONS

Based on the findings of this study, the following recommendations are proposed to improve EID service provision in the country. To improve coverage of eligible infants,

1. Health facility managers should invest in the use of electronic medical records which could improve communication between ANC, delivery and PNC units of facilities; provide PNC nurses access to information on exposed infants; and enable the tracing of those infants who miss their six-week EID sampling. Community health nurses should be equipped and supervised by District Health Directorates to adequately perform their outreach functions, especially in tracing infants who have been lost to follow up in the EID continuum
2. Education and counselling of HIV positive pregnant women about EID should be enhanced at all PMTCT sites. Mothers should also be sensitized on the importance of providing accurate addresses and phone numbers. Managers of health facilities will be responsible for ensuring
3. Facility managers at all PMTCT/EID sites should establish clear accountability for the tracing of exposed infants. An officer(s) should be assigned to actively follow up on all HIV positive pregnant women until their infants' HIV status have been conclusively determined and given appropriate care

To address the delays and other identified challenges in implementation,

4. The delay in delivery of PCR test results to facilities can be resolved through the use of technology such as electronic mailing, mobile SMS texting or 'Whatsapp' texting of results. To ensure confidentiality, samples can be labelled with unique codes from the EID site. When the results are being sent through any of these mediums, only the codes should be used. The results can be then decoded at the receiving end to assign each result to the right infant. The NACP needs to spearhead this recommendation.

5. EID service providers should be regularly trained and adequately motivated to deliver services. Trained staff should be adequately supervised to ensure that they provide services, including DBS sample collection, at all levels of care and avoid client referrals to other facilities for testing. The NACP, together with regional and district health directorates and facility managers should be responsible for these recommendations.
6. To enhance disclosure and prevent denial of HIV status, health facility managers should make the services of experienced counsellors and psychologists available to clients. This will help clients in managing the many issues associated with disclosure and denial.
7. Procurement, storage and distribution of EID supplies and reagents by the NACP and/or GHS should follow guidelines for Logistic Management of Public Sector Health Commodities in Ghana to prevent frequent stock outs and expiries. Preventive maintenance schedules should be developed and strictly followed to avoid regular breakdown of EID equipment.
8. Further decentralization of the testing of DBS samples will result in the removal of many barriers and reduce turn-around times. The NACP can achieve this by integrating point-of-care testing technologies into the national EID system, such that, areas underserved by the existing EID system will have access to these technologies. Point-of-care EID technologies come with several advantages, including rapid on-site testing with same-day result delivery; decentralization to increase access and coverage; easy to use in all settings and not requiring any skilled laboratory technicians to operate.
9. Regular quality assurance checks should be conducted on the equipment, reagents and processes employed for PCR testing to prevent the phenomenon of false positive results that have been documented by a midwife at the regional hospital. The NACP should coordinate such quality assurance monitoring.

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## APPENDICES

### APPENDIX 1A INTERVIEW GUIDE FOR CAREGIVERS

Date: .....

Unique No.:

Location: .....

Interviewer: .....

#### Background information on participant

Age: ..... Occupation: .....

Marital Status: ..... Number of children: .....

Religion: ..... Highest educational level: .....

Age of last child: ..... (weeks or months)

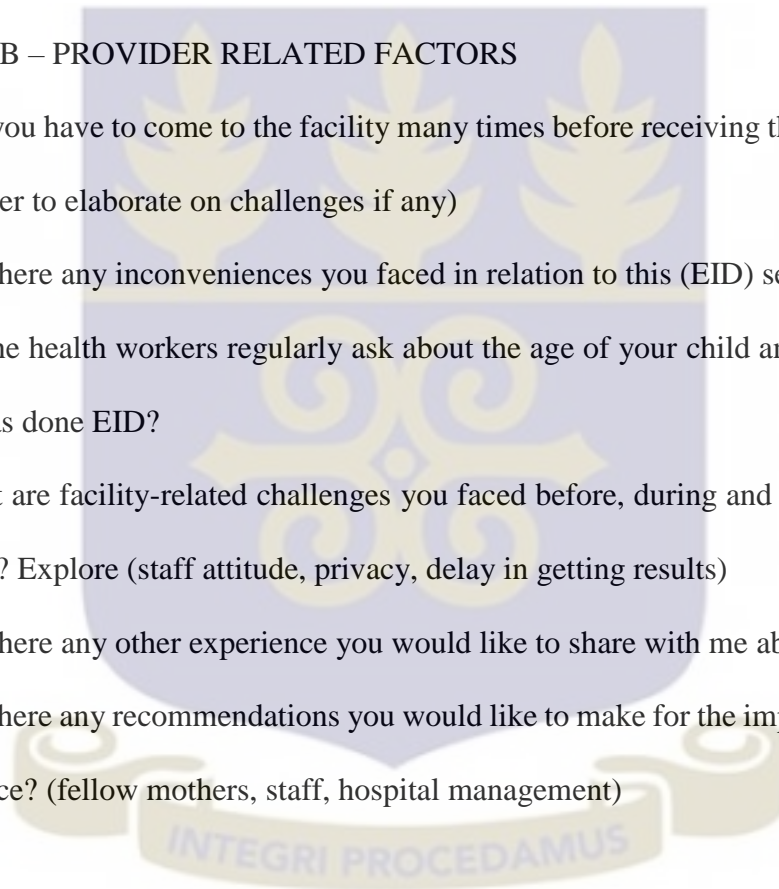
#### SECTION A – CLIENT-SPECIFIC FACTORS

1. What do you know about early infant diagnosis? (probe for knowledge on **importance** and **timelines**)
2. How did you hear about this information? (source of information)
3. Have you tested your infant for HIV?
4. If no, why not? (explore personal reasons and other hindrances)
5. If yes, what made it easy for you?
6. How old was your child when the test was done?
7. What type of test was done? (Let mother describe procedure e.g. finger prick onto a cassette, or heel prick onto a paper, etc.)
8. Do you know the results of the test? (Find out **how long it took** before getting results and **means of results delivery**)
9. What was the feeling like during the waiting period?

10. What are some of the challenges you faced before, during and after testing your baby? Explore (finance, social, distance, migration)
11. Is your partner aware of your HIV status? If yes, how supportive has he been with respect to the EID service? What form of support is offered?
12. Apart from your partner, is any other person aware of your status? Are they supportive? What form of support?

#### SECTION B – PROVIDER RELATED FACTORS

13. Did you have to come to the facility many times before receiving the results? (allow mother to elaborate on challenges if any)
14. Are there any inconveniences you faced in relation to this (EID) service?
15. Do the health workers regularly ask about the age of your child and whether or not he has done EID?
16. What are facility-related challenges you faced before, during and after testing your baby? Explore (staff attitude, privacy, delay in getting results)
17. Are there any other experience you would like to share with me about EID?
18. Are there any recommendations you would like to make for the improvement of this service? (fellow mothers, staff, hospital management)



**APPENDIX 1B INTERVIEW GUIDE FOR SERVICE PROVIDERS**

Date: .....

Unique No.:

Location: .....

Interviewer: .....

**Background information on participant**

Age: .....

Sex: .....

Qualification: .....

Since when: .....

Professional title: .....

Current position: .....

Since when: .....

**SECTION A – HEAD OF HIV CARE UNIT ONLY**

1. Which officers are involved in the delivery of EID service in this facility?
2. What systems are in place in this facility to identify HIV exposed infants for testing
3. Kindly describe how the EID system works at this facility: Who collects and prepares the samples? Who sends them? How are they sent? What do they do next? What data registers are used?
4. How long does it take to get samples back from the laboratory? How are the results delivered to the facility? Who receives the results and what do they do next? What data registers do they use?
5. Can you describe how the parents of the exposed infants are informed of the testing results? Who does that at this site? Is there any follow up with the parent?

**SECTION B – STAFF RELATED FACTORS (All HIV Care Staff)**

1. What do you know about early infant diagnosis (EID) of HIV? (explore staff's knowledge on eligibility, types of tests, rationale for various tests, timelines, etc.)

2. How often do you attend trainings on PMTCT and EID? (Ask when staff attended last training and whether EID was prominent in the modules)
3. How involved are you in the provision of EID services to clients?
4. What challenges have you faced in the delivery of this service to your clients?  
(Explore staff's own challenges e.g. workload, motivation, clients' attitude)
5. What complaints/challenges have your clients reported to you about this service?

#### SECTION C – FACILITY RELATED FACTORS (All HIV Care Staff)

6. What mechanisms are available in the facility to identify exposed infants for testing?
7. What referral systems are available in your facility for testing of exposed infants?
8. How are the tests carried out in your facility? (sample collection, transport systems)
9. What data registers do they use to register the EID testing?
10. How do you receive results for samples submitted for testing? (means of result delivery, time it takes to receive results, etc.)
11. Once you receive the results, how do you communicate them to clients concerned?
12. How often do you have loss to follow-up with EID services? How do you manage them?
13. What referral mechanisms are in place for care and treatment of HIV positive infants?
14. How often do you receive supportive supervisory visits on EID care in your facility?
15. What challenges have you faced in the delivery of this service to your clients?  
(Explore challenges related to the workplace e.g. logistics and supply of EID materials, infrastructure, privacy)
16. Are there any other experiences you would like to share with me about EID?
17. Are there any recommendations you would like to make for the improvement of this service? (clients, fellow providers, hospital management, programme managers)

## **APPENDIX 2A      INFORMATION SHEET**

Title:            Early Infant Diagnosis of HIV in Eastern Region of Ghana: Stakeholders  
                         Knowledge and Implementation Challenges

Investigator: Daniel Osei

Address:        Box LG 13, Department of Population, Family and Reproductive Health,  
                         School of Public Health, University of Ghana, Legon

Email:           naadjeigh@yahoo.co.uk      dosei012@st.ug.edu.gh

### **General Information about Research**

This study seeks to investigate the experiences of HIV positive mothers and service providers about the challenges they face in the delivery and uptake of EID services in health facilities. Findings will be used as a basis to make recommendations towards improvement in service delivery and uptake. Data will be collected from study participants through interviews which will last approximately 20 minutes. Data collection will extend from 6<sup>th</sup> – 24<sup>th</sup> June 2016.

### **Potential Risks**

This study will not pose any risk to you. The interview will be in relation to your experiences concerning early HIV diagnosis of HIV-exposed infants. About 20 minutes of your time will be required to complete this interview.

### **Benefits**

Participating in this study will not bring any direct financial benefits to you, since the study is self-funded by the researcher. However, findings and recommendations from the study could help improve the delivery and uptake of EID services in the country. HIV positive women may benefit from such improvements when they decide to have a child in the future. If it is found that an HIV positive mother has not accessed EID services for her infant, she

will be educated on the importance of EID and referred to the appropriate unit for those services.

### **Compensation / Payment**

This study is not sponsored by a funding agency. It is self-financed by the researcher. Cash compensation will not be paid to you for participating in the study. However, your participation will be recognized and appreciated.

### **Costs**

You will not have to bear any cost for accepting to participate in this study, besides your time. Where you have to travel from your residence to the health facility, the cost of your travel will be borne by the researcher

### **Privacy/Confidentiality**

In order to protect your identity at all times, the interview will be conducted at a venue that will not expose you to other individuals who may not know your HIV status. We will not be asking for your name and your voice will be muffled so that it cannot be linked to you in any way. The interview guide will be given a unique identification number.

### **Data Collection, Usage and Storage**

Interviews will be recorded and later transcribed in the English language. Data collected will be used for research purposes only. To ensure confidentiality, audio tapes will be stored in password-protected folders and hard copies will be kept under lock and key. Only the researcher and supervisor will have access to all forms of data collected. Recordings will be kept for a period of 12 months, by which time all processes relating to this study would have been completed.

### **Voluntary Participation / Withdrawal**

Your participation in this study is entirely voluntary. You have a right to withdraw from the study at any time during the interview process. You have the right to refuse to answer any question which you may feel uncomfortable about. You will not be penalized in any way for your refusal to participate in the study or withdrawal from the study.

### **Conflict of Interest**

The researcher declares no conflict of interest with respect to the conduct of this study.

### **Outcome and Feedback**

Findings and recommendations of the study will be disseminated to the hospital authorities. The hospital management will be encouraged to further disseminate relevant portions of the findings and recommendations to clients and staff involved.

### **Funding Information**

This study is funded by the investigator, Daniel Osei.

### **Contact for Further Information**

For any further information regarding this study, please contact the investigator, Daniel Osei on the following numbers: 020 5582014 or 024 4871316

**OR**

Dr Amos Laar (Supervisor): 024 4982176

**OR**

Hannah Frimpong (Administrator, Ghana Health Service Ethics Review Committee)

050 7041223

**APPENDIX 2B CONSENT FORM**

I have understood the contents of the information sheet describing the benefits, risks and procedures regarding the study titled “Early Infant Diagnosis of HIV in Eastern Region of Ghana: Stakeholders Knowledge and Implementation Challenges”. I have been given the opportunity to ask any questions about the study and they have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study. I understand that I have the right to withdraw from the study at any time without suffering any consequences as a result. I agree to participate as a volunteer.

\_\_\_\_\_  
Signature/Thumbprint of Participant

\_\_\_\_\_  
Date

**For volunteers who cannot read**

I was present when the benefits, risks and procedures of the study were read and explained to the volunteer. All questions were answered and the volunteer has agreed to participate in the study.

\_\_\_\_\_  
Signature/Thumbprint of Witness

\_\_\_\_\_  
Date

**Person obtaining consent**

I certify that the nature and purpose, potential benefits and potential risks associated with participating in this study have been explained to the above individual, who has voluntarily consented to participate in the study.

\_\_\_\_\_  
Signature/Thumbprint of Person

\_\_\_\_\_  
Date

Who Obtained Consent

**APPENDIX 3: ETHICAL APPROVAL**

