

**BARRIERS TO EARLY INFANT DIAGNOSIS OF HIV IN THE WA
MUNICIPAL AND LAWRA DISTRICT OF THE UPPER WEST
REGION OF GHANA**

BY

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DECLARATION

I Robert Domo Nuoh, hereby declare that apart from specific reference to other people's work which have been duly acknowledged, this thesis is my own original work. The views and findings presented here are a result of the study I conducted under supervision, among HIV positive mothers at selected antiretroviral treatment centers (ART) and Antenatal clinics (ANC) in Lawra district and Wa Municipal of the Upper West Region of Ghana. I wish to assert that this work has neither been published nor submitted to any other academic institution for an academic award.

Signature..... Date.....

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INTEGRI PROCEDAMUS

DEDICATION

I dedicate this work to the many HIV exposed infants who have not been diagnosed and reached with lifesaving interventions. Also to all the Nuoh Family especially my Father (Mr. J.K Nuoh) and Mother (Mrs. F. P Nuoh) as well as Ruby, Elvis and Maureen for their support and encouragement.



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LIST OF ABBREVIATIONS AND ACRONYMS

Ab	Antibody
Ag	Antigen
AIDS:	Acquired Immunodeficiency Syndrome
AFENET:	African Field Epidemiology Network
ANC:	Antenatal Care
ART:	Anti-Retroviral Therapy
AZT:	Zidovudine
CI	Confidence interval
CDC:	Center for Disease Control and Prevention
CHPS:	Community-based Health Planning and Services
CHAI:	Clinton Health Access Initiative
CHER:	Children with HIV antiretroviral therapy
CI:	Confidence Interval
CNS	Central Nervous System
CT:	Counseling and Testing
DBS:	Dried Blood Spots
DHA:	District Health Administration
DHMT:	District Health Management Team
EID:	Early Infant diagnosis
EFV:	Efavirenz
EPP	Estimations and Projections Package
FP:	False Positive

FN:	False Negative
FTC:	Emitricitabine
ERC:	Ethics Review Committee
EMTCT:	Elimination of Mother-to- Child Transmission
GRADE	Grading of Recommendations, Assessment Development Evaluation
HEI:	HIV Exposed Infant
HIV:	Human Immunodeficiency Virus
Ig	Immunoglobulin
IATT:	Inter Agency Task Team
IQR	Interquartile Range
HSS:	HIV Sentinel Survey
IDSR:	Integrated Disease Surveillance Response
IMCI:	Integrated Management of Childhood Illnesses
MSM	Men having sex with men
NACP:	National AIDS/STI Control Program
NNRTIs:	Non-Nucleoside/Nucleotide Reverse Transcriptase Inhibitor
NRTIs:	Nucleotide Reverse Transcriptase Inhibitor
OR	Odds Ratio
PEPFAR:	President Emergency Plan for AIDS Relief
PHRL:	Public Health and Reference Laboratory
PITC:	Provider Initiated Counseling and Testing
PLHIV:	People Living With HIV

P24Ag:	P24 antigen assay
MTCT:	Mother-to-Child transmission
PMBC:	Peripheral Mononuclear Blood Cells
PMTCT:	Prevention of Mother-to-Child Transmission
PCR:	Polymerase Chain Reaction
RNA:	Ribonucleic Acid
SMS	Short Message Service
STI:	Sexually Transmitted Infections
Sd-NVP:	Single Dose Nevirapine
TAT	Turnaround time
TDF:	Tenofovir
3TC:	Lamivudine
UNAIDS:	Joint United Nations Programme on HIV/AIDS
UNGASS:	United Nations General Assembly Special Session
UNICEF:	United Nations Children's Fund
WHO:	World Health Organization



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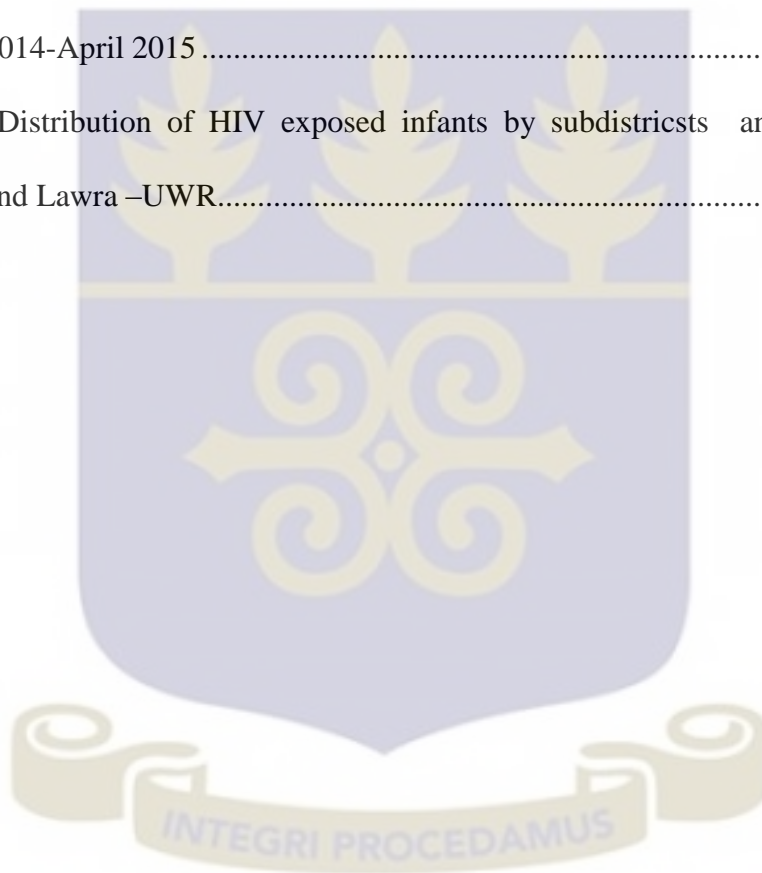
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ABSTRACT

Introduction

About 90% of HIV new infections among infant and children younger than 14 years are due to mother-to-child transmission. More than half of these children die before their second birthday in the absence of treatment. However, mortality among HIV positive infants can be reduced by over 70% if treatment is initiated within the first three months after birth. Though Ghana has well established Prevention of Mother to Child/Early infant diagnosis (PMTCT/EID) service, over 80 % of HIV Exposed Infants (HEIs) are not tested by DNA PCR at 4 to 6 Weeks as recommended by WHO. The consequence of this is that thousands of HEIs are left undiagnosed and the NACPs (National AIDS control Program) goal of eliminating new infections among infant or reducing HIV related child deaths by 50% by 2015 does not appear to be likely. This study seeks to identify the socio-demographic, health system and psychosocial factors influencing the decision of HIV positive mothers to test their infants for early infant diagnosis by DBS-PCR (Dry Blood Spot DNA polymerase chain reaction)

Methods

A case control study was conducted at ART centers in the Lawra district and Wa Municipal between December 2014 and June 2015 to determine significant barriers to early infant diagnosis of HIV at one ART center in Wa and one in Lawra in the upper west region of Ghana. Early infant diagnosis registers and ANC/PMTCT records were reviewed to obtain a list of HIV positive mothers attending ART. The list of mothers who tested their infants (controls) and those who did not (cases) between January 2011 and December 2014 were then extracted. Data was collected with a checklist and questionnaire, entered into Epi info, cleaned, and exported to Stata 13 for analysis.

Results

One hundred and ninety two HIV positive Mother-infants-pairs including 96 cases and 96 controls were interviewed. Maternal age ranged between 20 -45 years with a median age of 29 years while infant ages ranged from 3 weeks to 205 week. Median age of infant at testing was 10weeks IQR 6-26 weeks and median turn- around-time of DNA-PCR result was 11 weeks IQR 4-27 Weeks. Factors that were significantly associated with follow up for EID were: lack of maternal independent income source with Adjusted Odds Ratio (AOR), 0.4 (95% CI 0.2-0.8) maternal formal education AOR 0.5 (95% CI 0.2-0.9), accessing testing information after delivery (AOR, 18.6 95% CI 1.7-202.5). Mother-to-child-transmission-rate was 2.3 % and 62.4% of infants were not tested due to stock-outs of reagents. Receiving PMTCT intervention reduced the odds of becoming a case. Infants who received only six week AZT were about 14 times more likely to become cases compared to those who received all PMTCT interventions.(AOR=14.6 95% CI 1.1-186.4). Infants of mothers who heard of infant testing after delivery were 18 times likely to become cases compared to infants of mother who heard of testing during pregnancy,(AOR=18.6 ,95% CI 1.7-202.5).

Conclusion

Lack of maternal-independent-income, poor timing of EID information, and stock outs of Laboratory reagents are major barriers to early infant diagnosis. Women who are educated, employed or trading were most likely to test their infants. Efforts towards EID coverage improvement must focus on decentralizing and strengthening laboratory test as well as empowering mothers.

Key Words: Barriers, HIV, early infant diagnosis, DNA-PCR, Ghana.

CHAPTER ONE

INTRODUCTION

1.1 Background

Acquired immunodeficiency syndrome (AIDS) is an infection of human T Lymphocytes and other organs caused by a retrovirus, human immune deficiency virus (HIV). It is a complex set of signs and symptoms and infections resulting from gradual and progressive damage of the immune system due to infection with the virus (Weiss, 1993; Wolters Kluwer/Lippincott Williams & Wilkins, 2009). AIDS marks the late clinical stage of HIV infection, which is characterized by a cluster of diseases and loss of cellular immunity (Heymann D. L, 2008). People infected with HIV often die from opportunistic infections and tumors as a result of reduced effectiveness of their immune system (Heymann D. L, 2008).

The virus is present in blood, semen, vaginal fluid, pre-seminal fluid, breast milk and other body fluids of an infected person and is transmitted through direct contact of mucus membranes with these fluids (Ballinger, Kumar, & Clark, 2011). Sexual contact is the most common mode of transmission, however, other forms of transmission such as sharing sharps, mother to child transmission and transfusion of infected blood or blood products also occur with less frequency. Among infants and children less than 14years of age, mother-to-child or vertical transmission is responsible for over 90% of all infections (WHO, 2010b). Newly infected persons may take up to three months to seroconvert (develop antibodies to HIV), however progression of infection depend on several factors including ARV treatment (Sabin & Lundgren, 2013). Infection with other sexually transmitted infections is known to increase the chances of HIV transmission. Several epidemiologic studies have shown that ulcerative lesions due to infectious agents (*Treponema pallidum*, *Haemophilus ducreyi*, *Trichomonas vaginalis* and *Herpes simplex*

virus) have been reported to enhance HIV transmission. Similarly, treating other sexually transmitted infections in people who are co-infected has been found to be beneficial, in improving CD4 counts thereby reducing viral loads significantly (Kissinger et al., 2009)

1.1.1 Risk factors for transmission

Major risk groups for HIV infections within the general population are female sex workers, men having sex with men (MSM), injection drug users and children born to HIV positive mothers. Among infants and children less than 14 years, mother-to-child transmission (MTCT) accounts for over 90% of all infections (WHO, 2010b). In the absence of any intervention, MTCT rates of HIV is estimated to be between 25-30% among HIV exposed infants. An estimated 14,000 new infections occur every day globally in the general population (WHO, 2010b). These new infections include 700 infants, who acquire the infection through mother-to-child transmission and 50 young women each day through gender based violence involving intimate partners (UNAIDS, 2014b). Mother-to-child transmission is also believed to contribute 14% of all new infections globally. However, with appropriate PMTCT interventions, mother-to-child transmission rates of HIV could be reduced from about 40% to as low as 5% (“Prevention of Mother-to-Child Transmission (PMTCT) of HIV | AIDSTAR-One,” 2010; Rollins, Mzolo, Moodley, Esterhuizen, & van Rooyen, 2009, Rollins et al., 2009)

Investments in HIV and global efforts to control HIV over the year have resulted in several benefits including a reducing trends of new HIV infections and HIV related mortality (UNAIDS, 2014b). Between the years 2001 and 2012, there has been a 50% drop in the number of new infections in 26 countries and this reduction has been more significant among children (UNAIDS, 2014b). Analysis of exposed infant testing data from Zambia showed that mother to child transmission rates were drastically reduced

when both mother and exposed infant were put on treatment (Torpey et al., 2012). Similarly, Ghana achieved the greatest reduction in mother-to-child transmission rates of 75% between 2009 and 2012 among 21 global plan priority countries (UNAIDS, 2013b)

1.1.2 Global Burden of HIV

As of December 2013, an estimated 35.3 million people were reported to be living with HIV globally. About 69% of all HIV infections are believed to occur in Africa. Seven hundred infants are infected with HIV every day because their families lack access to HIV service (UNAIDS, 2014b). About 15% -45% of all children born to HIV positive mothers will acquire HIV from their mothers in the absence of intervention. In the year 2012 alone, an estimated 200,000 children acquired HIV infection ((Flannery et al., 2014) and as many as 240,000 new infections among infants in 2013 alone (UNAIDS, 2014a). Therefore scaling up of PMTCT services to reduce and reverse HIV transmission among infants and young children has been the priority of all HIV control programs (WHO, 2010b)

1.1.3 African Burden

Out of the total global HIV population, 24.7 million of them are estimated to be living in sub Saharan Africa which represents up to 68% of the global HIV burden (UNAIDS, 2014). The region also account for about 70% of all new HIV infections. About 210,000 children were newly infected with HIV in sub-Saharan Africa in 2013 alone (UNAIDS, 2014a). Though over 12 million people were reached with lifesaving drugs in 2013 alone and a target of 15 million has been set for the year 2015, access to treatment is still poor in Africa with less than 40% of eligible people getting the needed treatment. The

situation is even worse in countries like Nigeria where it is reported that an estimated 80% of persons who require treatment are not receiving it (Anoje et al., 2012)

1.1.4 Ghana Burden

As of December 2013, the total number of people living with HIV (PLHIV) in Ghana was 205,523 with a national prevalence of 1.31% and number of new infections was just a little over seven thousand (NACP, 2013b). Even though the national HIV prevalence has declined over the years from 3.7 in 2003 to 1.3 in 2013, the epidemic is still concentrated in some key towns. Over fifteen thousand (15,763) pregnant women tested positive for HIV in 2011, which declined slightly to eleven thousand one hundred and forty five (11,145) in 2012 (NACP, 2013a). This translates to about twenty seven thousand potentially HIV exposed infants in two years, however, only four thousand (4,046) of them were screened using DNA PCR during the two years (NACP, 2013b). Though HIV prevalence among pregnant women has been declining over the years, the number of children aged less than 14 years living with HIV is still high (over 28000 as of December 2012), this calls for scaling up of PMTCT Services. PMTCT interventions have been found to reduce the risk of HIV transmission 3-4 folds from around fifty percent to about 2%-5% (WHO, 2010b) The National AIDS Control program of Ghana (NACP) has set a target of zero new HIV infections among exposed infants by 2015 (NACP, 2013b). The program hopes to achieve this through improved and enhanced PMTCT including early infant diagnosis using dry blood spot DNA PCR.

1.1.5 Diagnosis and Treatment

Diagnosis of HIV in person suspected of having HIV infection requires confirmation with a laboratory test which usually involves testing for antibodies to the HIV virus or direct detection of HIV viral particles or nucleic acid. Antibody testing is recommended for screening adults and children above 18 months. Current WHO guidelines on HIV testing requires that infant less than 18 months of age should be tested by a virologic test using DNA PCR. These techniques typically detect HIV DNA, RNA of Gag P 24 proteins. Antigen test and virologic testing is only used for confirmation of screening test among adults, while the less expensive antibody test are generally used for screening purposes (WHO, 2010a). Antibody or serologic testing is however not recommended for infants because maternal HIV antibodies could diffuse across the placenta and persist in the infant until up to 18 months after delivery (Creek et al., 2007; Penazzato et al., 2014).

Ghana introduced dry blood spot DNA PCR testing in 2009 and has targeted to eliminate new HIV Infection in infants by 2015 (NACP, 2013b). Previously treatment of HIV in PMTCT programs required staging of HIV positive pregnant women before treatment however most recent guidelines require that all HIV positive women be put on treatment regardless of clinical stage and CD4 count (WHO, 2013c). These guidelines also recommends treatment of all HIV positive children under five years old. For prompt identification and early initiation of treatment of HIV positive infants, WHO guideline require testing of all HEI (HIV exposed infants) for HIV at six weeks or earliest opportunity there after using nucleic acid or viral antigen identification techniques (WHO, 2010d). After delivery however most HIV positive mother and their infants are not identified and enrolled into care and some of those who are identified do not complete the EID cascade (Sibanda, Weller, Hakim, & Cowan, 2013). Though it has been suggested that the time of testing of exposed infants be shifted closer to birth

(Lilian, Kalk, Technau, & Sherman, 2013) to minimize loss to follow up, it has also been observed that sensitivity of the test increases with increase in infant age given that about 50% of infant infection occur postnatal (UNAIDS, 2013a,UNAIDS, 2013c). If infants are tested at birth, infection that are acquired after birth would not be detected since most PCR techniques especially those that detect RNA require 8 to 10 days after infection to detect HIV infection (Nesheim et al., 2003).

1.1.6 Control and prevention

HIV/AIDS is a disease of special public health focus targeted for reduced transmission through different interventions. Among these interventions are primary interventions (public education on abstinence, faithfulness to single uninfected partners, continuous and consistent condom use, screening of blood for safe blood), secondary interventions (prevention of mother to child transmission and treatment of infected persons to reduce the chances of new infections) and tertiary prevention in the form of lifelong treatment and prevention of opportunistic infections. It is therefore not surprising that PMTCT service is one of the interventions that have been widely and vigorously implemented by HIV control programs across the world. Ghana was among the first six countries in west Africa to adopt a policy of elimination of mother to child transmission (e-MTCT), (Ghana Health Service, 2013).

Ghana introduced DBS PCR for early infant diagnosis in 2009 with a policy of testing all exposed infant six weeks after birth and presenting mothers with counseling and follow up opportunities for up to 18 months. The country has a well-established PMTCT service including over 1,450 PMTCT centers (NACP, 2013b). Seventy five of these centers are located in the upper west region with at least one PMTCT center in each sub district (Ghana Health Service, 2013). All pregnant women who make their first visit to an ANC

clinic in a current pregnancy are counselled and given an option to voluntarily test for HIV. Pregnant women who test positive for HIV, have their status indicated on their ANC card using a special code and they are referred to PMTCT/ART center. An enhanced referral system is used in which nurses at the point of testing take the patient/positive women directly to the PMTCT nurse. This arrangement has been put in place to limit number of positive women who default/refuse referral (personal communication with PMTCT and ART nurses). Another opportunity presents during labour when women in labour with unknown HIV status are counselled and tested for HIV. As part of PMTCT, all HIV positive pregnant women receive triple ARV combination during pregnancy and single dose nevirapine (sdNVP) during labour while their new born babies also receive sdNVP with 72 hours after birth, followed by Zidovudine (AZT) syrup for six weeks (NACP, 2010).

Currently in Ghana the recommended triple ARV regimens are separated into first line drugs and second line drugs. The first line drugs are used for all HIV positive persons who meet the criteria for treatment, while the second line drug are reserved for patients with demonstrated treatment resistance. The recommended first line include two (2) Nucleoside/tide Reverse Transcriptase Inhibitors (NRTIs) and 1 Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), while the second line consist of 2 NRTIs and 1 boosted Protease Inhibitor (PI), (NACP, 2010). Where available, fixed dose combinations of these drugs are preferred to single dose preparations because they improve adherence to treatment. Some of these fixed dose combinations are AZT/3TC, AZT/3TC/NVP (Zidovudine, Lamivudine, and Nevirapine), AZT/3TC/EFV (Zidovudine, Lamivudine, Efavirenz) and TDF/FTC (Tenofovir, Efavirenz). Where contraindicated, Nevirapine is replaced with Efavirenz in liver dysfunction and hypersensitivity while Zidovudine is replaced with Tenofovir in patients with severe

anaemia. In women who are in their first trimester of pregnancy or patients who show adverse central nervous system (CNS) effect with Efavirenz treatment, Efavirenz is replaced with Nevirapine. Lamivudine and Tenofovir combinations is used for HIV and Hepatitis B co infected patients (NACP, 2010).

Some study findings have outlined best practices that could maximize the benefits of PMTCT programs, which include intra-partum HIV testing and treatment (Tejiokem et al., 2011), having caesarian section instead of normal natural delivery has been found to influence the HIV status of exposed infants (Liu & Chibwasha, 2014). If HIV infection is not prevented by PMTCT, early testing presents an opportunity for the infant to be enrolled into care to reduce chances of death. With the latest WHO treatment guidelines and option B+ treatment of HIV which require that all HIV positive pregnant women be put on treatment regardless of stage, many more lives could be save through early infant diagnosis of HIV (WHO, 2013a). Initiation of treatment in HIV positive infants within the first three months of live can reduce mortality by 70% (Violari et al., 2008).

1.2 Problem statement

HIV disease progression is faster in children than in Adults and about 30% of HIV positive infant die before their first birthday and up 50% before their second birthday. Evidence from the Children with HIV early antiretroviral therapy (CHER) study of South Africa suggested that early detection and treatment could reverse this trend. This significant finding informed WHO decision to revise testing guidelines and recommending the testing of HIV exposed infants at six week using DNA PCR (WHO, 2010a). Most infants especially in resource poor settings are however not covered by Early Infant Diagnosis (EID) using a viral DNA/RNA detection method for definite diagnosis. It is estimated that over 85% of HIV exposed infants are not tested for HIV

and 35% of those who get tested and are positive are without treatment (UNAIDS, 2014b). Early treatment of these infants is crucial to promote their survival, thus, Ghana introduced early infant diagnosis to identify these infants for prompt treatment and allow mothers make informed choices. The country has a well-established PMTCT service and is among the few countries in sub Saharan Africa to achieve over 80% PMTCT coverage(UNAIDS, 2014b).

Though dry blood spot PCR testing offers an opportunity for measuring the impact of PMTCT and timely initiation of treatment for infected infants, most exposed infants are not returned to clinics for testing by dry blood spot PCR (UNAIDS, 2014b). EID coverage in Ghana continue to be low, ranging from 1% (UNAIDS, 2014a) in 2010 to about 14.9% in 2012 (NACP, 2013b). In 2011 alone over fifteen thousand (15,763) pregnant women tested positive for HIV and over eleven thousand (11,145) in 2013. However, only a little over four thousand (4,019) exposed infants were screened by DBS-PCR for early infant diagnosis. The National AIDS Control Programme of Ghana (NACP) has a target of achieving zero new infections among exposed infants by the end of 2015(NACP, 2012). This target though ambitious, agrees with the targets of similar global programmes which aim at eliminating new infections among infants and ensuring the survival of their mothers (UNAIDS, 2013c). The NACP also targeted to test at least 13,200 exposed infants within 12 months of delivery in 2013 alone (NACP, 2013b). A review of HIV surveillance data during an evaluation exercise, however reveals that just a little over six thousand (6114) exposed infants were screened by DBS PCR between 2011 and 2013 (Nuoh, Unpublished). This suggest that only 14.9% of HIV exposed infants (HEI) are covered by EID with about 85% of them having an unmet need for early infant diagnosis. In Lawra for example coverage is 24.3% Even though this system was introduced to improve care of HIV exposed infants there is a clear

indication that it is underutilized. If this large numbers of HIV exposed infants is left undiagnosed, the targets of eliminating HIV new infections among infants and reducing HIV related child mortality by 50% by 2015 would not be realized. It is therefore necessary to identify factors accounting for the poor uptake of EID services to help the NACP improve early infant diagnosis services and scale up interventions towards achieving zero new infections and reduce the number of children living with HIV.

1.3 Conceptual Framework

Figure 1.1 below demonstrates how various factors interplay to influence the outcome of early infant diagnosis services. The factors outlined in the framework are those identified by other researchers and those perceived to be contributing to poor uptake of early infant diagnosis of HIV especially in resource poor settings (Ciaranello et al., 2011; Ghadrshenas et al., 2013; IATT, 2012). In this framework these factors have been classified into Health System, Sociodemographic and Psychosocial factors.

Health system factor that have been demonstrated to influence the uptake of EID are cost of DNA PCR testing and reagents, lack of integration of EID with other services, inadequate staff and poor staff training, reagent stock outs, Poor turnaround time of DNA PCR results (Binagwaho et al., 2013). Other health system factors are poor patient counselling and referral and lack of clear procedure for identifying exposed infant (Ciampa et al., 2011). Collection of blood sample transportation to centralized laboratories have also posed a significant challenge to scaling up EID service (Sherman, Stevens, Jones, Horsfield, & Stevens, 2005).

Access to early infant diagnosis service has also been economically challenging for mothers, especially in resource poor setting (Creek et al., 2007; Penazzato et al., 2014). Poverty and lack of access to DNA PCR testing in rural areas is believed to be causing

poor EID coverage (Adebimpe, 2013; Meyers et al., 2007). Even in situations where poverty is not a barrier, ignorance about infant testing opportunities and its associated benefits could still be keeping HIV exposed infant Mothers away from accessing EID. Though skilled delivery is consistently improving in Ghana (Ghana Health Service, 2013), a considerable proportion of infants are still outside health facilities with their mothers' HIV status unknown and are very unlikely to be covered by PMTCT. Also, larger household sizes and many children may take a huge toll on the resources of already poor families and this may hinder women from such homes to make the repeated health facility visits that are required to complete the EID cascade.

Finally, psychosocial factors play a role in a Mother's decision to test her exposed infant. Varga and others reported fear, stigmatization and a mother feeling guilty of transferring HIV to their infants as a challenge to EID of HIV (Varga, Sherman, Maphosa, & Jones, 2005). In a country where people place high value on children and childlessness is a major social concern (Donkor & Sandall, 2009; Tabong & Adongo, 2013), it may also be interesting to know how having one or many children will influence a woman's decision to test. Studies from Malawi and Kenya found HIV disclosure and discrimination significantly associated with a 14% loss to follow up of HIV positive Mothers and their infant from care (Braitstein et al., 2011; Donahue et al., 2012). This Kenyan study also found that transportation was a barrier to follow up with over 6% of women not making follow up visits because of transportation challenges.

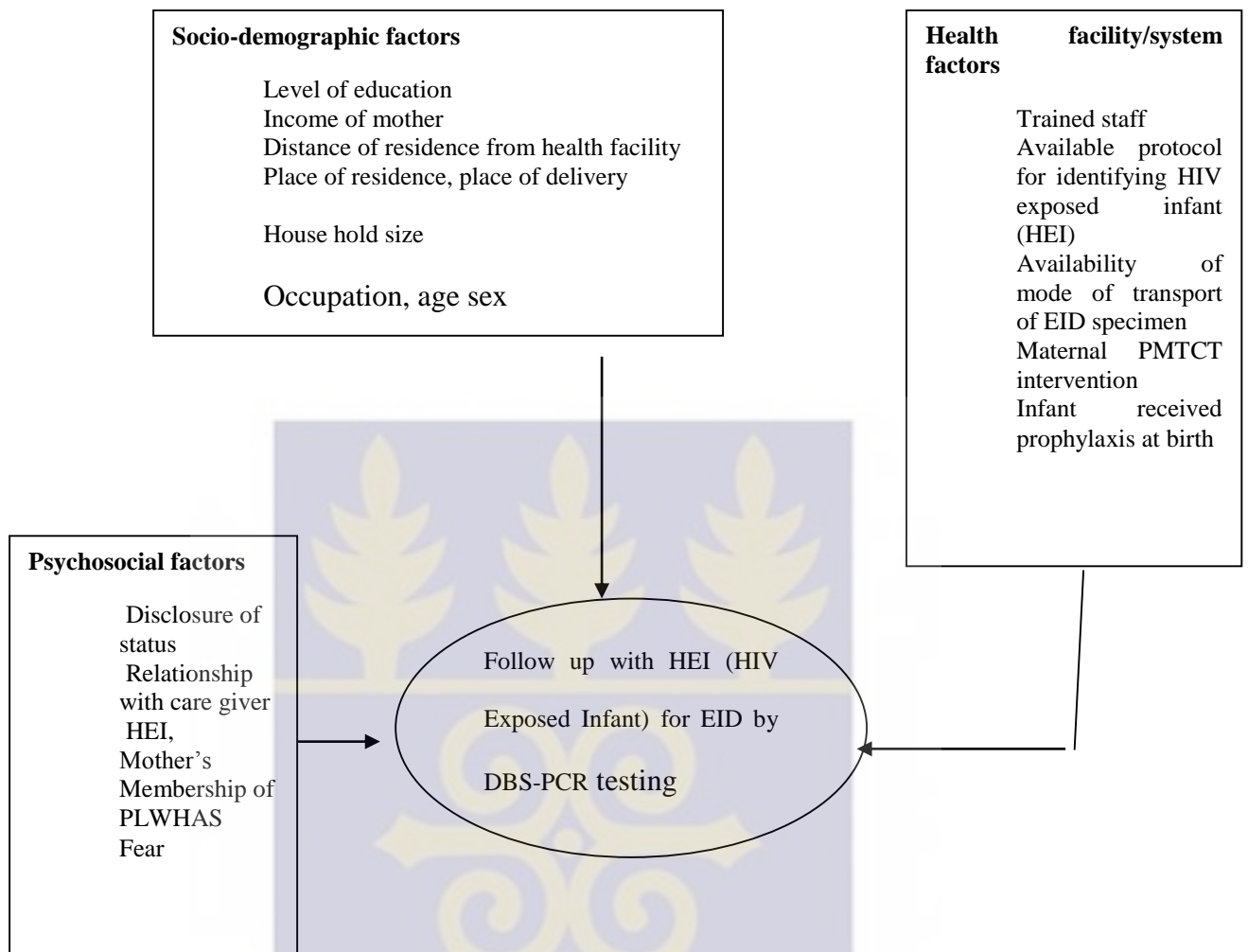


Figure:1.2 Conceptual frame work, showing how various factors interplay to influence EID of HIV.

Improve coverage of Early infant diagnosis will lead, mother knowing their infant's HIV status early making a choice to avoid infecting the infant or initiate early treatment for infected infant. This will lead to a reduction of new infant infection and reduction in HIV related child mortality

1.4 Justification

For country that aims at eliminating new HIV infections among infants by 2015, reduction of mother-to-child transmission rates need to be accelerated. This can be achieved mainly in two ways i.e. preventing transmission during pregnancy and delivery and secondly preventing transmission during breastfeeding. The later requires that the HIV status be determined as soon as possible after delivery and also after cessation of breastfeeding.

The number of children living with HIV in Ghana as of December 2012 was about twenty eight thousand. The NACP ((NACP, 2013b)National AIDS/STI control program) has a target to screen every exposed infant within 12 months of delivery and achieve zero new infections among exposed infants by 2015 (Ghana Health Service, 2013; NACP, 2013b). Screening will ensure that most infections that occurs postpartum will be eliminated and child mortality will be reduced. Out of all global plan countries with a rapid decline in infant HIV infections Ghana is reported to have made the greatest progress achieving a 76 % reduction in new infant infections between 2009 and 2012 (UNAIDS, 2013c). With the current rates at which exposed infants are screened it is unlikely that these targets will be achieved or maintained. This is largely due to poor uptake of the early infant diagnosis and late initiation of treatment among HIV positive infants. The findings of this study will contribute significantly to eliminating pediatric HIV, which is a common goal for both the NACP and PMTCT strategic vision 2010-2015. Also, infant HIV infections estimated directly is a measure of the impact of PMTCT and also used for modeling new infection in the population, therefore it is important that all eligible infant, are tested to obtain accurate figures (Rollins et al., 2012). Understanding the socio-economic, psychosocial and health system factors that

affect the ability of women to comply with follow up for early infant diagnosis will assist Ghana in devising strategies to achieve effective follow up of HIV-exposed infants.

1.5 Research questions

1. What health system factors account for poor uptake of early infant HIV diagnosis services in the upper west region?
2. What socio-demographic and psychosocial factors influence the decision of HIV positive pregnant women to return/ follow up to health facilities after delivery with their babies for early infant diagnosis?
3. How early are HIV exposed infants tested by DNA PCR and what proportion of HIV exposed infant are infected with HIV from their Mothers?

1.6 Objectives of the study

Main objective

To determine the factors associated with follow-up for early infant diagnosis (EID) by DNA PCR testing among Mothers with HIV exposed infants in Wa municipal and Lawra district in Upper West Region of Ghana

1.6.1 Specific objectives

1. To determine the socio-demographic factors that are associated with successful follow up for EID HIV
2. to identify the psychosocial factors associated with successful follow up for early infant diagnosis
3. to determine the health system factors associated with returning for early infant diagnosis
4. to estimate proportion of mother to child transmission among exposed infants

5. To determine the timeliness of EID among exposed infant and turnaround time DNA PCR results.



CHAPTER TWO

LITERATURE REVIEW

2.1 HIV among Exposed infants, children and early infant Diagnosis

Globally, an estimated 210,000 new HIV infections occurred in children under 14 years in 2012 alone, with over sixty percent of them in low and middle income countries (UNAIDS, 2014b). Up to about 17.8 million children have been exposed and have lost one or both parents to HIV worldwide. This figure could even be underestimated considering the challenges that exist regarding exposed infant identification and testing. Socioeconomic, health system policy, as well as psychosocial barriers have been reported as major challenges with exposed infant diagnosis (Penazzato et al., 2014; Sherman et al., 2005). Apart from the ones mentioned, technical challenges due to interference from maternal antibodies associated with antibody testing, workload and laboratory error associated with manual testing procedures and stock-outs are significant barriers to early infants' diagnosis.

Until PCR testing procedures were developed (Sherman et al., 2005), health workers relied on antibody testing to detect or identify HIV infection status of infants. There was a difficulty differentiating maternal HIV antibodies from that of infants because maternal HIV antibodies can persist in the exposed infant for up to 18 months (Lambert et al., 2003; WHO, 2010a) this meant that mothers who needed to know the true HIV status of their babies had to wait until the infant is 18 months and by this time the opportunity for intervention is lost (Lilian et al., 2013). In resource limited settings, only up to 25% of HIV exposed infants undergo EID to determine their status, and about 35% of those who test HIV positive are without appropriate therapeutic intervention (Chatterjee et al., 2011). Early initiation of antiretroviral therapy reduces HIV-related infant mortality by over 70% if treatment is initiated in HIV positive infants within the first three months of

life(Lilian et al., 2012; Violari et al., 2008). Based on evidence from several studies to prove that early initiation of highly active antiretroviral therapy (HAART) reduces morbidity and mortality among exposed infants the WHO recommends that all HIV positive infants be put on treatments within the first two years of life irrespective of CD4 count or WHO clinical staging(WHO, 2013a). As part of efforts towards meeting PMTCT objectives, many countries across the world especially those with high HIV burden in sub Saharan Africa are developing and scaling up EID services (Creek et al., 2007).

Early infant diagnosis (EID) is not just an opportunity for early intervention in HEIs (HIV exposed infants), but also an opportunity to measure the impact of PMTCT programs by directly measuring the number of new infection averted among exposed infants; a key indicator for measuring PMTCT success. Scale up of EID could further be beneficial since current HIV treatment guidelines require viral load testing to be performed on all patients on antiretroviral treatment (WHO, 2013a). The equipment, technology and technical skills available through EID services has been utilized for achieving this purpose of viral load testing in most countries (Ciampa et al., 2011). Data from a South African study suggest that the benefits of early infant diagnosis will be maximized if the time of testing is shifted from 4-6 weeks after birth to the exact time of birth. Those advocating this, think that testing at birth and shifting the task of testing from centralized laboratories to clinic and Maternity wards of hospitals would reduce the chances of loss to follow-up (Liu & Chibwasha, 2014). However, findings from other works suggest that sensitivity of testing at the time of birth is low compared to the WHO recommended age at testing of 4-6 weeks (Dube et al., 2012). Secondly, most point of care DNA PCR technologies that have been proposed for this purpose are either still under evaluation or too expensive while serological testing is not also a good option for

infants (Haleyur Giri Setty & Hewlett, 2014). There are also arguments that peri-partum infections including those acquired from mothers during breastfeeding will not be captured if infants are tested at birth (Lilian et al., 2012).

2.2 Proportions of HIV Exposed Infants Tested for HIV.

It is estimated that up to 85% of HIV exposed infants in sub Saharan Africa have unmet needs for early infant diagnosis of HIV (UNAIDS, 2013a, 2013b; WHO, 2010b). During the 2012 reporting year alone, over one million infected infants were tested by DNA PCR for EID of HIV, however this number represent only about one third of the world's HIV exposed infant (UNAIDS, 2013c). UNAIDS progress report on the global plan for HIV suggest that about 210, 000 new HIV infections occurred in infants from 21 global plan priority countries with 40% of HIV positive pregnant women and 50% of HIV positive breast feeding women not receiving PMTCT intervention (UNAIDS, 2013c). Only four out of 22 WHO global plan priority countries including South Africa, Swaziland, Namibia, and Zambia had more than 50% coverage for early infant diagnosis of HIV in 2012, while five countries (Angola, Chad, Democratic Republic of Congo, Malawi, and Nigeria) reported coverage below 6% (UNAIDS, 2013c). Ghana lags behind in this area with a reported EID coverage of 19% in 2012 while setting a target of reducing child deaths due to HIV by 50% by the end of 2015 (UNAIDS, 2012). Similarly, about 19% of exposed infants received treatment in 2010 and only one percent of all exposed infant were tested for EID in the same year (United for Children, United Against AIDS, 2012) Initiation of life saving therapy and enrollment into care of HIV exposed infants who test positive for HIV depends on early infant diagnosis. Early testing of infants aims at improving the outcomes of PMTCT programs by identifying early opportunities for intervention. In well-resourced countries, participation in EID

service could be as high as 70% (Lilian et al., 2013). The same cannot be said for most other African countries and the percentage of HIV positive pregnant women who access EID services vary from country to country. Even among global plan priority countries that seem to be doing well, EID coverage ranges from 58% in Zambia to about 72% in south Africa (Torpey et al., 2012). Among those infants covered EID about 11%-15% infection rates have been reported (Torpey et al., 2012).

Disclosure of HIV status to a partner in some setting could lead to social violence and influence the health seeking behavior (Varga et al., 2005). There has been instances in which male partners have blamed their women for the HIV status of their infant (Varga et al., 2005). Also, knowing the infant's HIV status could create mixed feelings among parents; especially women. While those with babies who test negative may be contempt with their child's results, those who's infant test positive may try to blame themselves for their child's HIV positive status. Perceptions about what the results could be, and interventions available following testing could also influence a woman's decision to test her child (Varga et al., 2005).

2.3 Demographic factors Affecting testing

Though early infant diagnosis and initiation of treatment, reduces mortality among HIV positive infants, it is complex, expensive and inaccessible in many settings (Penazzato et al., 2014). Dry blood collection from young infants for centralized testing by DNA PCR is however feasible in low resource setting and has proven to be a solution to inaccessibility in these areas (shearman 2005, Creak 2007). Where an appropriate PCR method (e.g Roche amplicon HIV version 1.5 Branchburg NJ) suitable for routine laboratory testing is available it is cheaper and more convenient to use dry blood spots collected on filter paper for diagnosis of HIV(Sherman et al., 2005). Poverty,

geographical location, lack of support from husbands, unemployment are demographic factors found to influence successful follow-up for early infant diagnosis of HIV (Jones, Sherman, & Varga, 2005). Other factors affecting EID services are educational attainment of mother, distance from residential community to health service facility where the service is offered as well as type of referral. In situations where referral for EID service have been enhanced by a health worker giving proper and private counseling to mothers at birth higher participation and retention in EID was observed (Kurewa et al., 2011). Also, payment of transportation fare to sample collection centers and sending text message reminders to mothers of exposed infants have also improved coverage and retention into care of exposed infants (Finocchiaro-Kessler et al., 2014)

2.4 Health facility factors influencing follow up for early infant Diagnosis

Program attrition, stock outs, lack of trained personnel and a system to identify exposed infants, as well as inaccessibility are among health system challenges affecting early infant diagnosis (Kellerman & Essajee, 2010). Other limitations are poor quality of patient counseling, and lack of integration with the general health system and late or no return of DNA PCR results. Implementing strategies to address health system limitations of EID remains a priority of two major programs; implementation of the Global Health initiative and the President Emergency Plan for AIDS relief (PEPFAR). In an attempt to resolve some of these challenges, some researchers have suggested the use of point of care testing devices, task shifting in patient counselling, SMS(short message service) reporting of results and the use of bundled commodities. Reviewing health records of infants and interviewing mothers during immunization visits provide a good platform for achieving early identification of HIV exposed infants. It has been argued that if health systems had a policy to test all infants at first contact with the health system (Rollins et

al., 2009), this could eliminate the barriers of missing exposed infant from mother with unknown HIV status who were not enrolled into PMTCT programs. It is believed that with about 95% PMTCT coverage and the option B+ HIV treatment strategy, prevalence of HIV in infants could be reduced to less than 5% if both PMTCT and treatment strategies are successfully implemented (WHO, 2010b). In areas where the national HIV prevalence is greater than 1% , it is recommended that the HIV status of all infants be checked at health centers before six (6) weeks of age by performing a serological test for mother and or baby (WHO, 2010a). It has also been demonstrated that decentralization of early infant diagnosis services to primary health clinics or maternal and child health clinics will offer an effective , more equitable and feasible approach to expand access to early infant diagnosis (McCollum et al., 2010).

Specimen collection, storage, transport and testing are health system factors that could influence the success of early infant diagnosis of HIV. Dry blood spot testing has been evaluated and adopted to address the challenges of specimen collection, transportation storage and testing (Mini et al 2008). While other methods of DNA-PCR testing requires collection of blood into EDTA and transportation under specific temperature requirements, using dry blood spots collected on filter paper eliminate all these requirements (Sherman et al., 2005). Despite the elimination of these barriers by testing using dry blood spots for DNA PCR at centralized laboratories, another challenge; poor turnaround time of results is encountered (Sutcliffe et al., 2014). On an average, DNA PCR results should be available in 14 days or two weeks, however, this has not been the case in some settings (Sutcliffe et al., 2014). Delayed results have resulted in loss to follow up in some situations. Point of care DNA/RNA testing has been suggested as the ideal way to address most challenges with testing for early infant diagnosis of HIV but

none of the point of care virologic testing techniques under development has been launched so far (Anderson, et al.,2011).

2.5 Recommended Infant HIV Testing, Procedures and Algorithm

Current WHO guidelines for the treatment of HIV require that all children with HIV younger than 5 years be put on treatment(WHO, 2013a). However initiating treatment among infants and children less than 18 months requires confirmation of the child's HIV status with a virologic HIV test to avoid unnecessary treatment of uninfected children (Chatterjee et al., 2011). The WHO recommends the use of a test that detects HIV viral DNA in whole blood or plasma based on high quality Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence and strong recommendations (WHO, 2010c). Infant testing techniques that utilize detection of RNA or p24 in plasma are not recommended for testing infants who have initiated treatment. It is preferred that HIV among infants is tested and confirmed with two different viral DNA test and both test should have sensitivity of 98% and specificity of up to 98% to minimize false positive and false negatives (WHO, 2010c).Confirmation is highly recommended in populations where the HIV prevalence is low but may not be very necessary in populations with HIV prevalence greater than 5% (WHO, 2010a). Though Plasma RNA detection is not strongly recommended, at least one study has reported suitability of Plasma RNA detection for early infant diagnosis with 100% sensitivity and 97% specificity, however this study did not include information on ART treatment among these children (Rouet et al., 2001).

Assays that have met WHO performance requirements are Amlicor DNA PCR v 1.5 (Roche) COBAS Ampliprep/Taqmanor CAP/CTM Qual (Roche) Versant HIV-1 RNA (bDNA) (Siemans), NucliSENSEasyQ (bio Merieux), Amplicor HIV Monitor v1.5 or

CAP/CTM v1.0 & 2.0 (Roche) , Real-time HIV-1 (Abbott) , Aptima (Gen-Probe) and Ultrasensitive p24 Ag (Perkin Elmer) (Sherman G, 2012). These tests are expensive and require technical expertise compared to antibody testing used for adults and older children. A review of implementations of early infant diagnosis services in four countries suggest that loss to follow up, delayed results, and perceived lack of treatment are common challenges of EID in low income countries (Chatterjee et al., 2011; Penazzato et al., 2014). It has therefore been argued that testing closer to birth or at birth would improve exposed infant identification and retention in care and subsequently reduce infant mortality since early testing could decide treatment initiation within the first 3 months of life (Lilian et al., 2012). Initiation of treatment at an early age is also thought to prevent seeding of viral reservoirs which possibly explains the a functional cure observed in a child in the USA (Persaud et al., 2013).

Testing for viral DNA, RNA, or Gag P24 using polymerase chain reaction performed ideally between four and six weeks of age for all exposed infants will detect up to 95% of all in utero and intra-partum HIV infections (WHO, 2013a). Proviral DNA sequences are detected in peripheral blood mononuclear blood cells(PMBC) Though virologic testing using PCR is very specific and highly sensitive (Sherman et al., 2005), false positives (FP) and false negatives (FN) still occur which can lead to failure to treat infected infants who really need treatment or unnecessary treatment of negative children with false positive results. Serological testing, though not recommended for infant testing is recommended for screening infants where maternal HIV status is unknown (WHO, 2010a).

HIV testing Algorithm for HIV exposed infants and children under 18 months

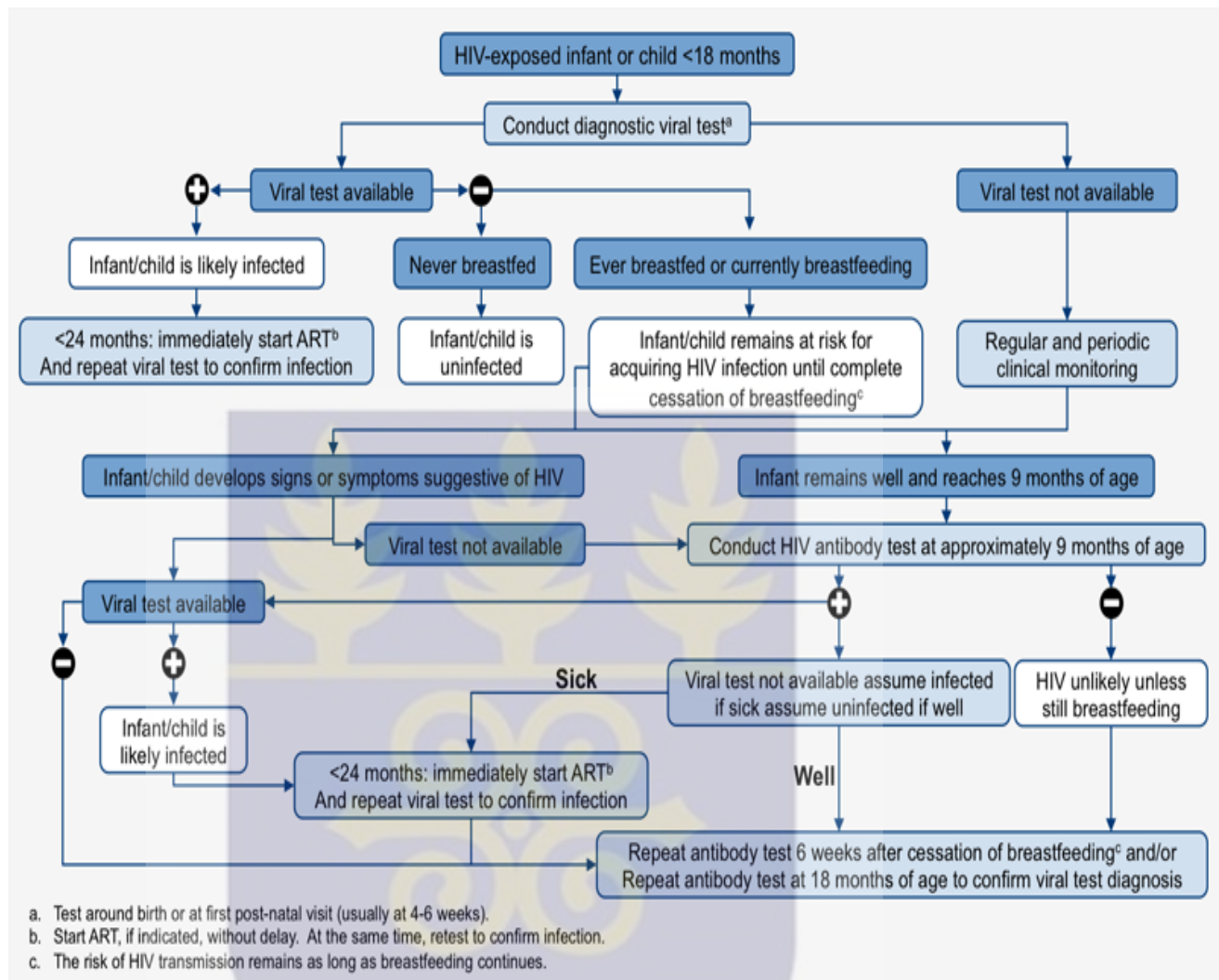


Figure 2.1 HIV testing Algorithm for infants less than 18 Months. Adopted (WHO, 2010a)

2.6 Documented Best Practices

According to the interagency task team (IATT) report, certain practice or policies that improved early infant diagnosis in countries like Kenya, Nigeria and South Africa, included effective collaboration between implementing partners, use of exposed infant follow-up cards, and development of national EID database system which were electronic (IATT, 2012). This allowed EID data to be transferred, accessed and monitored by authorized partners in real time. Automation of DNA PCR procedures and

use of Short Message service (SMS) printers contributed significantly to minimizing laboratory error and improving turnaround time of DNA PCR results (Finocchiaro-Kessler et al., 2014; United for Children, United Against AIDS, 2009). Similarly, the use of SMS printers was found to greatly improve turnaround times of early infant diagnosis test result in Nigeria in a program termed “SMS printers to accelerate the return of early infant diagnosis test result” (SMART) a piloted program sponsored by the Clinton health access initiative(CHAI), (IATT, 2012; WHO, 2013b). Provider initiated testing and counseling (PITC) with opt out has been demonstrated to improve coverage of EID and minimize loss to follow up of HIV exposed infant along the EID Cascade (Rollins et al., 2009), however, the cost effectiveness of this process has been questioned especially in setting where HIV prevalence is low or resources are limited. Where PITC is well tailored, the benefits could be maximized for the children (Penazzato et al., 2014) Another practice that has improved EID is shifting, where the task of counselling is shifted from Nurses and medical personal to lay counsellors who are usually family members of the exposed infant’s mother, also referred to as “patient escorts”.

Utilizing Integrated Management of Childhood Illnesses (IMCI) where health care workers are to be prompted by signs and symptoms to test infants for HIV. Infants may be treated several times and repeatedly for opportunistic infections without realizing the need to diagnose HIV. The vigilance of health care worker especially during consultation is also important in picking up infants for early diagnosis of HIV.

2.7 Estimation of infection rates and new infection in populations

The benefits of EID is not limited to early initiation of treatment in HIV positive infant and giving their parents the opportunity to enrol into care, but also provide direct estimates of pre-partum and post-partum HIV transmission rates. These figures are also utilized in projecting new infant infections using modelling.

Modelling approaches are widely used for estimation of new HIV infections in general and specific populations. The most commonly used soft wares /packages that are used for these estimations are, the Estimations and projections package (EPP) also used in Ghana(NACP, 2013b), and Spectrum projections package (SPP)(UNAIDS, 2013b). These models depend on input data such as the number of HIV-positive women receiving antiretroviral drug (ARV) interventions(Rollins et al., 2012). They also utilize both per partum and postnatal HIV transmission probabilities by ARV intervention and by timing of maternal infection (either incident or prevalent) to derive population based rates(Rollins et al., 2012). Spectrum computer package has specifically been used to measure the impact of prevention of mother to child transmission programmes (Stover et al., 2010).

Figure 1.2 demonstrate how new infant HIV infections could be estimated or projected based on specific population parameters using the spectrum projections package. This model is used to estimate peri partum and postpartum HIV transmission rates in exposed infant which serves as a direct measure of the impact of PMTCT programmes.

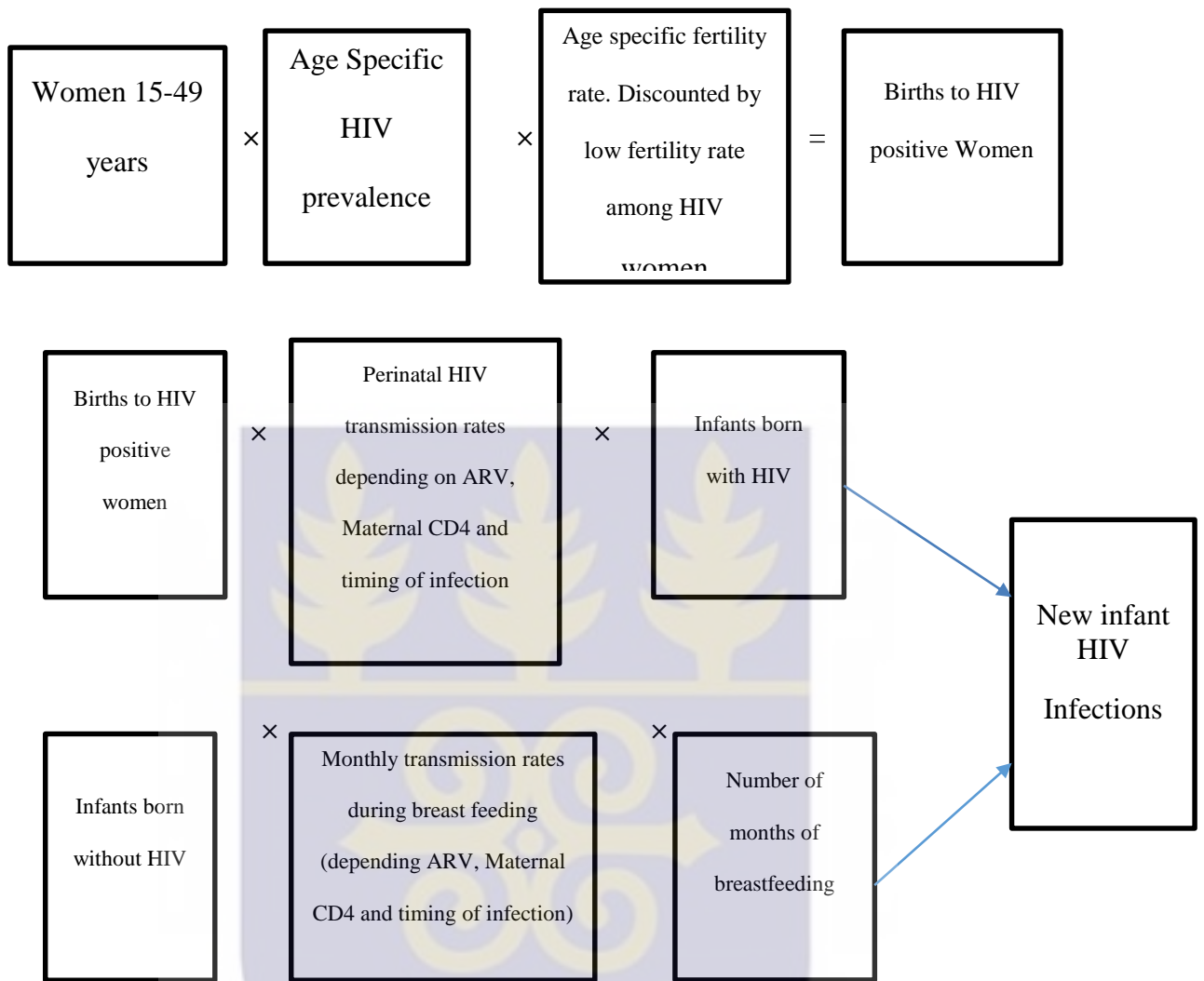


Figure 2.2 Estimation of New HIV infections Among Infants in general population. Adopted and modified(Rollins et al., 2012)

CHAPTER THREE

METHOD

3.1 Study design

A case control study was conducted at ART centers in the Lawra district and Wa Municipal between December 2014 and April 2015. Early infant diagnosis registers and ANC/PMTCT records were reviewed to obtain a list of HIV positive Mothers and their infant who were eligible for EID between January 2011 and December 2014.

3.1.1 Definition of cases

A case was any HIV positive mother aged 15-49 years with an infant or child more than six weeks old (born between January 2011 and December 2014) and living within the catchment areas served by the Two ART centers in the Wa municipal and Lawra district who did not test her infant/child for EID of HIV as per WHO Standards. A case was any HIV positive mother aged between 15 to 49 years who delivered a live baby between January 2011 and December 2014 who did not return to a health facility with her baby for DBS-PCR testing between 6 weeks and 18 months after delivery.

3.1.2 Definition of controls

A control was any positive mother with an infant/child more than six weeks old born between January 2011 and December 2014 and living within the study area as defined above who tested her child/infant for EID by DBS-DNA -PCR any time between 6 weeks and 18 months after delivery.

3.2 Study Area

The study was conducted in two ART centers of Wa municipal and Lawra district in the Upper West Region of Ghana. The Wa municipal and Lawra Districts were selected because of their regular participation in EID, location, and their ability to register a

significant number of potential EID cases. The selection was also done to represent both the urban and rural populations of the Region. Out of about 670 HIV positive pregnant women reported in the Region between January 2011 and December 2014, the two Districts alone contributed almost half (337) of the total, with 243 and 94 coming from Wa and Lawra respectively.

3.2.1 Geographical location

The Upper West region where this study was conducted had a projected population of about 725,000 people and lies within the guinea savanna area of northern Ghana. The region is bordered on the south by the Northern region, on the east by the Upper East Region and on the West by Cote d'ivoire and on the north Burkina Faso. Total land mass of the region is estimated to be approximately 18,478 square kilometers forming about 12.7% of the total geographical area of Ghana. It is located in northwest Ghana (longitude 1° 25'' W and 2° 45'' and latitudes 9° 30'' N and 11°N). There are 11 administrative districts and sixty five sub districts reporting for the health sector. A majority of communities in the region are rural, with 72% of the population engaged in peasant farming/agricultural work.

3.2.2 Administrative units

There are eleven administrative districts and sixty five health reporting subdistricts. Wa is the administrative capital of the region and also capital of Wa Municipal. The other ten districts are Lawra, Nandom, Jirapa, Nadowli Lambussei karni, Sisala East, Sisala West, Daffiama-Bussei- Issa, Wa East and Wa West. The Wa Municipal and Lawra District were conveniently selected for this study because of their active participation in early infant diagnosis services and also because they detect a significant number of HIV

positive pregnant women through screening at ANC sites. The Lawra district and Wa Municipal have nine and thirteen PMTCT centers respectively with one ART center in each District.

3.2.3 Regional Demographic characteristics

According to the 2010 Ghana population and housing census the population of the Upper West region was projected to be 757,011 with a growth rate of 1.9 (Ghana Statistical Service, 2012).

A high proportion of the Region's population lives in the Wa Municipality which is also the Hub major economic activities in the region. Until the creation of the Nandom District from the Lawra District in 2012, the Lawra District was the next most populated in the region after Wa municipal. Every year there is mass seasonal migration mostly involving children and young adult to southern Ghana to find jobs and other economic prospects which is driven largely by the long dry season that the region experiences annually. The current populations of Wa Municipal and Lawra District are 115,579 and 51,669 respectively (Ghana Statistical Service, 2012). The projected total population of the Region for 2014 was 757,011 representing about three per cent of the national population. About 90.1% are Ghanaians by birth while 2.9 % are naturalized Ghanaians with an estimated 0.3% of the people are from other ECOWAS member countries. The major ethnic groups in the region fall under the broad generic categories of the Mole Dagbon (75.7%) and Grusi (18.4%). The major languages of the region are Dagaare, Sissali, Wale and Lobi. There are three main religious groups in the region, Christianity Islam and Traditional African Religion with Catholics constituting the majority of Christians in all districts The proportion of the population not literate in any language among persons aged 15 year and above is 73.4 per cent, which is higher than the

national average (Ghana Statistical Service, 2012). Over 70% of the people in the region are engaged in Agriculture and related works. The rest are distributed among Transport and production Equipment work sector, Sales work(trading), Service and Professional category, and Technical and related works (Ghana Statistical Service, 2012).

3.2.4 Health sector information

There are about 174 health facilities, comprising of a Regional hospital ,five (5) district hospitals and the others are clinics, health centers, CHPS(community Health Planning and Services) compounds and some private health facilities(Ghana Health Service, 2015). PMTCT services are well established in the region with about 94 PMTCT centers. ART services are well integrated into these PMTCT centers, with five (5) ART centers in the region, located in Wa, Lawra, Nandom Jirapa, Nadowli and Tumu.

3.2.5 Health facility coverage and ownership

There are five public District hospitals (one each in Nadowli, Lawra Nandom Jirapa and Tumu) and one public Regional Hospital which is located in the regional capital. The District hospitals in Jirapa and Nandom are quasi-governmental, partly owned by the Catholic Dioceses of Wa. There are also 6 clinics 60 health centers, 91 Community-based health planning and services compounds (CHPs), 2 RCH clinics as well 3 private hospitals and 3 private clinics (Ghana Health Service, 2015).

3.2.6 Common causes of morbidity

In the Upper West Region, Malaria is the number one cause of morbidity and also ranked as a major cause of mortality in the region, other causes of morbidity are diarrhea, road traffic accidents involving mostly motor bikes, snake bites, sexually transmitted

infections including HIV/AIDS and Meningitis. Tuberculosis, Hepatitis and Maternal health issue also remain significant public health challenges that require attention.

3.2.7 The HIV/AIDS Situation, the Upper West Region/Ghana

From the Ghana HIV sentinel survey, the Region like the rest of the country has a declining HIV prevalence among pregnant women with Regional HIV prevalence dropping from 3.1 in 2009 to 1.2 in 2012 (NACP, 2013a). In terms of absolute numbers this could mean thousands of potentially exposed infants. Over nineteen thousand (19,688) pregnant women in the region were tested for HIV in 2012 and 1% of them had a positive test result representing 206 potentially exposed infants in that year alone (NACP, 2013a). Though the region has a relatively low HIV prevalence, seasonal migration in and out the regional every year could have implications for HIV control in the region. Between January 2011 and December 2014 the region record 673 HIV positive pregnant women. Approximately half of this number (337) came from the Wa Municipal and lawra district with 243 and 94 patients respectively.



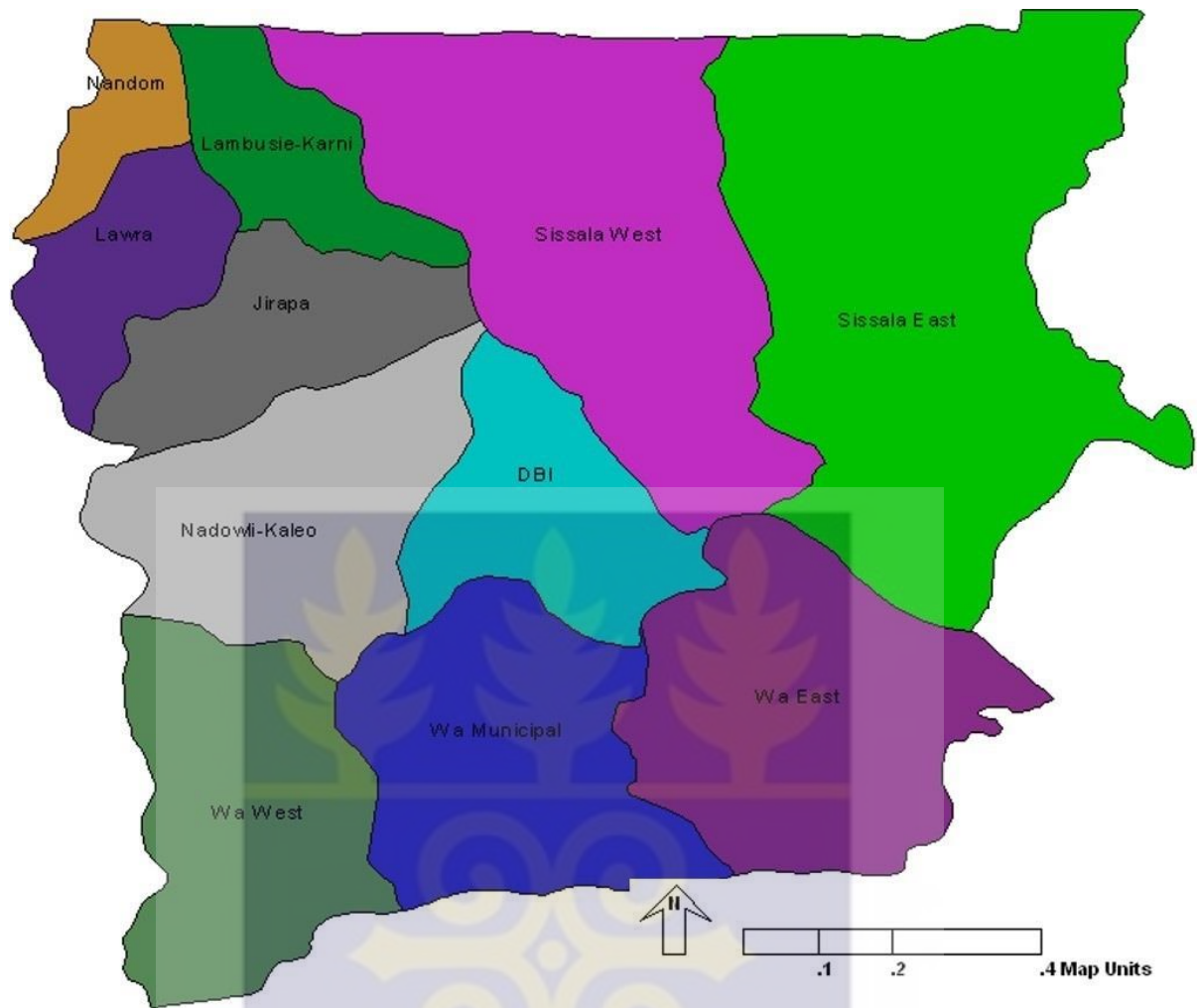


Figure 1.3 Map of Upper West Region Showing Administrative Districts including Wa Municipal and Lawra. Source:Upper West Regional Health Directorate

3.3 Study population

The study population included all HIV positive mothers and their babies born between January 2011 and December 2014 who were eligible for EID by DNA PCR. Mother/baby pairs that returned to health facilities for DBS-PCR (dry blood spot-PCR) testing or did not return for EID were identified from EID registers ANC attendance books.

3.3.1 Inclusion criteria

All HIV positive women aged 15-49 year identified during ANC and at ART clinic who delivered a live baby between January 2011 and December 2014 who assessed health services at the Wa Regional Hospital and Lawra District Hospital or have been referred to one of the ART centers in the two Districts were eligible to participate in the study.

3.3.2 Exclusion criteria

All women with unknown HIV status and their babies born between January 2011 and December 2014. HIV positive mother with eligible infant who had travelled out of the area at the time the infant was eligible for testing, or mother did not accept their positive HIV status were excluded. Also infants who died before attaining the age of testing and infants who were not yet six weeks old at the time of study and their mothers were also excluded?

3.4 Sampling.

3.4.1 Sample size determination

The required sample size was calculated based on statistical power of 80 and 95% confidence interval, and expected odds ratio was 2.5. Exposure among control was 19.5% this was based on the proportion HEI exposed infants receiving PMTCT intervention who were screened for EID (NACP, 2013a). The ratio of cases to controls is 1: 1. 96 cases and 96 controls. The required sample size was calculated using stat Cal epi info 7. However the formula for calculating sample size is shown below

$$n_1 = \frac{\left[z_{\alpha/2} \sqrt{(r+1)p_1q_1} + z_{1-\beta} \sqrt{rp_1q_1 + p_2q_2} \right]^2}{r(p_1 - p_2)^2}, \quad n_2 = r \times n_1$$

Where n_1 = number of cases

n_2 = number of controls P_1 = proportion of cases exposed 37.7% = proportion of controls exposed (19.5%) r = ratio of cases to controls = 1

$Z_{\alpha/2}$ = adjusting for the risk of making a type 1 error

$Z_{1-\beta}$ = adjusting for the risk of making a type 2 error or the power of the study.

3.4.2 Sampling Procedure

A list of all mother-baby pairs who tested for early infant diagnosis of HIV at ART centers in the Wa Municipal and Lawra district of the Upper West region between January 2011 and December 2014 was compiled. Three HIV Peer Educators were selected, trained as interviewers and assigned to ART and ANC clinic to identify and interview potential cases and controls. All women attending ART clinic in the two districts between early December 2014 and April 2015 were checked to determine if they have a child aged between six weeks and 4 years. ANC cards of Mothers attending ANC were also checked to identify exposed infants/children. Once an eligible mother -baby pair was identified, the study was explained to the mother and her consent sought. Consenting mother were made to complete a written informed consent form before commencement of interview. The women were asked if their child's blood was collected on filter paper for HIV testing any time between 6 weeks and 18 months after they have delivered the child. Those who answered yes were selected as controls and those answered no were selected and interviewed as cases. All controls were crosschecked from the compiled EID records to determine if they indeed had follow up for early infant

diagnosis. The study questionnaire was first translated from English to Dagaare and back to English to clarify difficult questions. PMTCT Nurses, ANC nurses ART data managers and HIV coordinators were also interviewed separately to better understand health system barriers to early infant diagnosis of HIV.

3.5 Data collection

3.5.1 Data Collection Tools

Data were collected using a standard questionnaire and checklist.

3.5.2 Training Data collectors and Pretesting of tools and Data collection procedure

Data were retrieved using a standard data extraction tool and the list of all exposed infants with follow up DNA PCR was obtained from laboratory EID registers. A structured questionnaire or interview guide was used to interview Mothers and key health personnel.

To ensure confidentiality HIV Peer Educators who have usually attended to these patients at the selected ART and ANC centers were trained to interview the women and collect data. Though patients names and phone contact were collected these were compiled in a separate book. Only folder numbers and or first names of Mother and Infants were collected on study questionnaire. No surnames or unique personal identifiers were indicated on the questionnaire. The questionnaire was first translated from English into Dagaare and back to English to allow easy administering. The questionnaire was pretested in another District which had not been selected for this study. Demographic information including age of mother and infants, setting of residence, distance from residence to testing facility, Mother's source of independent

income, marital status, Mother's level of formal education as well as employment status and occupation of mothers. Factor such as place of delivery (health facility versus home), Mother and infant PMTCT intervention, turnaround time of results for those tested, receipt of test result, having information of infant HIV testing were explored. Finally mothers were asked their reasons for testing or not testing their babies, disclosure of their HIV status and their membership to any association of people living with HIV and AIDS.

3.5.3 Quality assurance

The principal investigator reviewed all EID registers and randomly selected five (5) of the interviewed participants to recheck the accuracy of the data collected. Data was also double entered in two data entry templates and the two data sets compared for accuracy. Where discrepancies were identified the completed questionnaire were referred to and the differences resolved.

3.6 Data management and analysis

Data was entered into epi-info version 3.5.4, and cleaned by running frequencies to determine missing values. The data was then coded after removing all personal identifiers. A backup file was also created in epi data which was also used for crosschecking during data cleaning. The data was then exported into Stata for further recoding. Univariate analysis, binary logistic regression and multiple logistic regression was done using Stata 13 (Texas USA), while Graphs and charts were drawn using Microsoft excel. The dependent variable was follow up for EID by DNA PCR. Continuous variables including age of mothers, age of infants at testing, and turnaround time of results were analyzed as means with standard deviations or medians with

interquartile ranges. Categorical variables were analyzed as frequencies and percentages at 95% confidence interval. Age, turnaround time, number of children, family size, and infant age at testing were collected as continuous variable and recoded as categorical variables. Binary and multiple logistic regressions were performed for binary and categorical variables and odds ratios with 95% confidence intervals were calculated. Using follow up for EID by DNA PCR as outcome variable which was recoded as participant status, crude odds ratios were calculated for, place of delivery, maternal formal education, urban or rural residency, maternal independent source of income, living within 10km to testing facility, Maternal PMTCT Intervention, Infant PMTCT intervention, disclosure of mothers status, mothers membership of HIV/AIDS group/association and if the mother has ever heard about infant HIV testing. Significance was interpreted as P values less than 0.05 or 95% confidence intervals not including 1.0. Adjusted odds ratio were also calculated for all variables with significant crude odds ratios. Potential confounders including Maternal age and level of formal education were included in the final model that adjusted for significant factors. The final regression model included, Time of accessing EID information, maternal independent income, and place of residence which were significant at crude analysis as well as maternal age, maternal of education and maternal occupation which were potential confounders controlled for. Percentages of infants, who tested for HIV, by PCR, received EID result and type of result were also calculated. The results were presented in graphs and tables.

3.7 Variables

3.7.1 Dependent Variable

The dependent variable in this study was follow up at health facility of an HIV positive mother with her exposed infant for EID.

3.7.2 Independent variables are classified under three categories as shown below

1. Socio-demographic: age, occupation, family size, level of education, employment status and distance of residence from health facility (within 10km), Mother's independent source of income and ability to decide to return to clinic.
2. Psychosocial factors (disclosure of status, membership of a social PLWHAS group, fear of testing, relation/person to whom disclosure was made)
3. Health factors (PMTCT intervention for mother child pair, integration of EID with other Maternal and child health services, sources and timeliness of EID information for Health HIV positive mothers, and also resource and logistics availability for EID services)

3.7.3 Definition of some key Variables

Follow up for early infant diagnosis: Determining the HIV status of and HIV exposed infant using virologic test (DNA PCR) six weeks after delivery or at the earliest opportunity thereafter until the baby is 18 months.

Residence: Place of permanent Residence of mother/baby pairs, classified as rural or Urban. Sub districts within Wa and Lawra towns were classified as urban and those outside these towns in the two districts were rural.

Distance: the distance from the home of A Mother/Baby pair residence to the health facility where the DBS specimen collection site is located

Level of Education: the level of formal education attained by HIV positive mother included in the study

Turnaround time: time between the collection of DBS specimen and the return of DNA PCR HIV infant test result of the exposed to the mother/guardian of the exposed.

3.8 Ethical considerations

Ethical clearance was obtained from the Ghana Health Service Ethical Review Committee, after the study protocol had gone through institutional review at the School of Public Health University of Ghana. Local clearance was also obtained from the Upper West Regional Director of Health Services. An informed written consent was obtained from Mothers/guardians of HIV exposed infants prior to their participation after the details of the study had been explained to them. Privacy and confidentiality of participants was ensured by the following measures

Interviewing and record reviews were done in a private and conducive environment as far as possible. Participants were interviewed privately at ART clinics. Surname and personal identifiers were not written on questionnaire. Names and contacts of participant were collected separately for purposes of follow up, however this information as well as completed questionnaire were securely locked at the ART centers. Soft copies of the data was password protected and accessible only by the principal investigator and supervisors. All patients/participants were coded and only codes or number were used. All names were separated from the final dataset.

Individual study participants will not be referred to during publications

CHAPTER FOUR

RESULTS

This subsection presents the Characteristics of infants and mothers who returned for EID at the two ART centres between January 2011 and December 2014. The main finding here are that of a case control study conducted among HIV positive mother/infant pairs between December 2014 and April 2015. The characteristics of Mothers and babies who accessed EID services, identified from record review in the Lawra and Wa municipal ART centres is presented first, followed by the characteristics of infant and mothers included in the case control study. The association between sociodemographic factors, health system factors and psychosocial factors and having follow up for early infant diagnosis is also outlined.

4.1 Demographic characteristics of HIV positive Mothers and infants reporting to selected ART centres in the Upper West Region of Ghana.

Within the period January 2011-December 2014, 673 HIV positive pregnant women were reported in the region. Fifty percent or 337/673 were from the Wa Municipal (243) and Lawra Districts (94). A total 194 HIV exposed infants were returned to the two ART centres for early infant diagnosis by DNA PCR comprising of 51% males and 49% females. The mean infant age at testing was 17.3 weeks with standard deviation 14.9. Infant age at testing ranged from 6weeks-61 weeks. Thirty seven percent (37%) or 72 of 194 infants had dry blood spots collected from them at exactly six weeks as recommended by the WHO while over 54% of infants had their DBS samples collected after six weeks. Seventy five of 194 (39%) of DNA PCR results were received at EID clinic and by the mothers of exposed infants. Mother to Child Transmission (MTCT) rate was 2.7 % i.e. two DNA PCR positive test results of 75 DNA PCR test results received.

EID coverage in lawra was 27.6% (26/94) and Wa Municipal 55.5% (135/243)

4.2 Demographic characteristics of HIV positive Mothers and infants in the Case control Study

A total of 192 HIV positive mothers with exposed infants including 96 cases and 96 controls were selected for this study. The mean age of HIV positive mothers was 29.6 years with a standard deviation of 5.25. Ages of mothers ranged from 20-45 with median age being 29 years. Most mothers included in this study were aged between 25 year to 29 years constituting 64.3 % followed by age groups 30-34 and 20-24 contributing 28% and 16% of the total study population respectively. Exposed infant ages ranged from 3 weeks to 205 weeks with a mean of 53.4 weeks and standard deviation 33.1. The median age of infants included in the study was 48 weeks interquartile range (IQR) 28-72 weeks. Out the total of 192 infants /children, 107(55.7%) of them were males and 85(44.5%) females Table 4.1 One hundred and seventy five (91.1%) of mothers delivered their babies at a health facility and 113 (58.9%) of them lived in rural areas Figure 4.1. Up to 158 (78%) study participants were married, 14 (7.3%) were widows, 11 (5.7%) were single, 10 (5.2%) were cohabitating and 6 (3.1%) were divorced.

Overall unemployment was high among all study participants, 58.3 % (111/192). About 37.5 % (72/192) of mothers were self-employed with the remaining 4.2% employed in the public sector. Peasant farmers/agricultural workers, were 80 (43%) and artisans, (mostly hair dressers, seamstresses and beauticians), 62 (33.7%) constituted a majority (76.7) of the study participants. Most mothers (59%) did not have an independent source of income. Proximity to an EID clinic was good with up 82.3% of Mother-Baby pairs living within 10 kilometres to an EID clinic. Eight exposed infant mothers (4.3%) were educational workers, five (2.7%) were administrative or financial workers.

4.3 Sociodemographic Factors and Follow up for early infant diagnosis of HIV

The odds of an infant born to a mother with an independent source of income becoming a case (an HIV exposed infant without follow up for early infant diagnosis) **was reduced by 50% comparing women with an independent source of income to those without an independent source of income (AOR(Adjusted Odds Ratio)=0.5, 95% CI(confidence interval), 0.2-0.9)**. Living in a rural area was significantly associated with follow up. The odd of **a mother baby pair living in a rural area** becoming a case was increased by 90% comparing infants born to mother living in rural areas to those living in urban areas (**COR(Crude Odds Ratio)=1.9, 95% CI, 1.1-3.4**) Table 4.5. Up to eighty percent or 152 (82.3 %) of Mothers reported living within 10 Kilometres to an EID testing centre. The odds of exposed infants with mothers **living beyond 10 Kilometres** to a testing facility becoming a case was increased by 80% comparing mother/baby pair living beyond 10 km to those living within 10 km to a testing facility(**COR=1.8 ,95% CI 0.3-3.8**) Table 4.5.

Peasant farmers/agricultural workers, were 80 (43%) and artisans, (mostly hair dressers, seamstresses and beauticians), 62 (33.7%) constituted a majority (76.7) of the study participants. Eight exposed infant mothers (4.3%) were educational workers, five (2.7%) were administrative of financial workers, 28 (15.2%) were trader and 1% health care workers. At Bivariate analysis level, residential setting,(**OR =0.5 95% CI, 0.2-0.9**), **Maternal independent source of income (OR= 0.5 95% CI 0.2-0.9)**, **Maternal formal education (OR=0.5 95% CI, 0.3-0.9)** and having a **trading occupation** were significantly associated with follow up of HIV positive mother with their exposed infants to health facilities for early infant diagnosis, Table 3. There was no significant association between demographic factors such as marital status, and maternal

employment and follow up. The odds of an infant born to an unemployed woman becoming a case was increased by 30% but this was not significantly associated with follow up for EID (COR=1.3, 95% CI, 0.3-5.4) Table 4.3. Comparing mothers with no formal education to those with formal education, **maternal formal education** showed significance in bivariate logistic analysis (**COR=0.5, 95%CI, 0.3-0.9**), this association was however lost after adjustment (OR=0.5 95% CI, 0.3-1.1) table 4.3. After adjusting for potential confounding factors including age (both maternal and infant), maternal formal education and including factors that were significant at bivariate analysis level in the regression model, maternal formal education and **maternal independent income (AOR=0.4, 95% CI, 0.2-0.9)** remained significantly associated with the outcome variable. Place of residence was not significantly associated with follow up after adjustment (AOR= 2.1, 95% CI 0.8-6.7). Also a Mother being a trader reduced the odds of her infant becoming a case by about 70% (COR=0.3, 95%CI, 0.1-0.7), while occupations such as administrative work, Health care work, education and Artisanry were not significantly associated with follow up for EID using peasant farming/agricultural workers as reference occupation, Table 4.3. Marital status of Mothers was not significantly association with follow up for early infant diagnosis.

Parity (number of children), sex of infant and household size were not significantly associated with follow up for early infant diagnosis, Table 4.3 and Table 4.7. The odds of a child born to woman having 2-3 children not having a follow up for early infant diagnosis by DNA PCR was increased by 80 % comparing women with 2-3 to those with a single child(COR=1.8, 95% CI 0.9-3.4) . Similarly the odds of women with 4 or more children not following up with their child was increased by 60% comparing women with four or more children to those with a single child (COR= 1.6, 95% CI, 0.6-3.9) table 4.7.

Table 4.1 Demographic Characteristics of HIV Positive Mother-Baby Pairs Reporting to Selected ART centers, Upper West Region, December 2014-April 2015.

Characteristic	Cases 96 (%)	Controls 96 (%)	Total=192 (%)
Sex of HIV Exposed Infant			
Males	55(57.3)	52(54.2)	107 (55.7)
Females	41(42.7)	44(45.8)	85 (44.5)
Maternal age groups (Years)			
20-24	17 (20.2)	11(12.9)	28 (16.6)
25-29	52(61.9)	55(64.7)	107 (63.3)
30-34	11(13.1)	17 (20.0)	28 (16.6)
35-49	2 (2.4)	2(2.6)	4(2.4)
40-44	2.4 (2.4)	0	
Marital status			
Single	6 (6.3)	5(5.2)	11(5.7)
Married	78(81.2)	73(76.0)	151(78)
Cohabiting	5(5.2)	5(5.2)	10(5.2)
Divorced	2 (2.1)	4 (4.2)	6 (3.1)
Widowed	5 (5.2)	9(9.4)	14 (7.3)
Place of Delivery			
Health facility	85 (88.5)	90 (93.7)	175 (91.1)
Home	11 (11.5)	6 (6.3)	17 (8.9)
Employment Status of Mothers			
Self employed	29(30.2)	43(44.8)	72(37.5)
Public employed	4(4.2)	4 (4.2)	8 (4.2)
Unemployed	63 (65.6)	49 (51.0)	112 (58.3)
Occupation of Mothers			
Peasant farmer/Agriculture	47(50.5)	33 (36.3)	80 (43).
Trader	8(8.6)	20 (22.2)	28 (15.2)
Administrative/Finance worker	3(3.2)	2(2.2)	5 (2.7)
Educationist	3(3.2)	5(5.5)	8(4.3)
Health worker	1(1.1)	0 (0.0)	1(0.5)
Artisan	31 (33.4)	31 (34.1)	62 (33,7)
Maternal independent income source			
Have income source	30(31.3)	48 (50.5)	79 (40.8)
No income source	66 (68.8)	47 (49.5)	113 (59.2)
Mother Baby pair Residence			
Urban	49 (51.0)	64 (66.7)	113 (58.9)
Rural	47 (49.0)	32 (33.3)	79 (41.1)
Distance to EID Clinic			
≤10 km to EID clinic	75 (86.5)	83 (78.1)	158 (82.3)
>10 km to EID clinic	21 (13.5)	13 (21.9)	34 (17.7)

4.4 DNA PCR results, Turnaround Time, Timeliness of testing and MTCT.

Out of 96 infants who were returned to health facilities for follow up for DNA PCR testing, 47 (49.0%) were tested within two months(8 weeks) after delivery, while 49 (51.0%) were tested between 9 weeks and 18 months after delivery. DNA PCR results of 44 of 93 (47.3%) were received while the results of 52.7% of were pending. The median age of infants at time of testing was 10 weeks IQR 6-26weeks. About 30 %(9/30) of DNA PCR results were received within 4 weeks after collection of DBS. The median TAT of DNA PCR results was 11 weeks IQR 4-27 weeks. One out of 44 DNA PCR result received, was HIV positive (2.3%) and 43 (99.7%) were HIV negative. A majority of mothers (68%) tested their infants because they were eager to know the child's HIV status, while 29 out of 96 (30.2%) tested their infant because they were counselled by a healthcare worker.

The main reason why women did not test their infants was because health workers did not collect DBS samples for PCR testing. Out of 93 cases(mothers with infants not tested), 58 (62.8%) were not tested because mothers made one or more visits to EID sites but blood samples were not collected due to shortage of laboratory reagents at the testing laboratories. About 16 of 93(17.2%) mothers did not test their infant because they did not know the exact time to test, or were waiting to be prompted by PMTCT nurses. Other reasons for not testing were fear (4.3%), child looks healthy (4.3%) long distance to testing facility (2.2%) transportation challenges (1%) and other reasons including mother falling sick at time of testing/mother travelled(8.6%). One of 44 DNA PCR result received was positive representing a Mother Child transmission rate of 2.3%. Table 4.2.

Table 4.2 Characteristics of DNA PCR results, Timeliness, and Reasons for testing at Selected ART centers, Upper West Region-Ghana.

Characteristic	N (%)
Tested for EID by DNA PCR	96 (50.0)
Did not test for EID by DNA PCR	96 (50.0)
Age at testing/timeliness of EID	n=96 (100%)
≤ 8 weeks	47 (49.0)
9 weeks- 77 weeks (18 months)	49 (51.0)
DNA PCR result status	N=93
Result received	44 (47.3)
Results Pending	49 (52.7)
Turnaround time of PCR results	n=30(100%)
Results received within 4 weeks	9 (30.0)
Results received After 4week	21 (70.0)
Result type by DNA PCR	n=44 (100%)
Negative	43 (97.7)
Results Positive	1 (2.3)
Reasons for testing	n= 96(100%)
Counselling from health worker	29 (30.2)
Eager to know results/status of Baby	66(68.8)
Child was sick	0 (0.0)
Other reasons	1(1.0)
Reasons for not testing	n=93(100%)
Fear	4 (4.3)
Did not know/Waiting for prompt from nurse	16(17.2)
Long distance to testing facility	2 (2.2)
Child looks healthy	4 (4.3)
DBS not collected/ no reagents	58(62.4)
Transportation	1(1.0)
Other reasons	8 (8.6)



Table 4.3 Association of Selected Demographic Factors and Follow up for early infant diagnosis of HIV, Upper West Region, December 2014-April 2015

Characteristic	Case s 96	Controls 96	COR (CI)	P value	AOR (CI)	P value
Sex of HEI						
Females	41	44	0.9 (0.5-1.6)	0.663	--	--
Males	55	52	1.0		---	--
Maternal age groups						
20-24	17	11	1.0		1.0	
25-29	52	55	0.6 (0.3-1.4)	0.529	0.5(0.2-1.5)	0.534
30-34	11	17	0.4 (0.1-1.2)		0.4 (0.1-1.4)	
35-49	2	2	0.6 (0.1-5.3)		0.4 (0.1-7.8)	
40-44	2.4	0	--		---	
Employment Status of Mothers						
Self employed	29	43	0.7 (0.2-2.9)	0.105	--	
Unemployed	63	49	1.3(0.3-5.4)		--	
Public/formal	4	4	1.0		--	
Occupation of Mothers						
Trader	8	20	0.3(0.1-0.7)		0.5 (0.1-2.1)	
Administrative/Finance	3	2	1.1 (0.2-6.6)	0.075	5.5 (0.4-69.4)	0.197
Educationist	3	5	0.4(0.1-1.9)		0.4 (0.1-8.6)	
Health Care worker	1	---	---		---	
Artisan	31	31	0.7(0.3-1.3)		--	
Peasant farmer/Agriculture	47	33	1.0		--	
Marital status						
Married	78	73	1.0			
Single	6	5	1.1(0.3-3.8)			
Cohabiting	5	5	0.5(0.1-2.6)	0.260		
Divorced	2	4	0.9 (0.3-3.6)			
Widow	5	9	0.5 (0.1-1.6)			

4.5 Health System Factors and follow up for early infant diagnosis

All of the 192 HIV positive mothers with infants/children who were interviewed reported having received at least one form of PMTCT intervention, (single dose nevirapine, triple drug combination of ARV, or the form of ART). Out of their 192 exposed infants, 183 (95.3%) received at least one form of PMTCT intervention (single dose nevirapine, six week course Zidovudine syrup or both) and 9(4.7%) did not receive any PMTCT intervention. Infant and Maternal PMTCT intervention were not significantly associated with follow up. Mother receiving EID information from health care works was significantly associated with follow up. Table 4 and Table 5. About 95% of mothers with exposed infants ever heard of HIV testing of infants with the odds of being a case increased by over seven times, (COR= 7.5 ,95% CI 0.5-61.9) comparing mothers who ever heard of infant testing to mother who never heard of testing. The main source of EID information for mothers was from healthcare workers (mainly ANC/PMTCT/ART nurses), 90.5% (172/192). Out of those who heard about HIV testing, 69.7% (129/192) heard of testing before pregnancy and 23.4 %(44/192) heard of testing during pregnancy/labour. **Timing of EID information** was significantly associated with follow up for EID with the odds of an **infant born to a mother who heard of testing after delivery** becoming a case, increased by more than twelve times, **(COR=12.6 ,95% CI 1.5-100.8)** comparing mothers who heard about testing after delivery to mothers who heard about testing during pregnancy. This significance was maintained after adjusting for maternal educational level and age among other significant **factors (AOR=18.6, 95% CI: 1.7-202.5)** Forty four infants representing 49% (44/96) were tested within the first two months after delivery as recommended by WHO, table 4.5.

There was also a significant association between infant PMTCT type and follow up for early infant diagnosis. Infants who received only single dose nevirapine or only six week

course zidovudine syrup are most likely to become cases compared to infant who received both. The odds of becoming a case was increased by four times among infants who received no PMTCT intervention to those who received both. (COR =4.6 95% CI, 0.5-1.1). Also infants who received only six week zidovudine were nine times more likely to become cases (not have follow up) compared to those infants who received both sdNVP and AZT(COR=9.3, 95% CI 1.1-77.9). This association remained even after adjustment with their odds of becoming cases increased by 14 times (AOR =14.6 95%CI, 1.1-186.4) as shown in table 4.4.

4.6 Findings from interviews with Health staff

Key health worker directly involved in EID services were interviewed to determine specific barriers to early infant diagnosis of HIV in the region. They included PMTCT nurses (2), Labour ward nurses (2), ART data managers (2) ANC nurse (1) and laboratory staff (1). All staff said EID and PMTCT services were well integrated. About 25% (2/8) said they send or receive EID related information by telephone. Two out of 8 key health staff interviewed reported that mothers do not report early for EID. Seven out of 8 (87.5%) reported that DNA PCR result do not return or return late. All 8 or 100% said there were stock out of laboratory reagents at the testing laboratory and no laboratory staff was trained in DNA PCR procedures in the region.

Table 4.4 Health System Determinants: PMTCT Interventions, Sources and timing of EID information, and follow up for early infant diagnosis of HIV among HIV positive Mothers/Infants reporting to selected ART centres in Upper West Region - Ghana

Characteristic	Cases	Controls	^c OR(95%CI)	P value	^A OR(CI)	p value
Maternal PMTCT,						
Received PMTCT	96	96	-	--	--	
Did Not Receive PMTCT	0	0	-		--	
Type of Maternal PMTCT						
SdNVP only	8	15	0.5 (0.2-1.2)			
Other ARV	7	9	0.6 (0.2-1.9)	0.229		
Triple Drug ARV	81	15	1.0			
Infant PMTCT interventions						
Received PMTCT	89	94	0.3 (0.1-1.3)	0.079		
Did not Receive	7	2	1.0			
Type of Infant PMTCT ^A						
SdNVP at birth only	7	1	1.5(0.2-1.2)		1.4(0.6-3.4)	
Six week AZT only	32	28	9.3 (1.1-77.9)	0.014	14.6(1.1-186.4)	0.022
None	7	2	4.6(0.9-23.3)		0.7 (0.1-1.6)	
sdNVP and six week AZT	49	28	1.0			
Mother information on EID						
Informed	89	95	0.1(0.1-1.1)	0.065		
Not informed	7	1	1.0			
Timing of EID information ^A						
during pregnancy/labour	18	26	0.8(0.4-1.6)		0.6 (0.2-1.5)	0.089
after delivery	11	1	12.6(1.5-100.8)	0.003	18.6(1.7-202.5)	
before pregnancy	60	69	1.0			
Sources of EID information						
	N=89	N=95				
Radio/Television	2(2.1)	7(7.3)	0.2 (0.4-1.1)	0.036		
Online/brochure/Magazine	0	2	--			
From colleagues	2	0	--			
Health Care Worker	85	85	1.0			

Variables adjusted =^A

Table 4.5 Association of Selected Factors and Follow up for early infant Diagnosis of HIV Upper West Region-Ghana.

Variable	Cases	Controls	COR (CI)	Pvalue	AOR(CI)	P-value
Distance of Residence to EID Clinic						
≤10km	21	13	1.8(0.3-3.8)	0.128	--	--
>10km	75	83	1.0		--	
Place of delivery						
Home	11	6	1.9 (0.7-5.5)	0.201	--	--
Health Facility	85	83	1.0			
Setting of Residence[^]						
Rural	47	32	1.9 (1.1-3.4)	0.027	2.1(0.8-6.7)	0.084
Urban	49	64	1.0			
Maternal formal Education[^]						
Mother educated	32	48	0.5 (0.3-0.9)	0.013	0.5(0.3-1.1)	0.416
Mother not educated	64	48	1.0			
Level of formal education[^]						
No formal education	62	48	1.9(0.5-7.3)		0.6 (0.1-7.9)	
Primary	13	24	0.8(0.2-3.4)	0.136	0.2(0.1-3.0)	
Secondary	17	18	1.4 (0.3-5.9)		0.5 (0.1-6.5)	
College/university	4	6	Ref		1.0	
Maternal independent income source[^]						
Have income source	30	48	0.5 (0.3-0.8)	0.006	0.5 (0.2-0.9)	0.021
Have no income source	60	48	1.0			
Mother heard of EID						
Heard of testing	89	95	0.1 (0.1-1.1)	0.065	--	--
Not heard of testing	7	1	1.0			

Variables adjusted =[^]

4.7.0 Psychosocial Factors and follow up for early infant in diagnosis

Disclosure of Maternal HIV status, and membership to a PLHIV association or support group were not significantly associated with follow up. A majority of HIV positive Mothers (86.9%) or 166 of 191 included in this study had disclosed their HIV status, while 13.1% or 25 of 191 had not disclosed their status to anyone. There was no significant differences in proportions of disclosure between cases and controls. More than half (59.7%) of the mothers who disclosed their status made the disclosure to their husbands. The odds of an infant born to a mother with an undisclosed HIV status, becoming a case was increased by 10% comparing infant born to mothers who did not disclose to mother who disclosed their status (COR=1.1 95% CI 0.5-2.5). Similarly infants born to mothers who were part of support group or PLHIV association had their odds of becoming a case increased by 50% compared to an infant whose mother was not a member of any support group COR=1.5, 95% CI 0.8-2.7) . Table 4.6.

From table 4.2, Out of the 96 HIV positive mothers who returned to the EID clinic to test their babies by DNA PCR, 66 (68.8%) returned because they were eager to know the HIV status of their infants. Only six (4.2%) or 6 out 93 infants were cases (not tested) because their mothers fear to test them.



Table 4.6 Psychosocial Factors Associated with follow up for early infant diagnosis HIV -Upper West Region-Ghana

Variable	Cases n=96 (100%)	Controls n=96 (100%)	COR (95% CI)	P value
Disclosure of Maternal HIV status				
Mother disclosed status	12	13	1.1 (0.5-2.5)	0.654
Did not disclose status	84	82	1.0	
Person to whom HIV status was disclosed				
Husband	59	55	1.0	
Mother	11	13	0.8 (0.3-1.9)	0.803
Other person/Relative	15	14	0.9 (0.4-2.3)	
None	11	13	0.8 (0.3-1.9)	
Membership of PLWHA				
Member	37	28	1.5 (0.8-2.7)	
Not Member	59	67	1.0	

Note ^ = variables adjusted for,



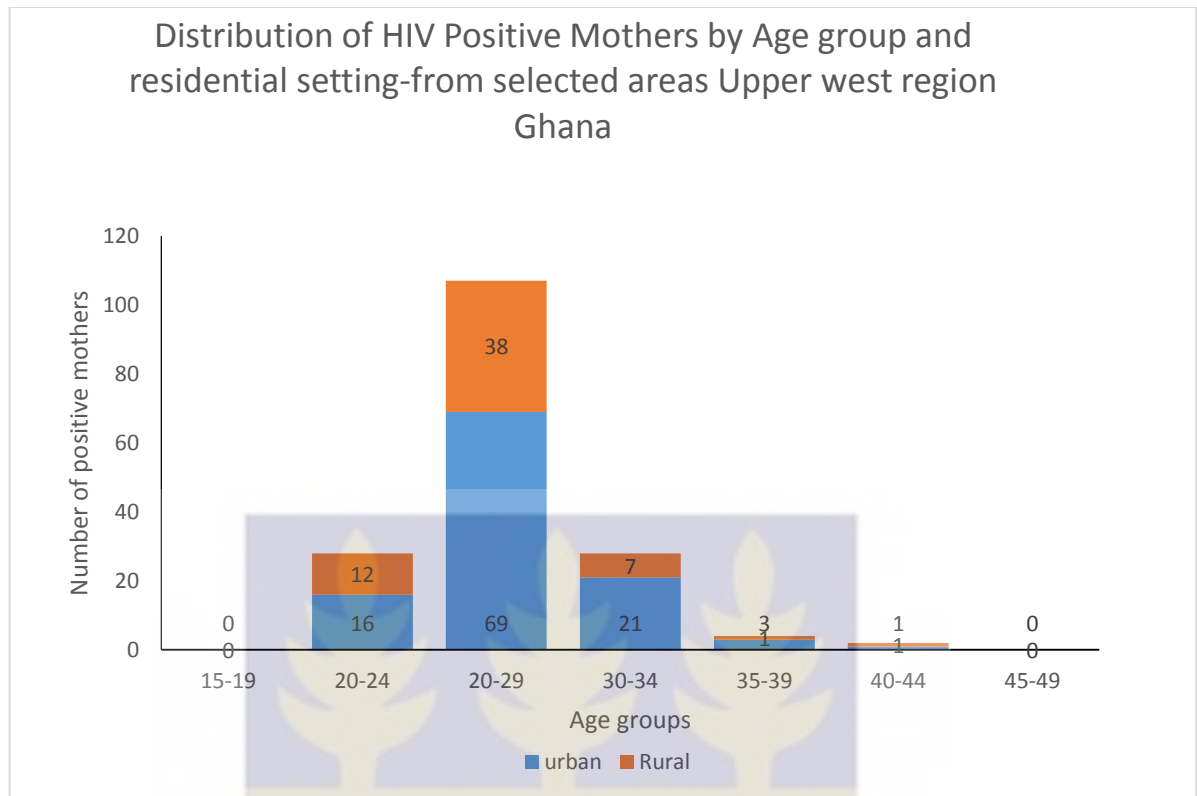


Figure 1.1 Age and residential Distribution of HIV positive Mother, upper West Region, December 2014-April 2015



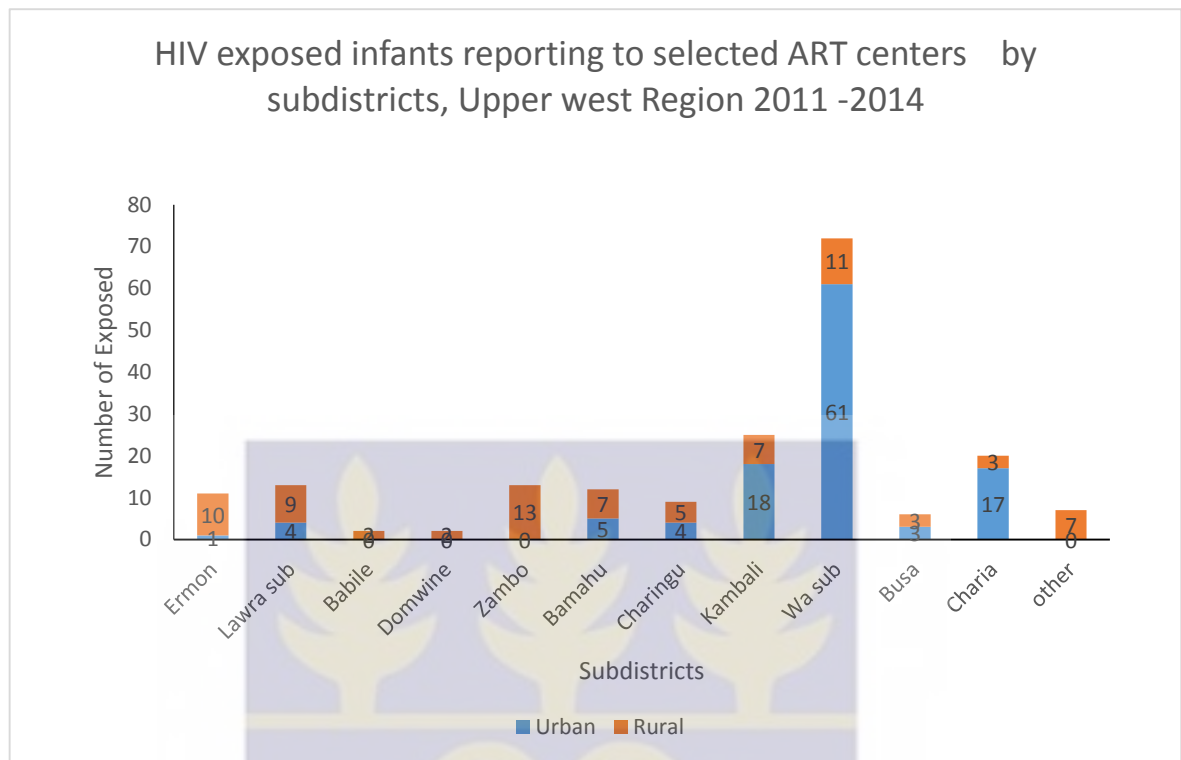
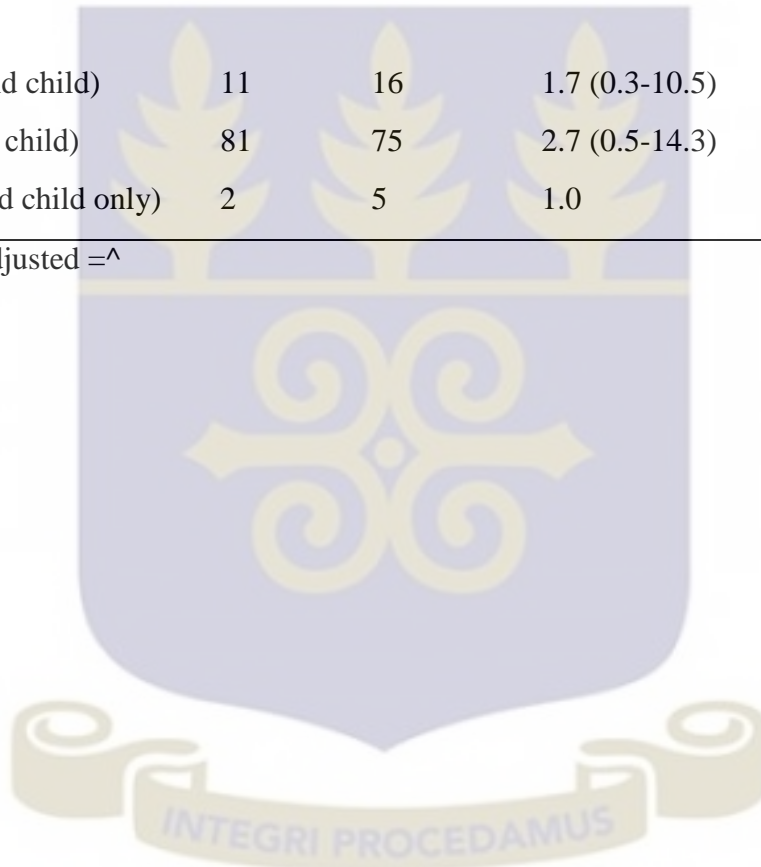


Figure 4.2 Distribution of HIV exposed infants by sub-districts and Residence, Wa Municipal and Lawra –UWR



Table 4.7 Family size Number of Children and follow up for early infant Diagnosis of HIV, Upper West Region.

Variable	Cases	controls	COR (95% CI)	P. value
Parity				
2-3 children	15	14	1.8 (0.9-3.4)	
≥ 4 children	55	46	1.6 (0.6-3.9)	0.075
1 child	24	36	1.0	
Family size				
3(Parents and child)	11	16	1.7 (0.3-10.5)	
≥4 (Parents, child)	81	75	2.7 (0.5-14.3)	0.290
2(mother and child only)	2	5	1.0	

Variables adjusted =[^]

CHAPTER FIVE

DISCUSSION

5.1 Sociodemographic Determinant of follow up for early infant

Despite its limitations the study found that having a rural residence, maternal unemployment, mothers without independent source of income, having no information about infant HIV testing are significantly associated with not returning HIV exposed infants to health facilities for early infant diagnosis. The role of poverty as a barrier to early infant diagnosis is demonstrated here with greater proportion of mother unemployed or without an independent source of income and consequently not testing their infants. Similar observations have been made in Kenya where poverty and lack of social support was reported as a barrier to early infant diagnosis (Hassan et al., 2012). This was possibly compounded by frequent and long standing stock outs of laboratory reagent which had to force mothers to make several visits to testing sites. Low maternal age was found to be associated with poor follow in rural Kenya and other places, however maternal age was not associated with follow up in this study (Hassan et al., 2012; Seidenberg et al., 2012).

Maternal educational level appeared to be a potential confounding factor in this study showing significance in bivariate analysis but losing this significance in multivariate/stratified analysis. Though maternal educational level lost significance in stratified analysis at all levels of education, it remained significant even after adjustment as a non-stratified variable. Similarly, maternal age showed significance when this variable was stratified by age groups. This informed the decision to include maternal age and formal education levels to the list of significant variable that were included in the final regression model. Tailor made EID services using point of care devices and SMS result transfer would be necessary to improve early infant diagnosis coverage in rural

communities. While poverty has not been cited here as direct cause of poor follow up for early infant diagnosis service, it has been demonstrated here that mothers who are either unemployed or have no independent source of income are less likely to follow up with their HIV exposed infants for early infant diagnosis.

5.2 Psychosocial factor that influenced follow up with infant for early infant diagnosis

Though it was initially thought that most mothers may not test their babies because of fear or stigmatization, the study found that there was rather a strong desire by most mothers to test and know the status of their babies. Over 60% of mothers who tested their babies did so because they were eager to know the results of their child. This finding agrees with findings of a survey conducted in a similar setting in Zimbabwe where a survey showed that about 92% of parents with HIV exposed infants will be happy to know the result of their infants. Contrary to what is being suggested in some study findings that mother may test their babies because this act may be tantamount to declaring their own status (Buzdugan et al., 2012) and also because of the fear of blame that they transferred the infection to their babies, up to sixty six percent (66.8%) of mothers were eager to know the result of their infants through testing by DNA PCR (Buzdugan et al., 2012). This suggests that the relief that mothers get from knowing the status of their infant especially when the infant test negative far outweighs the fear of testing.

From table seven, bigger family size and number of children are shown to adversely affect a woman's ability to have follow up. It appears to be economically challenging for women with a bigger family size or many children to make repeated visits to a health facility. Since it has reported that in a pronatalist society like the Upper West region,

childlessness is frowned upon (Tabong & Adongo, 2013), women who have a single child will tend to guide this child jealously through the uptake of PMTCT services as observed in this present study. This is evident in the fact that women with many children had an increased odds of not testing their infants.

5.3 Health system factors and early infant diagnosis

There are several documented health system challenges, including shortage of commodities, sample collections and transportation challenges, late reporting of mothers with infants to health facilities, poor data collection methods, late return of results and loss to follow up (Meyers et al., 2007; Penazzato et al., 2014). Other factors include poor coordination between different levels of the health system and lack of integration of EID into other MCH services (Braun et al., 2011). This study demonstrates clearly some of these challenges and strengths. An interview with health workers shows that personnel have been trained, EID services are well integrated into maternal and child health services in health facilities and enhanced referrals (personal communication with PMTCT nurses). Despite these achievements, poor turnaround time of DNA PCR results, stock outs and late reporting by mothers were key health system challenges similar to what has been observed in other places with similar settings (Hassan et al., 2012; Seidenberg et al., 2012).

Arguably, the poor turnaround time (TAT) of DNA PCR results or even non return of results of infants tested was also disincentive for mothers to keep testing their infants. While the average TAT for DNA PCR results is around two weeks with over eighty percent of results returning in Thailand (Sirirungsi & Samleerate, 2013; WHO, 2010a) self-reported median TAT in this study was eleven weeks. Even in other African setting like Ghana which may have similar resource challenges better turnaround times of DNA

PCR results (9-21 days) have been reported in Tanzania, Malawi and Botswana (Ciaranello et al., 2011; Nuwagaba-Biribonwoha et al., 2010), Hassan and others observed that the availability of result on caregiver or mother return visit dates was very important in determining adherence to scheduled follow up visits (Hassan et al., 2012) More than half of mothers who even tested their infant did so after the WHO recommended testing time of “two months after delivery”.

Also over 60% of mothers reported that they lost the opportunity to test their infants because of shortage of laboratory reagents and associated non return of DNA PCR results. This suggest that many more mothers could have been disappointed after several visits and lost confidence in the health system. Reagent and logistic shortages remains a major hindrance to early infant diagnosis of HIV because reagent have a very short shelf life of 6-9 months and manufacturers will only produce to meet the request of users (Ghadrshenas et al., 2013). the cost of DNA PCR test coupled with the short shelf life of reagent was reported as a major barrier which is also reported by a couple of studies (Ghadrshenas et al., 2013; Hassan et al., 2012). As part of efforts to solve this problem bundle EID commodities were introduced with single test EID packs which contain everything that is needed to collect a dry blood spot (Ghadrshenas et al., 2013).

Several researchers have proposed the integration of EID services into immunisation services since most countries with early infant diagnosis challenges have already achieved high immunization coverage levels (Ghadrshenas et al., 2013; Kellerman & Essajee, 2010; McCollum et al., 2010). This could improve and maximize health gains for HIV exposed infants in Ghana since the country has a high childhood immunization coverage. Ghana had a high coverage of most infant immunisations (over 80% of infant receiving all immunisations, 94% for DPT,96% for 3 doses of polio) in 2008(GSS & Macro, 2009). This high immunization coverage does not correspond to the rather lower

EID coverage observed in this study, that is, less than 20% EID coverage as of December 2012. This suggests that most mothers turn up for immunisation services but do not go for EID most probably due to stigmatization. Implementing PITC with opt-outs at child immunisation centres using HIV RDT could help in identification of infants at risk. The other reason why most women probably access immunisation service but do not go for EID could be their low Knowledge of HIV prevention. The 2014 Ghana Demographic and Health Survey (GDHS) reports that only 10% women in the Upper West Region have comprehensive knowledge about HIV prevention(GSS, 2014).

Health workers especially ANC and PMCT nurses need to pay particular attention to counselling of mothers given that up to 16% of mothers who did not test their babies were waiting to be prompted by nurses before they do so. Poor communication between facilities collecting and transporting DBS and the laboratories that test these samples is a well-documented challenge also found in this study(Braun et al., 2011). This is evident in this study given the fact that over 50% of those who got tested did not receive any result or an explanation for the delay in receiving results. Some results have been pending for over three years with PMTCT nurses settling on antibody testing once the infant has attained 18 months. Standard mails and occasionally telephone calls are used to send EID results in the region. The use of SMS and remote data printing has simplified EID result dissemination and improved turnaround times in countries like Kenya, (Finocchario-Kessler et al., 2014) Nigeria (WHO, 2013b) and South Africa . Such a service could also allow health worker make inquiries about outstanding results and allow laboratories to request a new sample where sample is lost or is inadequate for testing. A coordinated effort is also required at all levels of the health system to ensure that accurate EID data is collected. SMS and other innovative ways of sending

information including electronic mails have been found to improve coordination and reduce loss to follow up (Braun et al., 2011).

There is also a clear difference in the proportion of HIV exposed infants testing positive by DNA PCR comparing the National exposed infant HIV prevalence to what has been observed in this study. Both reviewed data and self-reported HIV result suggest a low HIV prevalence among exposed infants in the region. Only 2.7 % of infant results were positive from reviewed record results and a similar result of 2.3% of positive exposed infant PCR results was reported by mother in the case control study. This is far lower than the national rate of 7% reported in 2012 (Ghana Health Service, 2013). This low rate of transmission could be attributed to the success of PMTCT/ e-MTCT (elimination of Mother to Child transmission) program in the region.

The Main strengths of the study were that: a case control design was used which strongly measure association and could be used together with other factors to establish causality. Also a combination of both data review and interviews improved accuracy.

Key Limitations of the study were challenges with tracing HIV positive women from community especially patients who did not accept their status, and those who leave their district of residence to access services from other Districts because of stigmatization. The study was also facility based and is not likely to capture those not reporting to health facilities.

The study could also have included a focus group discussion and also assessed variables like, Mother's Autonomy, husband support, type of counselling received when mother was first diagnosed with HIV and the relationship of Health care worker with the study participant that could have influenced follow up visits .

In the determination of distance, it was not possible to pick coordinates of all locations, we determined the nearest 10 km community on all major routes to the two testing sites using google maps and also directly asked study participant to estimate the distance.



CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion

Based on the findings of this study, the conclusion is that health systems challenges are the main barriers to early infant diagnosis in the Upper west region including stock out of reagents and lack of adequate laboratory support, poor timing of early infant diagnosis information, inadequate counselling and poor turnaround time of DNA PCR results. Other barriers to early infant diagnosis are lack of access to the service due to poverty or distance. Babies of HIV positive mothers living in rural areas are most likely not to receive follow up for early infant diagnosis. A significant proportion of mothers are not reporting early (two months after delivery) to health facilities for early infant diagnosis. Where both mother and infant have received PMTCT intervention the rate of Mother to child transmission of HIV could be reduced to below 3% and elimination of mother to child transmission is possible with effective PMTC interventions. Over 50% of HIV exposed infants are not getting tested early enough within the WHO recommended time of two months after delivery. Disclosure of maternal HIV status, Mother's membership to a support group and number of children a mother has, did not significantly influence a mother's ability to follow up with her infant for early infant diagnosis of HIV. Mothers who were employed, educated, trading or received adequate and timely EID information were likely to follow up with their infants for early infant diagnosis. Expansion of early infant diagnosis services coverage for HIV exposed infant is possible with adequate decentralization of DNA PCR services, health staff training and effective and timely education of HIV positive Mothers.

6.2 Recommendations

Based on the findings of the study, the following targeted recommendations are suggested.

6.2.1 Recommendations for the NACP and Regional Health Directorate

They are:

- To decentralize EID testing by DNA PCR testing to the regional level, preferably by providing easy to use point of care testing devices. Currently DBS spots collected from the Upper West Region are transported to Sunyani, Tamale or Accra for infant HIV DNA PCR testing. The NACP have also procured for Regional hospital Laboratory a Cobas e-111 automated machine capable of HIV DNA testing. Provision of appropriate reagent and training of Laboratory staff could eliminate the challenge of long waiting and non-testing of exposed infants.
- To Build laboratory capacity in the Region to be able to conduct DNA PCR testing
The RHD and regional hospital should provide space for DNA PCR equipment and build laboratory capacity in the form of technical training and increased personnel to the regional hospital laboratory to make it capable of running DNA PCR testing.
- To introduce EID follow up cards and train health worker on how to identify HIV exposed infants especially at areas within the health facility where exposed infant identification efforts are alien. Exposed infant identification is currently not done at children's wards, OPDs Laboratories and Pharmacies. Infant immunization and clinic cards and Mothers ANC cards can be modified to include space for HIV

testing and counselling, referral for ART, and maternal HIV status on child health record cards. Special codes could be used for this to minimize stigmatization.

- To Step up education of women on the benefits of early infant diagnosis using posters television and radio. A significant proportion of HIV positive mothers either do not know when to send their infants for testing or were waiting to be prompted by a nurse before they test.
- The NACP should establish an electronic EID data base for EID result, which can be accessed by authorized users. This will allow accessing of EID information and result in real time
- Introduce SMS printers with remote printing of EID result to allow rapid transmission of EID results
- Pay transport fares of mother who turn up at health facility for EID

6.2.2. Recommendations for DHMT (District Health Management Team).

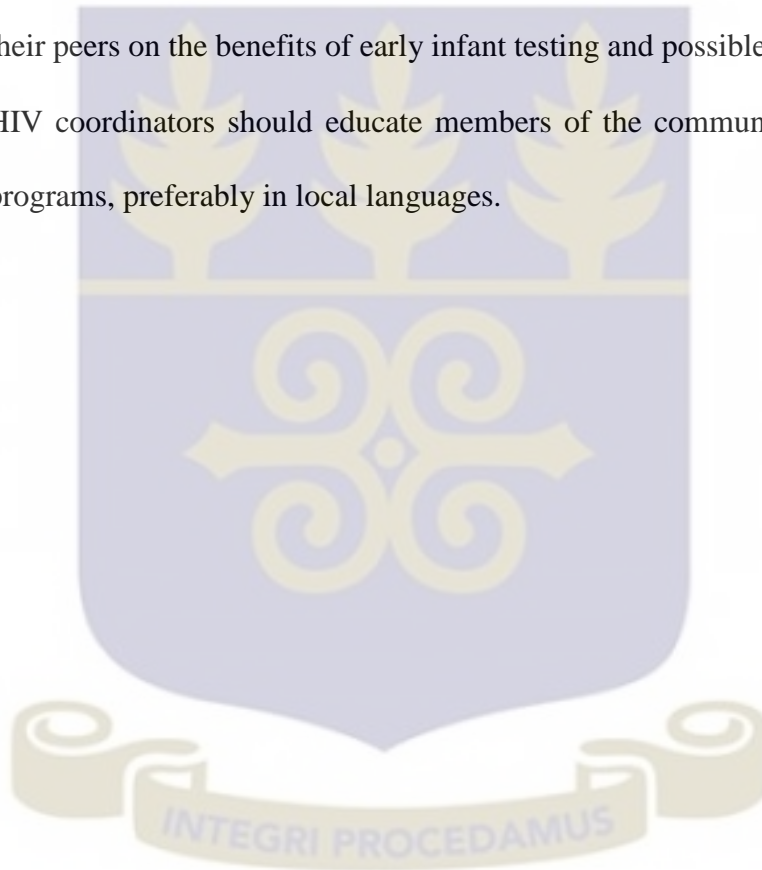
The DHMTS

- Train and assign ANC/PMTCT Nurses to Educate HIV positive pregnant women on the benefits of EID and the exact time of testing infant. Since health worker may be too busy to dedicate enough time for counselling each mother, and the hospital environment itself may not be too conducive for counselling, the task of explaining the benefits of early testing could be shifted to relatives (patient escorts)
- Train nurses to identify and refer exposed infants at immunization clinic and refer them to EID clinics
- Develop a schedule for follow up of all exposed infant and ensure they turn up to health facilities on the scheduled dates. This could be done through provision of

EID hotlines and sending text message reminders to mothers to remind them of EID testing dates through nurses and HIV coordinators. These messages could be kept anonymous by only inviting the mother to bring baby to the hospital without specifying the purpose.

6.2.3 Community Level.

- HIV coordinators should train HIV peer Educators and use them to educate their peers on the benefits of early infant testing and possible e-MTCT.
- HIV coordinators should educate members of the community through radio programs, preferably in local languages.



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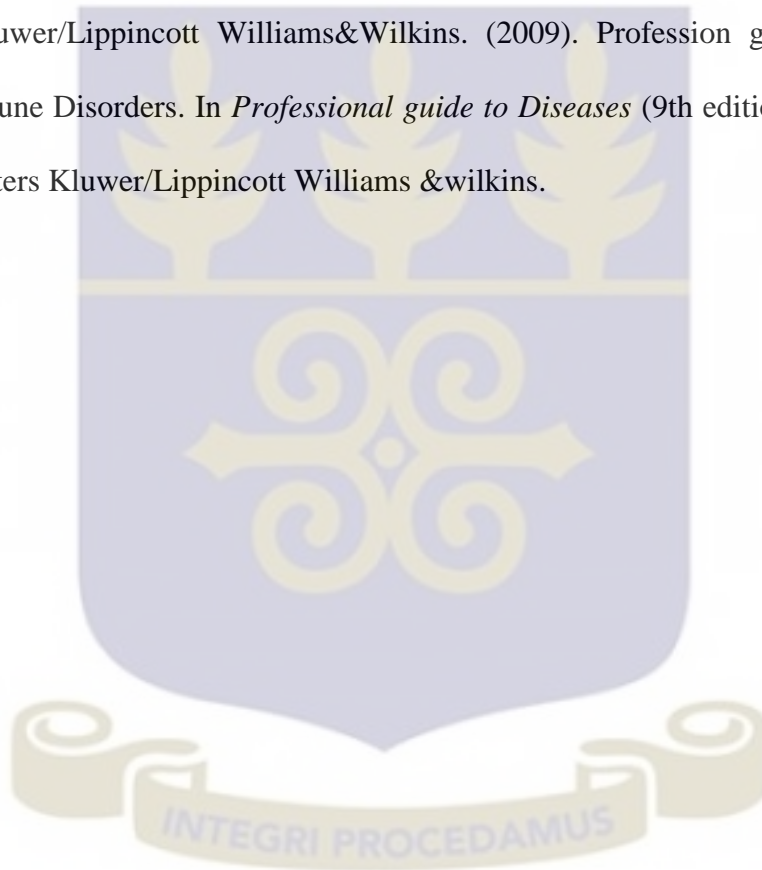
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**APPENDIX: A: CHECKLIST AND QUESTIONNAIRE FOR DATA
COLLECTION**

**QUESTIONNAIRE BARRIERS TO EARLY INFANT DIAGNOSIS OF HIV IN
WA MUNICIPAL AND LAWRA DISTRICTS, UPPER WEST REGION-GHANA**

I will like to ask a few questions about yourself and your child. These questions will take about 30 minutes of your time. Please you may ask question about anything you don't understand at any time.

Instruction thick or write most answer(s)

BACKGROUND AND ID

Study number..... Status: case control

Name of health facility.....

District.....

Sub district.....

Name of town/community.....Date:

DEMOGRAPHIC CHARACTERIS

No	Question	Answer	Skip to
1	What is your name (Mother)/Initials/Folder No?		
2	What is your age (Mother of HEI)?		
3	What is your date of delivery?		
4	Where did you deliver your baby?	Home yes/no if yes Health facility yes/ no	7
6	Name of health facility?		
7	What is the name or initials of your child (HEI)?		
8	Date of birth of HEI? Age and sex of HEI in weeks/...../.....weeks , sex; M / F	
9	Level of Education of Mother/Guardian	i. No formal education ii. Primary education iii. Secondary education iv. College /university	
10 a	What is the employment status of mother/guardian	i. Employed private/self ii. Employed public iii. Unemployed	
10 b	Occupation of the mother/ father/ guardian	I. Peasant farmer/agric worker ii. trader iii. health care worker ivAdministrative/financial staff security officer	

		V. Educationist Vi artisan(hair dresser,dressmaker, etc)	
11	Marital status of the mother	i. Single ii. Married/Cohabiting iii divorced/widowed	
12	How many children do you have?	I	
13	How many members are in your family?		
14	How far in kilometers from the health facility do you stay	i. Within 10 kilometers ii. More than 10 kilometers	
15	Mother has independent source of income.	Yes No	
16	Setting of residence	Rural Urban	
PMTCT INTERVENTIONS			
17	Is mother enrolled to PMTCT/CTC?	I. Yes ii. No iii Unknown	
18	What PMTCT intervention did mother receive TDF=Tenofovir 3TC=Lamivudine EFV=Efavirenz NVP= Nevirapine FTC=Emitricitabine AZT=zidovudine	i. Single dose nevirapine ii. Triple drugs (Lamivudine +AZT +NVP) (ART)(TDF,3TC EFV),(TDF,FTC,NVP), (TDF, FTC,EFV) iii. None	
19	Did infant receive any PMTCT intervention?	Yes No	
20	What PMTCT intervention did infant receive?	i. SdNVP ii. AZT (six weeks) iii. None	
21	Have you ever heard of HIV testing in infants?	i. YES ii. NO if no skip to	24
22	When did you hear about HIV testing in infants?	i. Before pregnancy ii. During delivery iii. After delivery	
23	Where did you hear?	i. Television/radio ii brochure/ magazine/online iii.health facility staff iv from colleagues	
24	Was blood from your infant collected on filter paper for HIV testing	I. Yes if yes skip to ii. No if No skip to iii.Unknown	25 32
25	What makes you to test your baby? (controls only)	i. Counseling from HCWs ii. Eager to know results iii child was sick iii. Others (specify)	
26	What date was your child tested?/...../.....	
27	What was the age of your child at the time of		

	testing? (specify age in weeks) weeks/months/years	
28	Have you received the HIV test result of the baby?	Yes if yes go to No if no go to	29 31
29	How long did it take to receive test result?		
30	What is the result of your child's HIV test?	i. POSITIVE ii. NEGATIVE iii. I do not know	
31	Why have you not received results?	i. Fear ii. Results delayed in previous visits iii. Long distance iv. Other (specify).....	
32 a	What makes you not test your baby? (cases only)	i. Fear ii. I did not know about the test iii. long distance iv. child looks healthy V. reported but DBS not collected vi. transportation/Others (specify)	
PSYCHOSOCIAL FACTORS			
33	Did you disclose your HIV status?	i Yes ii No	
34	To who have you disclosed your HIV status	i. Husband ii. Mother/ relative iii none	
35	Are you a member of any social/support groups of PLWHA (people living with HIV association)?	Yes No	

HEALTH SYSTEM FACTORS (to be administered at health facility)			
SECTION B: HEALTH SYSTEM FACTORS (to be administer to health facility staff)			
36	Are PMTCT/ART together	Yes No	
37	Is there someone trained about early infant diagnosis of HIV in this unit/facility? How many?		
38	What is Average turnaround time for DNA PCR result in weeksweeks	
39	Is there a system for identifying HEI at delivery or during child care clinics?	Yes if yes No	
40	How are HEI infants Identified for testing		
41	Is there a system for collecting and transporting dry blood spots from infants for testing at this facility	Yes No	
42	Do you have challenges with logistics for EID at this facility	Yes No	
43	Do you encounter any other challenge with EID	Yes, specify..... No	

APPENDIX B: CONSENT FORM

I.....Have read/understood the content of this study. I have been adequately informed about the purpose, procedure, potential risk and benefits of the study. I have been given the opportunity to ask questions about the study and my questions were answered satisfactorily. I know that I can choose not to participate in this study or withdraw from this study at any time without the loss of any benefit which I would have otherwise been entitled to. I agree to participate in this study

Signature/thumbprint of participant/Guardian.....

Signature/thumbprint of Witness

Interviewer statement

I have clearly explained the study to the participant in the language that he or she understands best and he/she has agreed to participate in the study.

Signature of interviewer.....

Date consent signed.....

Contacts for Additional Information

For any enquiries about the study you may call the chairman, Ghana Health Service Ethical review committee, P. O. Box MB 190

Accra, Ghana .Tel : +233-302-681109 email: *Hannah.Frimpong@ghsmail.org* or Madam Abena kwaa Addai at *nanatuesdaykad@yahoo.com*

APPENDIX C: CHECKLIST AND QUESTIONNAIRE FOR DATA COLLECTION IN DAGAARE

Surbie, Nang Char Bibilpaalba Gbemiele Baalo Filibu, A Wa Ning Lawra Paalong Puo-Ghana.

N booro ka an sori yele mine a char fo ning fo bie. A yelsur nga nang ta la minti lizeri ning pie (30 minutes). Ka fo bawa won yelzaa, fona bang sosri ma la, ka N yel ko fo

A FOR NING FOR BIE YELE

study number Status: case control

Asipti na Fo Nang gere

Paalong.....

Longbor.....

Yiri longbor.....

Demographic Characteristics / a fo ning fo bie yele.

No	Sor bir	Sor bir nuori iribu	Skip to
1	Foyouri le bo		
2	Yuomoaawulakafonye?		
3	Bibiribuo la kafo da dog a bie?		
4	Yeng la kafo dog a bie?	Die Asipti. Ka die wa le gaa	7
6	Aasiptiyuori la bo?		
7	A fobieyuori la bo?		
8	A biengadogbubibiri la bo? A bienye la youmoawula/daariawula?/...../....., dao / pogo M/F	
9	Yengkafogaasakuua ta?	i. N ba gaa sakuu ii. N gaa sakuu ta jss iii. N gaa sakuu a ta sss iv. N gaa la sakuu ta colloge/university	
10	Bo tomakafotona?	i. N menga toma ii. Governmenti tontona iii. (N ba taa toma)	
11	Fo taala sire bi? Fo sir kul yele	I.nyong/n bataa sire ii. N taa sire/ sen/dao iii (Pogkuuori la ma)	
12	Biiri ba wulo ka fo taa?		
13	Nubabawula la be a fo die?		

14	A yi a fo die kye waara a asipti puo ta la mile/kilometers a wola	i.aba ta kilometer pie(<10km) ii a zuo la kilometer pie (> 10km)	
15	Fotaa la fo minge libiepii?	Yes(N) No(ayi)	
16	Fokpiebuziewaa la yirikpenpuobiikoraa?	Rural(koraa) Urban(yirkpenpuo)	
PMTCT INTERVENTIONS			
17	Fo da mang gaate de la a gbemiile baalong ting fo nang da taa fo puo na bii?	i.Yes(N) ii. No(Ayi) iii Unknown(N ba bang)	
18	Bo gbemiile baalong ting la kaba da kofo a fo pogpugaalu sang?	i. Single dose nevirapine ii. Triple drugs (Lamivudine +AZT +NVP) iii. Antiretroviral treatment (ART) iv. None	
19	Ba da ko la a fobiegbemiilebaalong ting bii?	Yes (N) No(ayi)	
20	Bo gbemiile baalong ting la kaba da ko a fo bie?	i. SdNVP ii. AZT iii. None	
21	Wo dang wong la a bibilpaalba gbemiile babaalo fiilbu yele bii?	i. YES (N) ii. NO(Ayi) if no skip to	24
22	Bo sang la kafo da wong a bibilpaalbagbemiilebaalongfiilbuyele?	i. fonang da taapuona ii. fonangwadogrona iii.fo nang dog a biebaarena	
23	Yengkafo da wongyelenga?	i. Television/radio ii.Brochure/ magazine/online iii. Health facility staff	
24	ba da de la a fobie zing a dogli gang zuka be tefiiligbemiilepii?	i.Yes(N) if yes skip to ii. No (Ayi) if No skip to iii.Nba bang	25 32
25	Bo la da vengkafo sag kabafiili a fobie? (cases only)	i. asiptitongtona la da yelyelekuma) ii. N da borka N bong) iii. Others (specify)	
26	Bibiribu la kabafiili a fobie?/...../.....	
27	Ba nang da fiili a biena, ka a bienye la yuomo a wola?		
28	Fo da gaate de la a biefiiluduoro/ganbie?	Yes(N) if yes go to No (Ayi) if no go to	29 31
29	Wolaka a da koori sing chekafonye a biefiilbugan/duoro?		
30	A wobiegbemiilefiilbuduoro da la bo?	i. A bietaagbemiile	

		ii. a biebataagbemiele iii N ba bang	
31	Bo zuingkafobanye a fobiefiillbuduoro/gan?	i. Fear(Dabiengpkemang) ii. Results delayed in previous visits(a fiilbugan da bawa) iii. Long distance(N yiri/pkeziwaa la toori) iv.Other (specify).....	
32	What makes you not to test your baby? Bo la da vengkawobafiili a fobie? (controls only)	i. Fear(Dabieng) ii.Nba bang/wong a fiilbuyele) iii.aAsiptitongtona da bairi a bie zing. iii. Others (specify)	
PSYCHOSOCIAL FACTORS			
33	Fo da yel la a for gbemiele baalong yele a ko nie kang bie?	i. Yes(N) ii.No(Ayi)	
34	Neng buo la ka wo da yele a fo gbemiile baalo ko?	. i. Husband(N sire) ii. Mother/ relative(N ma) iii none (N ba yel)	
35	Wo puo la gbemiile deme langbu kanga puo bii?	Yes (N) No (Ayi)	

