DETERMINANTS OF HIV TRANSMISSION AMONG CHILDREN BORN TO HIV-INFECTED MOTHERS ON PMTCT PROGRAM IN KILIFI COUNTY: A CASE CONTROL STUDY

BY

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DECLARATION

I declare that this is my original academic work and it has not been presented elsewhere for approval and examination.

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DEDICATION

Dedicated to Allah for His continuous blessings in my life and to my mother Aisha Abdullahi and my loving husband Ibrahim Hussein for their tremendous support and encouragement without whom none of this would be possible.

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All glory and honor be to God.

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ABBREVIATIONS

ANC – Antenatal Clinic

ART – Antiretroviral Therapy

CASCO – County Aids and STI Coordinator

DHIS – District Health Information System

DRC – Democratic Republic of Congo

EMTCT – Elimination of Mother To Child Transmission

HAART – Highly Active Antiretroviral Therapy

HEI – HIV Exposed Infant

HIV – Human Immunodeficiency Virus

HRIO – Health Records Information Officer

MTCT – Mother to Child Transmission

NACC – National AIDS Control Council

NASCOP – National Aids and STI Control Program

PCR – Polymerase Chain Reaction

PMTCT – Prevention of Mother to Child Transmission

SCASCO – Sub County Aids and STI Coordinator

STI – Sexually Transmitted Infections

UNAIDS – Joint United Nations Program on HIV

SPSS – Statistical Package for the Social Sciences

UNITID – University of Nairobi Institute of Tropical & Infectious Diseases

UON – University of Nairobi

WHO – World Health Organization

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ABSTRACT

BACKGROUND: Globally, mother to child elimination and prevention of human immunodeficiency virus transmission remains a public health concern. The transmission rate is still high especially in sub Saharan countries despite introduction of antiretroviral therapy to breastfeeding mothers and all HIV-positive pregnant women. Identification of significant risk factors of mother to child transmission is essential and might reduce the burden of pediatric HIV in terms of cost of treatment, morbidity and mortality.

OBJECTIVE: To determine maternal risk factors related to HIV transmission among children born to HIV-infected mothers enrolled in PMTCT program in Kilifi County between July 2018 and June 2019

METHODS: This was a retrospective unmatched case control study covering a period of 1 year. Systematic random sampling was used to select medical records of 183 exposed infants (61 cases and 122controls) with cases defined as HIV-positive mother enrolled in the PMTCT program with a confirmed HIV-positive infant and controls as HIV-positive mother enrolled in PMTCT program with a confirmed HIV-negative infant. Data on maternal and infant socio-demographic and exposure related factors was collected by use of a structured tool. Analysis was done using MS Excel and SPSS version 21. Proportions and frequency distribution was done in univariate analysis. In bivariate analysis, chi-square and logistic regression (odds ratio) was used to determine any association between categorical variables and to estimate the strength between exposure and outcome variable.

RESULTS: The study showed a relationship between ANC attendance of the mothers and outcome of their infants' HIV status. Majority of mothers (88%) to all infants sampled in the study had attended ANC at least once. All the mothers who had a HIV negative infant had attended ANC while 33% of those who had a HIV positive infant did not attend ANC. Knowledge of mother's HIV status and outcome of their infants was not different between the cases and the control group. Majority of the mothers (95%) knew their HIV status prior to attending ANC. Seventy five (75%) of all the mothers had received Maternal HAART. Of the mothers who had a HIV positive infant 62% did not receive maternal HAART while of those who had a HIV negative infant only 3% did

not receive maternal HAART. 82% of the mothers who were studied delivered at a health facility compared to 18% who delivered at home. 42% of the infants who tested HIV positive were delivered at home. Only 3% of the infants who were confirmed to be negative were delivered at home. Only 4 of the infants enrolled into the study did not receive ART prophylaxis and cotrimoxazole. For the infants who received ART prophylaxis, 88% received both NVP and AZT while 12% received only NVP. Out of the infants who tested HIV positive, 91% were on both NVP and AZT while 9% were on NVP alone. For those who tested HIV negative, 87% were on NVP and AZT while 13% were on NVP alone.

CONCLUSION: The study established the importance of PMTCT service delivery in reduction of vertical transmission of HIV. ANC attendance, early diagnosis of maternal HIV, prompt initiation and adherence to HAART, skilled delivery of the HIV positive pregnant woman were all associated with reduction of mother to child transmission rate. Women who defaulted on the PMTCT cascade services had higher odds of having a HIV positive infant compared to women who accessed all the PMTCT services at the recommended time.

CHAPTER 1: INTRODUCTION

Among all age groups, Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) is a lifelong disease with significant morbidity and mortality. Globally, over 38 million people in 2018 were living with HIV/AIDS, with two-thirds of this population and 2.1 million children below 15 years residing in Sub-Saharan Africa (WHO, 2019). Approximately 75 million people worldwide have become infected with 32 million people having been reported to die due to AIDS related illnesses since the beginning of the epidemic. Out of these, 770,000 died in 2018. However, the number of deaths has significantly reduced since 2004 from the peak of 1.7 million to 1.4 million reported in 2010 (UNAIDS, 2019).

New HIV infections among children less than 15 years old have globally reduced (47%) from 280,000 in 2010 to 160,000 in 2018, which reflects a 42.9% reduction (WHO, 2018; UNAIDS, 2017). Approximately 1% of pregnant women worldwide are HIV infected. In 2015, 1.4 million women of reproductive age living with HIV became pregnant and majority were from sub-Saharan Africa (UNAIDS, 2018). HIV transmission from an infected mother to her child i.e. vertical transmission may occur during pregnancy, childbirth or while breastfeeding (Gunn *et al.*, 2016). More than 90% of the mother to child HIV transmission cases are due to vertical transmission (Tsehay, 2019; WHO, 2018). This transmission can entirely be eliminated. However, this has proved to be a challenge, especially in some of the 22 priority countries listed by the Global Plan to accelerate efforts in prevention of transmission (PMTCT) of HIV and syphilis among the newborns from the mother (Goga *et al.*, 2019; UNAIDS, 2018; WHO, 2017). In 2015, six African countries (Botswana, Mozambique, Namibia, South Africa, Swaziland and Uganda) listed among the priority countries met the 90% target of reducing mother to child transmission. Cuba, in mid-2015, was the first country to eliminate MTCT. Similar achievements were noted in the Asia and pacific region of Thailand in 2016, with Belarus and Armenia reporting less than 5% transmission rate (Alachew *et al.*, 2019). Kenya is among the sub-Saharan Africa countries most affected by HIV/AIDS pandemic, with at least 2 million adults living with HIV/AIDS. In 2017, it was reported that there were110,000 children living with HIV and 8,000 new infections, with a reduction from 25,000 to 13,000 in 2005 and 2010 respectively. In addition, 54,000 HIV positive mothers were on PMTCT program and 76% had access to antiretroviral treatment (ART), which was

significantly higher compared to 2010 (56%) (UNAIDS, 2018). Much has been done in elimination of mother to child transmission (e-MTCT) reducing new infections and increasing access to ART among pregnant women. This is due to adoption and implementation of United Nations four-pronged strategy for PMTCT (UNAIDS, 2017; NASCOP, 2018b). Kenya, which is among the 22 priority countries listed, has made tremendous efforts, which have seen the mother to child transmission rate of HIV infection reduce from 16% in 2013 to 8.3% in 2015 (Waruru *et al.*, 2018). However, this success was short-lived as the MTCT rate increased to 11.5% by 2017 and up to 12.4% by 2018 (NASCOP, 2018b). Kenya adopted the Global Plan and formulated the Kenya Framework for EMTC transmission 2016-2021 to give the country strategic guidance on validation of goals for elimination of mother to child transmission by 2021 (NASCOP, 2019). To realize this dream, Kenya has to achieve more than 95% on each of the process indicators depicted on the PMTCT cascade (NASCOP, 2018b). In previous studies conducted in sub-Saharan African countries including Kenya, to investigate the possible determinants of vertical transmission of HIV infection among HIV positive mothers, only a few demonstrated the importance of the PMTCT cascade, including the indicators, and how missing one of the crucial steps of the cascade could increase the risk of HIV transmission from the mother to the infant (Dionne-Odom *et al.*, 2016). Kilifi, a rural-urban county in the coastal region of Kenya has a HIV prevalence of 4.4%. It is one of the counties identified in the Kenya framework for elimination of mother to child transmission (2016-2021) due to the upward increase in MTCT rate from 7.7% (2015) to 8.3% (2018) (National AIDS Control Council, 2020; NASCOP, 2019). During the financial year 2018-2019, Kilifi County had a total of 62 HIV-exposed infants who were confirmed to be HIV infected despite many efforts geared to reverse the incidence of pediatric HIV. Due to this, the county has set up several innovative ways to improve key PMTCT indicators and despite laudable progress, the county's goal to eliminate HIV remains unaccomplished. The worrying numbers show a default in the PMTCT cascade by the HIV positive women.

This study, will aim to determine the risk factors associated with the outcomes of HIV exposed infants with the uptake of PMTCT indicators among the HIV-positive mothers based on the hypothesis that HIV exposed infants who become HIV infected are born to HIV positive women who default on the PMTCT cascade.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

PMTCT is said to be successful when a HIV positive mother enrolled in a PMTCT service delivery point gives birth to an infant who has a definitive HIV negative test result (Spensley *et al.*, 2009). This usually requires a series of sequential steps which start with identification of the HIV positive mother at the Antenatal clinic (ANC). For many women in Kenya, ANC provides an opportunity for HIV health education, counselling and testing. PMTCT is demystified at this point where a HIV positive mother is educated on the very likely possibility of having a baby free from HIV (Kei *et al.*, 2015). The goal of PMTCT is to have a HIV free baby and this can only be attained with proper follow-up of the HIV positive mother as she takes the steps of the PMTCT cascade (MOH, 2016; Spensley *et al.*, 2009). This success depends on prompt diagnosis in early pregnancy, prompt initiation of an efficacious ART regimen, proper adherence to ART by the HIV positive mother to achieve viral load suppression, skilled delivery and finally administering infant ART prophylaxis regimens as recommended while practicing safe feeding practices for the infants and following up of the HIV exposed infant (MOH, 2016).

Many studies have been conducted worldwide with the aim of bringing to light the many determinants of vertical transmission of HIV infection. Majority of the studies on causes of vertical transmission of HIV infection have been conducted in Sub-Saharan Africa. These studies listed several causes such as a high maternal HIV viral load, obstetric causes (such as repeated vaginal examinations, instrument assisted delivery) and infant factors (prematurity and low birth weight). Overall, the major cause of vertical transmission of HIV infection is a high maternal viral load (Tolle and Dewey, 2009). However most of these studies have focussed on biological determinants of HIV mother to child transmission and few have looked within the PMTCT cascade to draw a correlation between poor uptake of the PMTCT process indicators and seroconversion of HIV exposed infant.

2.2 Prevention of Mother to Child Transmission Cascade

The HIV PMTCT Cascade has its roots from the Prongs of PMTCT which were formulated in the Global Plan towards elimination of mother to child transmission in 2011-2015 (NASCOP, 2019; UNAIDS, 2017). In an attempt to accelerate efforts in PMTCT, the global plan by the UNAIDS in 2011 projected a vision of a world free of children born with HIV infection. The 22 priority

countries were tasked to fulfil this vision as they harboured approximately 90% of pregnant women living with HIV (Hamilton *et al.*, 2017).

The World Health Organization (WHO) emphasizes on PMTCT programmes using the 4-Pronged Approach (Tolle and Dewey, 2009) which includes:

- Primary prevention of HIV for PMTCT
- Preventing unintended pregnancies among HIV positive women
- Preventing HIV transmission from HIV positive pregnant women to their children.
- Providing appropriate treatment, care and support to women living with HIV, their children and their families

Prong 1 was set as the 1st step in prevention of HIV transmission from mother to child. If women of child bearing age are kept HIV free there will be no vertical transmission. This requires advocacy by both national and county governments and would entail health education to the masses on the various modes of HIV prevention, including behavioral, biomedical and structural interventions (Tolle and Dewey, 2009).

Prong 2 in the 4-pronged approaches outlined by The Global Plan for prevention of HIV transmission from mother to child considers that once primary prevention failed, the HIV positive women should not have unplanned pregnancies. This Prong has been a key component of the Reproductive and Maternal Child Health Division of the Ministry of Health-Kenya by advocating for contraceptive use. The PMTCT program in NASCOP has put in a lot of efforts by integration of Family Planning services at PMTCT service delivery points. Unfortunately, more than 60% of ANC attendees are HIV infected and demonstrate potential unmet need for family planning. In addition, Kenya has a large population of adolescents and young adults. This population have an increasing number of new infections and pregnancies. They also face stigma and discrimination which hinders their health seeking behaviour. Hence vertical transmission of HIV infection is seen more among teenage HIV positive mothers (Tolle and Dewey, 2009; NASCOP, 2019).

PMTCT Program in Kenya has had its focus in Prong 3 and Prong 4 (NASCOP, 2018b; NASCOP, 2019). Prong 3 was derived from these 2 prongs and although the cascades have evolved with time

considering advances in the field of prevention of HIV vertical transmission and WHO guidelines, its origin was based on 5 key indicators which are still crucial to date (Hamilton *et al.*, 2017). The 5 key indicators include:

- ANC attendance
- HIV testing and receipt of results
- Maternal HAART initiation
- Issuance of infant prophylaxis
- Skilled delivery

The PMTCT cascade has traditionally been divided into 3 components (ANC Cascade, Maternal Cascade, Infant Cascade) where 2 of the components focus on the HIV positive mother while the 3rd component focus on the HIV exposed infant and puts emphasis on early diagnosis among this cohort. An analysis of the indicators depicted on each of the components of the cascades can help identify gaps in PMTCT service delivery and provide a novel tool for measuring performance in terms of PMTCT (Stringer *et al.*, 2010). Review of these indicators is important for decision making both at county and national level. Use of the PMTCT cascade however is challenging especially in settings where communities are highly mobile and systems of tracking HIV positive mother baby pairs across different services are weak (Hamilton *et al.*, 2017; Tolle and Dewey, 2009).

The cascade form an important pathway in achieving success in any PMTCT program as it provides a tool to predict the success of prevention efforts and highlights opportunities for improvement as depicted in The Pearl Study that focused on community and facility based component and showed that cascade completion rates were suboptimal among women (Stringer *et al.*, 2010). PMTCT cascade analysis showed that new HIV infections among children were seen among women who did not complete their cascade (Hamilton *et al.*, 2017).

According to a surveillance study conducted in South Africa between 2010 and 2013 of all infants receiving 6 weeks immunization, infants of mothers who reported to be HIV positive underwent the viral antibody testing with infants who turned out positive undergoing PCR testing. The surveillance data showed approximately 35% of the enrolled women were defauters at some point of the cascade. Analysis of the cascades further showed missing one or more of the steps explained the 33.8% of HIV transmission among the infants. Missing HIV diagnosis from women who did not receive a test (2.4%) or those who said are negative without testing (8.6%) may be attributed

to the early MTCT (15.3%). A reduction to 2.8% of MTCT could be achieved if the missed chances and opprotunities could be eliminated (Woldesenbet *et al.*, 2015). Elimination of MTCT and successful health MCH outcomes can be noted if mother and infant are followed upto 2 years after post delivery (Woldesenbet *et al.*, 2015; Tolle and Dewey, 2009).

PMTCT cascade implementation in most of the African countries has led to improvement in the PMTCT efforts (Hamilton *et al.*, 2017). In Kenya, after implementation of the PMTCT cascade as a progress monitoring tool, it has led to better recording of PMTCT data as depicted by the cascade in the DHIS2 and demonstrated that the huge drop off in the cascade in the indicator for women receiving antiretroviral medicine was due to clerical errors. Atleast 15 counties contributed to 75% of the reported and identified (17,432) as missed opportunities (NASCOP, 2018b). Kilifi was one of the counties (NASCOP, 2019). In response to this, the Ministry of Health initiated 'Bring back the women and children campaign' and programmatic changes were made to strengthen reporting of PMTCT indicators. This showed a significant improvement of the MTCT rate in the country to a low of 8.3% from 16% in 2003 (MOH, 2016; NASCOP, 2019).

2.3 Antenatal Clinic and Knowledge of HIV Status

Antenatal clinic attendance, the 1st step of the PMTCT cascadee provides an opportunity for the women to access integrated antenatal care services in relation to PMTCT. This involves HIV health education, counselling and testing services. In addition, it provides an opportunity for the whole family to access health care services and prevention with positives. The PMTCT services during ANC include information on the importance of at least 4 ANC visits, HIV counseling and testing where the mother would be counseled about the scheduled HIV tests during the antenatal and postnatal period. The pregnant women (unless known to be HIV positive) are tested at 1st ANC and if negative a repeat test is done 3 months later, at labour and delivery, 6 weeks postpartum and every 6 months during the breastfeeding period. Those who are known to be HIV positive at 1st ANC or test HIV positive during ANC are encouraged to bring their family for testing and encouraged on HIV status disclosure to their partner and family. The HIV positive women are offered STI counseling and support to avoid intimate partner violence. They are also encouraged to join support groups under the leadership of mentor-mother. For those who opt out/decline testing or are not tested during the 1st contact they are offered HIV counseling and testing in subsequent visits with appropriate linkage and referral for prevention care and support services (MOH, 2016; NASCOP, 2019; Woldesenbet *et al.*, 2015).

Several studies have shown correlation between ANC attendance and outcome of HIV exposed infants. Access to ANC services among pregnant women has been shown to reduce MTCT rate as they are able to access HIV testing services and ultimately PMTCT services (Gunn *et al.*, 2016). Several case control studies looking at risk factors of HIV transmission from mother to child based on this indicator showed that the mothers whose infants seroconverted did not attend ANC or had less visits compared to the mothers who had successful PMTCT (Lovero *et al.*, 2018; Beyene, Dadi and Mogas, 2018). Similar study by Stringer et al in 2010 showed a correlation between less ANC visit, young age among the women and non-adherence to prophylaxis and hence an increase in vertical transmission (Stringer *et al.*, 2010).

2.4 Maternal HAART and Infant Prophylaxis

Prompt initiation of maternal HAART is essential in suppression of maternal HIV viral load. This suppression is of benefit to both the mother and the unborn child. The viral load suppression enables the restoration of the immune status of the mother preventing transmission in utero, labour/delivery and while breastfeeding. Similarly, benefits of suppressed viral load is protective to the partner (MOH, 2016; WHO, 2019; Makau, Okwara and Oyore, 2015).

World Health Organization recommended adoption of Option B+ since 2012 as the best intervention replacing the early ART eligibility criteria i.e. use of Cluster of differentiation (CD4) and pregnancy status. With this recommendation, all pregnant women and those breastfeeding were to be put on lifetime ART (Makau, Okwara and Oyore, 2015; MOH, 2016). Option B+ was shown to reduce MTCT rate to less than 2%. Start ART in all pregnant women and the mothers who are breastfeeding and are HIV infected. These women should have enhanced adherence counseling and routine viral load monitoring. For newly identified HIV positive women, 1st viral load monitoring should be done after 3 months thereafter after every 6 months until cessation of breastfeeding. For the known positive women already on ART at the time of confirming pregnancy, a viral load test should be done at that point and thereafter every 6 months until complete cessation of breastfeeding (MOH, 2016). Several studies in different parts of Africa showed HIV positive mothers who were not or did not adhere to ART and had high viral load had high chance up-to 5 folds of HIV transmission to their children (Beyene, Dadi and Mogas, 2018; Ogalo *et al.*, 2018).

2.5 Skilled Delivery and Role in PMTCT

Skilled delivery is defined as delivery conducted by trained healthcare personnel. It is important in reducing chances of vertical transmission. Labour and delivery poses the greatest transmission risk of HIV with 10-20% exposed infants being infected during this time. Several interventions have been put in place to mitigate the possible transmission that may occur during delivery (MOH, 2016).

The following guideline (Kassaw *et al.*, 2020; MOH, 2016) is recommended for all women hospitalized in the labour and also those in the delivery units

- Examination of the vagina should be minimized
- Aseptic techniques to be used while conducting delivery.
- Artificial rupture of membranes (ARM) avoided
- Partograph use to avoid prolonged labour
- Minimal trauma during delivery
- Risk of postpartum hemorrhage to be minimized.
- Use safe practices in blood transfusion

Studies done in Ethiopia and Kenya have demonstrated the benefit of skilled delivery in preventing vertical transmission of HIV. Among the studies, Beyene et al (Ethiopia), Oga et al and Lorenzo et al (western Kenya) showed women who were HIV positive and had home delivery were 5 times more likely to transmit HIV to their children (Ogalo *et al.*, 2018; Azcoaga-lorenzo, Ferreyra and Alvarez, 2011; Beyene, Dadi and Mogas, 2018).

2.6 Conceptual framework

This shows the interlinkage of independent and outcome variable in this study. Based on literature, there is interconnection between maternal characteristics of HIV infected women and transmission of the virus to the index child. Interventions focusing on the interlinkage of socio-demographic, characteristics of mothers seeking services in PMTCT program and infant related factors may prevent HIV MTCT facilitating elimination of MTCT.

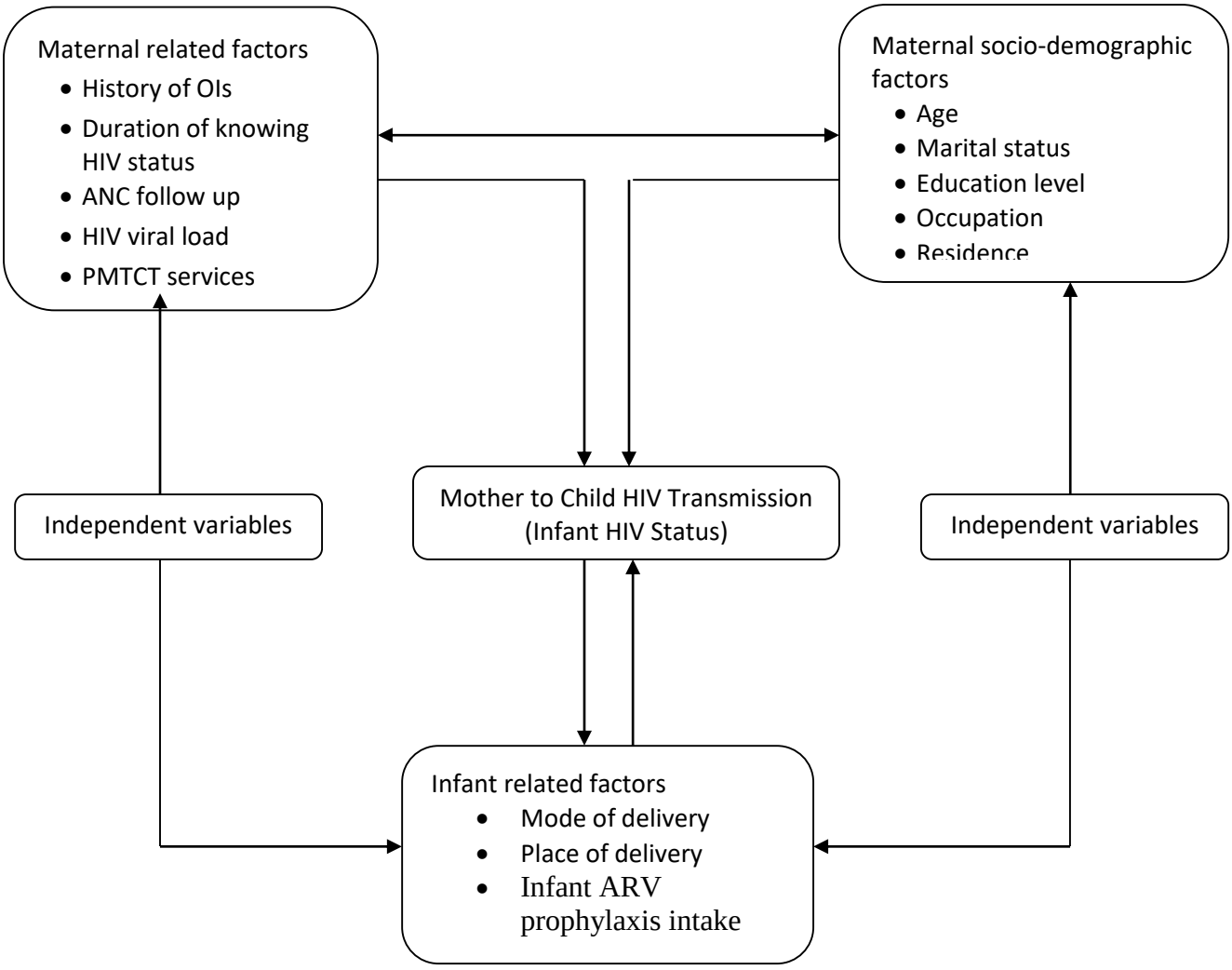

Fig. 1 Diagrammatic representation of the conceptual framework

2.7 Study justification

Kenya has recorded significant progress towards elimination of MTCT having reduced (MTCT) HIV transmission rate from 16% in 2013 to 8.3% by 2015 (Waruru *et al.*, 2018). Unfortunately, the transmission rate has been shown to be rising; 11.5% in 2017 and further projected to 12.4% in 2018. This is unacceptably high compared to the target (<5%). New pediatric infections have also increased to 7,978 in 2018 up from 6,613 in 2016 (NASCOP, 2019; NASCOP, 2018b). Mathematical modeling has shown close to 50% of the 7,978 new infections occurred because women were not retained on ART during antenatal and breastfeeding period. Further, the

proportion tested among the exposed infants before the recommended age of 8 weeks stagnated at 67.3% (UNAIDS, 2017; UNAIDS, 2019; Mahy *et al.*, 2017).

Kenya's reversed progress in MTCT rate may be attributed to lack of optimal coverage at the community level and missed opportunities at the facility level. The lack of optimal coverage in ANC attendance has led to decreased HIV identification among the women in need of PMTCT services while the missed opportunities continue to be present with challenges in the elimination of HIV transmission from mother to child.

Most of the research studies done in Kenya determining factors of mother to child HIV transmission focused largely on western Kenya. This study aims at determining the risk factors for mother to child transmission of HIV infection among children born to HIV positive mothers on PMTCT Program in Kilifi County, which was identified as a priority region in the Kenya framework for elimination of mother to child transmission (2016-2021) due to the upward increase in MTCT rate of HIV infection from 7.7% (2015) to 8.3% (2018) (National AIDS Control Council, 2020; NASCOP, 2019).

Results from this study may be used by HIV and PMTCT programs to prioritize and formulate intervention policies particularly in resource limited healthcare facilities within the county. This may guide HCWs in counseling and treatment of HIV positive mothers, their children and their family. The information may also be used as a foundation in assessing and evaluating PMTCT cascade towards elimination of MTCT by 2021.

2.8 Study question

What are the determinants of mother to child transmission among children born to HIV positive mothers on PMTCT Program in Kilifi County between July 2018 and June 2019?

2.9 Study objective

To identify determinants of mother to child transmission among children born to HIV positive mothers on PMTCT Program in Kilifi County between July 2018 and June 2019

2.10 Specific objective

1. To determine the association between the ANC attendance of mothers and the outcome of their HIV exposed children.

2. To determine the association between HIV testing of mothers at ANC and the outcome of their HIV exposed children.
3. To determine the association between Maternal HAART and Infant prophylaxis with the outcome of their HIV exposed children
4. To determine the association between the skilled delivery of a HIV positive mother and the HIV status of her child.

CHAPTER 3: METHODOLOGY

3.1 Study design

This was a retrospective unmatched case control study, based on patient records. The study participants did not necessarily have the same characteristics, but were from the same population. Selection of the study participants was based on HIV positive mothers who were enrolled in the PMTCT program and their index children. The mothers had a confirmatory HIV test done between July 2018 and June 2019 in Kilifi County.

A Case was defined as a HIV positive mother who was enrolled in the PMTCT program with her child who was tested and confirmed to be HIV infected between July 2018-June 2019 while a control was defined as a HIV positive mother who was enrolled in the PMTCT program with her child who was tested and confirmed to be HIV negative between July 2018-June 2019.

3.2 Study site

The study was carried out in Kilifi County which is located at the coastal region of Kenya. The county has a total population of 1,545,211 (KNBS, 2019). It is divided into 7 sub-counties with a total of 143 public health facilities and 151 private health facilities. Out of these, 173 offer PMTCT services to approximately 7% of the HIV infected female population. Staff directly involved in PMTCT Program in the county include; the County AIDS/STI Coordinator (CASCO), PMTCT County focal person, Sub County AIDS/STI coordinator, County and Sub-county HRIO (Health Records Information Officer), Nurses in ANC, PMTCT clinics, Mentor mothers and Community Health Volunteers/ workers.

3.3 Study population

All HIV positive mothers whose HIV exposed child or children had a confirmatory HIV test result, positive for cases and negative for controls between July 2018-June 2019 in the different healthcare facilties.

3.3.1 Inclusion criteria

- A HIV positive woman enrolled in the PMTCT program in Kilifi County
- A HIV positive mother whose child had a confirmatory HIV test, positive for cases and negative for controls between July 2018 and June 2019.

3.3.2 Exclusion criteria

- A HIV positive mother whose child had an undetermined or unknown HIV test result.
- A HIV positive mother not enrolled for PMTCT services in Kilifi County

3.4 Sample size

To determine the sample size, Epi Info Version 3.01 Statcalc function of sample size calculation for unmatched case-control study was used (Sullivan and Soe, 2012). At 95% confidence interval and 80% power estimates were derived from studies done on determinants of mother to child HIV transmission in Ethiopia (Burusie and Deyessa, 2015). Least odds ratio of 1.80 assuming 32.4% and 74.9% of mothers in the cases and control group respectively exposed to PMTCT follow up atleast four times. Considering a 1:2 ratio of cases to controls, a sample size of 183 mother baby pairs (61 cases and 122 controls) was estimated.

$$n_1 = \left(\frac{r+1}{r}\right) \frac{(\overline{p})(1-\overline{p})(Z\beta + Z\alpha/2)^2}{(p1 - p2)^2}$$

$$\overline{p} = \frac{p1+rp2}{r+1}$$

Where:

n_1 = sample size of the cases

n_2 = sample size of the controls

N = study sample size

$Z\alpha/2$ is the desired level of statistical significance = 1.96

r= ratio of controls to cases = 2.0

Z_β = desired power = 0.84

p1 = proportion of cases with exposure = 32.4%

p2 = proportion of controls with exposure = 74.9%

Least extreme Odds Ratio to be detected = 1.80

$\overline{p} = \frac{p1+rp2}{r+1} = 0.6073$

$$n_1 = \left(\frac{2+1}{2}\right)\left(\frac{0.6073 \times 0.3927 \times 7.84}{0.04605}\right) = 61$$

Therefore: $n_1 = 61$

$n_2 = rn_1 = 122$

Total sample size $N = n_1 + n_2 =$ **183**

3.5 Sampling technique

The 173 public and private facilities in the county offering PMTCT services were selected. The stratified random sampling method was applied to select study subjects from the different county healthcare facilities proportionate to their study population size. Cases and controls were selected by accessing the available digital/online medical registry. In reference to the infant DNA PCR HIV test results, strata (the different healthcare facilities within the county) numbers were identified from the county population and by simple random sampling; cases and controls were selected proportionately (Fig. 2).

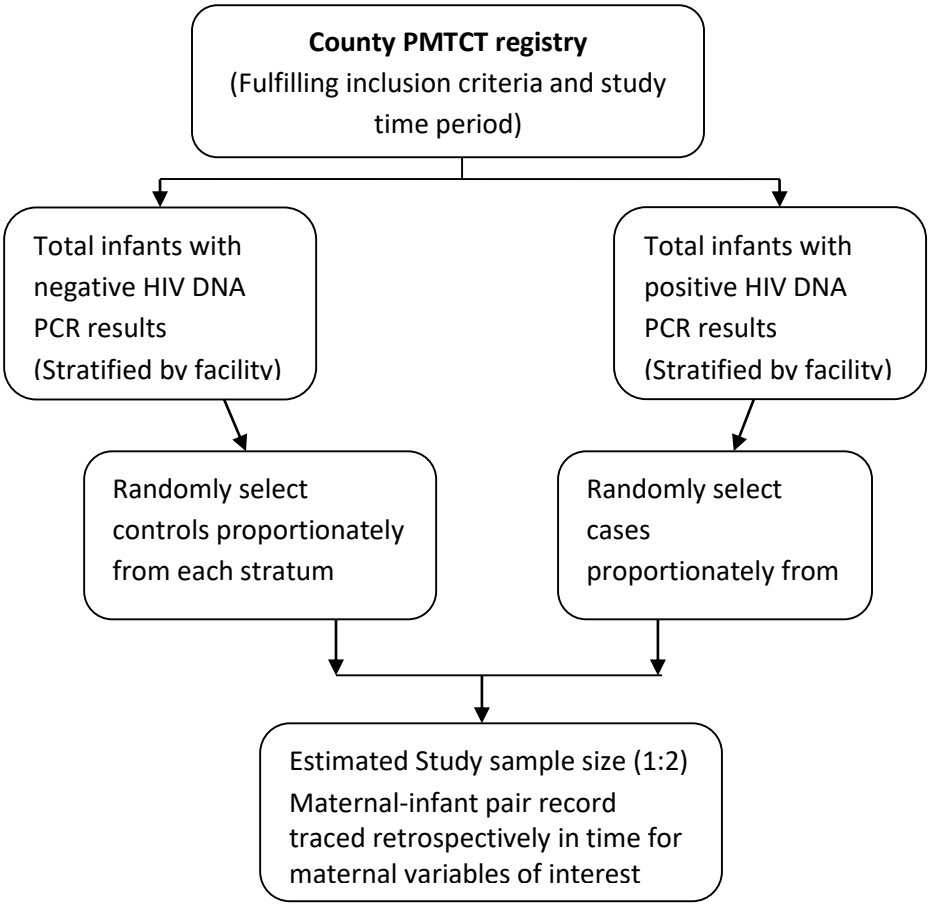

Fig. 2 Selection of cases and controls in Kilifi County

3.6 Variables

3.6.1 Dependent Variables

Infant HIV status confirmed by DNA PCR testing (mother to child HIV transmission).

3.6.2 Independent Variables

ANC attendance of mother, Knowledge of HIV status of mother, Maternal HAART and Infant prophylaxis and place of delivery of mother.

3.7 Data collection procedures

To collect data, a researcher structured tool consisting of socio-demographic, infant and maternal characteristics was used (Appendix 1). Data was extracted from ANC, Maternal and Postnatal registers. Data was collected by clinical nurses who had been trained and had atleast 1 year experience in PMTCT service delivery at the selected facilities. The data was shared in MS Excel in a password controlled computer and backed up in a flash disk owned by the principal investigator.

3.8 Ethical consideration

Ethical review of the proposal was done by KNH-UON Ethics and Research Committee. This was a retrospective study based on secondary data; therefore, a waiver for informed consent was requested. Permission and approval to conduct the study was also sought from the Kilifi County Health Management Team, Medical Superintended and the Medical Records Officer in Charge, Kilifi County. Patient information including names, file and clinic number were excluded and the data collection tool recoded. In addition, the patient's medical records will be maintained in a safe lockable cabinet and destroyed after 5 years by burning to maintain confidentiality. Patients may not benefit directly from the study but the report will be shared with clinicians and relevant stakeholders to improve general patient care and management. The probable risk associated with the study includes loss of patient information, although the risk will be mitigated by use of trained healthcare workers and use of password controlled computers and lockable cabinets.

3.9 Data management

Data in MS Excel was cleaned and assessed for completeness and analysis done using MS Excel and IBM SPSS Statistics version 21. For categorical variables such as study categories (cases and

controls) and gender, frequency and proportions was used. Chi-square test and logistic regression was done to assess any relationship between the dependent variable and categorical independent variables such as the breast infection, mixed feeding ANC visits. Odds ratio (OR) was used to estimate the strength of association between the exposure variables like ANC follow up, duration of knowing HIV status and mother to child HIV transmission. Data was presented in tables.

CHAPTER FOUR: RESULTS

4.1. Demographic Characteristics

4.1.1 Gender and Age distribution

The study sampled 161 infants enrolled in HEI program across various health facilities within Kilifi County. Of these, 49% were male and 51% females. Across the infant HIV test outcome categories, there were nearly same proportion of males as females though only 59 participants were sampled as Positive and 101 as negatives.

In terms of age in weeks at enrolment into the HEI program, 56% of the infants were between 4 and 24 weeks while 33% of the infants were less than a month old. Of all the HIV positive infants 58% were between 4 and 24 weeks of age while 17% were less than 4 weeks old. Of all the HIV negative infants 55% were between 4 and 24 weeks old while 43% were less than a month old at time of enrollment

Table 1 Summary of demographic characteristics of infants sampled

Sex:	***Infant HIV Test Outcome:***				**Total (n=160)**	
	Positive (n=59)		**Negative (n=101)**			
Male	29	49%	50	50%	79	49%
Female	30	51%	51	50%	81	51%
Age of infant at Enrolment into HEI Program (weeks)	***Infant HIV Test Outcome:***				**Total (n=161)**	
	Positive (n=60)		**Negative (n=101)**			
<4	10	17%	43	43%	53	33%
4-24	35	58%	55	55%	90	56%
25-36	8	13%	1	1%	9	6%
37-72	7	12%	0	0%	7	4%

4.1.2 Other Infant Variables

- Identification point of care
- PCR test results
- Infant prophylaxis regimen

In terms of identification, 81% of the infants were identified through MCH/PMTCT program, 7% were identified through OPD and the others were identified through CCC, Maternity and in Pediatrics ward. Among all the positive infants, 58% were identified through MCH/PMTCT and 17% through OPD, 10% through pediatrics ward and 7% in CCC. Among those confirmed to be negative, 95% of them were identified through MCH/PMTCT services.

Majority (90%) of the infants enrolled received their PCR test results within the 1st 6 weeks or at first contact. Only 10% of the infants were not provided PCR test within the initial 6 weeks or at first contact overall. Among those who tested positive, 20% did not receive their PCR test in the initial 6 weeks or at first contact. This proportion stood at 4% for those confirmed to be negative

Out of all the infants enrolled only 4 did not receive infant prophylaxis and cotrimoxazole. Of those that had received infant prophylaxis, 88% had received both NVP and AZT while 12% received only NVP. 91% of the positive infants were on NVP and AZT while 9% were on NVP alone. 87% of the negative infants were on NVP and AZT while 13% were on NVP alone

Table 2: Other Infant Variables

Entry Point	***Infant HIV Test Outcome:***				**Total (n=157)**	
	Positive (n=59)		**Negative (n=98)**			
CCC	4	7%	3	3%	7	4%
Maternity	5	8%	1	1%	6	4%
MCH/PMTCT	34	58%	93	95%	127	81%
OPD	10	17%	1	1%	11	7%
Pediatrics Ward	6	10%	0	0%	6	4%
PCR Test Type:	***Infant HIV Test Outcome:***				**Total (n=158)**	
	Positive (n=60)		**Negative (n=98)**			
Initial 6 weeks/First Contact	48	80%	94	96%	142	90%
2nd PCR (6 months)	4	7%	3	3%	7	4%
3rd PCR (12 months)	3	5%	0	0%	3	2%
Other Time	5	8%	1	1%	6	4%
Infant prophylaxis Regimen	***Infant HIV Test Outcome:***				**Total (n=161)**	
	Positive (n=55)		**Negative (n=101)**			
NVP	5	9%	13	13%	18	12%
NVP & AZT	50	91%	88	87%	138	88%

4.2 Maternal Variables

- ANC attendance
- Knowledge of HIV status
- Maternal HAART
- Disclosure of Maternal HIV Status
- Place of delivery (Skilled delivery or home delivery)

Majority (88%) of mothers to all infants sampled in the study had attended ANC at least once. All the mothers who had a HIV negative infant had attended ANC while 33% of those who had a HIV positive infant did not attend ANC.

Most of the mothers (95%) of the infants sampled knew their HIV status prior to attending ANC. This proportion was the same in both cases and control group.

On disclosure of HIV status, mothers to 86% of all the infants confirmed disclosing their HIV status. Among the HIV positive infants, 76% had disclosed while for the HIV negative infants, 91% had disclosed.

Overall, most mothers (80%) had disclosed their status to their partners. More specifically, this was 88% among the mothers to 88% of the infants that were positive and mothers to 76% of the infants that were negative from the HEI outcomes.

Seventy-five (75%) of the mothers of all infants sampled received maternal HAART. Majority (62%) of the mothers whose infants tested positive for HIV did not receive maternal HAART while this proportion was only 3% among the mothers of HIV negative infants.

For the mothers that had started maternal HAART in ANC, 47% started at 1st trimester. Among positive, the proportion of those initiated on HAART within 1st trimester was 23% compared to 53% of those in the negative arm started on HAART around the same reference period.

Of these deliveries, 82% of the mothers to all the sampled infants delivered at the health facility compared to 18% at home. Among the positive, home deliveries were 42% compared to 3% among negatives while hospital deliveries were 58% among the positive compared to 97% among negatives.

Table 3: Summary of Maternal Variables

Mother Attended ANC?	*Infant HIV Test Outcome:* Positive (n=57)		Negative (n=99)		Total (n=156)	
Yes	38	67%	99	100%	137	88%
No	19	33%	0	0%	19	12%

HIV positive Status Known:	Positive (n=59)		Negative (n=101)		Total (n=160)	
Yes	56	95%	96	95%	152	95%
No	3	5%	5	5%	8	5%

Disclosed	Positive (n=59)		Negative (n=101)		Total (n=160)	
Yes	45	76%	92	91%	137	86%
No	14	24%	9	9%	23	14%

Received Maternal HAART in ANC	Positive (n=60)		Negative (n=101)		Total (n=161)	
HAART	23	38%	98	97%	121	75%
None	37	62%	3	3%	40	25%

When HAART was started	Positive (n=23)		Negative (n=98)		Total (n=121)	
1st Trimester	5	23%	52	53%	57	47%
2nd Trimester	4	17%	17	17%	21	17%
3rd Trimester	3	13%	4	4%	7	6%
Not Stated	11	47%	25	26%	36	30%

Place of Delivery	Positive (n=59)		Negative (n=100)		Total (n=159)	
Home	25	42%	3	3%	28	18%
Hospital	34	58%	97	97%	131	82%

Infant prophylaxis Regimen	Positive (n=55)		Negative (n=101)		Total (n=161)	
NVP	5	9%	13	13%	18	12%
NVP & AZT	50	91%	88	87%	138	88%

4.3 Bivariate and Multivariate Analysis

The study established a significant relationship between the HIV status of the HIV exposed infant and the ANC attendance of the mother (p=0.00) and the mother receiving HAART in ANC (p=0.00) using the chi-square test at a 5% level of significance. Only receipt of maternal HAART in ANC was established as the major determinant of a favorable HEI outcome in this study. On the nature of the relationships between the outcome of the HEI and the independent factors, disclosure of HIV status by the mother at ANC was 3.18 (1.28 - 7.90) times more likely to determine a favorable outcome of the HEI compared to non-disclosure at a 5% level of significance when taken independently. When adjusted for other factors, it was 6.27 (1.20 - 20.05) times more likely to determine a favorable outcome of the HEI at 1% level of significance. On maternal HAART at ANC, infants whose mothers had received maternal HAART in ANC were 52.55 (14.89 - 185.48) times more likely to be HIV negative compared to those whose mothers did not receive maternal HAART in ANC at 1% level of significance and taken independently of other factors. This came down to 30.23 (7.56 - 120.96) times when adjusted for other factors at the same level of significance.

Table 4: Summary of Bivariate and Multivariate analysis

Variables:	***Infant HIV Test Outcome:***				**Total**	**P-value**	**COR (95% CI)**	**AOR (95% CI)**
	Positive		**Negative**					
Mother Attended ANC?								
Yes	38	67%	99	100%	137	-	-	-
No	19	33%	0	0%	19			
HIV positive Status Known:								
Yes	56	95%	96	95%	152	.970	1.03 (0.24 - 4.47)	0.74 (0.98 - 5.64)
No	3	5%	5	5%	8			
Disclosed								
Yes	45	76%	92	91%	137	.010	3.18 (1.28 - 7.90) *	6.27 (1.20 - 20.05) **
No	14	24%	9	9%	23			
Received Maternal HAART in ANC								
HAART	23	38%	98	97%	121	.000	52.55 (14.89 - 185.48) **	30.23 (7.56 - 120.96) **
None	37	62%	3	3%	40			

Mode of Delivery								
SVD	58	97%	97	96%	155	.839	0.84 (0.15 - 4.71)	0.53 (0.03 - 9.65)
CS	2	3%	4	4%	6			

CHAPTER 5: DISCUSSION

ANC services provides an opportunity for key interventions in prevention of vertical transmission of HIV. Such interventions include early diagnosis of the HIV positive pregnant woman, prompt initiation of HAART, Viral load monitoring and Enhanced Adherence Counselling when necessary, psychosocial support and health education on importance of skilled delivery. All these interventions contribute towards a HIV negative infant.

The current National ANC attendance is at 74%, there is need to improve this to 95% as ANC provides an opportunity for HIV testing and initiation of HAART for the HIV positive mother. Importance of improving this indicator is evidenced by Kenya National Bureau of Statistics/Government of Kenya, 2015 which showed that only 19% of Kenyan women visit the ANC within the first 4 months of pregnancy and 31% make their initial visits at 4-5months and 6-7 months respectively and only 68% visit the clinic at least 4 times.

On attendance of antenatal care clinics, the study found that all mothers who had HIV negative infant had attended ANC at least once while for the mothers who had a HIV infected infant only 67% had attended at least 1 ANC visit. This finding demonstrates the importance of Antenatal care clinics and is consistent with literature on access to ANC services and reduction of mother to child transmission rate. In a study done by *Gunn et al* on Antenatal care and uptake of HIV testing among pregnant women in Sub Saharan Africa, it was established that women who had access to ANC services accessed HIV testing services which is the entry point in PMTCT care cascade (Gunn *et al.*, 2016). In another study done in Brazil, it showed that lack of antenatal care and late diagnosis underlie substantial gaps in PMTCT cascade (Lovero, de Oliveira, *et al.*, 2018) No studies were found that do not agree with importance of ANC in prevention of vertical transmission of HIV.

Our study evaluated the relationship between knowledge of the mother's HIV status and outcome of their infants. The study sought to find out whether women who know their HIV positive status early in pregnancy had lower risk of having a HIV positive infant on the basis that interventions of PMTCT would be started early. Identification coverage of HIV positive women in reproductive age is important in reducing MTCT of HIV. Women who know their HIV status are more likely

to have started HAART and are more likely to have achieved viral load suppression at the time of conception, during pregnancy and breastfeeding. Planned pregnancies among the HIV positive women decreases the odds of a mother transmitting HIV virus to her baby. The study did not show any difference in knowledge of HIV status of the mother and outcome of their children as 95% of women in both the control and cases group knew of their status before ANC. This finding was similar to a study done in Western Kenya which aimed at describing the mother baby pairs enrolling in PMTCT program. It showed that 68% of Known Positive women enrolled in PMTCT were not on ART at time of conception despite their knowledge of their HIV status. For those on HAART, a significant number (14%) had an unsuppressed viral load. All which suggested that knowledge of HIV status alone may not contribute to prevention of mother to child transmission (Edith A. Ogalo *et al.*, 2018) This finding was however contrary to a study done in South Africa that showed that women aware of their HIV status before the index pregnancy were more likely to receive PMTCT and to test their infants early hence have a HIV negative infant. (Jonathan Posner and Bradley S. Peterson, 2008) Several case control studies looking at determinants of mother to child transmission showed a positive correlation between women who did not know their status and mother to child transmission of HIV infection (Beyene, Dadi and Mogas, 2018) (Lovero, de Oliveira, *et al.*, 2018)

Disclosure of one's HIV status improves uptake and retention in prevention of mother to child transmission of HIV services. Disclosure of HIV status allows the mother to have psychosocial support this in turns leads to increased adherence to PMTCT services. Our study evaluated whether disclosure of the mother's HIV positive status had any relationship to the outcome of the HIV status of the infant. On disclosure of HIV status, mothers to 86% of all the infants confirmed disclosing their HIV status. Among the HIV positive infants, 76% had disclosed while for the HIV negative infants, 91% had disclosed their status. This finding is consistent with a study done in Kenya that assessed HIV positive status disclosure and use of essential PMTCT and Maternal Health services. It established that women living with HIV who had not disclosed to anyone had the lowest levels of PMTCT service utilization (Spangler *et al.*, 2014) In another study done in Kenya looking at the prevalence and correlates of non-disclosure of maternal HIV status to male partners; it established that non-disclosure was associated with lower use of

PMTCT services and facilitating maternal disclosure to male partners may enhance PMTCT uptake (Kinuthia *et al.*, 2018).

Prompt HAART initiation is associated with rapid Viral load suppression consequently reduction in vertical transmission of HIV. Our study evaluated the relationship between uptake of maternal HAART among the mothers and HIV status outcome of their infants. It also looked at the relationship between uptake of infant prophylaxis among HIV exposed infants and their HIV status. The study found that 75% of all the mothers were on HAART while 25% of them were not on HAART. On relationship between maternal HAART and HIV status of the HIV exposed infant it was established that 97% of the mothers of the infants in the control group were on HAART while only 38% of the mothers of the infants in the cases group were on HAART. 62% of the infants who became HIV infected were born of mothers who were not on HAART. Several studies have shown the importance of maternal HAART in prevention of vertical transmission. As lack of Maternal HAART leads to maternal HIV viremia which increases the odds of vertical transmission (Edith A. Ogalo *et al.*, 2018). In another study done in Nigeria looking at the impact of Maternal HAART in its prevention of vertical transmission of HIV showed that, none of the exposed children born to HIV positive mothers on HAART were vertically infected with HIV-1 and HIV-2 (Ewenighi-Amankwah *et al.*, 2020).

Early initiation of maternal HAART by HIV positive pregnant women has been shown to reduce viral load of HIV to undetectable levels and hence reduce vertical transmission of HIV. Our study also agreed with this as 53% of the infants who confirmed to be HIV negative were born of mothers who were initiated on HAART during 1st trimester compared to the 23% of HIV positive infants whose mothers initiated HAART in 1st trimester.

On adherence to maternal HAART, 71% of the mothers were rated to have good adherence while 16% were rated poor. 94% of the infants who tested and confirmed to be negative were born of mothers who were rated to have good adherence. A study done in neighboring Ethiopia established that poor adherence to maternal HAART was associated with an increased risk of vertical transmission of HIV(Beyene, Dadi and Mogas, 2018)

Skilled delivery is defined as delivery conducted by trained healthcare personnel. Labor and delivery poses the greatest transmission risk of HIV with 10-20% exposed infants being infected during this time. The study evaluated the relationship between skilled delivery and outcome of the HIV exposed infant. The study established 82% of the mothers delivered at the health facility compared to 18% at home. Among the positive, home deliveries were 42% compared to 3% among negatives while hospital deliveries were 58% among the positive compared to 97% among negatives. Similar studies done established the importance of skilled delivery in prevention of mother to child transmission of HIV (Edith A. Ogalo *et al.*, 2018) (Beyene, Dadi and Mogas, 2018) (Azcoaga-Lorenzo *et al.*, 2011).

STUDY LIMITATION

Data reporting and documentation remains a challenge in the country due to varied understanding of PMTCT indicators among HCW, non-reporting by private facilities and lack of all the appropriate tools for reporting. In addition, the country also lacks a coordinating mechanism for monitoring progress towards WHO validation for EMTCT. Further, since the study relies on retrospective data, accuracy of data recording at the primary sources cannot be established.
Main limitation of this study was missing some of the data from the records.

CONCLUSION

Similar to literature reviewed from other countries this study established the importance of PMTCT service delivery in reduction of vertical transmission of HIV. ANC attendance, early diagnosis of maternal HIV, prompt initiation and adherence to HAART, skilled delivery of the HIV positive pregnant woman were all associated with reduction of mother to child transmission rate. Based on the findings it was established that women who defaulted on the PMTCT cascade services had higher odds of having a HIV positive infant compared to women who accessed all the PMTCT services at the recommended time. This agreed with a study by *Hamilton et al* PMTCT cascade analysis which showed that new HIV infections among children were seen among women who did not complete their cascade (Hamilton *et al.*, 2017).

Other variables that showed association were male partner involvement and involvement of the mother in psychosocial support groups. These findings are similar to studies which looked at such

determinants (Beyene, Dadi and Mogas, 2018) (Lovero, de Oliveira, *et al.*, 2018) (Edith A. Ogalo *et al.*, 2018) (Hamilton *et al.*, 2017).

RECOMMENDATIONS

Future studies may look at the missed opportunities for the interventions on the cascade from facility level and how to mitigate them.

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APPENDICES

1. Data collection tool

TOOL USED FOR COLLECTION OF DATA MOTHER BABY PAIR (CASES)

Facility Data

Serial Number of facility

Sub-county

Facility Name and MFL code

Testing Lab/POC

HIV INFECTED INFANT DATA

Date of enrollment into HEI

HEI Unique ID

Sex

Date of Birth

Age of Infant at enrollment into HEI program

Entry point (OPD, Peads ward, MCH/PMTCT/CCC/Maternity/Others)

Date of first positive PCR results received

Date infant sample taken

PCR test type(initial/subsequent test on follow up)

Was the infant enrolled into care (Y/N)

CCC number (MFLCODE)

Infant started on which ART regimen

Reason for non-enrollment (For those not enrolled)

If PCR was positive was a confirmatory test done?

Date sample for confirmatory test taken

Date results received from PCR lab

Date guardian given results

Age of infant with confirmed positive PCR

Received cotrimoxazole

Received infant prophylaxis (Y/N)

Reason for not issued infant prophylaxis (if No to above question)

Age at which infant started prophylaxis

Duration for which infant has been on prophylaxis (in months)

Infant baseline viral load (if any)

Infant Viral load (date done)

Infant Viral load result (LDL, Detectable)

Infant Viral load copies

Infant Feeding 0-6 months (EBF, ERF, MF)

Feeding method 7-18 months (BF/NBF)

Immunization status (On schedule, not on schedule, unknown)

HIV INFECTED MOTHER DATA

Age of mother (age recorded when child is being seen/HEI enrollment)

Mother attended ANC (Y/N)

Gestational Age (weeks) at 1st ANC

Parity of mother for this infant

HIV Positive status (Known positive, newly positive)

Partner tested for HIV (Yes, No, Unknown)

Partner HIV status (Positive, Negative, Unknown)

Disclosed (Yes/No)

Received Maternal HAART in ANC (Yes, No, Unknown)

Date initiated on HAART

When HAART was started (at what trimester or L&D or postnatal)

Which regimen was started?

Adherence (Good, fair, poor)

Maternal First Viral load in ANC (LDL, Not done, Detectable VL, Not applicable)

Maternal Latest VL done

Maternal Latest VL copies

Enhanced adherence done in relation to the latest highest Viral load if any (Yes/No/N. A)

Number of Enhanced adherence done

Mode of delivery

Place of delivery

TB status (at the time infant turned positive)

IPT status (Is on IPT, Completed IPT, on treatment for TB, no TB intervention, Unknown)

Mother part of psychosocial support group (Yes/No)

Status of the Mother at exit of PMTCT (Alive/Dead)

Any other comments

TOOL FOR USED FOR COLLECTION OF DATA MOTHER BABY PAIR (CONTROLS)

Facility Data

Serial Number of facility

Sub County

Facility Name and MFL code

Testing Lab/POC

HIV INFECTED INFANT DATA

Date of enrollment into HEI

HEI Unique ID

Sex

Date of Birth

Age of Infant at enrollment into HEI program

Entry point (OPD, Paediatric ward, MCH/PMTCT/CCC/Maternity/Others)

Date of first negative PCR results received

Date infant sample taken

PCR test type (initial/subsequent test on follow up)

Date infant sample for confirmatory test taken

Date results received from PCR lab

Date guardian given results

Age of infant with confirmed negative PCR

Received cotrimoxazole

Received infant prophylaxis

Reason for not issued prophylaxis

Infant prophylaxis regimen given

Age at which infant started prophylaxis

Duration for which infant prophylaxis has been issued (in months)

Infant Feeding 0-6 months (EBF, ERF, MF)

Feeding method 7-18 months (BF/NBF)

Immunization status (On schedule, not on schedule, unknown)

HIV INFECTED MOTHER DATA

Age of mother (age recorded when child is being seen/HEI enrollment)

Mother attended ANC (Y/N)

Gestational Age (weeks) at 1st ANC

Parity of mother for this infant

HIV Positive status (Known positive, newly positive)

Partner tested for HIV (Yes, No, Unknown)

Partner HIV status (Positive, Negative, Unknown)

Disclosed (Yes/No)

Received Maternal HAART in ANC (Yes, No, Unknown)

Date initiated on HAART

When HAART was started (at what trimester or L&D or postnatal)

Which regimen was started?

Adherence (Good, fair, poor)

Maternal First Viral load in ANC (LDL, not done, Detectable VL, Not applicable)

Maternal Latest VL done

Maternal Latest VL copies

Enhanced adherence done in relation to the latest highest Viral load if any (Yes/No/N. A)

Number of Enhanced adherence done

Mode of delivery

Place of delivery

TB status (at the time infant turned positive)

IPT status (Is on IPT, Completed IPT, on treatment for TB, no TB intervention, Unknown)

Mother part of psychosocial support group (Yes/No)

Status of the Mother at exit of PMTCT (Alive/Dead)

Any other comments

No	Infant indicators	Indicator Significance
1	Infant Biodata	for identification purpose
2	Age of infant at Enrolment into HEI Program	determine late or early enrolment
3	Entry Point	determine level at which seroconversion
4	Date of 1st Positive PCR results	TAT
5	Date infant sample taken	TAT
6	PCR test type	guideline adherence,
7	Infant ART regimen started	Knowledge of HCW in service delivery
8	Reasons for non-enrollment	Understand barriers to provision of treatment
9	Date infant sample for confirmatory taken	TAT, adherence to guideline
10	Date results received from the Laboratory	TAT
11	Age of infant at Positive PCR	Duration of use of infant prophylaxis
12	Receive infant prophylaxis	Service delivery, if achieved prevention of HIV transmission
13	Reasons for not issued infant prophylaxis	understand barriers to prophylaxis issuing at each service delivery point
14	Infant Prophylaxis Regimen	Isolate use of non-efficacious regimen/service delivery
15	AGE at which infant started on prophylaxis	Duration of use of infant prophylaxis to achieve prevention
16	Infant Base line viral Load	guideline adherence
17	Infant Feeding	Duration of exposure

18	Immunization status	To confirm if facility has implemented the HIV status ascertainment on the immunization register
19	Age of Mother	Determine the age of pregnant mother to rule out teenage pregnancy
20	Mother Attended ANC	Checks if she is a missed opportunity/attended 1st ANC visit and further determine if she was tested at the visit
21	Gestation Age(weeks)	Determine late or early in ANC attendance during pregnancy
22	Partner tested for HIV	Partner Involvement… to know status of the partner and provide necessary counselling as per status
23	Enhanced Adherence done in relation to the latest highest viral load if any	To elicit barrier to adherence