EVALUATION OF THE EFFECTIVENESS OF PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV (PMTCT) INTERVENTIONS IN TWO SELECTED HEALTH FACILITIES IN ADAMAWA STATE, NIGERIA

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July, 2017

KEYWORDS

Antenatal Clinic (ANC)

Antiretroviral drugs prophylaxis (ARVP)

Antiretroviral Therapy (ART)

Deoxyribonucleic Acid (DNA) Polymerase Chain Reaction (PCR) test

Federal Medical Centre, Yola (FMC Yola)

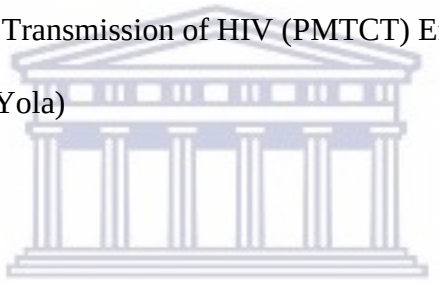
Human Immunodeficiency Virus (HIV)

HIV Testing and Counselling (HTC) Uptake

Mother to Child Transmission of HIV (MTCT) risk

Prevention of Mother to Child Transmission of HIV (PMTCT) Effectiveness

Specialist Hospital, Yola (SH Yola)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DECLARATION

I declare that *Evaluation of the effectiveness of Prevention of Mother to Child Transmission of HIV (PMTCT) interventions in two selected health facilities in Adamawa State, Nigeria* is my own work that has not been submitted for any degree or examination in other universities or other institutions of higher learning in Nigeria or outside Nigeria. Furthermore all the sources of information herein have been indicated and given full acknowledgement in the reference list.

ITIOLA, Ademola Joshua

Signed

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ACKNOWLEDGEMENTS

My profound appreciation goes to the Almighty God for seeing me through my MPH programme. The gift of life and sound health are what I could not have been able to afford if I were to pay.

The completion of my mini-thesis is largely predicated on the invaluable guidance and mentoring I received from my supervisors: Prof. Ameena Goga and Dr. Vundli Ramokolo - I must say that the success of this research project is a function of your untiring support when it mattered the most. The administrative support provided by Prof. Tanya Doherty is also worthy of mention. The conveners of all the modules I took equally deserve great commendation for providing the theoretical foundation upon which this project work was built. The administrative staff of the School of Public Health, University of the Western Cape: Corinne and Janine were simply superb and prompt in attending to all my queries in the course of my study.

My appreciation will be incomplete if I fail to mention the motivation I received from my friends: Kunle, Tomi and Joke to keep pressing till I achieve my MPH goal.

I strongly believe that my parents paid the ultimate sacrifice by ensuring that I had the requisite basic academic training; without this foundation, I would not have gone this far.

Finally, I acknowledge that it is practically impossible to mention all those that had contributed in one way or the other to my MPH success and to you all I say a very big thank you.

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ACRONYMS

3TC	Lamivudine
ABC	Abacavir
AFASS	Acceptable, Feasible, Affordable, Sustainable and Safe
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Clinic
ART	Triple Antiretroviral Therapy
ARV	Antiretroviral Drug
ARVP	Antiretroviral Prophylaxis
AZT	Zidovudine
CHAI	Clinton Health Access Initiative
CTX	Cotrimoxazole
DBS	Dried Blood Spot
DCT	Data Collection Tool
DNA	Deoxyribonucleic Acid
DRC	Democratic Republic of Congo
EBF	Exclusive Breastfeeding
ECSD	Elective Ceasarian Section Delivery
EFV	Efavirenz
EID	Early Infant Diagnosis
eMTCT	Elimination of Mother to Child Transmission of HIV
FHI	Family Health International
FMC	Federal Medical Centre
FTC	Emtricitabine
GhAIN	Global HIV/AIDS Project in Nigeria
HEI	HIV Exposed Infant
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
IB	Infant Breastfed
IDV/r	Indinavir ritonavir
IP	Infant Prophylaxis
IQR	Interquartile Range
LGA	Local Government Area
LPV/r	Lopinavir/ritonavir
mART	Maternal Antiretroviral Therapy
MHP	Maternal HIV Positivity Rate
MP	Maternal Prophylaxis
MPH	Masters in Public Health
MTCT	Mother to Child Transmission of HIV
NPC	National Population Commission
NVP	Nevirapine
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Fund For AIDS Relief

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PLHIV	People Living With HIV
PMTCT	Prevention of Mother to Child Transmission of HIV
RF	Replacement Feeding
sdNVP	single dose Nevirapine
SH	Specialist Hospital
SIDHAS	Strengthening Integrated Delivery of HIV/AIDS Services
TAT	Turnaround Time
TDF	Tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UWC	University of the Western Cape
VL	Viral Load
WHO	World Health Organization
ZDV	Zidovudine

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DEFINITIONS

Antiretroviral Therapy (ART)

Refers to when an HIV (Human Immunodeficiency Virus) positive woman takes a combination of three antiretroviral drugs both for her own health (treatment) and for prevention of mother to child transmission of HIV (prophylaxis). The primary reason for the use of triple regimen is for the mother's health with a secondary reason of preventing mother to child transmission of HIV. The triple regimen is started as soon as the mother is assessed to be eligible for ART (based on CD4+ cell count and WHO clinical stage) and continued for life.

Antiretroviral Prophylaxis (ARVP)

Refers to when an HIV-positive pregnant woman takes single, dual or triple antiretroviral drugs solely to prevent mother to child transmission of HIV. Triple regimen for ARVP is distinct from that of ART in that in the former, the triple regimen is started from 14 weeks of gestation and stopped 1 week post cessation of breastfeeding. For the study period (2008 - 2014) women on triple regimen for ARVP have higher $CD4^{+}$ cell count than those on triple regimen for ART and were either in WHO Clinical Stage I or II. The terms "Option B" or "Triple regimen (ARVP)" were used interchangeably to qualify triple regimen used for ARVP throughout this thesis. Triple regimen for ART was referred to as "ART" while unqualified triple regimen refers to either "Option B" or "ART".

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Confirmation of First Test

Refers to a Deoxyribonucleic Acid (DNA) Polymerase Chain Reaction (PCR) test conducted for HIV exposed infants (HEIs) when the attending clinician has reason(s) to doubt the outcome of the first DNA PCR test and wants to re-confirm the first result for the 7 years under review (2008 – 2014). This is however not officially recognized in the national

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PMTCT guidelines. It should be noted that DNA PCR test and early infant diagnosis (EID) test were used interchangeably throughout the thesis.

Exclusive Breastfeeding

Refers to the breastfeeding option where infant is solely fed with breast milk for the first six months of life. This option excludes the use of formula feed or any other liquids or solids. Use of prescribed medications and oral rehydration salt (ORS) is however allowed.

First Test for Healthy Exposed Infant

Refers to the first DNA PCR test conducted for healthy HEI as per the national testing algorithm of Nigeria for the 7 years under review (2008 – 2014).

First Test for Sick Infant

Refers to the first DNA PCR test conducted for sick HEI as per national testing algorithm i.e. the infant has fallen sick at the time of testing for the 7 years under review (2008 – 2014).

Maternal/Antenatal Human Immunodeficiency Virus (HIV) Positivity Rate

Refers to the proportion of first ANC attendees that accepted HIV testing that tested HIV positive. The numerator for this indicator is the total number of pregnant women that tested positive for HIV during the first ANC visit while the denominator is the total number of pregnant women that tested for HIV at their first visit.

Mixed Feeding

Refers to the breastfeeding option where an infant is fed with both breast milk and formula feed or any other liquid or solids.

MTCT Risk

Refers to the proportion of tested HEIs that tested HIV positive. The numerator for this indicator is the total number of HEIs that tested HIV positive while the denominator is the total number of HEIs that tested for HIV.

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Option B+

Refers to the ARV intervention in which an HIV positive pregnant or breastfeeding woman takes combination of three antiretroviral drugs for a life time irrespective of $CD4^+$ cell count and WHO clinical stage.

Period 1 (Jan 2008 – Jan 2010)

Refers to the period when only the 2007 National PMTCT guidelines was in use for PMTCT at the two health facilities used for this study.

Period 2 (Jun 2012-Dec 2014)

Refers to the period when only the 2010 National PMTCT guidelines was in use for PMTCT at the two health facilities used for this study.

Problem with First Test

Refers to the repeat DNA PCR test conducted when the first dried blood spot (DBS) sample collected was either not testable or the result did not get to the ordering health facility hence the need to reorder the "first" test for the 7 years under review (2008 – 2014). For a test to be in this category the result of the first test ordered must have been indeterminate or missing.

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Repeat Test 6 weeks Post Cessation of Breastfeeding

Refers to the second (and final) DNA PCR test conducted for HEI at six weeks post cessation of breastfeeding as per Nigeria's national testing algorithm for the 7 years under review (2008 – 2014).

Replacement Feeding /Not Breastfed at all

Refers to the breastfeeding option where an infant is never fed with breast milk. The infant is fed with formula feed or any liquid or solid meal.

Secondary Health Facility

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Refers to health facilities that provide secondary health care; these health facilities provide specialized services to patients referred from the primary health care level (first point of medical consultation) and are managed by the state governments.

Tertiary Health Facility

Refers to health facilities that provide highly specialized referral services to the primary and secondary levels of the health care delivery system and are largely managed by the federal government. Most of the tertiary health facilities also serve as teaching hospitals for medical training.

Transitional Period (Feb 2010 – May 2012)

Refers to the period when both the 2007 and 2010 National PMTCT guidelines were in use for PMTCT at the 2 health facilities used for this study.

Turnaround Time

Refers to the time interval (in days) between when a DBS sample was collected from HEI and when the DNA PCR result was returned to the ordering health facility.

Uptake of ART/ARVP

Refers to the proportion of ANC attendees who tested HIV positive at their first visit that received antiretroviral drugs (ARVs) (either for prophylaxis or treatment). The numerator for this indicator is the total number of pregnant women that received ARVs (either for prophylaxis or treatment) while the denominator is the total number of pregnant women that tested positive for HIV at the first ANC visit.

Uptake of HIV Testing and Counselling (HTC)

Refers to the proportion of pregnant women that attended ANC for the first time in the most recent pregnancy that tested for HIV. The numerator for this indicator is the total number of pregnant women that tested for HIV during their first visit while the denominator is the total

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number of pregnant women that attended ANC for the first time in the most recent pregnancy.

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ABSTRACT

Background: Most (90%) Human Immunodeficiency Virus (HIV) positive children are infected through mother to child transmission of HIV (MTCT). Without any interventions the risk of MTCT is between 20% and 45% at the final endpoint of 18 – 24 months. Efficacy studies have however proven that with antiretroviral interventions, MTCT risk can be reduced to less than 2% or 5% in non-breastfeeding and breastfeeding populations respectively. It is important to evaluate the effectiveness of Prevention of MTCT (PMTCT) interventions in routine health facility settings where service delivery may not be optimal. The current pool of evidence on PMTCT effectiveness in Sub-Saharan Africa is limited and no PMTCT effectiveness study has been conducted in Adamawa State, Nigeria since the programme started in 2007.

Aim: To evaluate the effectiveness of the PMTCT programme in two health facilities in Adamawa State, Nigeria.

Methodology: This study involved a retrospective review and analysis of routine antenatal clinic (ANC), PMTCT/HIV Testing and Counseling (HTC) and early infant diagnosis /infant follow up records gathered from 2008-2014 (seven years) in two health facilities in Adamawa State, Nigeria. Routine data were analyzed using STATA 14.2 to establish uptake of HTC among ANC attendees, uptake of antiretroviral therapy (ART)/antiretroviral prophylaxis (ARVP) among those that tested HIV positive, turnaround time (TAT) for Deoxyribonucleic Acid (DNA) Polymerase Chain Reaction (PCR) test results and MTCT risk among HIV exposed infants (HEIs) segregated by age, breastfeeding option, ART/ARVP option and PMTCT protocol periods. Simple and multiple logistic regression analyses were conducted to establish predictors of ART/ARVP uptake and MTCT risk.

Results: Among the 62,224 pregnant women (FMC Yola = 14,892; SH Yola = 47,332) that attended ANC for the first time from 2008 to 2014, the overall uptake of HTC was estimated

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to be 75.9% [47,217/62,224] (95% Confidence Interval: 74.3% – 77.5%). This increased from 60.8% [5,365/8,824] (49.9%-71.7%) in 2008 to 82.2% [7,636/9,293] (77.1%-87.2%) in 2014. Average maternal HIV positivity rate among the 47,217 pregnant women tested for HIV was 3.1% [1,475/47,217] (3.0% - 3.3%) across the seven years, ranging from 5.5% [297/5,365] (4.8% - 6.2%) in 2008 to 1.5% [117/7,636] (1.2% - 1.9%) in 2014. The overall uptake of ART/ARVP among 224 HIV positive pregnant women was 85.7% [192/224] (81.1% - 90.3%), increasing from 76.5% [13/17] (55.6%-97.4%) in 2008 to 80.0% [52/65] (70.1%-89.9%) in 2014. The overall MTCT risk among 1,651 HEIs (FMC Yola = 746, SH Yola = 905) with first DNA PCR test results across the seven years was 9.7% [160/1,651] (8.3%-11.1%) at median age of 8 weeks (IQR: 6-20), decreasing from 14.3% [7/49] (4.4%-24.2%) in 2008 to 4.9% [11/226] (2.1%-7.7%) in 2014. Across all seven years, pooled data demonstrated that infants aged ≤ 6 weeks and those between >6 months and 12 months had a cumulative MTCT risk of 3.0% [15/499] (1.5% - 4.5%) and 21.1% [51/242] (15.9%-26.2%) respectively; infants that were exclusively breastfed, mixed fed and those not breastfed at all had MTCT risks of 8.3% [74/892] (6.5% - 10.1%), 22.4% [58/259] (17.3% - 27.5%) and 5.4% [23/429] (3.2% - 7.5%) respectively at median age of 8 weeks; MTCT risk was 2.4% [25/1,034] (1.5% – 3.4%) when both mother and infant received antiretroviral drugs (ART/ARVP) and 48.8% [83/170] (41.3% - 56.4%) when they did not at median age of 8 weeks. MTCT risk was lowest (5.4% [39/726] (3.7% - 7.0%)) during the period (June 2012 – December 2014) when Option B was in use for ARVP at median age of 8 weeks. The overall median TAT for DNA PCR test results was 48 days (IQR: 31-78) (n=1,298), increasing from 37 days (31-51) (n=49) in 2008 to 133 days (76-172) (n=168) in 2014. Multiple regression analysis showed that HIV positive pregnant women aged between 25-34 years had three times (Adjusted Odds Ratio (AOR) 3.07 [1.04 - 9.01]) the odds to receive ART/ARVP than those aged 15-24 years. The odds of being HIV positive was higher in HEIs that were older

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than 12 months (AOR 3.29 [1.24 - 8.75]), those that were mixed fed (AOR 2.44 [1.08 - 5.52]) and when neither mother nor HEI received ART/ARVP (AOR 26.37 [13.96 - 49.81]. HEIs born in 2012 had lower odds (AOR 0.18 [0.03 – 0.99]) of being HIV positive than those born in 2008.

Conclusion: Despite operational challenges, MTCT risk declined drastically between 2008 and 2014 in these two routine health facility settings in Nigeria and this reduction in MTCT coincided with an increase in the uptake of HTC services and ART/ARVP among HIV positive pregnant women. Option B or Option B+ is therefore strongly recommended, where feasible, to achieve elimination of MTCT as a public health problem.

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1.0 INTRODUCTION

1.1 Background

Human Immunodeficiency Virus (HIV) infections disproportionately affect women and children with approximately 37,000 pregnant women dying of the virus globally in 2010 (WHO, 2015a; WHO, 2015b; WHO, 2015c; UNAIDS, 2012). Most (over 90%) HIV-positive children (aged 0-14 years) were infected through mother to child transmission of HIV (MTCT) (WHO, 2010d; WHO, 2015e). Without any interventions, the risk of MTCT is between 20-45%, while with antiretroviral interventions the risk of MTCT can be reduced to less than 2% and 5% in non-breastfeeding and breastfeeding populations, respectively, at the final endpoint of 18 – 24 months (De Cock et al., 2000; Kumar, Uduman, & Khurranna, 1995; Lallemant et al., 1994; WHO, 2010a). MTCT can occur during pregnancy, childbirth (labour and delivery) and breastfeeding (WHO, 2010a). Research has demonstrated that most cases of MTCT occur late in pregnancy and during delivery due to contact between the maternal and fetal blood when the placenta separates from the uterine wall and as the infant passes through the birth canal (for babies delivered through the vaginal route) (Kourtis et al., 2001; Rouzioux et al., 1995). When infants are breastfed, the postnatal period is also critical as around 39% of cumulative MTCT can occur during this period (Kourtis et al., 2006). Factors such as viral load (VL), mode of delivery and feeding practice (breastfeeding versus avoiding breastfeeding, exclusive breastfeeding versus mixed breastfeeding) have been found to influence the risk of MTCT (Newell, 2001). HIV-infected women with high VL are more likely to infect their children while elective cesarean section reduced MTCT risk by half in some settings (Newell, 2001). Research has also demonstrated that mixed-fed infants have higher MTCT risk than exclusively breastfed or formula fed infants while the risk of MTCT

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increases with the duration of breastfeeding (Newell, 2001; Wise, 2001; The Breastfeeding and HIV International Transmission Study Group et al., 2004).

Interventions geared to prevent MTCT follow a cascade of steps which begins with HIV testing and counseling (HTC) of the pregnant mother and culminates in establishing the HIV status of the HIV-exposed infant (HEI) and enrolment of the HIV-positive child into HIV care and treatment as presented in Appendix 1 (see Appendix 2 for Nigeria's eligibility criteria and recommended antiretroviral drugs (ARVs) between 2007 and 2014 (Federal Ministry of Health, 2007; Federal Ministry of Health Nigeria, 2010a; Federal Ministry of Health, 2014a)). It is important to evaluate the effectiveness of these interventions to determine real-life impact of interventions to prevent MTCT. Currently, the numbers of Prevention of Mother to Child Transmission of HIV (PMTCT) effectiveness studies are limited in Africa ((Goga, Dinh, & Jackson, 2012; Lussiana et al., 2012; Nkwo, 2012; Goga et al., 2016).

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1.2 Problem statement

As asserted by UNAIDS in 2011, it is possible to keep pregnant HIV-positive women alive and prevent new infant HIV infections by timely provision of appropriate ARVs either as treatment for the mother's health or as 'treatment as prophylaxis' to prevent MTCT (UNAIDS, 2011). Even though efficacy of PMTCT is established, there are real life scenarios that are not accounted for by the controlled conditions under which efficacy studies are conducted. Adamawa State, Nigeria commenced implementation of the PMTCT programme in September, 2007; however no study has been carried out to investigate the effectiveness of the interventions provided.

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1.3 Purpose

The World Health Organization (WHO) has recommended that all countries track the achievement of elimination of MTCT (eMTCT) targets even beyond 2015 (WHO, 2011; WHO, 2014). To date, the only country-level findings available in Nigeria are from operational research conducted in 2005 when only 11 tertiary sites offered PMTCT services (Agboghoroma, Sagay, & Ikechebelu, 2013).

The purpose of this research project was therefore to evaluate the effectiveness of the PMTCT interventions provided in two health facilities in Adamawa State, Nigeria. This would help in several ways: (i) service providers would get to know the effectiveness of PMTCT-related interventions/investments; (ii) it would help the Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) programme meet one of its programme objectives of providing evidence on the effectiveness of PMTCT interventions in two of their supported health facilities; (iii) it would also add to the body of knowledge and provide evidence on the effectiveness of the programme in two large health facilities after over a decade of PMTCT implementation in Nigeria; (iv) while most of the facility-based PMTCT effectiveness studies in Nigeria were single-site studies conducted at tertiary or teaching hospitals (Agboghoroma, Audu and Iregbu, 2015; Chama, Gashau, & Oguche, 2007; Chama et al., 2010; Esene & Omoigberale, 2012; Okafor et al., 2014; Isah et al, 2016), this study included a secondary health facility , thus providing additional evidence on PMTCT effectiveness in a secondary health facility which may not have as much specialized health personnel as tertiary or teaching hospitals; (v) most published Nigerian studies report findings during one period of the PMTCT protocol (Agboghoroma, Audu and Iregbu, 2015; Chama, Gashau, & Oguche, 2007; Afe et al., 2011; Audu et al.,2014; Anoje et al., 2012; Sagay et al., 2015; Kalu et al., 2014; Chukwuemeka et al., 2014); this study however compared MTCT risks during 2 periods of PMTCT policy changes in Nigeria as well as during the transitional period and (vi)

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the sample sizes used in this study were also larger than most of the other Nigerian studies (see appendix 5).

1.4 Aim

This study aimed to evaluate the effectiveness of the PMTCT programme in two health facilities in Adamawa State, Nigeria.

1.5 Objectives

The objectives of this study were to:

1. determine the uptake of HTC by pregnant women attending ANC for the first time in the most recent pregnancy
2. describe maternal/antenatal HIV positivity rate between 2008 and 2014
3. determine the uptake of maternal antiretroviral therapy (ART)/antiretroviral prophylaxis (ARVP) amongst HIV positive pregnant women
4. determine overall MTCT risk and turnaround time for DNA PCR test results
5. determine the MTCT risk at ages 4 weeks to 2 months, >2months – 6 months, >6 months to 12 months and >12 months
6. compare the MTCT risk by receipt/non-receipt of antiretroviral drugs (prophylaxis versus treatment) amongst HIV positive mothers
7. compare the MTCT risk by breastfeeding option (exclusively breast fed, mixed fed and not breastfed at all)
8. compare MTCT risk during two periods of PMTCT protocol policy changes and the transitional period (Period 1 - Jan 2008 – Jan 2010, Transitional Phase - Feb 2010 – May 2012 and Period 2 - Jun 2012-Dec 2014)

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2.0 LITERATURE REVIEW

This chapter provides a brief overview of the burden of HIV/AIDS across the globe and in Nigeria. It then summarizes the evolution of the PMTCT programme in Nigeria, the PMTCT cascade and the PMTCT regimens that were in use in Nigeria from 2007 to 2014. Finally this chapter concludes with a review of the recommended methodologies for evaluating effectiveness of PMTCT and some findings from previous national and facility-level PMTCT effectiveness studies in other countries and Nigeria.

2.1 The global burden of HIV and AIDS

The burden of HIV and AIDS is of major public health concern both in Africa and the world at large (Ortblad, Lozano, & Murray, 2013). According to WHO, as at end of 2013, the global population of people living with HIV/AIDS (PLHIV) stood at 35 million (WHO, 2015d). Since the start of the HIV/AIDS epidemic, approximately 39 million lives have been claimed by the virus (WHO, 2015d). Sub Saharan Africa bears the highest burden of HIV/AIDS (WHO, 2015d) as 71% of PLHIV are resident in the region (WHO, 2010a; WHO, 2015d) even though it is home to approximately one-eighth of the world's population (The World Bank Group, 2017).

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Approximately 55% of all people infected with HIV/AIDS are women and children (WHO, 2015a; WHO, 2015b; WHO, 2015c). In 2010, HIV infection was responsible for approximately 37,000 deaths among pregnant women globally (UNAIDS, 2012). In 2015, an estimated total of 150,000 children were newly infected with HIV in low- and middle-income countries (UNAIDS, 2016a); most (over 90%) of these children (aged 0-14 years) were infected through MTCT (WHO, 2010a). Given the higher risk of MTCT associated with breastfeeding and vaginal delivery, many developed countries have adopted combination of

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ARVP, elective caesarian section and replacement feeding as set of interventions for PMTCT (Darak et al., 2014).

2.2 Uptake of HTC and ART/ARVP

To establish the HIV status of pregnant women during ANC, the attendee must accept to test for HIV. The major approaches employed for this are the "opt in" and "opt out" methods (Walmsley, 2003). In the former, pregnant women are informed about the availability of screening service and are given the liberty to request for the test if they so wish. In the latter approach however, screening for HIV is offered as part of routine ANC services and the only pregnant women that are not screened are those that do not give their consent. This latter approach has been the recommended method for HIV screening among ANC attendees in Nigeria since 2007 (Federal Ministry of Health, 2007; Federal Ministry of Health Nigeria, 2010a; Federal Ministry of Health, 2014a). This testing strategy did not change in Nigeria between 2008 and 2014 and women that test positive for HIV are placed on antiretroviral drugs.

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Available evidence shows that the "opt out" approach is associated with a higher level of uptake when compared to the "opt in" method (Walmsley, 2003).

Reported data across selected 13 African countries in 2010 suggested that HTC uptake can range between nine percent as seen in Democratic Republic of Congo (DRC) to as high as >95% in South Africa and Zambia. Uptake of ARV among HIV positive women was also the lowest in DRC (4 -11%) while the highest rate of >95% was among Botswana women (Adane, 2012).

According to NDHS 2013 only 20 percent of women surveyed in Nigeria were counselled, tested and received result during ANC. The rate of ~39% for Adamawa State is above this

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national average. UNAIDS (2016b) noted that only 30% of pregnant women living with HIV in Nigeria are accessing ARVs to prevent MTCT.

A number of factors can affect uptake of HTC/ARVP as well as other elements of PMCT interventions. Based on the study reported by Chabikuli et al. (2013), poor quality counseling by the healthcare worker due to high workload was one of the factors constraining service delivery. Counselling has wide ranging effect on the client's decision to accept HIV testing and adhere to treatment. Mirkuzie et al. (2011) in their study in Addis Ababa observed a decline in medication adherence across the perinatal period. It is often assumed that once HIV positive mothers receive prophylaxis, they end up using the medication. This study however revealed decline in adherence which might be as a result of poor counseling. NACA (2013) also acknowledged poor counseling on infant feeding as one of the problems plaguing PMTCT programme in Nigeria. While work overload might be one of the reasons why counseling is poor; a study conducted in one of the states in Nigeria suggested that knowledge gap could also be responsible (Ndikom & Onibokun, 2007; Nkwo, 2012). The study reported that nurses were moderately knowledgeable about PMTCT with fairly appropriate behavior and recommended the need for educational interventions and a more conducive environment for practice (Ndikom & Onibokun, 2007).

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Staff attrition was also reported by Chabikuli et al. (2013) while a rapid assessment in the Eastern Cape province of South Africa equally identified lack of staff and inadequate training as factors plaguing PMTCT service delivery (Peltzer et al., 2008).

Inadequate resources for service delivery including shortage of ARVs required for prophylaxis also impact negatively on service delivery in a wide variety of settings (NACA, 2013; Oladokun et al., 2010; Chama, Audu & Kyari, 2004). Follow up of HIV pregnant women and HIV exposed infants is equally crucial. Inadequate follow up was identified in a

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study carried out in Uganda using key informants working in five PMTCT sites in the country (Nuwagaba-Biribonwoha et al., 2007); the study by Chabikuli et al. (2013) also identified inadequate resources for patient tracking as a challenge.

In Uganda, reluctance to test, non-disclosure of HIV status and difficulties with infant feeding for HIV positive patients were identified as barriers to PMTCT service provision. A variety of studies have also identified lack of male partner involvement in testing, stigma and discrimination as well as illiteracy (Rogers-Bloc & Quail, 2002; Peltzer et al., 2008; Oladokun et al, 2010) as constraining factors. Instances also exist where patients do not return for prophylaxis after test due to lack of finance, domestic violence amongst other reasons (Chabikuli et al., 2013).

2.3 Diagnosis of infant HIV infection

Given that maternal antibodies are retained in infants' foetal circulation for up to eighteen months after birth, tests that rely on detection of HIV antibodies are not used for the diagnosis of HIV infection in children (WHO, 2010b). HIV infection is diagnosed in infants using PCR test. Unlike antibody test, the PCR test detects viral antigens in the blood of HEIs. The blood sample is typically collected from the heel of the HEI using a dried blood spot (DBS) and then transported to a central laboratory where the sample is analyzed with the final result shared with the originating health facility. The use of DBS eases collection of blood samples at a relatively cheap rate and do not require high level of expertise (Smit, 2014). Collected samples can be stored over an extended period of time and are also easily transported to the central laboratory (Smit, 2014). As of 2012, there were 23 PCR laboratories across the states in Nigeria (CHAI, 2012). Early diagnosis of HIV in infants is critical as this ensures that HIV positive infants are promptly initiated on ART with consequent increase in chances of child survival (WHO, 2010b).

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2.4 Turnaround time for PCR test results

Findings from nine studies carried out in six African countries (Botswana, Kenya, Côte d'Ivoire, Swaziland, Tanzania, and South Africa) between 2008 and 2011 as reported by Ciaranello et al. (2011) revealed that turnaround time (TAT) can range between four and 147 days. The lowest median estimate of nine days was for the study conducted in Botswana while the highest TAT of 70 days (for negative PCR results) was reported for one of the studies conducted in Tanzania. Another study conducted in a rural clinic in Southern Zambia reported a median TAT of 54 days (IQR: 38-73; n=462) while the study carried out at a regional referral hospital in Uganda between January 2008 and February 2009 reported a lower median TAT of 38 days (IQR: 25-54) (Sutcliffe et al., 2014; Mugambi et al., 2013)

A nationally representative study conducted in Zimbabwe from August to December 2012 showed that more than 80 percent of facilities had TAT that were more than four weeks (Wiegert et al., 2014).

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Studies had also shown that various interventions can reduce TAT. Following centralization of DNA PCR testing through the use of hub network system, TAT reduced from 49 days (greater than 55 in rural areas) to 26 days in Uganda while introduction of SMS printers resulted in a further decrease to 14 days (Kiyaga et al., 2013). HIV Infant Tracking System (HITSystem) that sends automatic text message alerts to service providers, laboratory technicians and mothers in order to trigger action also reduced TAT in Kenya (Urban: 6.3 (4.7–13·6) for control group Vs 5.0 (3.7–6.1) for intervention group $p<0.001$ and Peri-Urban: 8.1 (4.9–12.9) for control group Vs 3.4 (2.8–4.7) for intervention group $p<0.001$; all in weeks) (Finocchario-Kessler et al., 2014).

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The study conducted by Anoje et al. (2012) at six health facilities in two states in South-South Nigeria estimated the median TAT to be 47 days (IQR: 35-58) (57 days for rural settings versus 40 days for urban locations; $p<0.01$). A lower median TAT of 25 days was reported by Audu et al. (2014) for the study they conducted in six health facilities in Lagos State, Nigeria. In general TAT is typically higher for rural locations than for urban areas (Anoje et al., 2012; Kiyaga et al., 2013). This is likely due to the longer distance that needs to be covered for sample transportation and result transmission.

2.5 HIV/AIDS and PMTCT in Nigeria

Nigeria has the highest number of children living with HIV in the world (about 260 000 (190 000 - 360 000)) in 2015 (UNAIDS, 2016a; UNAIDS 2017). An estimated 41 000 (28 000–57 000) children in the country were newly infected with HIV in 2015, representing 27% of the global new pediatric HIV infections for the year (UNAIDS, 2016a). Approximately 2.2 million children in Nigeria have been orphaned by HIV/AIDS (Federal Ministry of Health Nigeria, 2010a).

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In order to prevent MTCT, Nigeria implemented the PMTCT programme in 2002 in six health facilities; one in each geo-political zone of the country (Agboghoroma et al., 2013). This was subsequently scaled up to 11 tertiary health facilities with 10 of these health facilities in operation by 2003 (Agboghoroma et al., 2013; Federal Ministry of Health Nigeria, 2010a). By the end of December 2012, a total of 1,320 health facilities comprising tertiary, secondary, primary and private health facilities were offering PMTCT services in Nigeria (National Agency for the Control of AIDS, 2014). These programmes are largely supported through international donor agencies (Agboghoroma et al., 2013) with the United States Government President's Emergency Plan for AIDS Relief (PEPFAR) ranking as the largest funder (supports 75% of the country's HIV programme) of HIV programme in the country (Ezegbe & Stephenson, 2012).

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As recommended by WHO, Nigeria implements a comprehensive 4-pronged strategy to prevent HIV/AIDS in infants and children (Ezegbe & Stephenson, 2012; Federal Ministry of Health Nigeria, 2010a). The strategy includes: primary prevention of HIV infection in women of reproductive age and their partners; prevention of unintended pregnancies among HIV positive women; prevention of HIV transmission from HIV infected mothers to their infants and care and support for HIV infected mothers, their infants and family members (Federal Ministry of Health Nigeria, 2010a). The first PMTCT guidelines in Nigeria was produced in 2001 and was reviewed in 2005, 2007, 2010, 2014 and 2016 (Agboghoroma et al., 2013; Federal Ministry of Health, 2016)- the 2007 and 2010 PMTCT guidelines were the guidelines in use during the study period. The PMTCT strategy aligns with Nigeria's National PMTCT scale up plan (2010-2015) which has the overarching goal of improving maternal health and child survival through the provision of comprehensive PMTCT services, see targets in Appendix 3 (Federal Ministry of Health Nigeria, 2010a).

2.5.1 PMTCT cascade in Nigeria

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As shown in Appendix 1, the PMTCT cascade in Nigeria starts with the offering to and acceptance of HIV testing and counselling by pregnant women that attend ANC. Pregnant women that test positive for HIV are evaluated for ART eligibility while women test negative are re-tested in three months' time. ART-eligible pregnant women are placed on ART while ineligible women receive ARVP. Details of eligibility criteria and ARVs used between 2007 and 2014 are available in sections 2.5.2-2.5.4 and Appendix 2.

In addition, HIV positive women are counselled on infant feeding options. The first option is for mothers to breastfeed exclusively for the first six months after which complementary feeds can be introduced and feeding continues for up to 1 year. The second option is for mothers to avoid breastfeeding, using replacement milk (commercial infant formula and others). However as this is associated with an increased risk of child morbidity and mortality,

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replacement feeding is only recommended between 2008 and 2014 if the AFASS (Acceptable, Feasible, Affordable, Sustainable and Safe) criteria are met. Currently in Nigeria, women are strongly advised to adopt the first option.

HIV positive pregnant women are typically advised to deliver at the health facility. Upon delivery, HEIs receive ARV prophylaxis and are tested for HIV at six weeks of birth and six weeks post cessation of breastfeeding using DNA PCR. ART is immediately commenced if any of these two tests turn out to be positive (Federal Ministry of Health, 2007; Federal Ministry of Health Nigeria, 2010a; Federal Ministry of Health, 2014a).

2.5.2 ART and PMTCT eligibility criteria: Nigeria's 2007 PMTCT guidelines

The 2007 guidelines recommended that a woman is eligible for ART if she is in WHO Clinical Stage IV irrespective of CD4+ cell count, WHO Clinical Stage III if her CD4+ cell count is < 350 cells/mm^3 and if her CD4+ cell count is ≤ 200 cells/mm^3 irrespective of WHO clinical staging. Women that did not meet ART eligibility criteria were placed on ARVP (Federal Ministry of Health, 2007).

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2.5.3 ART and PMTCT eligibility criteria: Nigeria's 2010 and 2014 PMTCT guidelines

The 2010 and 2014 guidelines stipulated that a woman is eligible for ART if she is in WHO clinical stages III or IV irrespective of CD4+ cell count. While the 2010 guideline stipulated a CD4+ cell count of ≤350 cells/mm^3 irrespective of WHO clinical stage the 2014 guidelines stipulated a CD4 cell count of ≤500 cells/mm^3 irrespective of WHO clinical stage for ART eligibility. ART ineligible women were placed on ARVP (Federal Ministry of Health Nigeria, 2010a; Federal Ministry of Health, 2014a).

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2.5.4 PMTCT regimens used in Nigeria

Single dose Nevirapine (sdNVP)/Nevirapine (NVP) (2007 to date)

Though not currently in use as monotherapy for PMTCT due to availability of more effective ARV combination and concerns around resistance, Nigeria's 2007 PMTCT guideline recommended sdNVP at the onset of labour for mothers as part of their PMTCT regimen and also at birth for HEIs. Similarly the 2010's guideline recommended sdNVP at onset of labour and delivery as part of PMTCT regimen (Option A). From 2010 upwards, daily dose of NVP is recommended for HEIs for 6 weeks or more (see appendix 2) in Nigeria. Effectiveness studies have shown that sdNVP as monotherapy is the least effective for preventing MTCT which justifies why it is no longer used for maternal ARVP (Chama, Gashau, & Oguche, 2007; Moodley et al., 2013).

Zidovudine plus sdNVP (2007 – 2014)

Nigeria's 2007 and 2010 PMTCT guidelines recommended Zidovudine (AZT) from 28 and 14 weeks (Option A) respectively for PMTCT in addition to sdNVP at the onset of labour and delivery. This regimen is followed by AZT+3TC during labour and delivery and continued for 1 week post-partum. Up until 2014, AZT (Option A) was the major ARV used for maternal ARVP in health facilities that only provide PMTCT services (and not comprehensive ART services) in Nigeria. The 2007 guideline equally recommended AZT for 6 weeks for HEIs. AZT has been acclaimed to be the oldest and the most studied of all ARVs used for PMTCT (Connor et al., 1994; Paintsil & Andiman, 2009; Thorne & Newell, 2007).

Zidovudine plus Lamivudine (2007 – 2014)

In Nigeria, this dual combination was used for maternal ARVP (at the onset of labour/during labour and delivery as well as post-partum) between 2007 and 2014. It is also worthy to note that between 2007 and 2010, pregnant women diagnosed with HIV at 34-36 weeks of gestation received AZT+3TC instead of just AZT.

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Triple regimen (2010 till to date)

Following the release of ART treatment guidelines by WHO in 2010, Nigeria in 2010 adopted the use of triple regimen (Option B) for PMTCT in health facilities (mainly secondary and tertiary) that can monitor pregnant women placed on this regimen. Some of the recommended triple regimens are:

- AZT + 3TC + EFV
- AZT + 3TC + NVP
- AZT + 3TC + LPV/r
- TDF+ 3TC+ EFV

While in 2010, the triple regimen is recommend from 14 weeks of gestation, by the end of 2014 HIV positive pregnant women in all health facilities in the country are expected to be placed on triple regimen irrespective of gestation age and CD4+ cell count and continued till one week post cessation of breastfeeding. Studies have established the triple regimen as the most effective PMTCT regimen (Adane, 2012).

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2.6 Evaluation of PMTCT programmes

2.6.1 PMTCT programme evaluation: Global

The WHO's technical consultation report titled "Towards the elimination of Mother-to-Child Transmission of HIV: Report of a WHO technical consultation 9-11 November 2010 Geneva, Switzerland" noted the need to track progress towards meeting the PMTCT targets to eliminate overall MTCT to less than 5% by the end of 2015 (WHO, 2011). Few studies have however been conducted to evaluate the effectiveness of these interventions in resource limited settings and in particular Nigeria (Lussiana et al., 2012; Nkwo, 2012). Evaluation of effectiveness is important even though the efficacy of PMTCT has been established in a

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number of carefully designed and well controlled clinical trials such as PACTG076/ANRS 024 trial, DITRAME/Plus ANRS 1201.1 trial and Thai ZDV + 3TC trial (see appendix 4) (Chaisilwattana et al., 2002; Connor et al., 1994; Dabis et al., 2005). These efficacy studies do not take into account the uncertainties around service provision in programmatic settings hence the need to evaluate effectiveness at operational level (Chabikuli et al., 2013; Stringer et al., 2008). Effectiveness of PMTCT is an impact evaluation and it is defined as the "prophylactic benefit of a PMTCT intervention when implemented in real practice" (Stringer et al., 2008). There is no standard measure of PMTCT effectiveness as studies often report one of the following indicators: PMTCT intervention coverage (used as proxy for infant infections prevented); actual infant infections prevented; infant deaths prevented and HIV-free survival (Stringer et al., 2008). According to Stringer et al. (2008) any component of PMTCT cascade can also be used to evaluate the effectiveness of PMTCT programme (Stringer et al., 2008; UNICEF, WHO, & UNAIDS, 2009). This however could be debatable. Assessing the HIV status of an HEI at 6 weeks post-delivery and 6 weeks after cessation of breastfeeding provides a way of estimating the number of infant infections prevented (WHO, 2012).

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Studies have evaluated PMTCT programme effectiveness at a national scale. In Canada, effectiveness was evaluated by reviewing routine PMTCT data reported from 22 HIV referral sites between 1990 and 2010 through the National Perinatal HIV Surveillance Programme (Forbes et al., 2012). The evaluation (which only included HIV positive women that were referred before, during or within 3 months of delivery, n=2,692) yielded an overall MTCT risk (1990-2010) of 5.2%, dropping from 20.2% (1990-1996) to 2.9% (1997-2010). MTCT risk for pregnant women on ART was 1.0%; in women receiving more than 4 weeks of ART, the risk of MTCT was 0.4% compared with 9.0% in women receiving less than 4 weeks of ART. In mothers exposed to ARVP (2 drugs) or no ART, HEIs born through caesarian

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section had a lower risk of MTCT than those born through vaginal delivery (3.8% compared with 10.3%; p=0.016). Race, which is often a proxy for socio economic status and access to services, was also a risk factor as Blacks and Aboriginals were found to form the highest proportion of HIV positive pregnant women (Forbes et al., 2012). South Africa and some other African countries like Kenya, Mozambique, and Rwanda had also conducted national evaluations of their PMTCT programme in order to track progress (IAS, 2011). Given that South Africa has high immunization coverage of over 99%; their evaluation was based on collecting DBS samples of infants attending immunization clinic for HIV PCR testing. The evaluation revealed high uptake (of over 90%) for both HTC during pregnancy and ARVP and a population-level perinatal MTCT risk of 3.5% in 2010 for infants aged 4-8 weeks. MTCT at 18 months will be a better measure of postnatal PMTCT effectiveness, but these population-level data are sparse. This was rightly acknowledged by the report (Goga, Dinh, & Jackson, 2012; Leach-Lemens, 2011). Results from another evaluation that assessed HIV free survival by 18 months in South Africa was released in 2016 (Goga et al., 2016). The nationally representative survey estimated the infant HIV exposure at 4-8 weeks (n=9,120) to be 33.1% (31.8% - 34.3%) in 2012-13 while MTCT risk was 2.6% (2.0%-3.2%). Among 1,880 (71%) of HEIs that were followed up for 18 months, cumulative MTCT risk and "MTCT risk-or-death" by 3, 6, 12 and 18 months were 2.7% (2.6%-12.6%) and 2.8% (2.6%-19.0%); 3.5% (3.1%-4.4%) and 4.2% (3.5%-5.4%); 3.9% (3.4%-4.7%) and 5.7% (5.0%-6.8%); 4.3% (3.7%-5.0%) and 6.2% (5.5%-7.3%) respectively. Eighty one percent of the MTCT and 67% of "MTCT-or-death" occurred by 6 months postpartum (Goga et al., 2016). Evidence from several smaller scale studies that assessed PMTCT effectiveness is summarized in appendix 5. In the KwaZulu-Natal province of South Africa, studies have reported a MTCT risk at 6 weeks that ranges from 27.5% (95% Confidence Interval (CI): 19.1 – 36.2%) when the PMTCT drug regimen only included single dose Nevirapine

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(sdNVP) for the HIV positive mother and her infant to 2.9% (95%CI: 2.8 – 3.0%) when the mother either received triple regimen for ART and a combination of AZT from 14 weeks of gestation, sdNVP in labour and stat dose of Tenofovir (TDF) and Emtritabine (FTC) post-delivery for ARVP in the same region (Moodley, Parboosing, & Moodley, 2013). Ayouba et al. (2003) however reported a lower MTCT risk of 10.6% (5.1-16.0) for a NVP-based PMTCT programme in 3 health facilities in Cameroon (Ayouba et al., 2003). Reported results also suggest that in comparison with single or dual ARVs, MTCT risk was lower when HIV positive pregnant women receive triple regimen for ARVP or ART (Moodley et al., 2013; Torpey et al., 2012). Findings from Saint Camille Medical Centre Ouagadougou Burkina Faso suggests that complete eMTCT is achievable when HIV positive pregnant women are on ART and their infants had replacement feeding (MTCT risk at 6 months in this category of mother-infant pair was found to be 0.0%) (Sagna et al., 2015). These studies also revealed that even though PMTCT services are available at health facilities, not all mothers receive interventions (Coetzee et al., 2005; Torpey et al., 2012) .

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2.6.2 PMTCT programme evaluation: Nigeria

Nigerian researchers conducted formative research between 2001 and 2002 at the commencement of PMTCT programme in the country (Agboghoroma et al., 2013). This was followed by operational research three years later (2005) using the 11 tertiary health facilities that were offering the PMTCT services in the country at that time (Agboghoroma et al., 2013). The evaluation concluded that there was high uptake of HTC (77.8%); 63.1% of HIV positive pregnant women received ARVP. MTCT risk was found to be 3-5% even though less than 10% of women accessed this service (Galadanci et al., Undated). In general, only 60% of pregnant women attended ANC while less than 40% of pregnant women deliver in health facilities while the rest deliver at home (National Population Commission (NPC) [Nigeria] & ICF International, 2014).

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Small scale facility-level studies conducted in Nigeria revealed that the highest MTCT risk of 33.3% - 37.5% was also recorded when sdNVP was used for ARVP (Chama, Gashau, & Oguche, 2007; Agboghoroma, Audu & Iregbu, 2015) while the lowest risks were observed when HIV positive pregnant woman were on lifelong ART or triple regimen and their infants got ARVP (Ben & Yusuf, 2014; Chama et al., 2010; Esene & Omoigberale, 2012; Kalu et al., 2014; Isah et al., 2016). Chama, Gashau, & Oguche (2007) and Okafor et al. (2014) also reported complete eMTCT (MTCT risk of 0.0%) in HIV positive pregnant Nigerian women that were on ART. While the infants in the Chama, Gashau, & Oguche (2007) study were bottle fed, over 90% of the HEIs in the latter study were exclusively breastfed (Chama, Gashau, & Oguche, 2007; Okafor et al., 2014). Sagay et al. (2015) found pregnant women on lifelong ART before pregnancy to be at lower risk than those that started during pregnancy or at delivery. MTCT risk is also lower when only HIV positive pregnant women receive ARVP when compared to when HEIs alone received ARVP (Anoje et al., 2012; Chukwuemeka et al., 2014). The study conducted at Nnamdi Azikwe University Teaching Hospital suggests that breastfed infants are at higher risk of contracting HIV from their mothers than those not breastfed (Ikechebelu et al., 2011).

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Overall these studies prove the effectiveness and feasibility of PMTCT in resource poor countries: HIV positive pregnant women who received no or partial PMTCT interventions were more likely to give birth to HIV positive infants compared with those who received full PMTCT interventions (Azcoaga-Lorenzo et al., 2011; Afe et al., 2011).

These studies assessed the effectiveness of the PMTCT programme by determining the HIV status of HEIs and other elements of the PMTCT service provision. Factors impeding service delivery such as lack of adequate follow up; lack of adequate training for staff etc. were equally highlighted while they recommend the need to replicate studies in other health facilities. A range of methodologies were adopted in evaluating PMTCT effectiveness; these

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include cross sectional, retrospective and prospective cohort studies, case control study and analysis of EID records/HIV DNA PCR result. None of these studies were nationally representative.

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3.0 METHODOLOGY

This chapter describes the study setting, study population, ethical considerations, sampling and data collection procedures and data analysis methods.

3.1 Study design

This study was a retrospective record review and analysis of routine individual-level patient data collected in facility-based registers (ANC, PMTCT/HTC and EID/Infant follow up records) during the study periods (2008-2014) at Specialist Hospital (SH), Yola and Federal Medical Centre (FMC), Yola.

3.2 Study setting

The two health facilities in Adamawa State were purposively selected because the student worked with the consortium - Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) that supported PMTCT services in the state and it was easy to obtain approval to access patient records. Background information about the two health facilities is summarized in table 3.1 below.

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Table 3.1: Data collection sites' background information

Background Information		SH Yola	FMC Yola
Category of Health Facility		Secondary	Tertiary
Local Government Area (LGA)		Yola North	Yola South
Date of antiretroviral therapy (ART)/PMTCT Services Commencement		September, 2007	January, 2008
[1]ART client load as at December 2014		4,043	4,694
[1, 2, 3] Antenatal (ANC) HIV prevalence		4%	3%
Programme support (Presidents Emergency Plan for AIDS Relief (PEPFAR) - funded HIV/AIDS	2007-2011	Global HIV/AIDS Project in Nigeria (GhAIN)	
Programme implemented by a consortium led by Family Health International (FHI 360).	2011-2016	Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS)	
Other Services rendered		ANC, General outpatient and specialist service	

[1]Routine service data [2] (Bashorun et al., 2014) [3] (Federal Ministry of Health, 2010b)

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In addition to the reasons cited above, these health facilities were chosen because they have the highest patient load and antenatal clinic (ANC) attendance rates in the state, thus providing a large pool of pregnant women and by extension HIV positive pregnant women and their HEIs. They are also accessible by road. The facilities render services to pregnant women and HEIs following the cascade of events shown in Appendix 1 and prophylaxis/treatment protocol summarized in section 2.3 and Appendix 2. In conducting HIV Deoxyribonucleic Acid Polymerase Chain Reaction (DNA PCR) testing, the dried blood spot (DBS) samples of HEIs are collected using Lasec® DBS Collection kits with 5 spots and couriered to a DNA PCR testing facility (Federal Medical Centre, Jalingo; uses Roche® brand of PCR machine) located approximately 167 kilometers away from the two health facilities. The average turnaround time (TAT) for test results was projected to be three weeks

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and caregivers are typically advised to return in four weeks to receive the DNA PCR test results.

3.3 Study population

The study population included the individual-level patient data from six sample groups (see table 3.2 below for detailed sample group and the reason for choice of each group)

Table 3.2: Sample group and the reason for choice of each group

S/N	Group	Reason
1	All pregnant women that attended ANC for the first time between 2008 and 2014 in the two health facilities.	Denominator for uptake of HTC
2	All pregnant women who tested for HIV during first ANC visit	Numerator for uptake of HTC and denominator for Maternal HIV positivity rate
3	All pregnant women that tested positive for HIV during first ANC visit between 2008 and 2014 in the two health facilities	Numerator for maternal HIV positivity rate and denominator for ART/ARVP uptake
4	All pregnant women who received ARVs (either for prophylaxis or treatment)	Numerator for ART/ARVP uptake
5	All HEIs (aged 4 weeks to >12 months) that tested for HIV between 2008 and 2014	Denominator for MTCT risk
6	All HEIs (aged 4 weeks to >12 months) with HIV positive DNA PCR results between 2008 and 2014	Numerator for MTCT risk

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The first and second groups were used to establish the uptake of HTC. The third and fourth groups were used to establish the uptake of maternal ART/ARVP while fifth and sixth groups were used to establish the risk of MTCT in the two health facilities.

3.4 Sampling procedure

For all objectives all individual-level patient data recorded using facility-based registers during the study period were used. There was no sampling as all available records with data were used. This approach was taken to increase the sample size, given that routine data may be incomplete or inaccurate; thus sampling may reduce final sample size.

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3.5 Data collection and processing

Data were collected for the six groups of women highlighted in table 3.2. Three Microsoft Excel-based data collection tools (DCTs) were used to manually extract information for all sample groups in accordance with Appendix 6 (see Appendix 7, 8 and 9 for DCTs). These tools were piloted in two health facilities similar to the study sites prior to their use for the main data collection. Some modifications were eventually made to these tools based on the observations and feedbacks from the pilot. DCT1 was used to collect information on sample groups 1 and 2 (2 independent data collectors were employed to count this data to avoid mistakes /and for validity), DCT 2 for sample groups 3 and 4 and DCT 3 for sample groups 5 and 6. All HEIs and all HIV positive pregnant women were given unique identifiers. Manually extracted information was later entered into a pass word protected electronic database that was accessible to the student and data collectors during the period of data collection. Trained data collectors with experience in patient record management were used for the data collection process. Use of these DCTs ensured uniformity of collected data.

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3.6 Analysis

Data analyses were performed using STATA 14.2 (Stata, 2017). The proportion of first ANC attendees that accepted HTC and maternal HIV positivity rate among those that accepted HTC as well as the associated 95% CI was estimated. Frequency counts and proportions were estimated for the following categorical variables: pregnant women's age in years (15-24, 25-34, 35-44, 45 and above), parity (0-4, >4), gestation age (14 -27 and 28 and above weeks), marital status (single, married, widowed, separated, divorced), educational level (none, primary, senior secondary, qur'anic, junior secondary, post-secondary) and occupational status (unemployed, employed, student, retired). Proportions were calculated for uptake of ART/ARVP among HIV positive pregnant women and the type of ARVs used (ART, Triple Regimen, AZT/3TC, AZT, NVP). Simple and multiple logistics regression were carried out

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and resultant odds ratio or adjusted odds ratios estimated to determine associations between pregnant women's age, gestation age, parity, marital status, educational level, occupational status, hospital and year and uptake of ART or ARVP based on the categorization highlighted above.

Frequency counts (and proportions) of tested HEI's gender (male, female), age (4 weeks -2 months, >2months – 6 months and >6 months – 12 months, and >12 months) infant feeding option (exclusive breastfeeding, mixed feeding and not breastfed), reason for PCR (first test for healthy exposed infant, first test for sick infant and problem with first test) and maternal ART/ARVP and infant prophylaxis were calculated. Overall MTCT risk (with 95% confidence interval) and median facility TAT (with interquartile range) were calculated. MTCT risk (with 95% confidence interval) by age (4 weeks -2 months, >2months – 6 months and >6 months – 12 months, and >12 months), feeding option (exclusive breastfeeding, replacement feeding and mixed feeding), intervention (mother alone, infant alone, either mother or infant, both mother and infant) and PMTCT protocol period (period 1, transitional phase and period 2) were also estimated. Simple and multiple logistic regression analysis were then performed and odds ratio compared based on gender, HEI age of testing, intervention received, feeding option (based on earlier stated categorizations), hospital and year. P-values were estimated and a p-value of <0.05 was considered as statistically significant, non-overlap of confidence intervals (CIs) was also considered as statistically significant. In selected instances where CIs overlap, CI difference and p-value were estimated to establish statistical significance. The difference was regarded as significant if the CI did not contain zero. The STATA procedure that was used to estimate the proportions in this thesis does not respect that the estimates have to be between 0.0% and 100.0%. In cases where the estimate was extreme or where there was an uncertainty in the estimation, the

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confidence intervals tended to go beyond the bounds of 0.0% and 100.0%. Confidence intervals of proportions that were negative were therefore converted to zero percent while those that were above 100 percent were converted to 100 percent (Stark, 2017). Also in instances where point estimate for proportion was either 0.0% or 100.0%, STATA did not estimate confidence intervals. Details of the data analysis plan are available in appendix 10. Table 3.3 shows the assumptions that were made for the analyses.

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Table 3.3: Analysis assumptions

Objectives/Indicator	Definition	Assumptions	Denominator	Numerator
Objective 1 Determine the uptake of HTC by pregnant women attending ANC for the first time in the most recent pregnancy	Proportion of pregnant women that attended ANC for the first time in the most recent pregnancy that tested for HIV.	Pregnant women who tested for HIV all came for the first visit to this facility There is no time lag between 1st visit and 1st HIV test	Total number of pregnant women that attended ANC for the first time in this pregnancy	Total number of pregnant women that tested for HIV during their first visit
Objective 2 Maternal/Antenatal HIV positivity rate during pregnancy	Proportion of first ANC attendees that accepted HIV testing that tested HIV positive	Results were obtained for all pregnant women that tested for HIV	Total number of pregnant women that tested for HIV during the first ANC visit	Total number of pregnant women that tested positive for HIV at their first visit.
Objective 3 Determine the uptake of maternal ART/ARVP amongst HIV positive pregnant women	Proportion of ANC attendees who tested HIV positive at their first visit that received ARVs (either for prophylaxis or treatment)	All pregnant women that tested HIV positive and started on ARVs received their ARVs at the same facility where they were diagnosed to be HIV positive	Total number of pregnant women that tested positive for HIV at the first ANC visit	Total number of pregnant women that received ARVs (either for prophylaxis or treatment)
Objective 4 Determine turnaround time	Time interval (in days) between when a DBS sample was collected from HEI and when the DNA PCR result was returned to the health facility.	Only tests with both the dates when DBS sample was collected and when the DNA PCR result was returned to the health facility were included in the analysis Only samples collected between January 2008 and December 2014 were included in the analysis	Not Applicable	Not applicable

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Objectives/Indicator	Definition	Assumptions	Denominator	Numerator
Objective 4 Overall MTCT risk	Proportion of tested HIV exposed babies that tested HIV positive	All second tests/repeat tests 6 weeks post cessation of breastfeeding (89 in number) that cannot be longitudinally linked with the first tests were excluded from all analysis For longitudinally linked results, if an infant test HIV negative at first test and HIV positive at second testing. The HIV positive result was used in the analysis	Total number of HEIs that tested for HIV.	Total number of HEIs that tested HIV positive
Objective 5 Determine the MTCT risk at ages 4 weeks to 2 months, >2months – 6 months, >6 months to 12 months and >12 months.		An infant with first and second test results that fall within different age brackets was analyzed twice. Note: all equivocal results were left out of numerator and denominator	Total number of PCR results	Total number of HIV positive PCR result
Objective 6 Compare the MTCT risk by receipt/non-receipt of antiretroviral drugs (prophylaxis versus treatment) amongst HIV positive mothers		For longitudinally linked results, if an infant test HIV negative at first test and HIV positive at second testing. The HIV positive result was used in the analysis	Total number of PCR results	Total number of HIV positive PCR result

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Objectives/Indicator	Definition	Assumptions	Denominator	Numerator
Objective 7 Compare the MTCT risk by breastfeeding option (exclusively breast fed, mixed fed and not breastfed at all).		For longitudinally linked results, if an infant test HIV negative at first test and HIV positive at second testing. The HIV positive result was used in the analysis	Total number of PCR results	Total number of HIV positive PCR result
Objective 8 Compare MTCT risk during two periods of PMTCT protocol policy changes and the transitional period		If the first test is negative and the 2nd test is positive the 2nd test results was used to calculate MTCT risk if it falls within this period	Total number of PCR results	Total number of HIV positive PCR result

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3.7 Validity

Selection bias at the health facility level was avoided by the review of all available data. Records of a total of 62,224 pregnant women (FMC Yola = 14,892; SH Yola = 47,332) were reviewed while that of HEIs was 1,809 (FMC Yola = 832, SH Yola= 977). The study is however biased towards clients that visited the two health facilities. Data collectors were trained and uniform tools were used in order to reduce measurement bias. Also nomenclatures used in the tools in most cases were the same as those contained in the registers and forms. The student supervised the data collectors to ensure that they functioned according to the standardized operating procedure that the student developed for this study. The student also checked ten percent of the data collected by data collectors for accuracy.

3.8 Reliability

To improve reliability of the study, the DCTs were tested for intra-data-collector and inter-data-collector reliability prior to use for data collection. Also data collectors were trained while entries by these data collectors were randomly checked by the student for accuracy and completeness. To check for reliability, data was recollected for 10% of participants using the same set of DCTs, the collected data was then cross-checked by the student with the first set of data collected in order to confirm that they closely match. In order to assess inter-observer bias between two trained data collectors, the two data collectors extracted information from the same set of records. The agreement level between the two data collections was 88% which is within the acceptable range of 81 – 100% (McHugh, 2012).

3.9 Generalizability

While the result of this study may not be statistically generalizable to health facilities within the North Eastern sub region of Nigeria as a representative sample of health facilities was not selected, the problems identified may be similar to those experienced in health facilities with

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similar service conditions to the health facilities under investigation. These health facilities include all the other eighteen secondary health facilities in Adamawa State offering PMTCT services as well as ninety three other secondary and tertiary health facilities within the North Eastern sub region of Nigeria with similar maternal/antenatal HIV positivity profile, individuals with poor access to education, poorly resourced healthcare infrastructure and high patient to healthcare worker ratio.

3.10 Ethics and legal consideration

Ethics approval for this protocol was sought from the Senate Research Committee of the University of the Western Cape while permission to access patients' records was obtained from the research ethics committee of the two health facilities involved in this study and the State Ministry of Health (SMoH) (see Appendix 11, 12, 13 and 14 for approvals). No individual patient-level consent was obtained and no harm to patients is anticipated as the data collection involved retrospective review of routine facility-level data. Names of participants were not extracted; personal identifying information of participants were only available to the data collectors and the student but were not documented. All collected information were kept in a locked cupboard (for hard copies) and a password protected computer (for electronic copies); also the final analyses and results only report on aggregated data thereby protecting the identities of the study participants. Findings from this study were made available to the SMoH, research ethics committee and PMTCT service coordinator in the two health facilities as well as FHI360 which is the implementing partner/non-governmental organization supporting service delivery at these two health facilities.

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4.0 RESULTS

This chapter summarizes the results of this study in line with the study objectives.

4.1 Objective 1: Uptake of HTC by pregnant women attending ANC for the first time in the most recent pregnancy

This indicator was defined in accordance with Table 3.2.

Tables 4.1 and 4.2 below show the uptake of HTC among first ANC attendees and maternal HIV positivity rates respectively disaggregated by year for the two health facilities used for this study. A total of 62,224 pregnant women attended ANC for the first time between 2008 and 2014 out of which 47,217 (75.9%) accepted HIV testing and counselling. While SH Yola had more ANC attendees than FMC Yola, uptake of HTC in FMC Yola was higher than that of SH Yola ([12,897/14,892] 86.6% Vs [34,320/47,332] 72.5%).

Table 4.1: Uptake of HTC among first ANC attendees (N = 62,224)

Year	FMC Yola		SH Yola		Total	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
2008	1,360 (77.3%)	65.4% - 89.1%	4,005 (56.7%)	44.1% - 69.3%	5,365 (60.8%)	49.9% - 71.7%
2009	3,034 (92.3%)	88.7% - 95.9%	5,606 (78.9%)	72.1% - 85.7%	8,640 (83.1%)	77.7% - 88.6%
2010	2,134 (88.5%)	79.5% - 97.6%	4,004 (70.9%)	62.5% - 79.4%	6,138 (76.2%)	68.7% - 83.7%
2011	1,550 (82.3%)	76.1% - 88.4%	3,991 (63.7%)	51.3% - 76.1%	5,541 (68.0%)	57.8% - 78.2%
2012	1,640 (82.8%)	74.1% - 91.6%	4,963 (75.4%)	71.0% - 79.7%	6,603 (77.1%)	73.1% - 81.1%
2013	1,767 (90.1%)	85.6% - 94.5%	5,527 (79.1%)	72.3% - 86.0%	7,294 (81.5%)	75.9% - 87.1%
2014	*1,412 (87.8%)	83.3% -92.2%	6,224 (81.0%)	74.9% - 87.1%	7,636 (82.2%)	77.1% - 87.2%
Total	12,897 (86.6%)	83.8% - 89.4%	34,320 (72.5%)	68.7% - 76.3%	47,217 (75.9%)	74.3% - 77.5%

N= number of first ANC attendees
n= number of pregnant first ANC attendees that accepted HIV testing and counselling
*there was no HTC in FMC Yola in December 2014 due to industrial action by health workers
95% CI = 95% confidence interval

4.2 Objective 2: Maternal/Antenatal HIV positivity rate

This indicator was defined in accordance with Table 3.2.

The overall maternal HIV positivity rate for the two health facilities was 3.1% (1,475 pregnant women out of 47,217 pregnant women that tested for HIV). The maternal HIV

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positivity rate for FMC Yola was 2.9% [372/12,897] (95%CI 2.5% - 3.3%) while that of SH Yola was 3.2% [1,103/34,320] (95%CI: 2.8% - 3.6%).

Table 4.2: HIV positivity rate among pregnant women that tested for HIV (N = 47,217)

Year	FMC Yola		SH Yola		Total	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
2008	58 (4.3%)	3.4% - 5.1%	239 (6.0%)	5.1% - 6.8%	297 (5.5%)	4.8% - 6.2%
2009	103 (3.4%)	2.7% - 4.1%	245 (4.4%)	3.8% - 4.9%	348 (4.0%)	3.6% - 4.5%
2010	66 (3.1%)	1.6% - 4.6%	148 (3.7%)	3.1% - 4.3%	214 (3.5%)	2.8% - 4.1%
2011	37 (2.4%)	1.6% - 3.2%	108 (2.7%)	2.1% - 3.3%	145 (2.6%)	2.1% - 3.1%
2012	45 (2.7%)	1.9% - 3.6%	179 (3.6%)	2.8% - 4.4%	224 (3.4%)	2.7% - 4.0%
2013	29 (1.6%)	1.2% - 2.1%	101 (1.8%)	1.4% - 2.2%	130 (1.8%)	1.5% - 2.1%
2014	34 (2.4%)	1.6% - 3.2%	83 (1.3%)	1.0% - 1.7%	117 (1.5%)	1.2% - 1.9%
Total	372 (2.9%)	2.5% - 3.3%	1,103 (3.2%)	2.8% - 3.6%	1,475 (3.1%)	3.0% - 3.3%

N= number of pregnant women that accepted HIV testing and counselling
n= number of pregnant women that accepted HIV testing and counselling that tested HIV positive

Graphical trends of uptake of HTC and HIV positivity rates for FMC Yola, SH Yola and the two health facilities combined are presented in figures 4.1, 4.2 and 4.3 respectively. The lowest uptake of HTC across the two health facilities was in 2008 (combined uptake of 60.8% [5,365/8,824]) while the highest uptake was in 2009 (combined uptake of 83.1% [8,640/10,391). There was a general decline in HIV positivity rate from 2008 to 2014 (5.5% [297/5,365] to 1.5% [117/7,636]), there was however a slight rise in HIV positivity rate in 2012 (3.4% [224/6,603]).

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Figure 4.1: Trend of uptake of HTC and HIV positivity rate for FMC Yola

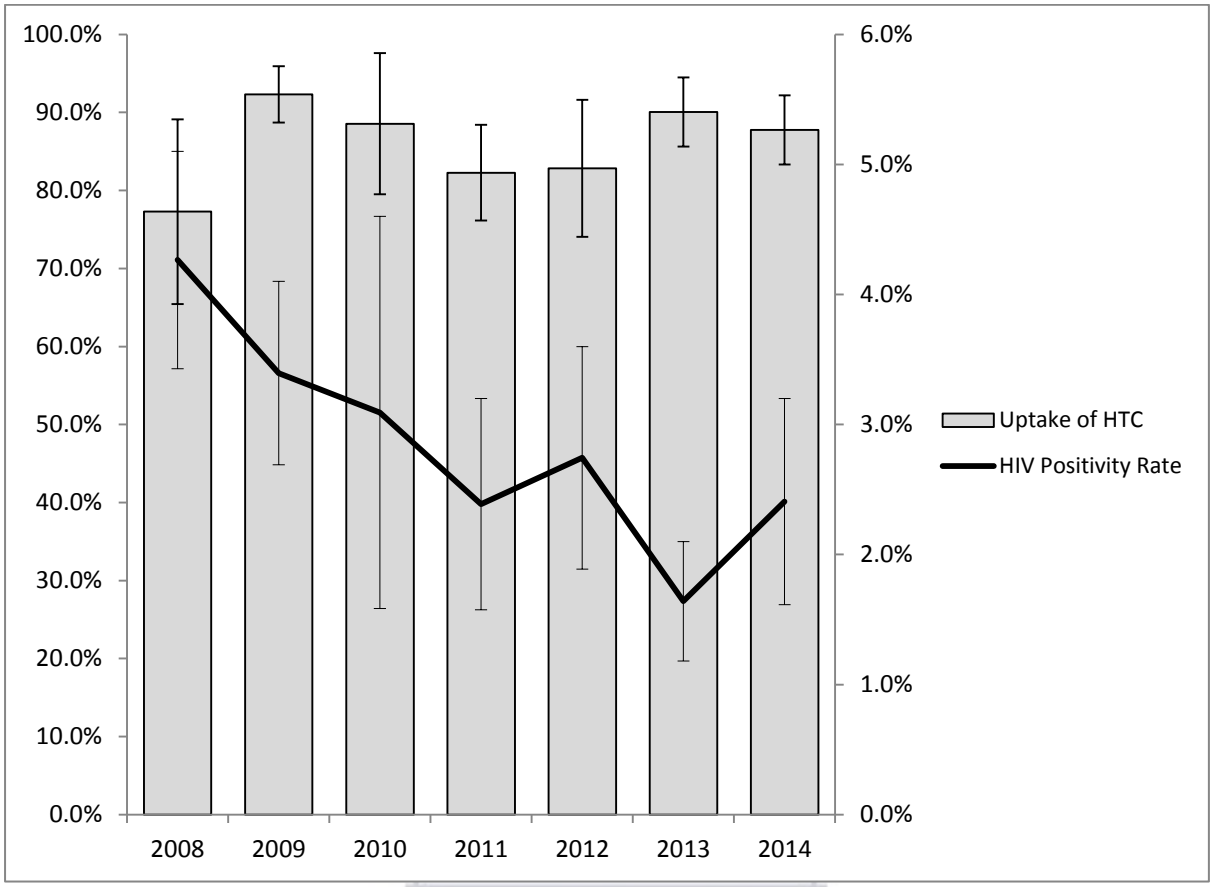

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Figure 4.2: Trend of uptake of HTC and HIV positivity rate for SH Yola

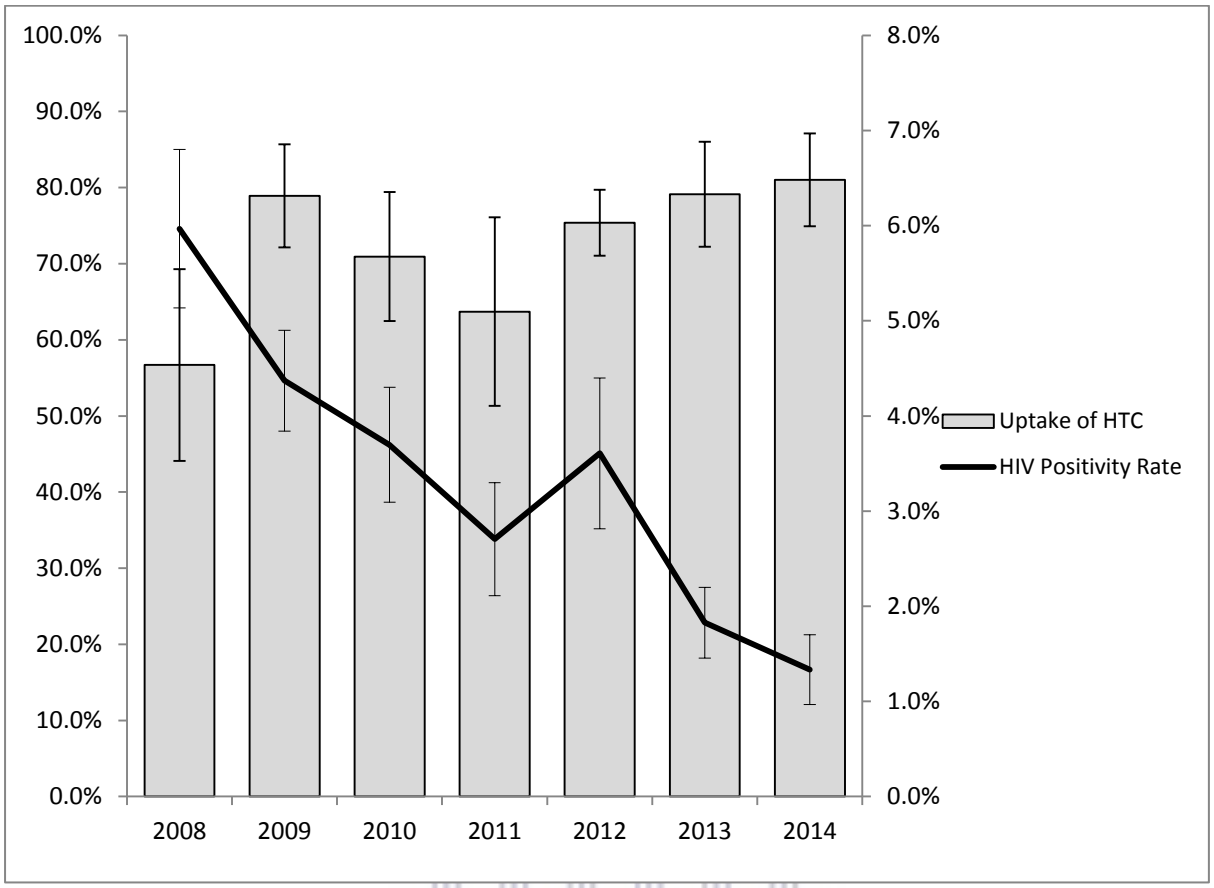

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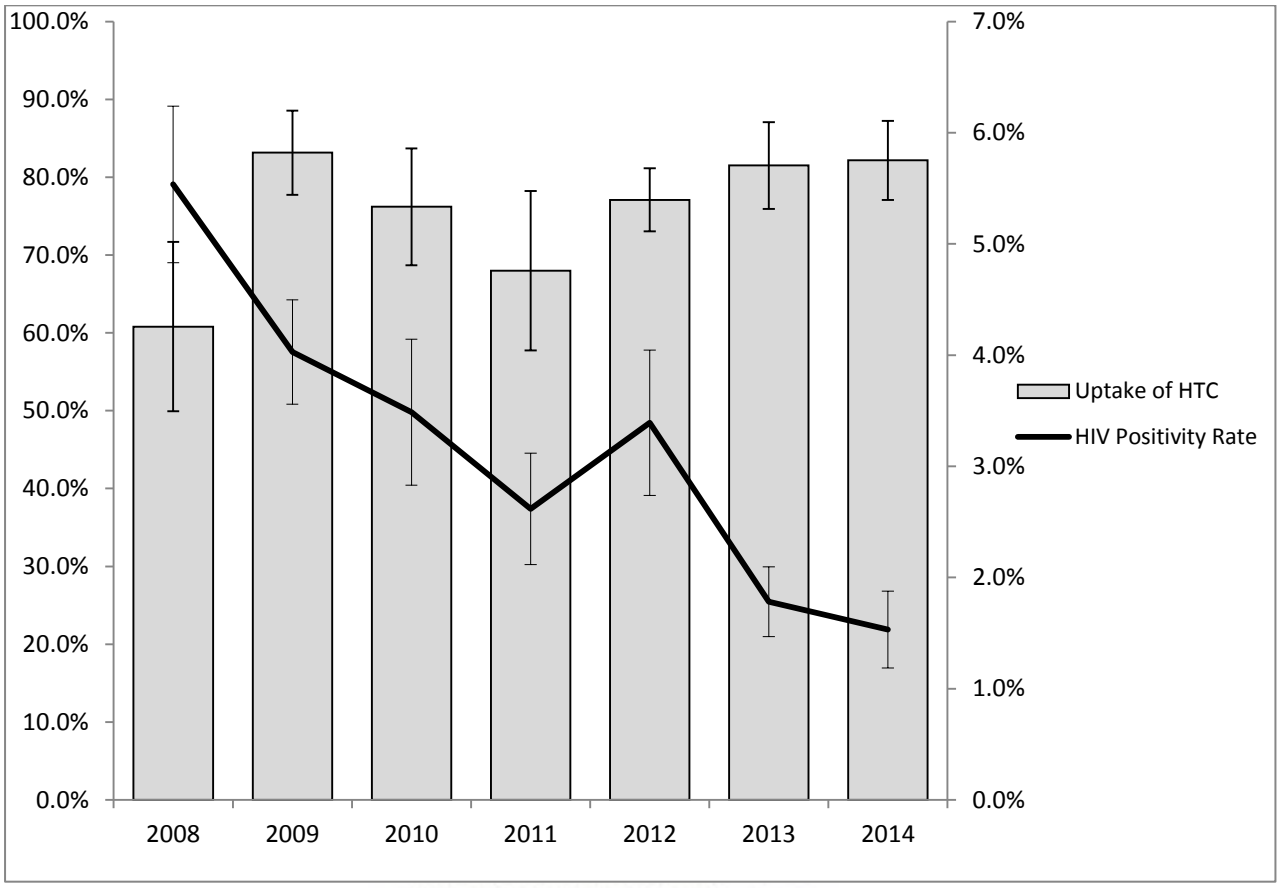
Figure 4.3: Trend of uptake of HTC and HIV positivity rate for the two health facilities combined



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4.2.1 Baseline characteristics of HIV positive pregnant women

Table 4.3 below shows the baseline characteristics of the 1,475 pregnant women that tested HIV positive over the seven year period (2008 – 2014). Most (46.0%) of the women were between the ages of 25-34 years; most (54.0%) of them were also in second trimester at the time of first attendance. The gravida and parity for most of the women was between 0 and 4 and available data showed that majority of women were married and had attained senior secondary education. Approximately ten percent (10.2%) of the women were unemployed.

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Table 4.3: Socio-demographic characteristics of HIV positive pregnant women from 2008 -2014 (N=1475)

Variable		FMC Yola n (%)	SH Yola n (%)	Total n (%)
Age	15-24 years	42 (11.3%)	373 (33.8%)	415 (28.2%)
	25-34 years	105 (28.2%)	574 (52.0%)	679 (46.0%)
	35-44 years	14 (3.8%)	91 (8.3%)	105 (7.1%)
	45 and above	0 (0.0%)	2 (0.2%)	2 (0.1%)
	Missing	211 (56.7%)	63 (5.7%)	274 (18.6%)
	Total	372 (100.0%)	1,103 (100.0%)	1,475 (100.0%)
Gestation Age	<14 weeks	8 (2.2%)	120 (10.9%)	128 (8.7%)
	14 -27 weeks	79 (21.2%)	717 (65.0%)	796 (54.0%)
	28 weeks and above	31 (8.3%)	178 (16.1%)	209 (14.2%)
	Missing	254 (68.3%)	88 (8.0%)	342 (23.2%)
	Total	372 (100.0%)	1,103 (100.0%)	1,475 (100.0%)
Gravida	0-4	101 (27.2%)	814 (73.8%)	915 (62.0%)
	>4	23 (6.2%)	222 (20.1%)	245 (16.6%)
	Missing	248 (66.7%)	67 (6.1%)	315 (21.4%)
	Total	372 (100.0%)	1,103 (100.0%)	1,475 (100.0%)
Parity	0-4	113 (30.4%)	937 (85.0%)	1,050 (71.2%)
	>4	11 (3.0%)	93 (8.4%)	104 (7.1%)
	Missing	248 (66.7%)	73 (6.6%)	321 (21.8%)
	Total	372 (100.0%)	1,103 (100.0%)	1,475 (100.0%)
Marital Status	Single	1 (0.3%)	6 (0.2%)	7 (0.5%)
	Married	55 (14.8%)	151 (13.7%)	206 (14.0%)
	Widowed	2 (0.5%)	6 (0.5%)	8 (0.5%)
	Separated	1 (0.3%)	3 (0.3%)	4 (0.3%)
	Divorced	1 (0.3%)	2 (0.5%)	3 (0.2%)
	Missing	312 (83.9%)	935 (84.8%)	1,247 (84.5%)

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Variable		FMC Yola n (%)	SH Yola n (%)	Total n (%)
	Total	372 (100.0%)	1,103 (100.0%)	1,475 (100.0%)
Educational Level	None	8 (2.2%)	9 (0.8%)	17 (1.2%)
	Primary	12 (3.2%)	24 (2.2%)	36 (2.4%)
	Junior Secondary	4 (1.1%)	1 (0.1%)	5 (0.3%)
	Senior Secondary	18 (4.8%)	71 (6.4%)	89 (6.0%)
	Post-Secondary	12 (3.2%)	24 (2.2%)	36 (2.4%)
	Qur'anic	3 (0.8%)	39 (3.5%)	42 (2.9%)
	Missing	315 (84.7%)	935 (84.8%)	1,250 (84.8%)
	Total	372 (100.0%)	1103 (100.0%)	1,475 (100.0%)
Occupational Status	Unemployed	31 (8.3%)	119 (10.8%)	150 (10.2%)
	Employed	18 (4.8%)	32 (2.9%)	50 (3.4%)
	Student	2 (0.5%)	2 (0.2%)	4 (0.3%)
	Missing	321 (86.3%)	950 (86.1%)	1,271 (86.2%)
	Total	372 (100.0%)	1,103 (100.0%)	1,475 (100.0%)

N= number of pregnant women that accepted HIV testing and counselling that tested HIV positive

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4.3 Objective 3: Uptake of maternal ART/ARVP amongst HIV positive pregnant women

This indicator was defined in accordance with Table 3.2.

Out of the 1,475 pregnant women that tested HIV positive, records about antiretroviral drug use were only available for 224 (15.2%) of the women –the other records were either missing or could not be longitudinally linked. The overall uptake of ART/ARVP among these women was 85.7% [192/224] (81.1% - 90.3%). The highest uptake was recorded in 2009 (100.0% [10/10]) while the lowest was in 2008 (76.5% [13/17]). ART/ARVP uptake for the other years as well as the trend of uptake is available in Table 4.4 and Figure 4.4 respectively.

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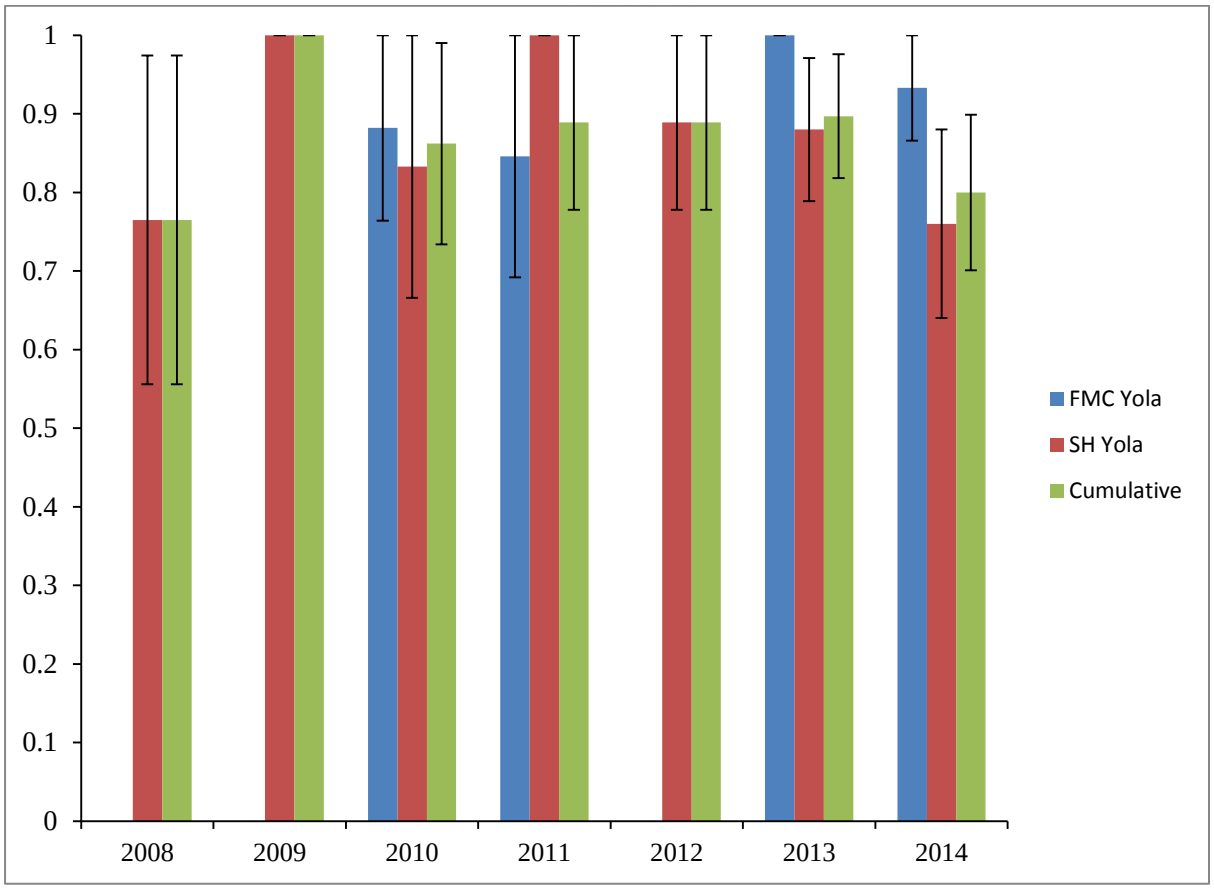
Table 4.4: Uptake of ART/ARVP among HIV positive pregnant women (N=224)

Year	FMC Yola		SH Yola		Total	
	n %	95% CI	n %	95% CI	n %	95% CI
2008	No data	No data	13 (76.5%)	55.6% -97.4%	13 (76.5%)	55.6% - 97.4%
2009	No data	No data	10 (100.0%)	[redacted]	10 (100.0%)	[redacted]
2010	15 (88.2%)	72.4% - *100.0%	10 (83.3%)	61.2% -*100.0%	25 (86.2%)	73.4% - 99.0%
2011	11 (84.6%)	64.1% - *100.0%	5 (100.0%)	[redacted]	16 (88.9%)	73.9% - *100.0%
2012	No data	No data	24 (88.9%)	76.7% -*100.0%	24 (88.9%)	76.7% -*100.0%
2013	8 (100.0%)	[redacted]	44 (88.0%)	78.9% -97.1%	52 (89.7%)	81.7% - 97.6%
2014	14 (93.3%)	80.2% - *100.0%	38 (76.0%)	64.0% -88.0%	52 (80.0%)	70.1% - 89.9%
Total	48 (90.6%)	82.6% - 98.6%	144 (84.2%)	78.7% - 89.7%	192 (85.7%)	81.1% - 90.3%

N= number of HIV positive pregnant women with information on ARV prophylaxis use
n = number of HIV positive pregnant women that received ARV prophylaxis
* confidence limit was amended so that the confidence intervals are bound between 0.0 and 100.0%.
[redacted] STATA did not estimate confidence intervals because point estimate was 100.0%

Figure 4.4: Trend of ART/ARVP uptake among HIV positive pregnant women



As shown in table 4.5 below most (60.9% [117/192]) of the pregnant women that received antiretroviral intervention got the triple regimen for PMTCT. This is followed by ART (for prevention and treatment) which was received by 19.8% [38/192] of the pregnant women.

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Table 4.5: ARV regimen for women that received ARVs (2008 -2014) (N= 192)

Regimen	FMC Yola n (%)	SH Yola n (%)	Total n (%)
sdNVP	0 (0.0%)	1 (0.7%)	1 (0.5%)
AZT	1 (2.1%)	0 (0.0%)	1 (0.5%)
AZT+3TC	0 (0.0%)	9 (6.3%)	9 (4.7%)
AZT+3TC+sdNVP	11 (22.9%)	9 (6.3%)	20 (10.4%)
Triple regimen (ARVP)	6 (12.5%)	111 (77.1%)	117 (60.9%)
ART	24 (50.0%)	14 (9.7%)	38 (19.8%)
Missing	6 (12.5%)	0 (0.0%)	6 (3.1%)
Total	48 (100.0%)	144 (100.0%)	192 (100.0%)

Summary of uptake of HTC, maternal HIV positivity rate and maternal ART/ ARVP uptake including missing data is presented in figure 4.5.

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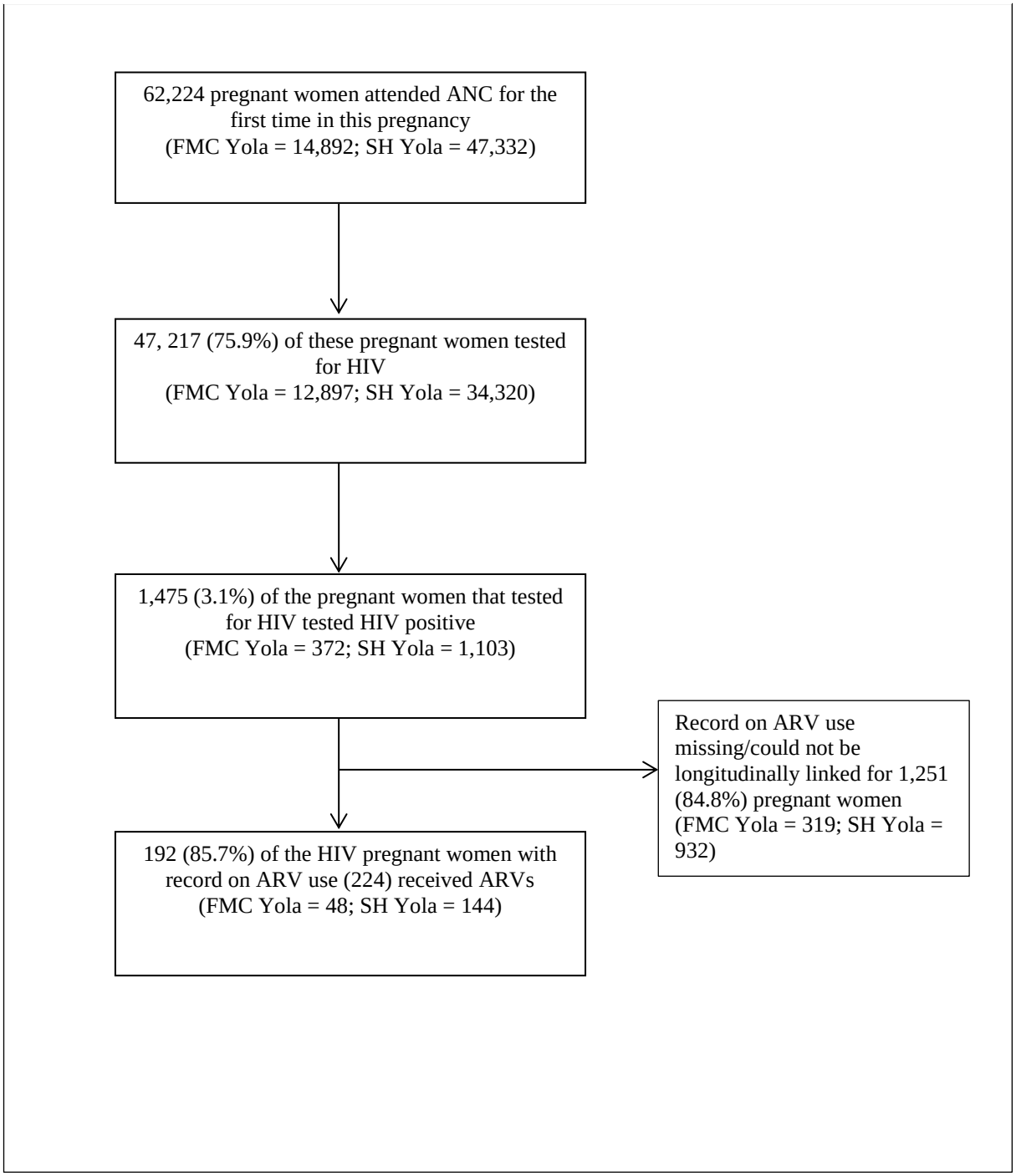
Figure 4.5: Flow Chart for Uptake of HTC, maternal HIV positivity rate and maternal ART/ ARVP Uptake



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4.3.1 Predictors of ART/ARVP uptake

To establish factors that predict ART/ARVP uptake, simple and multiple logistic regressions analysis were carried out with resultant odds ratio estimated. From the simple regression analysis (see table 4.6) age, marital status and occupational status were found to be predictors of ART/ARVP uptake.

All the variables listed in table 4.6 below were included in a multiple regression model. Parity was not included because of its high correlation of 0.9 with gravida. From this analysis, only age statistically predicted uptake of ART/ARVP. Women aged between 25-34 years had three times (3.07) the odds to receive ART/ARVP than those aged 15-24 years.

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Table 4.6: Factors associated with uptake of ART/ARVP with odds ratio using cumulative pooled data

Variable		Crude Odds Ratio	95% CI	P value	Adjusted Odds Ratio	95% CI	P value
Age	15-24	1.00			1.00		
	25-34	***3.40**	**1.53 - 7.55**	**0.00**	***3.07**	**1.04 - 9.01**	**0.04**
	35-44	3.23	0.68 - 15.23	0.14	2.65	0.32 - 22.13	0.37
Gestation Age	<14 weeks	1.00			1.00		
	14-27 weeks	1.62	0.54 - 4.83	0.39	2.41	0.55 - 10.54	0.24
	28 weeks and above	2.05	0.53 - 7.96	0.30	1.75	0.31 - 9.69	0.52
Gravida	1-4	1.00			1.00		
	>4	1..98	0.66 - 5.99	0.23	1.50	0.35 - 6.42	0.59
Marital Status	Single, Widowed, Separated, Divorced	1.00			1.00		
	Married	***3.23**	**1.20 - 8.69**	**0.02**	1.97	0.50 - 7.75	0.33
Educational Level	None	1.00			1.00		
	Primary	0.67	0.15- 2.94	0.60	0.33	0.04 - 2.63	0.29
	Qur'anic	0.79	0.18- 3.34	0.74	0.57	0.08- 3.91	0.56
	Secondary	1.43	0.36 - 5.72	0.61	0.58	0.09 - 3.97	0.58
	Post-Secondary	1.00			1.00		
Occupational Status	Unemployed	1.00			1.00		
	Employed	***10.54**	**1.39- 79.72**	**0.02**	4.57	0.51- 40.62	0.17
	Student	0.66	0.07 - 6.58	0.72	1.00	1.00	
Hospital	FMC Yola	1.00					
	SH Yola	0.56	0.20 – 1.52	0.25	1.10	0.21 – 5.70	0.91
Year	2008	1.00			1.00		

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Variable		Crude Odds Ratio	95% CI	P value	Adjusted Odds Ratio	95% CI	P value
	2009	1.00			1.00		
	2010	1.92	0.41 – 8.97	0.41	1.29	0.15 – 10.83	0.82
	2011	2.46	0.39 – 15.63	0.34	1.61	0.12 – 20.95	0.72
	2012	2.46	0.48 – 12.72	0.28	1.55	0.21 – 11.73	0.67
	2013	2.67	0.66 – 10.85	0.17	1.84	0.32 – 10.57	0.50
	2014	1.23	0.34 - 4.40	0.75	0.51	0.09 – 2.86	0.44

*Statistically significant odds ratio

4.4 Objectives 4-8: MTCT risk in general and DNA PCR test turnaround time, MTCT risk by age, by feeding option, by ARV use and by PMTCT protocol period

4.4.1 Records used for EID-related analysis

Given that personal identifiers were not collected, second tests (repeat tests six weeks post cessation of breastfeeding) conducted prior to August 2012 could not be longitudinally linked with first tests - the design of the EID register used prior to August 2012 did not allow for longitudinal linkage of the first and second test results. A total of 89 of these tests were excluded from all analyses. Also one test with missing reason for PCR test and another test with confirmation of first test (not recognized in the national testing algorithm) as the reason for testing were also excluded.

'First test for healthy exposed infant', 'first test for sick infant' and 'problem with first test' indicators were taken as first EID test as per national algorithm and it was assumed there was no duplication of babies within the 'problem with first test' versus 'first test for healthy exposed infant' and 'first test for sick infant' groups. For 'problem with first test' to be conducted, the result of the first test must be indeterminate or missing. There was no

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indeterminate test result and only 120 babies had missing results for both 'first test for healthy exposed infant' and 'first test for sick infant' compared to the 374 results available for infants with 'problem with first test' as the reason for HIV DNA PCR test.

Of the 1,809 babies included in the final analysis only 1,651 (91.3%) had first HIV DNA PCR test results. Out of the 1,279 HEIs that were expected to have a second PCR test by virtue of their breastfeeding option (exclusively breastfed and mixed fed), only 35 (2.7%) of them had longitudinally linked second PCR test results. It should be noted that information on feeding option was not available for 81 HEIs.

4.4.2 Baseline characteristics and prophylaxis status for HIV exposed infants (2008 – 2014)

Table 4.7 below summarizes the baseline characteristics of the 1,809 HIV exposed infants included in the analysis for this study. More than half of the babies were male (50.6%) and only 30.0% of the babies tested for HIV by the recommended age of 6 weeks. The commonest mode of feeding adopted by mothers at the time the infant was brought for testing (median age of 8 weeks) was exclusive breastfeeding (54.7%) while mixed feeding (16.0%) was the least common for the entire 7 years under review.

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Close to seventy percent (68.4%) of mothers of HEIs received either ART or ARVP while ~65% of infants received sdNVP, sdNVP+AZT or NVP as prophylaxis for the entire 7 years under review.

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Table 4.7: Baseline characteristics and prophylaxis status for HIV exposed infants (2008 -2014) (N = 1809)

Variable		FMC Yola n (%)	SH Yola n (%)	Total n (%)
Gender	Male	426 (51.2%)	489 (50.1%)	915 (50.6%)
	Female	406 (48.8%)	488 (49.9%)	894(49.4%)
	Total	832 (100.0%)	977 (100.0%)	1,809 (100.0%)
Age	≤6 weeks	306 (36.8%)	237 (24.3%)	543 (30.0%)
	>6 weeks to 2 months	166 (20.0%)	249 (25.5%)	415 (22.9%)
	>2months – 6 months	201 (24.2%)	279 (28.6%)	480 (26.5%)
	>6 - 12 months	112 (13.5%)	149 (15.3%)	261 (14.4%)
	>12 months	39 (4.7%)	43 (4.4%)	82 (4.5%)
	Missing	8 (1.0%)	20 (2.1%)	28 (1.6%)
	Total	832 (100.0%)	977 (100.0%)	1,809 (100.0%)
Infant Feeding Option	Exclusive breastfeeding	433 (52.0%)	557 (57.0%)	990 (54.7%)
	Not breastfed or Replacement feeding	266 (32.0%)	183 (18.7%)	449 (24.8%)
	Mixed feeding	86 (10.3%)	203 (20.8%)	289 (16.0%)
	Missing	47 (5.7%)	34 (3.5%)	81(4.5%)
	Total	832 (100.0%)	977 (100.0%)	1,809 (100.0%)
Reason for PCR	First test for healthy exposed infant	641 (77.0%)	762 (78.0%)	1,403 (77.6%)
	First test for sick infant	19 (2.3%)	13 (1.3%)	32 (1.8%)
	Problem with first test	172 (20.7%)	202 (20.7%)	374 (20.7%)
	Total	832 (100.0%)	977 (100.0%)	1,809 (100.0%)
Maternal ARVs	ART	425 (51.1%)	179 (18.3%)	604 (33.3%)
	ARVP	188 (22.6%)	182 (18.6%)	370 (20.4%)
	*ART or Triple Regimen	86 (10.3%)	180 (18.4%)	266 (14.7%)
	None	97 (11.7%)	134 (13.7%)	231 (12.8%)
	Missing	36 (4.3%)	302 (30.9%)	338 (18.7%)

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Variable		FMC Yola n (%)	SH Yola n (%)	Total n (%)
	Total	832 (100.0%)	977 (100.0%)	1,809 (100.0%)
Type of Maternal ARVP	AZT + 3TC and sdNVP	136 (72.3%)	44 (24.2%)	180 (48.7%)
	AZT and sdNVP in labour	9 (4.8%)	29 (15.9%)	38 (10.3%)
	Triple regimen	38 (20.2%)	82 (45.1%)	120 (32.4%)
	sdNVP	3 (1.6%)	21 (11.5%)	24 (6.5%)
	Unknown	2 (1.1%)	1 (0.6%)	3 (0.8%)
	Missing	0 (0.0%)	5 (2.8%)	5 (1.4%)
	Total	188 (100.0%)	182 (100.0%)	370 (100.0%)
Infant ARVs	sdNVP at birth	36 (4.3%)	0 (0.0%)	36 (2.0%)
	sdNVP at birth and AZT for 4 weeks	255 (30.6%)	132 (13.5%)	387 (21.4%)
	NVP for 6 weeks	366 (44.0%)	394 (40.3%)	760 (42.0%)
	Unknown	3 (0.4%)	0 (0.0%)	3 (0.2%)
	None	122 (14.7%)	167 (17.1%)	289 (16.0%)
	Missing (ARV Type)	5 (0.6%)	4 (0.4%)	9 (0.5%)
	Missing (Prophylaxis use)	45 (5.4%)	280 (28.7%)	325 (18.0%)
	Total	832 (100.0%)	977 (100.0%)	1,809 (100.0%)

N= Total number of HIV Exposed Infants
*Pregnant women took triple regimen either solely for PMTCT (ARVP) or as ART (both for PMTCT and their health). Documentation was not clear enough to delineate as ART or ARVP

Summary of overall MTCT risk, MTCT risk segregated by age, breastfeeding option, ART/ARVP option and PMTCT protocol periods including missing data is presented in figure 4.6. It should be noted that records of HIV positive pregnant women were not longitudinally linked to that of their HEIs hence HEIs were not necessarily delivered by the pregnant women that tested positive during ANC. Information on mother and infant's ARV use and breastfeeding option were however available in either or both the EID follow up register and PCR request and result form.

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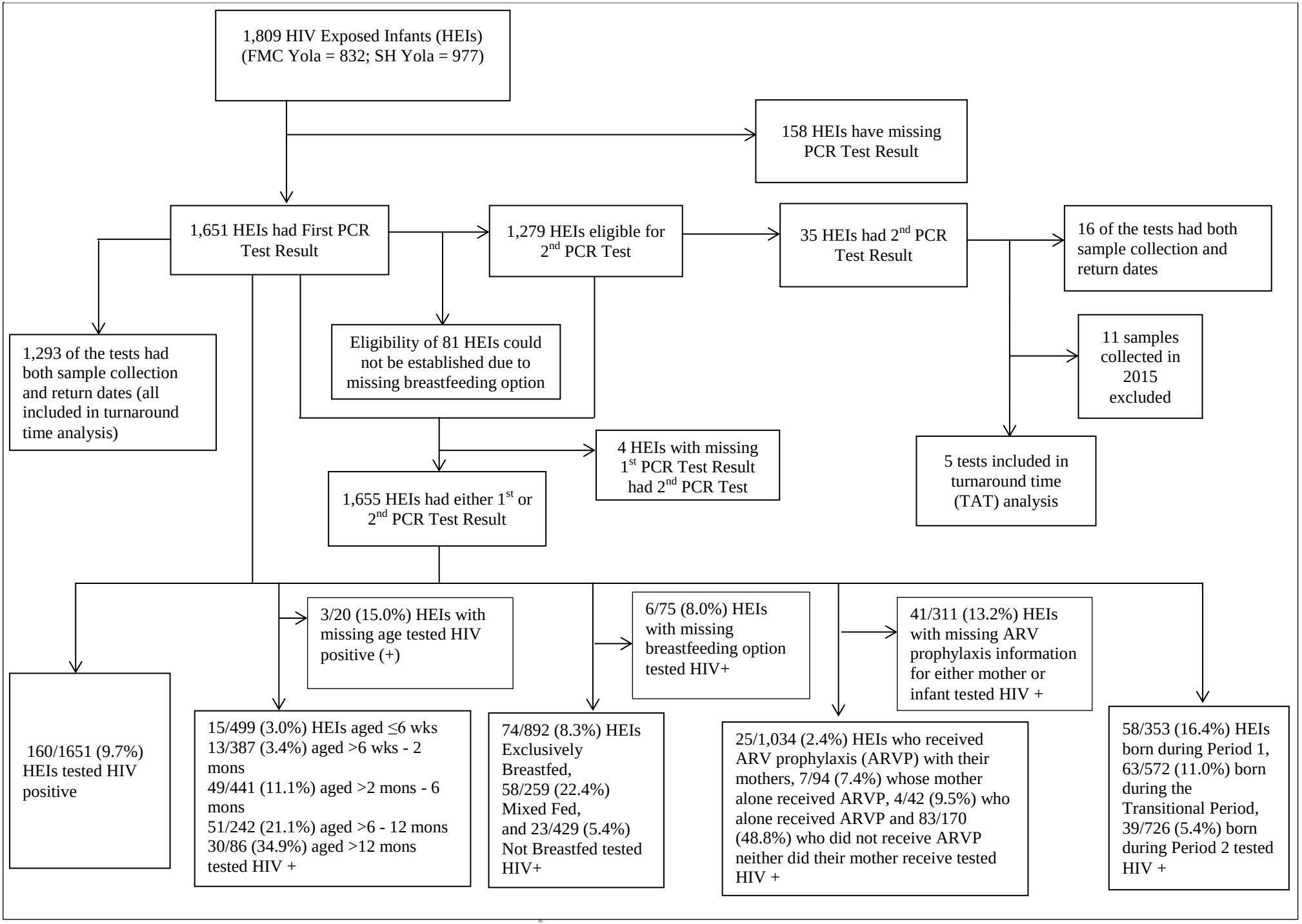
Figure 4.6: Flow Chart for overall MTCT risk, MTCT risk segregated by age, breastfeeding option, ART/ARVP option and PMTCT protocol periods



4.4.3 Objective 4: Overall MTCT risk and turnaround time

The overall MTCT risk for all HEIs with first HIV DNA PCR test result, between 2008 and 2014 was 9.7% [160/1,651] (95% CI 8.3% - 11.1%) at median age of 8 weeks (IQR= 6-20). Although the overall MTCT risk for SH Yola was higher than that of FMC Yola, the difference was not statistically significant (95% CI difference = -4.4% - 1.2%; p=0.273) (see table 4.8). Except for the increase seen in 2009 (from 14.3% [7/49] to 17.9% [44/246]), MTCT risk generally declined over the 7 year period even though the decline between consecutive years was not statistically significant (see table 4.9) - the only exception to this is 2011 versus 2012 (95% CI difference = 0.1% -8.1%). The median age across most of the years (5 out of 7) was 8 weeks (see table 4.10)

The overall median turnaround time for the two health facilities was 48 days (IQR: 31-78; n=1,298). For the first three years reviewed (2008 -2010), median TAT was less than 40 days. It however increased from 53 in 2011 to 133 in 2014 (see table 4.11).

Table 4.8: Overall MTCT risk and turnaround time at median age of 8 weeks (N=1651)

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	FMC Yola		SH Yola		Total	
	n (%)	**95% CI**	**n (%)**	**95% CI**	**n (%)**	**95% CI**
Overall MTCT Risk	66 (8.8%)	6.8%-10.9%	94 (10.4%)	8.4%-12.4%	160 (9.7%)	8.3%-11.1%
	Median	**IQR**	**Median**	**IQR**	**Median**	**IQR**
Age in weeks	8	6-20	8	7-20	8	6 – 20
Turn Around Time in Days	48 (593)	33-75	48 (705)	30-81	48 (1,298)	31-78

n = number of HIV exposed infants that tested HIV positive; IQR= interquartile range; ( ) number of EID tests

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Table 4.9: Yearly trend of MTCT risk for FMC Yola and SH Yola at median age of 8 weeks (N=1651)

	FMC Yola		SH Yola		Total	
Year	**n (%)**	**95% CI**	**n (%)**	**95% CI**	**n (%)**	**95% CI**
2008	2 (14.3%)	*0.0%-33.3%	5 (14.3%)	2.5%-26.1%	7 (14.3%)	4.4%-24.2%
2009	14 (13.3%)	6.8%-19.9%	30 (21.3%)	14.5%-28.1%	44 (17.9%)	13.1%-22.7%
2010	16 (11.3%)	6%-16.5%	22 (15.9%)	9.8%-22.1%	38 (13.6%)	9.5%-17.6%
2011	17 (9.4%)	5.1%-13.7%	14 (9.1%)	4.5%-13.6%	31 (9.3%)	6.1%-12.4%
2012	4 (3.8%)	0.1%-7.4%	11 (6%)	2.5%-9.4%	15 (5.2%)	2.6%-7.7%
2013	5 (5.6%)	0.8%-10.3%	9 (6.7%)	2.4%-10.9%	14 (6.2%)	3.1%-9.4%
2014	8 (7.4%)	2.4%-12.4%	3 (2.5%)	*0.0%-5.4%	11 (4.9%)	2.1%-7.7%
Overall	66 (8.8%)	6.8%-10.9%	94 (10.4%)	8.4%-12.4%	160 (9.7%)	8.3%-11.1%

N= Total number of HIV Exposed Infants
* confidence limit was amended so that the confidence intervals are bound between 0 and 100%.

Table 4.10: Yearly trend of median age of HEIs (with IQR) for FMC Yola and SH Yola

	FMC Yola		SH Yola		Total	
Year	**Median**	**IQR**	**Median**	**IQR**	**Median**	**IQR**
2008	24.0	12-32	12	8-16	12	8-24
2009	12.0	8-26	10	7-28	12	8-28
2010	8.0	6-20	8	6-28	8	6-24
2011	7.0	6-16	8	6-23	8	6-20
2012	7.5	6-24	8	6-16	8	6-20
2013	7.0	6-11	8	7-20	8	6-16
2014	8.0	6-16	9	7-14	8	6-15
Overall	8.0	6-20	8	7-20	8	6-20

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Table 4.11: Yearly trend of TAT for FMC Yola and SH Yola (N=1298)

	FMC Yola		SH Yola		Total	
Year	median (n)	IQR	median (n)	IQR	median (n)	IQR
2008	38.5 (14)	31-46	37 (35)	25.5-51	37 (49)	31-51
2009	39.5 (106)	29-54	34 (141)	29-49	36 (247)	29-54
2010	35 (130)	25.25-44.75	29 (135)	22-48	32 (265)	25-45
2011	51 (179)	37.5-67	67 (154)	43-103	53 (333)	38-83
2012	85 (61)	68-96	47 (137)	40-56	54.5 (198)	40-78
2013	115 (13)	101-122	110 (25)	103-124	113 (38)	101.5-124
2014	133 (90)	44.25-164.75	133.5 (78)	109-172	133 (168)	76-172
Overall	48 (593)	33-75	48 (705)	30-81	48 (1,298)	31-78

N=Total number of EID tests
n=number of EID tests

4.4.4 Objective 5: MTCT risk by age

Table 4.12 below shows the age-specific MTCT rate among HEIs. MTCT risk was lowest among infants aged 2 months and below (3.0% [15/499] - 3.4% [13/387]). The risk was 11.1% [49/441] among those that were >2 months - 6 months while those that were older than 6 months had MTCT risk between 21.1% [51/242] and 34.9% [30/86]. From the yearly trend shown in Table 4.13, the lowest MTCT risks were among babies that were either 2 months or younger and highest among those >12 months for most of the years.

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Table 4.12: MTCT risk by age (N=1675[+])

Age	FMC Yola		SH Yola		Total	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
≤6 wks	7 (2.5%)	0.7% -4.4%	8 (3.6%)	1.1%-6.0%	15 (3.0%)	1.5%-4.5%
>6 wks - 2 mons	5 (3.4%)	0.5%-6.3%	8 (3.3%)	1.1%-5.6%	13 (3.4%)	1.6%-5.2%
>2 mons - 6 mons	23 (12.5%)	7.7%-17.3%	26 (10.1%)	6.4%-13.8%	49 (11.1%)	8.2%-14.0%
>6 - 12 mons	21 (19.8%)	12.2%-27.4%	30 (22.1%)	15.1%-29.1%	51 (21.1%)	15.9%-26.2%
>12 mons	10 (20.4%)	9.0%-31.8%	20 (54.1%)	37.8%-70.3%	30 (34.9%)	24.7%-45.0%
Missing	1 (14.3%)	*0.0%-42.3%	2 (15.4%)	*0.0%-35.8%	3 (15.0%)	*0.0%-31.1%
Total	6 7 (8.7%)	6.7%-10.7%	94 (10.4%)	8.4%-12.4%	161 (9.6%)	8.2%-11.0%

N = Total number of HIV Exposed Infants
+ Infants with first and second test results that fall within different age brackets were analyzed twice.
n = number of HIV exposed infants that tested HIV positive; wks = weeks; mons= months
*confidence limit was amended so that the confidence intervals are bound between 0% and 100%

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Table 4.13: Yearly trend of MTCT risk by age at FMC Yola and SH Yola (N=1675)

Year	≤6 wks		>6 wks - 2 mons		>2 mons - 6 mons		>6 - 12 mons		>12 mons		Missing	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
2008	0 (0.0%)	[redacted]	0 (0.0%)	[redacted]	5 (26.3%)	6%-46.7%	2 (25.0%)	*0.0%-57.1%	0 (0.0%)	[redacted]	0 (0.0%)	[redacted]
2009	3 (6.7%)	*0.0%-14.0%	5 (7.8%)	1.2%-14.4%	15 (20.8%)	11.4%-30.3%	16 (33.3%)	19.8%-46.8%	5 (35.7%)	9.6%-61.8%	0 (0.0%)	
2010	5 (5.7%)	0.8%-10.5%	2 (3.2%)	*0.0%-7.7%	8 (12.7%)	4.4%-21.0%	8 (16.7%)	6.0%-27.3%	15 (78.9%)	60.1%-97.8%	0 (0.0%)	
2011	1 (0.7%)	*0.0%-2.2%	4 (6.0%)	0.2%-11.7%	8 (11.1%)	3.8%-18.4%	14 (28.6%)	15.8%-41.4%	4 (36.4%)	6.5%-66.2%	0 (0.0%)	
2012	3 (3.2%)	*0.0%-6.8%	1 (1.5%)	*0.0%-4.4%	5 (6.3%)	0.9%-11.7%	3 (7.5%)	*0.0%-15.8%	2 (25.0%)	*0.0%-57.1%	1 (33.3%)	*0.0%-98.7%
2013	0 (0.0%)	[redacted]	1 (1.5%)	*0.0%-4.4%	5 (8.6%)	1.3%-15.9%	5 (21.7%)	4.5%-39.0%	2 (22.2%)	*0.0%-51.1%	1 (8.3%)	*0.0%-24.7%
2014	3 (4.1%)	*0.0%-8.7%	0 (0.0%)	[redacted]	3 (3.8%)	*0.0%-8.1%	3 (11.5%)	*0.0%-24.1%	2 (9.1%)	*0.0%-21.4%	1 (50.0%)	*0.0%-*100.0%
Overall	15 (3.0%)	1.5%-4.5%	13 (3.4%)	1.6%-5.2%	49 (11.1%)	8.2%-14%	51 (21.1%)	15.9%-26.2%	30 (34.9%)	24.7%-45.0%	3 (15.0%)	*0.0%-31.1%

N = Total number of HIV Exposed Infants

* confidence limit was amended so that the confidence intervals are bound between 0 and 100%.

[redacted] STATA did not estimate confidence intervals because point estimate was 0.0%

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4.4.5 Objective 6: MTCT risk by breastfeeding option

The least MTCT risk was found among infants that were not breastfed (5.4%) [23/429] while the highest was found among mixed fed infants (22.4%) [58/259] (see details in table 4.14). It should be noted that information on feeding option was only available for 1,580 of HEIs.

Table 4.14: MTCT risk by breastfeeding option at median age of 8 weeks (N=1655)

Breastfeeding option	FMC Yola		SH Yola		Total	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
Exclusive Breastfeeding	35 (9.1%)	6.2%-12.0%	39 (7.7%)	5.3%-10.0%	74 (8.3%)	6.5%-10.1%
Mixed Feeding	18 (25.0%)	14.9%-35.1%	40 (21.4%)	15.5%-27.3%	58 (22.4%)	17.3%-27.5%
Not Breastfed	10 (4.0%)	1.6%-6.4%	13 (7.3%)	3.5%-11.2%	23 (5.4%)	3.2%-7.5%
Missing	4 (9.3%)	0.5%-18.1%	2 (6.3%)	*0.0%-14.8%	6 (8.0%)	1.8%-14.2%
Total	67 (8.9%)	6.9%-11.0%	94 (10.4%)	8.4%-12.4%	161 (9.7%)	8.3%-11.2%

N= Total number of HIV Exposed Infants with either first or second EID test result
n = number of HIV exposed infants that tested HIV positive
* confidence limit was amended so that the confidence intervals are bound between 0 and 100%.

4.4.6 Objective 7: MTCT risk by receipt of ART/ARVP

At a median age of 8 weeks, MTCT risk was 2.4% [25/1,034] when mother-infant pairs received antiretroviral drugs for treatment, prophylaxis or both (ART/ARVP). MTCT risk was higher when infant alone received ART/ARVP compared to when mother alone did (9.5% [4/42] Vs 7.4% [7/94]; 95% CI difference = -8.2% - 12.4%; p=0.677) even though this difference was not statistically significant. MTCT risk was close to 50% when neither mother nor infant received ART/ARVP (48.8% [83/170]).

In instances where mothers received ART/ARVP irrespective of whether HEIs received ARV prophylaxis or not, MTCT risk ranged from 1.9% [7/359] – 3.7% [7/191]. MTCT risk on the other hand was 41.5% [90/217] when mothers did not receive any ARVs. MTCT risk was lower in women who started ART during pregnancy when compared with those who started before (difference was not statistically significant - 95% CI difference = -1.1% - 4.1%;

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p=0.326) while none of the mothers that received triple regimen (ARVP) for PMTCT delivered HIV positive infants.

MTCT risk among infants who received prophylaxis irrespective of mother's prophylactic option was 2.7% [30/1,098] while it was 34.4% [93/270] among those that did not. None of the infants who received sdNVP were HIV positive while infants who received daily dose of NVP for 6 weeks had a lower risk than those that received AZT+sdNVP (1.6% [11/667] Vs 4.7% [18/384] ; p=0.003) (See details of MTCT risk in table 4.15).

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Table 4.15: MTCT risk by receipt of ART/ARVP (2008 – 2014) (N=1,651)

Receipt of ART/ARVP		FMC Yola		SH Yola		Total	
		N	95% CI	N	95% CI	n	95% CI
ART/ ARV Prophylaxis Receipt (Mother and Infant Pair)	Mother and Infant received	15 (2.5%)	1.3%-3.8%	10 (2.3%)	0.9%-3.7%	25 (2.4%)	1.5%-3.4%
	Mother alone received	6 (14.0%)	3.5%-24.4%	1 (2.0%)	*0.0%-5.8%	7 (7.4%)	2.1%-12.8%
	Infant alone received	4 (20.0%)	2.0%-38.0%	0 (0.0%)	[redacted]	4 (9.5%)	0.5%-18.5%
	Neither mother nor infant received	36 (56.3%)	44.0%-68.5%	47 (44.3%)	34.8%-53.8%	83 (48.8%)	41.3%-56.4%
	Mother received and infant missing	3 (23.1%)	*0.0%-46.9%	31 (12.6%)	8.4%-16.7%	34 (13.1%)	9.0%-17.2%
	Mother missing Infant received	0 (0.0%)	[redacted]	1 (5.3%)	*0.0%-15.6%	1 (4.5%)	*0.0%-13.5%
	Mother missing Infant did not receive	1 (50.0%)	*0.0%-*100.0%	2 (50.0%)	*0.0%-*100.0%	3 (50.0%)	6.1%-93.9%
	Mother received Infant missing	0 (0.0%)	[redacted]	0 (0.0%)	[redacted]	0 (0.0%)	[redacted]
	Mother did not receive Infant missing	1 (33.3%)	*0.0%-98.7%	2 (100.0%)	[redacted]	3 (60.0%)	12.0%-*100.0%
	Total	66 (8.8%)	6.8%-10.9%	94 (10.4%)	8.4%-12.4%	160 (9.7%)	8.3%-11.1%
Maternal ARV/ART irrespective of infant prophylactic option	ART	16 (3.8%)	2.0%-5.7%	2 (1.1%)	*0.0%-2.7%	18 (3.0%)	1.6%-4.4%
	ARVP	2 (1.1%)	*0.0%-2.6%	5 (2.8%)	0.4%-5.3%	7 (1.9%)	0.5%-3.4%
	ART or ARVP	3 (7.1%)	*0.0%-15.0%	4 (2.7%)	0.1%-5.3%	7 (3.7%)	1.0%-6.3%
	No	41 (47.1%)	36.6%-57.7%	49 (37.7%)	29.3%-46.1%	90 (41.5%)	34.9%-48%
	Missing	4 (22.2%)	2.4%-42.0%	34 (12.6%)	8.6%-16.6%	38 (13.2%)	9.3%-17.1%
	Total	66 (8.8%)	6.8%-10.9%	94 (10.4%)	8.4%-12.4%	160 (9.7%)	8.3%-11.1%
Timing of Maternal ART	Before	13 (4.3%)	2.0%-6.7%	1 (0.8%)	*0.0%-2.3%	14 (3.3%)	1.6%-5.0%
	During	3 (2.5%)	*0.0%-5.4%	0 (0.0%)	[redacted]	3 (1.8%)	*0.0%-3.9%
	Missing	[redacted]		1 (16.7%)	*0.0%-49.4%	1 (16.7%)	*0.0%-49.4%
	Total	16 (8.8%)	6.8%-10.9%	2 (10.4%)	8.4%-12.4%	18 (9.7%)	8.3%-11.1%

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Receipt of ART/ARVP		FMC Yola		SH Yola		Total	
		N	95% CI	N	95% CI	n	95% CI
Maternal ARVP type irrespective of infant prophylactic option	sdNVP	0 (0.0%)		2 (10.5%)	*0.0%-24.8%	2 (9.1%)	*0.0%-21.4%
	AZTsdNVP	0 (0.0%)		1 (3.7%)	*0.0%-11.0%	1 (2.9%)	*0.0%-8.5%
	AZT3TCsdNVP	2 (1.5%)	*0.0%-3.6%	1 (1.5%)	*0.0%-3.6%	3 (1.7%)	*0.0%-3.6%
	Triple regimen	0 (0.0%)		0 (0.0%)		0 (0.0%)	
	Unknown	0 (0.0%)		0 (0.0%)		0 (0.0%)	
	Missing			1 (20.0%)	*0.0%-59.3%	1 (20.0%)	*0.0%-59.3%
	Total	2 (8.8%)	6.8%-10.9%	5 (10.4%)	8.4%-12.4%	7 (9.7%)	8.3%-11.1%
Infant Prophylaxis irrespective of maternal ART/ARVP	Yes	19 (3.1%)	1.7%-4.5%	11 (2.3%)	0.9%-3.6%	30 (2.7%)	1.8%-3.7%
	No	43 (39.4%)	30.2%-48.7%	50 (31.1%)	23.9%-38.2%	93 (34.4%)	28.8%-40.1%
	Missing	4 (19.0%)	1.8%-36.3%	33 (12.6%)	8.6%-16.6%	37 (13.1%)	9.1%-17.0%
	Total	66 (8.8%)	6.8%-10.9%	94 (10.4%)	8.4%-12.4%	160 (9.7%)	8.3%-11.1%
Infant ARV type irrespective of maternal ART/ARVP	AZT+sdNVP	12 (4.8%)	2.1%-7.4%	6 (4.5%)	1.0%-8.1%	18 (4.7%)	2.6%-6.8%
	NVP	6 (1.9%)	0.4%-3.4%	5 (1.4%)	0.2%-2.7%	11 (1.6%)	0.7%-2.6%
	sdNVP	0 (0.0%)		0 (0.0%)		0 (0.0%)	
	Unknown	0 (0.0%)		0 (0.0%)		0 (0.0%)	
	Missing	4 (22.2%)	2.4%-42%	31 (12.4%)	8.3%-16.4%	35 (13.0%)	9.0%-17.0%
	Total	22 (8.8%)	6.8%-10.9%	42 (10.4%)	8.4%-12.4%	64 (9.7%)	8.3%-11.1%

N=Total number of HIV Exposed Infants
n = number of HIV exposed infants that tested HIV positive
* confidence limit was amended so that the confidence intervals are bound between 0 and 100%.
Missing: information on ARV use was not available
■ STATA did not estimate confidence intervals because point estimate was 0.0%

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4.4.7 Objective 8: MTCT risk by PMTCT protocol periods

Two distinct protocols were in use during the 7 years under review. There was however a period of overlap (transitional period) between the two PMTCT protocol periods. The lowest MTCT risk was in period 2 (5.4%) [39/726] while the highest was in period 1 (16.4%) [58/353]. Details of MTCT risk are presented in Table 4.16. It took almost two and a half years for the two health facilities to fully transition from the 2007 to the 2010 PMTCT protocol.

Table 4.16: MTCT risk by periods of PMTCT protocol at median age of 8 weeks (N=1651)

PMTCT Period	FMC Yola		SH Yola		Total	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
Period 1 (Jan 2008 – Jan 2010)	20 (12.5%)	7.4%-17.6%	38 (19.7%)	14.1%-25.3%	58 (16.4%)	12.6%-20.3%
Transitional Period (Feb 2010 – May 2012)	30 (9.5%)	6.3%-12.7%	33 (12.8%)	8.7%-16.9%	63 (11.0%)	8.4%-13.6%
Period 2 (Jun 2012-Dec 2014)	16 (5.9%)	3.1%-8.7%	23 (5.1%)	3.0%-7.1%	39 (5.4%)	3.7%-7.0%
Total	66 (8.8%)	6.8%-10.9%	94 (10.4%)	8.4%-12.4%	160 (9.7%)	8.3%-11.1%

n= number of HIV exposed infants that tested HIV positive
Period 1 PMTCT regimen: Mother: Ante partum - AZT from 28 weeks of gestation or AZT+3TC from 34-36 weeks of gestation Intrapartum - SdNVP +AZT+3TC at onset of labour Postpartum - AZT+3TC for 7 days Infants: sdNVP at birth (preferably within 72 hours) plus AZT for 6 weeks.
Period 2 PMTCT regimen: Mother: AZT+ 3TC +EFV or NVP or LPV/r; TDF+ 3TC+ EFV from 14 weeks of gestation up to 1 week post cessation of breastfeeding
Infant: NVP at birth (preferably within 72 hours) up to 6 weeks of age.
Transitional Period: Both Period 1 and Period 2 Regimens (both regimens were in use during this period due to delayed transition)

4.5 Predictors of MTCT risk

To establish predictors of MTCT risk, simple and multiple logistic regressions analysis were carried out with resultant odds ratio estimated. From the simple regression analysis infant age, breastfeeding option, ART/ARVP receipts and year were found to be predictors of MTCT risk.

All the variables listed in table 4.17 below were included in a multiple regression model. Infant age (>12 months), breastfeeding option (mixed fed), ART/ARVP receipts and year

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(2012) were found to be predictors of MTCT risk. HEIs older than 12 months had 3.29 times (adjusted odds ratio (AOR)) the odds to be HIV positive than those ≤6 weeks while mixed fed infants had 2.44 times the odds to be HIV positive than infants that were not breastfed. The odds of the exposed infant being HIV positive was also higher (AOR = 26.37) when neither the mother nor the infant received prophylaxis. HEIs born in 2012 had lower odds of being HIV positive than those born in 2008.

Table 4.17: Multivariable analysis of factors associated with MTCT risk at final end point using cumulative pooled data

Variable		Crude Odds Ratio	95% CI	P value	**Adjusted Odds Ratio	95% CI	P value
Gender	Male	1.00			1.00		
	Female	1.32	0.95 - 1.83	0.096	1.16	0.71 - 1.89	0.546
Infant Age	≤6 wks	1.00			1.00		
	>6 wks - 2 mons	1.12	0.53 - 2.39	0.766	0.79	0.30 - 2.11	0.636
	>2 mons - 6 mons	***4.03**	**2.23 - 7.3**	**0.000**	1.67	0.76 - 3.66	0.198
	>6 - 12 mons	***8.67**	**4.75 - 15.82**	**0.000**	1.75	0.75 - 4.05	0.194
	>12 mons	***25.47**	**12.62 - 51.41**	**0.000**	***3.29**	**1.24 - 8.75**	0.017
Breastfeeding option	Not Breastfed	1.00			1.00		
	Exclusively Breastfed	1.60	0.99 - 2.59	0.056	1.94	0.98 - 3.86	0.058
	Mixed fed	***5.03**	**3.01 - 8.40**	**0.000**	***2.44**	**1.08 - 5.52**	0.032
ART/ARV Prophylaxis Receipt	Both Mother and Infant	1.00			1.00		
	Mother alone	***3.25**	**1.37 - 7.72**	**0.008**	***2.81**	**1.12 - 7.04**	0.028
	Infant alone	***4.25**	**1.41 - 12.81**	**0.010**	***5.64**	**1.79 - 17.79**	0.003
	Neither Mother nor Infant	***38.50**	**23.4 - 63.35**	**0.000**	***26.37**	**13.96 - 49.81**	0.000
Hospital	FMC Yola	1.00			1.00		
	SH Yola	1.19	0.86 – 1.66	0.293	0.47		0.005
Year	2008	1.00			1.00		
	2009	1.31	0.55 – 3.10	0.544	1.23	0.27 – 5.63	0.794
	2010	0.94	0.39 – 2.25	0.893	0.47	0.10 – 2.14	0.327
	2011	0.61	0.25 – 1.48	0.275	0.33	0.07 – 1.52	0.154
	2012	***0.33**	**0.13 – 0.85**	**0.022**	***0.18**	**0.03 – 0.99**	**0.049**
	2013	0.40	0.15 – 1.05	0.062	0.32	0.06 – 1.63	0.169
	2014	0.31	0.11 – 0.84	0.021	0.24	0.05 – 1.29	0.097

*Statistically significant odds ratio

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5.0 DISCUSSION

This chapter discusses the results from this study in line with the study objectives and also compares findings with that of other published studies. It also highlights the strengths, limitations and challenges encountered in the course of implementing this study.

5.1 Objective 1: Uptake of HTC

The overall uptake of HTC was 75.9% [47,217/62,224] (95%CI: 74.3 – 77.5%) which is lower than the national PMTCT scale up plan target of 90%. The upper confidence interval limit of this estimate is close to the 77.8% obtained from the operational research conducted in Nigeria in 2005. Facility-level uptake of over 98% had been reported in Nigeria (Galadanci et al., 2013; Markson & Umoh, 2012). Since this study's estimate only focused on women that attended ANC, estimated HTC uptake does necessarily reflect population level uptake. NDHS (2013) survey result revealed that only 20 percent of women surveyed in Nigeria were counselled, tested and received result during ANC.

There were some improvement in HTC uptake at the study sites over the years when compared with the 2008 baseline; the student thinks this could have been as a result of improvement in service delivery and programme acceptance by the end users. Going by the documentation in the HTC register and feedback from the health facility staff, a number of reasons accounted for women not getting tested. These include non-availability of HIV test kits and some mothers requesting to get their husband's consent before they can get tested. It should however be noted that this estimate does not include women with known HIV status at the time of ANC attendance who are typically not re-tested during ANC.

5.2 Objective 2: Maternal/Antenatal HIV positivity rate

The overall maternal HIV positivity rate at the two study sites was 3.1% [1,475/47,217] (95%CI. 3.0% - 3.3%). Expectedly in terms of absolute numbers, there were more HIV

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positive pregnant women for SH Yola than FMC Yola. There was however overlap in CIs for the overall maternal HIV positivity rates for the two health facilities. There was a general decline in maternal HIV positivity rate from 2008 to 2014 (5.5% [297/5,365] to 1.5% [117/7,636]) though there was a slight rise in 2012 (2.6% [145/5541] in 2011 to 3.4% [224/6,603] in 2012). A number of reasons could have contributed to this general decline one of which is the intensified effort towards prevention of HIV which translated to decline in new infections. The rise in maternal HIV positivity rate from 2011 to 2012 could have been a result of reduction in the number of people dying from HIV or recline to risky sexual behavior by the time people realized that HIV infection can be managed (Bashorun et al., 2014). Similar increase in national prevalence was observed between 2005 and 2008 (from 4.4% to 4.6%) in Nigeria. With the decentralization of ART services to primary health centres (PHCs) between 2012 and 2014, the student posits that it is likely that other HIV positive women that would have otherwise attended the 2 study sites received HTC services and were diagnosed at these PHCs. Again women with previously known HIV estimate were not included in this estimate since they are not typically re-tested during ANC.

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The cumulative estimate from this study is lower than the maternal HIV positivity rates of 3.7%, 5.5%, 12.7% and 15.1% that have been reported in some studies conducted in Nigeria using data from 2009 and 2011 (Chama et al., 2010; Galadanci et al., 2013; Okafor et al., 2014; Markson & Umoh, 2012).

The HIV positivity rate of 5.5% [297/5,365] (95% CI: 4.8%- 6.2%) for 2008 is lower than the national average of 4.6% (estimate falls within 95% CI) as well as the state specific estimate of 6.8% (FMoH, 2010b).

For 2010, the national HIV prevalence was 4.1% while the state specific prevalence was 3.8% (2.6% - 5.1%), Yola-the town in which the 2 study sites are located had a prevalence of

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2.7% (0.8% - 4.5%), the estimate of 3.5% [214/6,138] from this study falls within the confidence interval for both the state and Yola town (FMoH, 2010b). The National HIV/AIDS and Reproductive Health Survey (NARHS) conducted in 2012 estimated the national HIV prevalence to be 3.4% (NACA, 2014b), this value is the same as the 2012 estimate for this study. From the 2014 sentinel survey, the HIV prevalence for Nigeria and Adamawa State were 3.0%, 2.5% respectively while the urban areas in Adamawa state had a prevalence of 2.2% (1.3% - 3.7%) (FMoH, 2014b). The point estimate of 1.5% [117/7,636] for 2014 also falls with the confidence interval for urban areas in Adamawa State.

Except for the slight rise in maternal HIV positivity rate in 2012, findings from this study is similar to the results of the HIV seroprevalence sentinel survey which showed a consistent decline in prevalence from 2010 to 2014 (FMoH, 2014b). This finding suggests that the investment in HIV prevention, care and treatment is yielding positive results.

5.3 Objective 3: Uptake of ART/ARVP

Based on available records, the overall uptake of ART/ARVP was 85.7% [192/224] (95% CI 81.1% - 90.3%). Prophylactic records were however only available for 15.2 percent of women that tested HIV positive (other records are either missing or could not be longitudinally linked) hence the uptake of ART/ARVP may not be representative of true situation in the two health facilities and it is likely to be an overestimate. Most (84.8%) of the folders for HIV positive pregnant women could not be located either because the women did not receive antiretroviral interventions or because of poor record keeping practice. Review of routine data on ART/ARVP uptake from April 2011 to 2014 gave an overall ART/ARVP uptake of 57.7% (95% CI 44.6-70.7%). This data was however not limited to ANC attendees but also include pregnant women diagnosed during labour and delivery and those referred from other health facilities. UNAIDS's (2016b) statistics revealed that population level ART/ARVP uptake is much lower than the 2 estimates stated above as only 30% of pregnant

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women living with HIV are accessing ARVs to prevent MTCT. Several factors could have contributed to non-receipt of ART/ARVP by HIV positive pregnant women. This includes poor referral, lack of ARVs at the time of diagnosis, poor counselling due to inadequate time (occasioned by high workload due to inadequate manpower) and refusal of HIV positive pregnant women to receive ART/ARVP due to cultural belief (this is closely linked with low level of education (Rogers-Bloc & Quail, 2002; Chama, Audu & Kyari, 2004; Ndikom & Onibokun, 2007; Peltzer et al., 2008; Oladokun et al, 2010; Mirkuzie et al., 2011; Nkwo, 2012; Chabikuli et al., 2013; NACA, 2013). In order to tackle the scourge of MTCT; strategies must involve measures that will improve women's attendance at ANC and subsequent uptake of HTC and ART/ARVP as well as delivery at health facilities which will increase the likelihood of the infant receiving ARVP (Galadanci et al., Undated).

5.3.1 Predictors of ART/ARVP uptake

Women that were between 25-34 years were found to be approximately three times (3.04) more likely to receive ART/ARVP than those aged 15-24 years. The student thinks this is likely due to the fact that the former are more matured and appreciate the need to protect the HEI better.

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5.4 Objectives 4-8: MTCT risk in general and turnaround time for DNA PCR test results, MTCT risk by age, by feeding option, by ARV use and by PMTCT protocol period

5.4.1 Objective 4: Overall MTCT risk and turnaround time for DNA PCR test results

The overall MTCT risk for this study was 9.7% [160/1651] (95% CI 8.3% - 11.1%) at median age of 8 weeks (IQR= 6-20). This is very close to the MTCT risk of 9.8% reported by Inalegwu et al. (2016) and not too far from the MTCT risk of 11.0% reported by Aliyu et al.

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(2014) and 13.0% at 6 weeks projected for Nigeria by UNAIDS (UNAIDS, 2016b). Ayouba et al. (2003) also reported an overall MTCT risk of <13% in Cameroun. Studies done in other African countries had reported overall MTCT risks that ranged from 8.8 % - 15.7% (Coetzee et al., 2005; Azcoaga-Lorenzo et al., 2011; Ngemu et al., 2014).

The median turnaround time of 48 days (IQR: 31-78) is almost two times the recommended 28 days. This value is close to the 47 days (IQR: 35-58) reported by Anoje et al. (2012) in their study at selected health facilities in two states in South-South Nigeria and higher than the TAT of 25 days reported in a study conducted in Lagos, Nigeria (Audu et al., 2014). The health facility staff reported that the very high TAT of >100 days for 2013 and 2014 could have been as a result of lack of reagents or equipment breakdown at the central testing laboratory. High TAT could pose additional financial burden on caregivers as they may have to visit the health facility more than once to get the DNA PCR result of their infants. With this high TAT, they also have to wait anxiously for a longer time to know their infant's status. Additionally non-timeliness of result can result in delayed initiation of HIV positive infant on ART (Anoje et al., 2012).

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5.4.2 Objective 5: MTCT risk by age

With MTCT risk of 3.0% [15/499] - 3.4% [13/387] among infants aged 2 months and below, 11.1% [49/441] among those that are >2 months - 6 months and 21.1% [51/242] -34.9% [30/86] among those that are older than 6 months, MTCT risk increased with age. This trend is similar to the findings reported by Anoje et al. (2012) and Kalu et al. (2014) in their studies. This increased risk could have been as a result of prolonged breastfeeding, given that most infants (70.7%) were either exclusively breastfed or mixed fed. Prolonged breastfeeding has been proven to increase risk of MTCT (Newell, 2001; The Breastfeeding and HIV International Transmission Study Group et al., 2004). This is partly due to the fact that a

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higher proportion of the mother-infant pair in the older age bracket did not receive prophylaxis (37% for HEIs > 12months versus 2-7% for HEIs that were 2 months or less). When infants are breastfed, around 39% of MTCT can occur during this period (Kourtis et al., 2006).

5.4.3 Objective 6: MTCT risk by breastfeeding option

It has been established that one of the means through which MTCT occurs is through breastfeeding (WHO, 2010a). This discovery had informed the decision of developed countries to adopt the policy of replacement feeding for all HEIs (Darak et al., 2014). From the result of this study, infants that were not breastfed had the least MTCT risk (5.4%) [39/726] irrespective of prophylaxis use. With the challenge of meeting the AFASS criteria in developing countries, exclusive breastfeeding is recommended even though it carries a higher risk as this study has validated (8.3%) (Federal Ministry of Health, 2007; Federal Ministry of Health Nigeria, 2010a; Federal Ministry of Health, 2014a). Mixed fed infants had significantly higher risk (22.4%) [58/259] of MTCT than the babies fed using the other two breastfeeding options. Mixed feeding is known to predispose infants to HIV especially in early life as formula feeds can erode intestinal linings resulting in HIV infection (Wise, 2001).

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The study conducted by Kalu et al. (2014) also showed similar MTCT risk pattern.

5.4.4 Objective 7: MTCT risk by receipt of ART/ARVP

Efficacy studies have proven that antiretroviral interventions can reduce MTCT risk (Chaisilwattana et al., 2002; Connor et al., 1994; Dabis et al., 2005). Similar evidence is also available for effectiveness studies in a number of settings (De Cock et al., 2000; Kumar et al., 1995; Lallemant et al., 1994; WHO, 2010a). The result of this study further buttressed the effectiveness of PMTCT especially when mother and infant receive intervention irrespective of breastfeeding option. The low MTCT risk of 2.4% [25/1,034](95%CI: 1.5%-3.4%) among

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this category of mother-infant pair suggests that virtual elimination of MTCT is feasible in resource limited settings. The finding that MTCT risk is lower when mothers alone receive ART/ARVP compared to when infants alone did is consistent with the findings of some other studies in Nigeria (Anoje et al., 2012; Chukwuemeka et al., 2014).

The fact that not all mother-infant pairs are receiving prophylaxis despite the availability of these services at the health facilities (also seen in some other studies (Coetzee et al., 2005; Torpey et al., 2012)) calls for the need to put measures in place to ensure that pregnant women access antiretroviral interventions. The triple ARV regimen appears to be the most effective ARV regimen as none of the babies whose mothers received triple regimen for ARVP tested positive. In comparison with the meta-analysis conducted by Adane (2012) using PMTCT studies from Sub Saharan Africa countries, the MTCT rate of 9.1% [2/22] for mothers that received sdNVP is lower than the point estimate of 9.7% from Adane's (2012) study even though the 9.1% falls within the quoted 95% CI of 7.8 – 12.0%, the MTCT rate for the AZT +sdNVP and triple regimen groups were also lower than the risk obtained from the Adane's study (2.9% [1/35] Vs 7.1% (95% CI 6.0% -8.4%) and 0.0% [0/116] Vs 4.0% (95% CI: 2.7% - 6.1%) respectively). Unlike Kesho Bora's study that quoted similar effectiveness for AZT+sdNVP and triple regimen (AZT + sdNVP: 5·0% 95% CI 3·3-7·7%; triple regimen: 3·3% 95% CI: 1·9-5·6%), the fact that none of the HIV exposed babies in the latter group for this study was HIV positive suggests that triple regimen may be more effective.

5.4.5 Objective 8: MTCT risk by PMTCT protocol periods

The lowest PMTCT risk was observed during the period when triple regimen was in use for ARVP. This further buttressed the need for countries to adopt either Option B or Option B^+ as the preferred PMTCT regimen. With the recent adoption of Option B+ by Nigeria

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(UNAIDS, 2016b), Nigeria stands the chance of achieving virtual elimination if coverage of services can be improved.

The two and a half transitional period from the 2007 to the 2010 PMTCT guideline is however long and showed that prescribing habit may not change immediately after the introduction of a new guideline hence the need for intensified engagement to ensure prompt migration.

5.5 Predictors of MTCT risk

The predictors of MTCT risk (infant age, breastfeeding option, ART/ARVP receipt and year (closely linked with PMTCT protocol in use) identified in this study have been well documented in literature as factors associated with MTCT risk (Newell, 2001; Ikechebelu et al., 2011; Azcoaga-Lorenzo et al., 2011; Afe et al., 2011; Anoje et al., 2012; Chukwuemeka et al., 2014; Kalu et al., 2014).

Feeding option influences MTCT risk and the risk increases with breastfeeding duration. Prolonged breastfeeding can double MTCT risk (Newell, 2001; The Breastfeeding and HIV International Transmission Study Group et al., 2004). The 2016 WHO guidelines recommended that is settings where breastfeeding improves child survival; exclusive breastfeeding is recommended for the first six months of life after which complementary foods can be introduced with breastfeeding continued for up to 1 year (WHO, 2016). Use of ART/ARVP has also been found to substantially protect against MTCT (De Cock et al., 2000; Kumar, Uduman, & Khurranna, 1995; Lallemant et al., 1994; WHO, 2010a).

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5.6 Strengths, challenges and limitations of this study

5.6.1 Strengths of this study

This study analyzed data gathered from two health facilities over a 7-year period hence it provided evidence for more than one site over an extended period of time. Most of the facility-based PMTCT effectiveness studies in Nigeria were single-site studies conducted at

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tertiary or teaching hospitals. This study however included a secondary health facility as one of the two study health facilities thus providing additional evidence on PMTCT effectiveness in a secondary health facility which may not have as much specialized health personnel as tertiary or teaching hospitals. Most of the published Nigerian studies also reported findings during one period of the PMTCT protocol; this study however compared MTCT risks during 2 periods of PMTCT policy changes in Nigeria as well as during the transitional period. The sample sizes for this study were also larger than most of the other Nigerian studies.

5.6.2 Challenges encountered in the course of this study

The major challenge encountered in the course of implementation of this study is the poor documentation and record keeping practices at the two health facilities. This made data retrieval difficult and time consuming and also made linking of mother-infant pair record difficult. The pool of data that was included in the final analysis was also reduced due to missing records.

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5.6.3 Limitations of this study

This study is biased towards pregnant women that attended ANC and HEIs that were brought by their caregivers for HIV DNA PCR testing and for which results were available. As the study only focused on pregnant women that attended ANC, exclusion of non-attendees may lead to overestimation of uptake of HTC/ART/ARVP. Women that did not attend ANC would likely not have accepted HTC or ART/ARVP.) With missing record on ARV use for 84.8% (1,251) of HIV positive pregnant women, uptake of ART/ARVP may not be representative of true situation in the two health facilities and it is likely to be an overestimate. Similarly only HEIs that were brought back for HIV DNA PCR testing were studied, the exclusion of HEIs that may be HIV positive but not brought for testing by caregivers would result in underestimation of MTCT risk. Due to the poor tracking mechanism at the health facilities and non-documentation of some mother's hospital number in the EID/Child follow up register, it is difficult to link mother-infant pair record for information on mode of delivery, mother's CD4+ cell count, duration of ART/ARVP use, adherence to ART/ARVP and so on. This study therefore did not assess the effect of these variables on MTCT risk. The data for this study were mostly analyzed cross-sectionally therefore the numerators and denominators at each step of the PMTCT cascade do not necessarily refer to the same groups of women. The only exception to this was in the establishment of uptake of ART/ARVP where it was individually established if HIV positive women received ART/ARVP. Mother-infant pair record was not longitudinally tracked and the HEIs were not necessarily delivered by the pregnant women that tested positive during ANC. Information on mother and infant's ARV use and breastfeeding option were however available in either or both the EID follow up register and PCR request and result form. Finally given that second HIV DNA PCR test result was only available for 2.7% (35) of HEIs, our estimates largely assessed MTCT risk at the time of first testing and not at the final

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end point (post ceasation of breastfeeding). Reasons that could account for few babies getting final EID test include: poor PMTCT counselling, lack of money for transportation due to poor economic status, shortage of DBS test kits among others (NACA, 2013; Chabikuli et al., 2013). Routine data review may therefore not be the best approach for assessing effectiveness of PMTCT when the interest is to establish the final HIV status of HEIs post ceasation of breastfeeding. .

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6.0 CONCLUSION AND RECOMMENDATIONS

This chapter summarizes findings from this study and also provides key recommendations that can help improve PMTCT services and assess progress towards virtual elimination.

6.1 Conclusion

This study has demonstrated that PMTCT-related services are being accessed by pregnant women even though the uptake of HTC and ART/ARVP among pregnant women that visited the two health facilities were below the national PMTCT scale up plan's (2010-2015) target of 90 percent. The MTCT risk estimates also proved that PMTCT interventions are effective especially when both mother and infant received ARV interventions. Option B appears to be the most effective regimen against MTCT, compared with older regimens, and should be strongly encouraged. The high MTCT risk among infants that were mixed fed suggests that this mode of breastfeeding should be discouraged from a transmission perspective in the context of PMTCT Option A (not Option B+ with viral load suppression). With the high turnaround time of 49 days observed for this study, the logistics of DBS sample transportation need to be strengthened. Given the expansion of treatment sites and by extension service coverage since the last country-level evaluation, it is important that Nigeria carries out another evaluation of her program as was done in countries like South Africa. This will help in assessing progress towards Nigeria's PMTCT targets (Federal Ministry of Health Nigeria, 2010a).

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6.2 Recommendations

6.2.1 Recommendations at health facility and implementing partner level

- For ease of data retrieval and review, the administrations of the two health facilities need to improve on their record filing and retrieval system. In addition there is a need

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to put in place strategies for improving the quality of data and entrenching validation processes as a reasonable number of records and variables were missing.

- There is a need to strengthen the referral system between the ANC, patient monitoring and management (PMM) and pharmacy units in order to ensure that all diagnosed HIV positive women receive prophylaxis.
- The management of the two health facilities as well as the implementing partner also needs to improve the contract tracking system for pregnant women in order to ensure that they bring their infants on time for EID testing in accordance with the national testing algorithm.
- More effort is required to ensure timely transition during periods of PMTCT protocol changes.
- The logistics of DBS sample transportation needs to be strengthened in order to ensure that mothers have timely access to the DNA PCR result of their infant which in turn will ensure early initiation of HIV positive infant.

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6.2.2 Recommendation at policy level

- The country should ensure that Option B or Option B+ is in use in all health facilities offering PMTCT services in the country as this is highly effective against MTCT.
- The Government should also ensure that optimal number of health workers is available for service delivery in addition to guarantying continuous supply of HIV commodities.

6.2.3 Other recommendations

- Further research is required to:
    - identify strategies for increasing utilization of PMTCT services by women that are not currently accessing services at health facilities

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- assess cost effectiveness of Option B+ and strategies for improving adherence among women that do not require ARV for their own health.
- assess country-wide PMTCT effectiveness as none of the studies in Nigeria is nationally representative.

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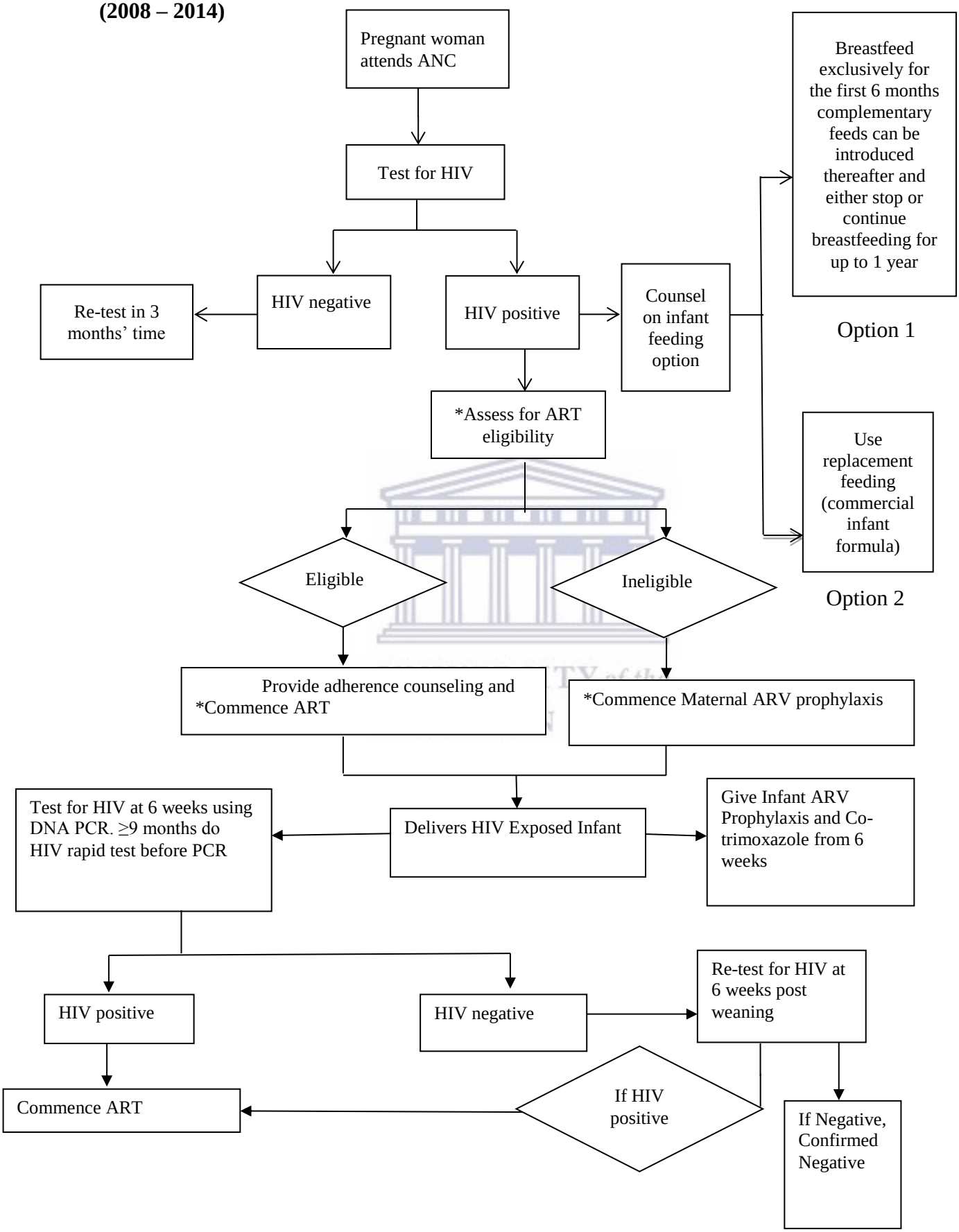
Appendix 1: Flow chart showing cascade of events involved in PMTCT interventions (2008 – 2014)



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ANC, Antenatal clinic; ART, Antiretroviral Therapy; ARV, Antiretroviral drugs; DNA PCR, Deoxyribonucleic Acid Polymerase Chain Reaction; See Appendix 2 for Nigeria's eligibility criteria and recommended ARVs between 2007 and 2014 (Federal Ministry of Health, 2007; Federal Ministry of Health Nigeria, 2010a ; Federal Ministry of Health, 2014a)

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Appendix 2: ART and PMTCT eligibility criteria and regimens

	2007 National Guidelines	2010 National Guidelines		2014 National Guidelines
PMTCT Eligibility Criteria/PMTCT Regimens				
Mother	WHO Clinical Stage I, II with CD4+ cell count >200 cells/mm^3; WHO Clinical Stage III with CD4$^+$ cell count >350 cells/mm^3 *Ante partum* Give AZT from 28 weeks of gestation or AZT+3TC from 34-36 weeks of gestation *Intrapartum* SdNVP +AZT+3TC at onset of labour *Postpartum* AZT+3TC for 7 days	Health Facility CAN monitor triple ARV (*Option B*) WHO Clinical Stage I or II with CD4$^+$ cell count >350 cells/mm^3, Give AZT+ 3TC +EFV or NVP or LPV/r; TDF+ 3TC+ EFV from 14 weeks of gestation up to 1 week post cessation of breastfeeding	Health Facility CANNOT monitor triple ARV (*Option A*) WHO Clinical Stage I or II with CD4$^+$ cell count >350 cells/mm^3 Give AZT from 14 weeks of gestation, sdNVP at onset of labour and delivery, AZT+3TC 12hourly during labour and delivery and 12 hourly for 7 days post-partum	WHO Clinical Stage I or II with CD4$^+$ cell count >500 cells/mm^3 Give TDF/3TC/EFV at the time of diagnosis up to 1 week post cessation of breastfeeding
*Infant	sdNVP at birth (preferably within 72 hours) plus AZT for 6 weeks.	NVP at birth (preferably within 72 hours) up to 6 weeks of age.	*Not Breastfeeding* NVP at birth (preferably within 72 hours) up to 6 weeks of age *Breast feeding* NVP at birth (preferably within 72 hours) up to 1 week post cessation of breastfeeding	NVP at birth (preferably within 72 hours) up to 6 weeks of age.
ART Eligibility Criteria/ART Regimens				
Mother	WHO Clinical Stage IV irrespective of CD4$^+$ cell count WHO Clinical Stage III if CD4$^+$ cell count < 350 cells/mm^3 WHO Clinical Stage I and II if CD4$^+$ cell count is ≤ 200 cells/mm^3 Give AZT+ 3TC +EFV or NVP or LPV/r	WHO clinical stages III or IV irrespective of CD4$^+$ cell count and CD4+ cell count ≤350 cells/mm^3 irrespective of WHO clinical staging Give AZT+3TC+LPV/r or EFV or ABC;	WHO clinical stages III or IV irrespective of CD4$^+$ cell count and CD4+ cell count ≤350 cells/mm3 irrespective of WHO clinical staging Give AZT+3TC+LPV/r or EFV or ABC; TDF+3TC or FTC + EFV	WHO clinical stages III or IV irrespective of CD4+ cell count and CD4+ cell count ≤500 cells/mm3 irrespective of WHO clinical staging Give TDF/3TC/EFV

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	2007 National Guidelines	2010 National Guidelines		2014 National Guidelines
		TDF+3TC or FTC + EFV		
Infant	WHO pediatric HIV Clinical Stage III or IV irrespective of $CD4^+$% WHO pediatric HIV Clinical Stage II if $CD4^+$% < 20% Give AZT+3TC+NVP or EFV. ABC+3TC+NVP or EFV d4T+3TC+NVP or EFV	All infants ≤ 2 years Give AZT+3TC+NVP or LPV/r or ABC or EFV. ABC+3TC+NVP or LPV/r d4T+3TC+NVP or LPV/r	All infants ≤ 2 years Give AZT+3TC+NVP or LPV/r or ABC or EFV. ABC+3TC+NVP or LPV/r d4T+3TC+NVP or LPV/r	All infants ≤5 years Give AZT+3TC+NVP or LPV/r or ABC or EFV

3TC, Lamivudine; ABC, Abacavir; ARV, Antiretroviral drug; AZT, Zidovudine; CTX, Co-trimoxazole; FTC, Emtricitabine; LPV/r, Lopinavir/ritonavir; NVP, Nevirapine; sdNVP, single dose; Stavudine, d4T; Tenofovir, TDF; WHO, World Health Organization. *Initiate CTX at 6 weeks and continue until infant is confirmed to be HIV negative-post cessation of breastfeeding

NB: SH Yola and FMC Yola implemented 2007 National guidelines between 2007 and January 2010 while Option B of 2010 National Guidelines was implemented between February 2010 and December 2014.

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Appendix 3: 2010-2015 National PMTCT scale up targets

- To provide access to at least 90% of all pregnant women to quality HIV counselling and testing by 2015
- To provide access to at least 90% of all HIV positive pregnant women to more efficacious ARV prophylaxis by 2015
- To provide access to at least 90% of HIV exposed infants to more efficacious ARV prophylaxis by 2015
- To provide access to at least 90% of HIV positive pregnant women to quality infant feeding counselling by 2015
- To provide access to at least 90% of all HIV exposed infants to early infant diagnosis services by 2015.

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Appendix 4: Summary of findings from PMTCT efficacy studies

Author	Study Name	Location	Prophylaxis	MTCT risk
Connor et al., 1994	*PACTG076/ ANRS 024	United States of America and France	*Mother* AZT from 14 weeks of gestation till birth *Infant* AZT for 6 weeks (formula fed)	8.3% at 18 months-infant pair received prophylaxis as opposed to 25.5% in the placebo group
Chaisilwattana et al., 2002	Thai ZDV + 3TC trial	Thailand	*Mother* AZT and 3TC from 34 weeks of gestation *Infants* AZT for 4 weeks (formula fed)	2.8% at 18 months
Dabis et al., 2005	DITRAME/Plus ANRS 1201.1 trial	Abidjan, Cote d'Ivoure	*Mother* AZT, 3TC and sdNVP from 32 weeks of gestation up to 3 days post-delivery	4.7% at six weeks
			AZT and sdNVP from 36 weeks of gestation up to three days post-delivery	6.5% at six weeks
			Short course AZT for 36 to 38 weeks. All exposed infants in the study group received sdNVP and 1 week course of AZT and were either formula fed or exclusively breastfed	12.5% at six weeks

* Ground breaking clinical trial that paved way for the use of ARVs for PMTCT

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Appendix 5: Summary of findings from selected facility-level PMTCT effectiveness studies

Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
FACILITY-LEVEL STUDIES FROM COUNTRIES OTHER THAN NIGERIA									
Ayouba et al., 2003	Jan 2000-Dec 2002	Three HFs in Yaoundé Cameroun	Prospective Cohort Study	123 HIV exposed infants	sdNVP at onset of labour	sdNVP within 72 hours of life	[+]Overall Infants with high viral load	<13% 10.6% (95% CI, 5.1-16.0)	6 wks
Coetzee et al., 2005	Mar – Nov 2003	Three Clinics in Khayelitsha, South Africa	Cross sectional study	658 mother-infant pairs	*Prior to July 2003* AZT from 34 weeks of gestation (AZT-based protocol) *July 2003 onwards* Mothers that had < 2 weeks of AZT also received sdNVP at onset of labour (NVP-based protocol)	NVP within 72 hours	Overall AZT-based protocol NVP-based protocol Either AZT-based protocol or NVP-based protocol	8.8% (6.2-10.9) 8.8% (5.5-13.1) 7.5% (3.1-14.9) 8.4% (5.7-11.9)	Median age of 6.6 wks (IQR, 6.1–10.1)
Azcoaga-Lorenzo et al., 2011	Jan 2006-Dec 2008	Western rural Kenya (Busia Kenya) 3dispensaries 5 health centres 2 sub-district hospital	Case-control study	22,566 Tested Pregnant Women 767 HIV Exposed Infants	AZT for 4 weeks, sdNVP and AZT + 3TC OR ART	SdNVP and AZT for 7 days	Overall (after breastfeeding)	15.68% (11.6-20.1)	6 wks post weaning

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
		1mission hospital							
Torpey et al., 2012	Sep 2007 – July 2010	Five Zambian Provinces	Analysis of PCR results	28,320 HIV Exposed Infants	*Period 1 (Sep 2007 – Jan 2009)* SdNVP *Period 2 (Feb 2009 – Jul 2010)* AZT + sdNVP	sdNVP	Overall Period 1 Period 2 MP + IP MP only IP only No intervention ART AZT+ sd NVP sdNVP No intervention	12.20% 15.10% 11.0% 5.8% (5.1% – 6.5%) 10.5% (7.7% - 13.4%) 15.8% (6.9% – 24.5%) 21.8% (16.8% - 26.9%) 4.2% (3.3% - 5.1%) 6.8% (5.8% - 7.9%) 8.7% (7.1% - 10.4%) 20.1% (15.8% - 24.3%)	6 weeks
Ngemu et al., 2014	Nov 2009 – Jan 2011	Daughters of Charity of St. Vincent De Paul DREAM	Cross Sectional	50 HIV positive pregnant women and their	AZT + 3TC +NVP	NVP	Overall	10.0%	

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
		Centre in Nairobi, Kenya		exposed infants					
Moodley et al., 2013	Oct 2004 – Dec 2012	KwaZulu – Natal, South Africa	Analysis of PCR results	369,615 HIV Exposed Infants	*Period 1* Sd NVP in labour and within 72 hours of delivery *Period 2* AZT from 14 wks, sdNVP in labour and stat dose of TDF +FTC post delivery	*Period 1* sdNVP within 72 hours of delivery *Period 2* 6 wks of NVP (if not breastfed), If breastfed continue for duration of breastfeeding	sdNVP Triple regimen	27.5% (19.1 – 36.2%) 2.9% (2.8 – 3.0%)	4 -8 wks
*Sagna et al., 2015	Oct 2009 – Jun 2013	Saint Camille Medical Centre Ouagadougou Burkina	Cohort	3,215 pregnant women with less than 32	*Prophylaxis* AZT from 28 weeks, AZT + 3TC + NVP during labour, AZT/3TC		Overall MP MP + RF MP + BF ART+RF	0.52% 1.75% 1.09% 4.55% 0.00%	6 months

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
		Faso		weeks of amenorrhea	first week post-partum				
				394 HIV positive pregnant women	*ART* AZT+3TC or d4T +3TC + NVP or LPV/r or IDV/r				
				388 HIV Exposed Infants					
NIGERIA'S FACILITY-LEVEL STUDIES									
Agboghoroma, Audu and Iregbu, 2015	Jan 2006 – Dec 2008	National Hospital, Abuja	Retrospective Cohort Study	643 pregnant women 247 HIV Exposed Infants	Prophylaxis Sd‑NVP in labor AZT + 3TC for 7 days postpartum *ART* AZT+3TC+NVP or LPV/r or IDV/r or SQV/r	sdNVP + AZT for 6 weeks	Overall Triple Regimen Intrapartum NVP ECSD Vaginal Delivery EBF MF RF	2.4% 1.3% 37.5% 1.6% 5.5% 12.5% ++0.0% 2.1%	6 weeks
Chama, Gashau, & Oguche, 2007	2007	University of Maiduguri Teaching Hospital, Nigeria	Cohort Study	5,461 tested pregnant women	*Prophylaxis* sdNVP in labour *ART* d4T+3TC+NVP	sdNVP within 72 hours of delivery	sdNVP ART ART+ECSD+RF	33.3% 9.1% 0.0%	
**Chama et al., 2010	2010			695 HIV-	ART	sdNVP within 72	Overall	1.1%	≥6 months

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
				positive pregnant women 446 mother-infant pairs		hours of delivery and AZT for 6 weeks			
Afe et al., 2011	Feb 2007 - Feb 2008	6 HFs in Lagos Nigeria	A review of DNA PCR result of HEIs	733 HIV exposed infants			Overall MP or mART only	22.5% 9.6%	
Audu et al.,2014	Feb 2007 - Oct 2008	6 Health Facilities in Lagos State	Analysis of EID Data	1,273 HIV Exposed Infants			Overall Range across health facilities At age 48-72 wks	22.0% 7.1%-38.4% 41.1%	12.6 wks (1 day - 71.6 wks)
Anoje et al., 2012	Nov 2007 - Jul 2009	6 HF in Cross River and Akwa Ibom States Nigeria	Review of Early Infant Diagnosis (EID) records	702 HIV Exposed Infants	*Prophylaxis* AZT from 28 weeks OR AZT + 3TC from 33 weeks sd NVP in labour *ART* AZT or d4T + 3TC + NVP or EFV	sd NVP within 72 hours and AZT for 6 weeks	MP or mART + IP No interventio n	4.8% (1.3- 8.3) 19.5% (3.0- 35.5)	13 weeks IQR 6.5 - 30.5

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
Esene & Omoigberale, 2012	Jan-Dec 2009	University of Benin Teaching Hospital, Nigeria	Retrospective Cohort Study	298 HIV Exposed Infants	ART		Overall	2.1%	13.6±12.7 wks
***Okafor et al., 2014	Jan 2009 – Dec 2011	Enugu State University Teaching Hospital, Nigeria	Cohort Study	5,946 ANC Attendees 184 HIV Exposed Infants	*ART* AZT + ETC +NVP or EFV OR TDF+3TC +EFV	NVP or AZT for 6 wks	Overall	$^{+++}$0.0%	6 wks and 18 months
Inalegwu et al., 2016	Jan 2008-Dec 2012	150 health facilities	Analysis of EID data	32,552 DBS test samples Number of samples tested (Accepted samples tested) = 31,766 Number of rejected samples			Accepted Samples Tested	9.8%	17.83 wks Standard Deviation (SD)= 15.29; 95%CI: 17.65-18.01)
							Rejected Samples Tested	15.9%	20.30 wks (SD = 14.31; 95%CI: 16.53-24.06)

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
				re-tested (Repeat samples tested) = 69					
Isah et al, 2016	2008 - 2012	University of Nigeria Teaching Hospital	Retrospective review	373 HIV positive pregnant women 367 HIV Exposed Infants	AZT/3TC/NVP, TDF/3TC+NVP and AZT/3TC+EFV	NVP and AZT	Overall	2.2%	6 weeks
Aliyu et al., 2014	2009-2012	Four secondary level facilities, namely: Sobi Specialist Hospital and Lafiagi General Hospital in Kwara state as well as Gawu Babangida Rural Hospital and	Observational study: retrospective review of routine data	712 HIV-infected pregnant women 357 HIV Exposed Infants	Option A or triple regimen ART AZT+3TC+NVP or 2 new NRTIs + LPV/r	NVP for 6 wks	Overall	****11.0%	17 wks (9-34 wks)

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk			Age of Testing
					Mother	Infant				
		Umaru Yar Adua Memorial Hospital in Niger State								
*****Marks on & Umoh, 2012	Jan - Dec 2010	General Hospital Oron, Akwa Ibom state, Nigeria	Cross Sectional Descriptive	2,632 First ANC Attendees 398 HIV positive pregnant women 398 HIV Exposed Infants			Overall	4.0%		18 months
Sagay et al., 2015	2010-2012	Jos University Teaching Hospital, Nigeria	Retrospective Observational Study	996 HIV Exposed Infants	Option B		Overall mART or MP (triple regimen) before pregnancy mART (triple regimen) during pregnancy	0.7% 0.4% 2.0%	P=0.05	18 months

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk			Age of Testing
					Mother	Infant				
							or delivery			
Ikechebelu et al., 2011	1 year		Prospective Descriptive Study	726 mother-infant pairs			mART+ IP + RF	2.8%	p<0.01	
							mART+ IP +IB	12.5%		
							No intervention + RF	21.1%	p<0.02	
							No intervention + IB	37.5%		
Kalu et al., 2014	Jan 2012 - Feb 2013	Nnamdi Azikiwe University Teaching Hospital, Nnewi Southeast Nigeria	Prospective Cohort Study	583 mother-infant pair	ART or Option B PMTCT		Overall	3.3% (2.0, 5.0)		6 weeks - >6 months
							MP or mART +IP+RF	0.8%		
							MP or mART +IP+EBF	1.7%		
							MP or mART +IP+MF	5.9%		
							No intervention + RF	5.1%		
							No intervention +EBF	6.7%		
							No interventio	23.5%		

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Authors name	Study Period	Study Site	Methodology	Sample Size	PMTCT/ART Regimen		MTCT Risk		Age of Testing
					Mother	Infant			
							n + MF		
Chukwuemeka et al., 2014	Jan 2011 - Dec 2012	National Hospital Abuja, Nigeria	Retrospective review of EID records of exposed infants	515 HIV Exposed Infants		sd NVP at birth AZT for 6 weeks	MP or mART + IP	1.30%	Mean age of 4 months
							MP or mART only	4.60%	
							IP only	20.0%	
							No intervention	66.7%	
Ben & Yusuf, 2014	Jan 2011 - Dec 2012	Usman Danfodio University Teaching Hospital, Sokoto, Nigeria	Cross Sectional Study	163 HIV Exposed Infants	*ART* AZT+3TC+NVP or EFV	sdNVP within 72 hours of birth and continued for 6 wks	Overall ART	1.8%	6-8 weeks
							Before Pregnancy ART	0.0%	
							During Pregnancy ART	1.6%	
							No intervention	16.7%	
							EBF	0.7%	
							MF	8.7%	

[+]Irrespective of viral load; [++]only one infant in the study was mixed fed, [+++]Mothers had ≥4 months of ART 2 infants died in utero and hence their HIV status could not be determined while 4 infants that tested HIV negative at 6 weeks also died the age of 18 months; *Maternal HIV positivity rate (MHP) =12.3%; **MHP=12.7%; *** MHP=3.7%; ****67 Results were missing,*****MHP= 15.1%, HIV Counselling and Testing Uptake = 99.2%; Overall represents MTCT risk in the entire study group irrespective of intervention; 3TC, Lamivudine; ART,

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Antiretroviral Therapy; AZT, Zidovudine; BF, Breastfeeding; CI, Confidence Interval; d4T, Stavudine; EBF, Exclusive Breast Feeding; ECSD, Elective Caesarian Section Delivery; FTC, Emtricitabine; HF, Health Facility; IB, Infant Breastfed; IDV/r, Indinavir/ritonavir; IP, Infant ARV Prophylaxis; LPV/r, Lopinavir/ritonavir; mART, maternal Antiretroviral Therapy; MF, Mixed Feeding; MP, Maternal ARV Prophylaxis; NVP, Nevirapine; sdNVP, single dose, Nevirapine; RF, Replacement Feeding; TDF, Tenofovir; wks, Weeks

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Appendix 6: Information to be extracted for HIV positive pregnant women and HEIs

Tool	Data Elements	Source	Location
Data Collection Tool 1	Aggregate count of pregnant women that attended ANC for the first time in the most recent pregnancy by month	ANC Register	ANC Clinic
	Aggregate count of pregnant women that tested for HIV during the first ANC visit by month	PMTCT/HTC register	ANC Clinic
	HIV positive pregnant mother's age, gestation age, gravida, parity, marital status, educational level and occupational status	ANC register For marital status, educational level and occupational status check adult initial clinical evaluation form present in the patient's folder	ANC clinic/ Patient Monitoring and Management Unit
Data Collection Tool 2:	Acceptance/non-acceptance of prophylaxis/ART and the type of ARV used	PMTCT/HTC register (if unavailable, use hospital number as a guide and check Pharmacy daily worksheet OR patient folder)	ANC clinic Pharmacy Department Patient Monitoring and Management Unit
Data Collection Tool 3:	Age of the infant, receipt or non-receipt of maternal/infant prophylaxis and the ARV used, infant feeding option, outcome of HIV test	EID register/infant follow up register HIV PCR request and result forms	Pediatric Unit

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Appendix 7: Data collection tool 1 for data abstraction

Data elements	Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	…	Dec-14
Aggregate count of pregnant women that attended ANC for the first time in the most recent pregnancy by month											
Aggregate count of pregnant women that tested for HIV during the first ANC visit by month											
Aggregate count of first ANC attendees that accepted HIV testing that tested HIV positive by month											

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Appendix 8: Data collection tool 2 for data abstraction

			Unique Identification number									
S/N	**Data Elements**		1	2	3	4	5	6	7	8	9	10
1	Age in years *(insert 99 for missing record)*											
2	Gestation Age in weeks *(insert 99 for missing record)*											
3	Gravida (*insert 99 for missing record)*											
4	Parity *(insert 99 for missing record)*											
5	Marital Status	Single (1)										
		Married (2)										
		Widowed (3)										
		Separated (4)										
		Divorced (5)										
		Missing (6)										
6	Educational Level	None (1)										
		Primary (2)										
		Senior Secondary (3)										
		Qur'anic (4)										
		Junior Secondary (5)										
		Post-Secondary (6)										
		Missing (7)										
7	Occupational Status	Unemployed (1)										
		Employed (2)										

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			Unique Identification number									
S/N	**Data Elements**		1	2	3	4	5	6	7	8	9	10
		Student (3)										
		Retired (4)										
		Missing (5)										
8	Received ARV	Yes (1)										
		No (2)										
		Missing (3)										
9	Type of ARV received	ART (1)										
		Triple (ARVP) (2)										
		AZT/3TC (3)										
		AZT (4)										
		Sd NVP (5)										
		Missing (6)										

- Data Elements 1-4 to be extracted from General ANC Register
- Data Elements 5-7 to be extracted from adult initial clinical evaluation form present in the patient folder
- Data element 8 and 9 to be extracted from PMTCT/HTC register if available, if not, it will be extracted from Pharmacy daily worksheet or Patient's folder

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Appendix 9: Data collection tool 3 for data abstraction

Data Elements		Unique identification number									
		1	2	3	4	5	6	7	8	9	10
Month/Year of Sample Collection											
Age in weeks *(insert 99 for missing record)*											
Reason for PCR	1st test for HEI (1)										
	1st test for sick infant (2)										
	Repeat 6 weeks post cessation of breastfeeding (3)										
	Prob with 1st test (4)										
	Confirmation of 1st test (5)										
	Missing (6)										
Result of rapid test for ≥ 9 months	Negative (1)										
	Positive (2)										
	Indeterminate (3)										
	Missing (4)										
ART During pregnancy	Yes (1)										
	No (2)										
	Missing (3)										
Time of	During (1)										

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Data Elements		Unique identification number									
		1	2	3	4	5	6	7	8	9	10
commencement if yes	After (2)										
	Missing (3)										
Received ARV prophylaxis	Yes (1)										
	No (2)										
	Missing (3)										
If Yes Type of ARV received	AZT+3TC+sdNVP in labour (1)										
	AZT+sdNVP in labour (2)										
	sdNVP in labour (3)										
	Triple Regimen ARVP (4)										
	Unknown (5)										
	Missing (6)										
Intervention received by infant	Yes (1)										
	No (2)										
	Missing (3)										
If Yes Type of ARV	AZT+sdNVP (1)										
	NVP (2)										
	Unknown (3)										
	Missing (4)										
Infant ever breastfed	Yes (1)										
	No (2)										

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Data Elements		Unique identification number									
		1	2	3	4	5	6	7	8	9	10
	Unknown (3)										
	Missing (4)										
Breastfeeding now	Yes (1)										
	No (2)										
	Unknown (3)										
	Missing (4)										
Breastfeeding option	Exclusively breast fed (1)										
	Mixed fed (2)										
	Not breastfed (3)										
	Missing (4)										
Age at breastfeeding cessation in months *(insert 99 for missing record)*											
CTX given to infant	No (1)										
	Yes takes daily (2)										
	Yes starts today (3)										
	Missing (4)										
PCR Test Result	Positive (1)										
	Negative (2)										
	Missing (3)										
Date Specimen Collected dd/mm/yy (*insert 00/00/00 for missing record)*											

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Data Elements		Unique identification number									
		1	2	3	4	5	6	7	8	9	10
Date test result received at facility dd/mm/yy (*insert 00/00/00 for missing record)*											
Age in months (2nd PCR Test) *(insert 99 for missing record)*											
Result of rapid test (2nd PCR Test)	Positive (1)										
	Negative (2)										
	Missing (3)										
PCR Test Result (2nd PCR Test)	Positive (1)										
	Negative (2)										
	Missing (3)										
Date Specimen Collected dd/mm/yy (2nd PCR Test) (*insert 00/00/00 for missing record)*											
Date test result received at facility dd/mm/yy (2nd PCR Test) (*insert 00/00/00 for missing record)*											

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- Information contained in the data collection tool is to be extracted from EID/Infant follow up register/PCR Request and Result form

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Appendix 10: Data analysis plan

Uptake of HTC, Antenatal HIV prevalence			
Total number of first ANC attendees	A		
Total number that accepted HTC	B	B/A %	*Uptake of HTC*
Total number that tested HIV positive	C	C/B %	*Antenatal HIV prevalence*
Baseline Characteristics of HIV Positive Pregnant women by Hospital			
Age			
15-24	(n)%		
25-34	(n)%		
35-44	(n)%		
45 and above	(n)%		
Missing	(n)%		
Gestation Age			
<14 weeks	(n)%		
14 -27 weeks (2nd Trimester)	(n)%		
28 weeks and above (3rd Trimester)	(n)%		
Missing	(n)%		
Gravida			
0-4	(n)%		
>4	(n)%		
Missing	(n)%		
Parity			
0-4	(n)%		
>4	(n)%		
Missing	(n)%		
Marital Status			
Single	(n)%		
Married	(n)%		
Widowed	(n)%		
Separated	(n)%		
Divorced	(n)%		
Missing	(n)%		
Educational Level			
None	(n)%		
Primary	(n)%		
Junior Secondary	(n)%		

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Senior Secondary	(n)%		
Post-Secondary	(n)%		
Qur'anic	(n)%		
Post-Secondary	(n)%		
Missing	(n)%		
Occupational Status			
Unemployed	(n)%		
Employed	(n)%		
Student	(n)%		
Missing	(n)%		
n=number			
Uptake of ART/ARV prophylaxis among **HIV positive pregnant women**			
Total number of HIV positive pregnant women that received ARV prophylaxis or ART	D	D/C %	*Uptake of ART/ARV prophylaxis*
Types of ARVs used by HIV positive pregnant women that received ART or ARVP			
sdNVP	(n)%		
AZT	(n)%		
AZT/3TC	(n)%		
AZT+3TC+sdNVP	(n)%		
Triple Regimen (ARVP)	(n)%		
ART	(n)%		
Missing	(n)%		
A, B, C, D are variables			
Association between Age, Parity, Gestation Age, Marital status, Educational level and Occupational status and ART/ARV prophylaxis uptake			
Age	*15-24		Estimate Odds Ratio (OR), Adjusted OR with associated p-values
	25-34		
	35-44		
	45 and above		
Gestation Age	*<14 weeks		
	14 -27 weeks		
	28 weeks and above		
Gravida	*0-4		
	>4		
Marital Status			
	*Single, Widowed, Separated, Divorced		
	Married		
Educational Level			
	*None		

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	Primary
	Qur'anic
	Secondary
	Post-Secondary
Occupational Status	
	*Unemployed
	Employed
	Student
Hospital	
	*FMC Yola
	SH Yola
Year	
	*2008
	2009
	2010
	2011
	2012
	2013
	2014
**reference*	
Baseline characteristics and prophylaxis status for HIV exposed infants/HIV outcome in HEI and average turnaround time	
Gender	
Male	(n) %
Female	(n) %
Age	
≤6 weeks	(n) %
>6 weeks to 2 months	(n) %
>2months – 6 months	(n) %
>6 - 12 months	(n) %
>12 months	(n) %
Missing	(n) %
Infant Feeding Option	
Exclusive breastfeeding	(n)%
Not Breastfed or Replacement feeding	(n)%
Mixed feeding	(n)%
Missing	(n)%
Reason for PCR	
First test for healthy HEIs	(n)%

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First test for sick infant	(n)%		
Problem with first test	(n)%		
Maternal ARVs			
ART	(n)%		
ARVP	(n)%		
ART or Triple Regimen	(n)%		
None	(n)%		
Missing	(n)%		
Type of Maternal ARVP			
AZT + 3TC and sdNVP	(n)%		
AZT and sdNVP in labour	(n)%		
Triple Regimen	(n)%		
sdNVP	(n)%		
Unknown	(n)%		
Missing	(n)%		
Infant ARVs			
sdNVP at birth	(n)%		
sdNVP at birth and AZT for 4 weeks	(n)%		
NVP for 6 weeks	(n)%		
Unknown	(n)%		
None	(n)%		
Missing (ARV Type)	(n)%		
Missing (Prophylaxis use)	(n)%		
HIV outcome			
Positive	(n)%		
Negative	(n)%		
Overall MTCT risk	(n)%		
Median Turnaround Time with IQR	x days		
x=variable			
MTCT risk by receipt of ART/ARV and breastfeeding option (Estimate 95% CI)			
	n (MTCT risk)	95% CI Lower band	95% CI Upper band
Age			
≤6 weeks			
>6 weeks to 2 months			
>2months – 6 months			
>6 - 12 months			
>12 months			
Missing			

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Infant feeding Option			
Exclusive breastfeeding			
Mixed feeding			
Not Breastfed or Replacement feeding			
Missing			
Receipt of ART/ARV			
Both Mother and Infant			
Mother alone			
Infant alone			
Neither mother or infant			
PMTCT Protocol Period			
January 2008 – January 2010 (Period 1)			
February 2010 – May 2012- Transitional period			
June 2012-December 2014 – Period 2			
Simple and Multiple Logistics Regression Analysis			
Gender		Estimate Odds Ratio (OR), Adjusted OR with associated p-values	
	*Male		
	Female		
Age			
	*≤6 weeks		
	>6 weeks to 2 months		
	>2months – 6 months		
	>6 - 12 months		
	>12 months		
Infant feeding Option			
	*Not Breastfed/Replacement Feeding		
	Exclusively Breastfed		
	Mixed fed		
Receipt of ART/ARV			
	*Both Mother and Infant		
	Mother alone		
	Infant alone		
	Neither mother or infant		
Hospital			

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	*FMC Yola	
	SH Yola	
Year	*2008	
	2009	
	2010	
	2011	
	2012	
	2013	
	2014	
*reference		

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Appendix 11 Ethics approval from the University of the Western Cape

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT

08 September 2015

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by:
Mr AJ Itiola (School of Public Health)

Research Project:	Evaluation of the effectiveness of prevention of mother to child transmission of HIV (PMTCT) interventions in two selected health facilities in Adamawa State, Nigeria.
Registration no:	15/6/24

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

Private Bag X17, Bellville 7535, South Africa
T: +27 21 959 2988/2948 . F: +27 21 959 3170
E: pjosias@uwc.ac.za
www.uwc.ac.za

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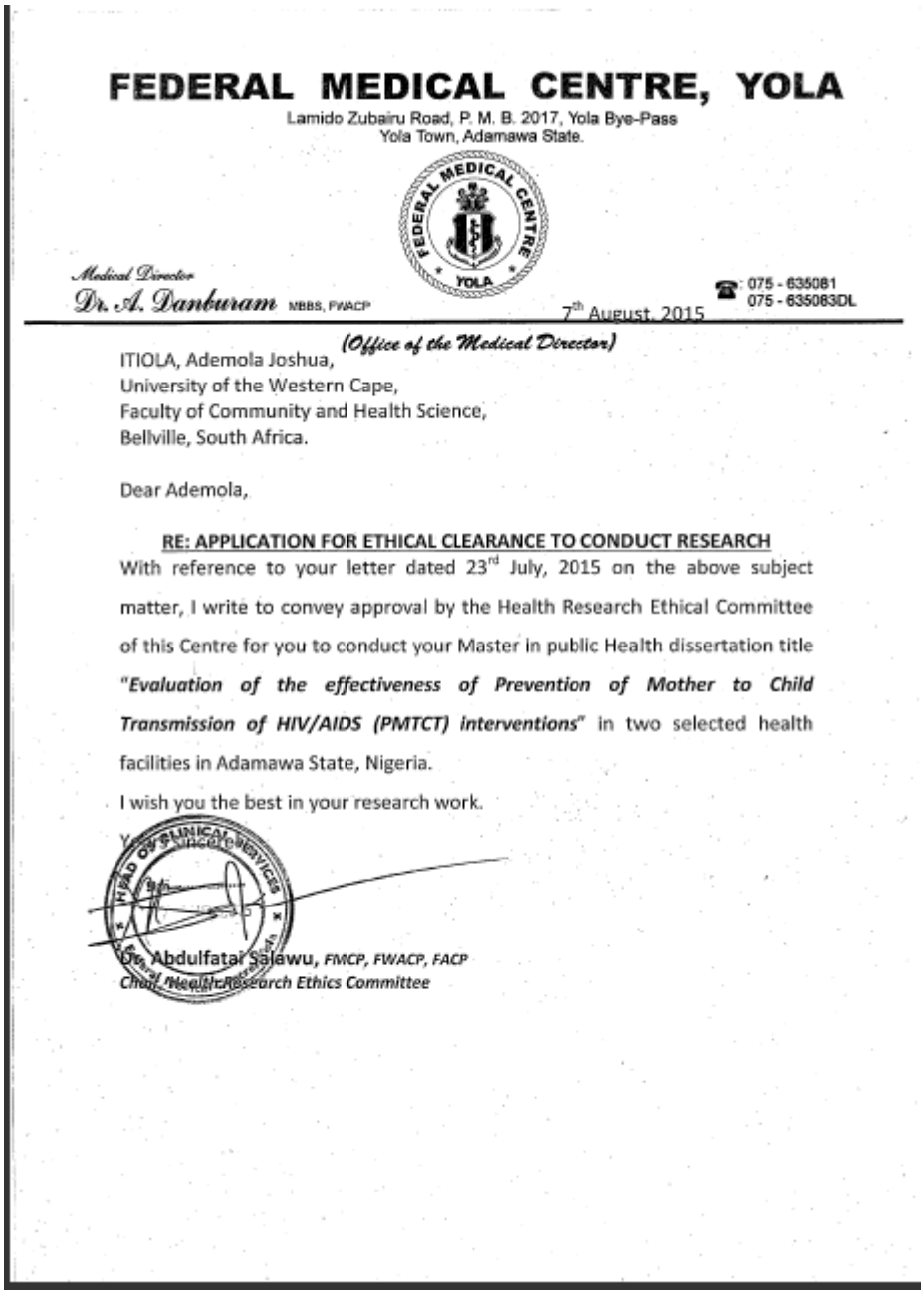
Appendix 12: Ethics approval for Federal Medical Centre Yola



FEDERAL MEDICAL CENTRE, YOLA

Lamido Zubairu Road, P. M. B. 2017, Yola Bye-Pass
Yola Town, Adamawa State.

Medical Director
Dr. A. Danburam MBBS, FWACP

☎ 075 - 635081
075 - 635083DL

7th August, 2015

(Office of the Medical Director)

ITIOLA, Ademola Joshua,
University of the Western Cape,
Faculty of Community and Health Science,
Bellville, South Africa.

Dear Ademola,

RE: APPLICATION FOR ETHICAL CLEARANCE TO CONDUCT RESEARCH

With reference to your letter dated 23rd July, 2015 on the above subject matter, I write to convey approval by the Health Research Ethical Committee of this Centre for you to conduct your Master in public Health dissertation title ***"Evaluation of the effectiveness of Prevention of Mother to Child Transmission of HIV/AIDS (PMTCT) interventions"*** in two selected health facilities in Adamawa State, Nigeria.

I wish you the best in your research work.

Y...

Dr. Abdulfatai Salawu, *FMCP, FWACP, FACP*
Chief Health Research Ethics Committee

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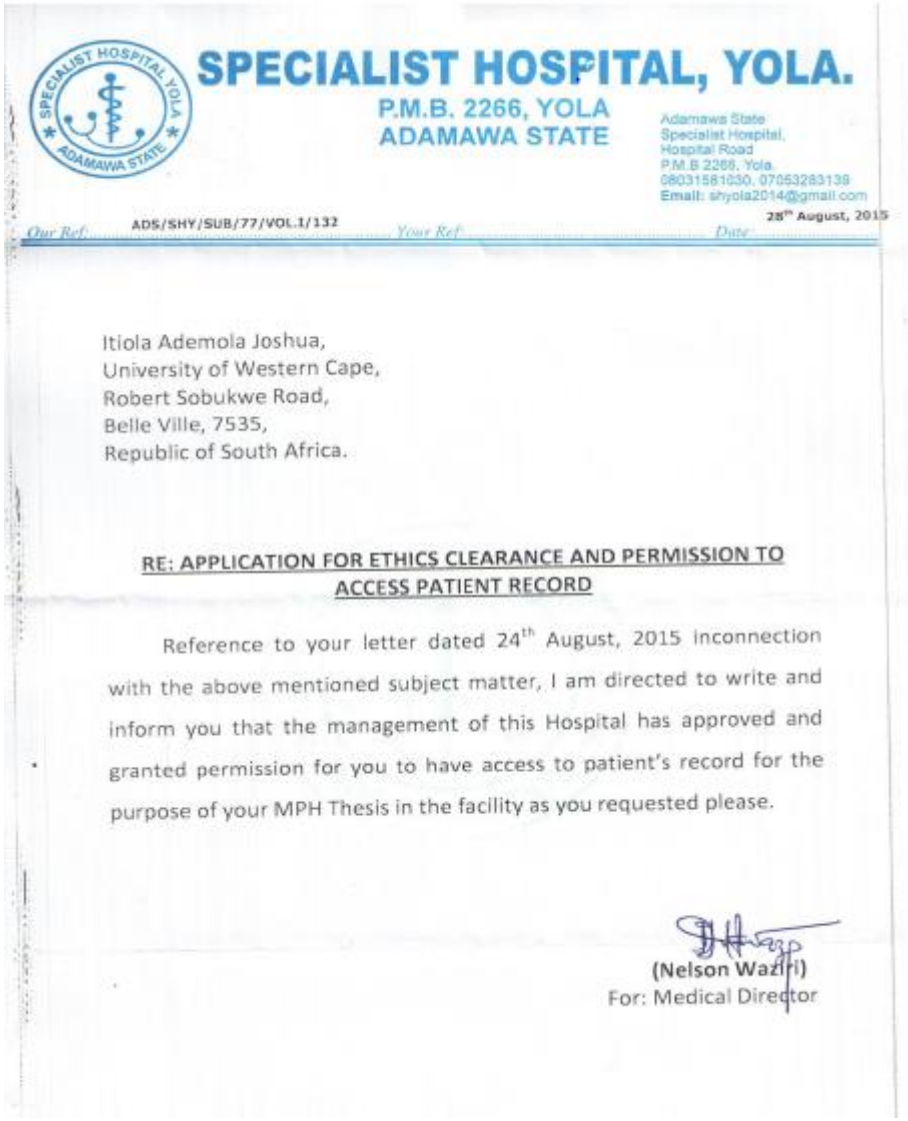
Appendix 13: Ethics approval for Specialist Hospital Yola



SPECIALIST HOSPITAL, YOLA.
P.M.B. 2266, YOLA
ADAMAWA STATE

Adamawa State Specialist Hospital, Hospital Road P.M.B 2266, Yola. 08031561030, 07053283139 Email: shyola2014@gmail.com

Our Ref: ADS/SHY/SUB/77/VOL.1/132 Your Ref: Date: 28th August, 2015

Itiola Ademola Joshua,
University of Western Cape,
Robert Sobukwe Road,
Belle Ville, 7535,
Republic of South Africa.

RE: APPLICATION FOR ETHICS CLEARANCE AND PERMISSION TO ACCESS PATIENT RECORD

Reference to your letter dated 24th August, 2015 inconnection with the above mentioned subject matter, I am directed to write and inform you that the management of this Hospital has approved and granted permission for you to have access to patient's record for the purpose of your MPH Thesis in the facility as you requested please.

(Nelson Wazri)
For: Medical Director

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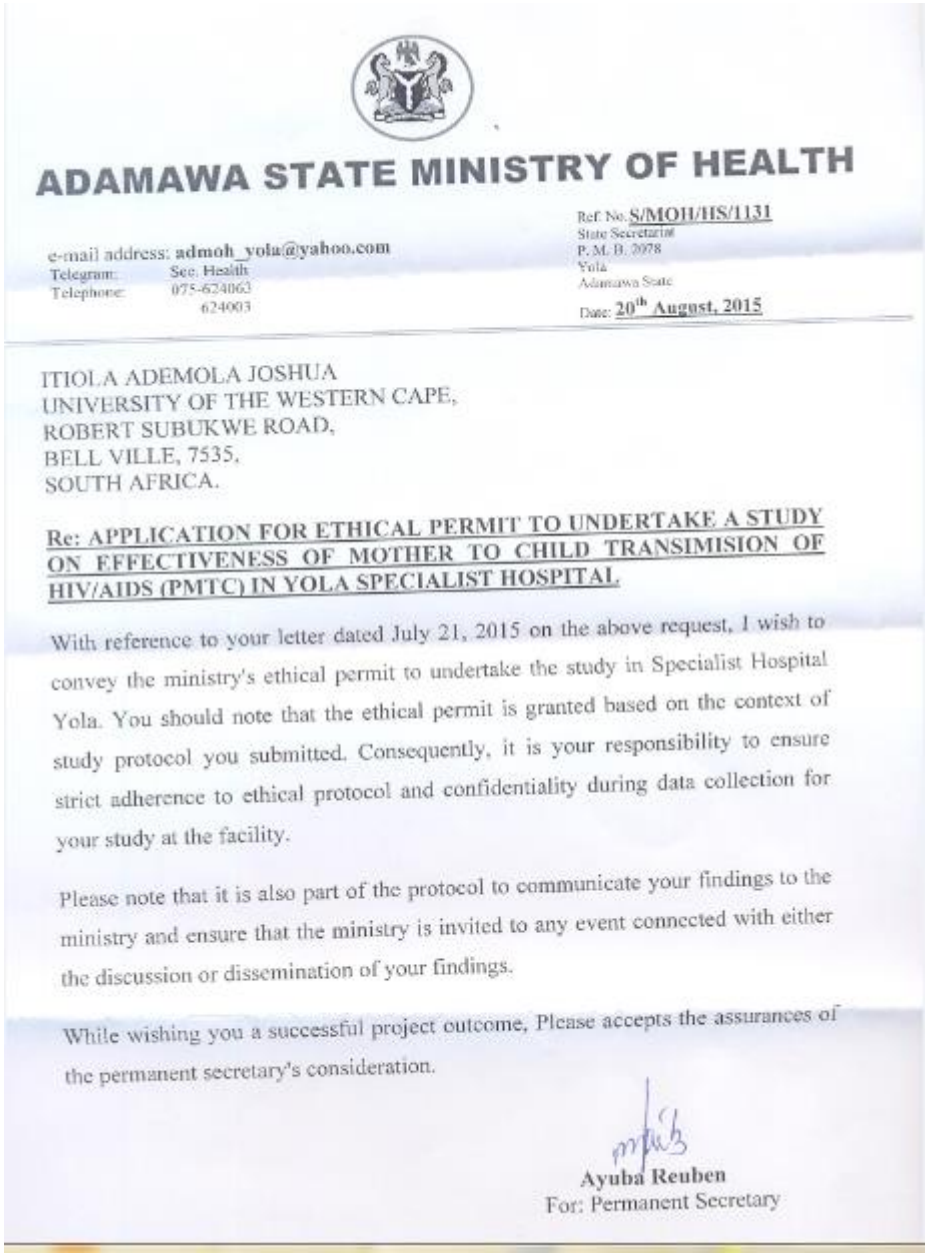
Appendix 14: Ethics approval from Adamawa State Ministry of Health



ADAMAWA STATE MINISTRY OF HEALTH

e-mail address: admoh_yola@yahoo.com
Telegram: Sec. Health
Telephone: 075-624063
624003

Ref. No. S/MOH/HS/1131
State Secretariat
P. M. B. 2078
Yola
Adamawa State
Date: 20th August, 2015

ITIOLA ADEMOLA JOSHUA
UNIVERSITY OF THE WESTERN CAPE,
ROBERT SUBUKWE ROAD,
BELL VILLE, 7535,
SOUTH AFRICA.

Re: APPLICATION FOR ETHICAL PERMIT TO UNDERTAKE A STUDY ON EFFECTIVENESS OF MOTHER TO CHILD TRANSIMISION OF HIV/AIDS (PMTC) IN YOLA SPECIALIST HOSPITAL

With reference to your letter dated July 21, 2015 on the above request, I wish to convey the ministry's ethical permit to undertake the study in Specialist Hospital Yola. You should note that the ethical permit is granted based on the context of study protocol you submitted. Consequently, it is your responsibility to ensure strict adherence to ethical protocol and confidentiality during data collection for your study at the facility.

Please note that it is also part of the protocol to communicate your findings to the ministry and ensure that the ministry is invited to any event connected with either the discussion or dissemination of your findings.

While wishing you a successful project outcome, Please accepts the assurances of the permanent secretary's consideration.

Ayuba Reuben
For: Permanent Secretary

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