EFFECTIVENESS OF NEVIRAPINE AND COTRIMOXAZOLE PROPHYLAXIS AND OUTCOME OF BREASTFED BABIES BORN TO HIV POSITIVE MOTHERS IN SELECTED HOSPITALS IN BUSHENYI DISTRICT

BY

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A RESEARCH DISSERTATION SUBMITTED TO FACULTY OF CLINICAL MEDICINE AND DENTISTRY IN PARTIAL FULLFILMENT FOR THE AWARD OF BACHELOR OF MEDICINE AND SURGERY OF KAMPALA INTERNATIONAL UNIVERSITY WESTERN CAMPUS

OCTOBER, 2018

DECLARATION

I **Mpanga Mary** declare that this research dissertation is my own work and has never been presented to any university or any other institution for any award or qualification whatsoever. Where the works of other people have been included, acknowledgement to this has been made in accordance with the ethical guidelines. This study has never been submitted before for either publication or award of any kind.

Signed……... **Date**……

Mpanga Mary

APPROVAL

I Dr. Lule Herman Certify that this research dissertation entitled **"Effectiveness of Nevirapine and Cotrimoxazole Prophylaxis and Outcome of Breastfed Babies Born to HIV Positive Mothers in Selected Hospitals in Bushenyi District",**has been developed under my close supervision and that its ready for submission to the faculty of clinical medicine and dentistry of Kampala International University.

Signed………**Date**…….

Dr. Lule Herman (MBChB, MMed Surgery , MSc.GHID)

ACKNOWLEDGEMENT

My sincere thanks go to God with whose guidance I was able to accomplish this piece of work successfully.Secondly, completion of this work would not be possible without the selfless guidance of my supervisor, Dr. Lule Herman.

LIST OF ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired immune deficiency syndrome
ALT	Alanine amino-transferase
ANC	Antenatal care
ART	Antiretroviral therapy
AZT	Zidovudine
BCG	Bacillus Calmette-Guerin
BP	Blood pressure
CASA	Community ART Support Agents
CBC	Complete blood count
CCLAD	Community client-led ART delivery
CD4	Cluster of differentiation 4
CDC	Centers for Diseases Control and Prevention
CPT	Cotrimoxazole preventive therapy
CTX	Cotrimoxazole
DNA	Deoxyribonucleic acid
E	Ethambutol
EB-F	Exclusive breastfeeding
EFV	Efavirenz
eMTCT	Elimination of mother to child HIV transmission
FP	Family planning
HEIs	HIV-exposed infants
HIV	Human immunodeficiency virus
IAC	Intensive adherence counseling
IMNC-I	Integrated maternal, newborn and childhood illnesses
LLINs	Long-lasting insecticide-treated nets
MCH	Maternal child health
MDR	Multi-drug resistant
MNCAH	Maternal, newborn, child and adolescent health

MOH	Ministry of Health
NAC	National ART advisory committee
NACS	Nutrition assessment, counseling and support
NVP	Nevirapine
OIs	Opportunistic infections
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PITC	Provider-initiated HIV testing and -counseling
PJP	Pneumocystis jiroveci pneumonia
SFP	Supplementary feeding programs
SMC	Safe male circumcision
SP	Sulfamethoxazole-Pyrimethamine
SUSTAIN	Strengthening Uganda's Systems for Treating AIDS Nationally
USAID	United States Agency for International Development

KEY DEFINITIONS

High Risk Infant: Breastfeeding infant whose mother has received ART for only four weeks or less before delivery or has a viral load greater than 1000 copies in four weeks before delivery or was newly diagnosed just before delivery.

Low risk Infant: Breastfeeding infant whose mother had received ART for longer than four weeks, or whose viral loads were controlled and lower than 1000 copies in four weeks prior to delivery.

HIV exposed infant: Infants and children born to mothers living with HIV until HIV infection in the infant or child is reliably excluded and the infant or child is no longer exposed through breastfeeding.

Prophylaxis: Protective treatment for a disease.

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ABSTRACT

Introduction: Globally, about 90% of children get HIV from their mothers during pregnancy, delivery, and breastfeeding. For a long time in Uganda vertical HIV transmission ranked second only to sexual transmission as the predominant mode of HIV infection in the country accounting for about 18% of new infections. In poor countries, HIV positive mothers are faced with the dilemma of either to breastfeed their children and increase the risk of transmitting HIV or not breastfeed and risk them dying of malnutrition and other infections. Nevirapine has been used in the PMTCT program in option B+ while Cotrimoxazole has been proved to protect against OIs and malaria in HEIs. The study aimed to find out the effectiveness of these two drugs amongst breastfed HEIs.

Objective: To determine the effectiveness of Nevirapine and Cotrimoxazole prophylaxis and outcome of breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district.

Method: A retrospective cohort study designwas employed. Both quantitative and qualitative approaches were utilized with checklist as the main method of data collection. A total of 73record reviews were enrolled in the study.

Results: Six out of the total 73 HEIs turned positive on DNA-PCR with only one reported mortality. Only two of the positive cases had been on breastfeeding while four were exclusively on formula milk. Malaria, OIs and death in the patient that succumbed was associated with home birth, Nevirapine initiation delay, and formula milk feeding.

Conclusion: Nevirapine and Cotrimoxazole prophylaxis are effective against MTCT of HIV and OIs and malaria respectively among breastfed HEIs. Transmission and mortality risk are lower among breastfed HEIs compared to those on formula milk. The study findings highlight the importance and effectiveness of NRP and Septrin prophylaxis in the current eMTCT strategy and the battle against the HIV/AIDS scourge in general.

CHAPTER ONE

1.0 INTRODUCTION

Globally, about 90% of children get HIV from their mothers during pregnancy, delivery, and breastfeeding(UNAIDS, 2016b). For a long time in Uganda vertical HIV transmission ranked second only tosexual transmission as the predominant mode of HIV infection in the country accounting forabout 18% of new infections(Uganda Ministry of Health, 2015). However, after implementing Option B+ since 2012, there has been a dramatic reduction in new vertical infections from 25,000 in the year 2000 to about 3,486 in 2015 (Uganda Ministry of Health, 2015).

Guidance is provided for delivering elimination of mother to child transmission of HIV (eMTCT) and HIV-exposed infant services to achieve the elimination of mother to child transmission of HIV and syphilis in-line with the national 90-90-90 targets for HIV epidemic control by 2030 (Drake, Wagner, Richardson, & John-Stewart, 2014).

HIV testing is the entry point to HIV prevention, care, treatment, and support services. The aim of HIV testing services (HTS) is to diagnose HIV early and correctly to ensure early access toprevention, treatment and support services. By 2015, only 65% of the estimated 1.46 millionHIV-positive persons in Uganda knew their HIV sero-status, and 51% of these were receiving

anti-retroviral treatment (Uganda Ministry of Health, 2015).

Prevention of mother-to-child transmission (PMTCT) programsprovides antiretroviral treatment (ART) to HIV-positive pregnant women to stop their infants from acquiring the virus. Without treatment, the likelihood of HIV passing from mother-to-child is 15% to 45%(Ngemu et al., 2014). However, ART and other effective PMTCT interventions can reduce this risk to below 5%(Banwat, Ochekpe, Auta, & Omale, 2014). Around 1.6 million new HIV infections among children have been prevented since 1995 due to the implementation of PMTCT services and of these, 1.3 million are estimated to have been averted in the five years, between 2010 and 2015(UNAIDS, 2016a). Despite this significant progress, in 2015, 23% of pregnant women living with HIV did not have access to ARVs and 150,000 children (400 children a day) became infected with HIV(UNAIDS, 2016b).

In 2016, UNAIDS with PEPFA among others launched start free, Stay free, AIDS free- a frame work calling for a worldwide sprint towards “Super-fast track targets” to end AIDS among

children, adolescents and young women by 2020(UNAIDS,PEPFAR, 2016). Targets relating to PMTCT include reducing the number of new HIV infections among children to fewer than 40,000 by 2018 and fewer than 20,000 by 2020(UNAIDS, PEPFAR, 2017). This strategy takes a "lifecycle approach" which means it considers how different stages of someone's life impacts on their vulnerability to HIV. In 2015, 6 priority countries (Botswana, Mozambique, Namibia, South Africa, Swaziland and Uganda) met the Global plan target of reducing MTCT by 90%(UNAIDS, PEPFAR, 2017). Another target of the global plan was to reduce the MTCT rate to 5% or less among breastfeeding mothers and to 2% or less among non-breastfeeding mothers(Drake et al., 2014).

This study sought to determine the HIV status outcome of such interventions particularly for exposed babies enrolled for nevirapine and cotrimoxazole prophylaxis. This chapter gives an account of the background to the study topic, problem statement, study objectives, conceptual framework and scope of the study.

1.1 BACKGROUND

HIV-exposed infants should receive care at the mother-baby care point, together with theirmothers, until they are 18 months of age. The goals of HIV-exposed infant care services are to prevent the infant from being infected with HIV through MTCT, diagnose HIV infection early and treat and to offer child survival interventions to prevent early death from preventableChildhood illnesses (World Vision International, 2014).

There have been significant developments in knowledge of interventions that can save lives of HIV-exposed infants. Current WHO guidelines recommend HIV testing of HIV-exposed infants at 4–6 weeks postnatally (early infant diagnosis, EID), and immediate antiretroviral therapy (ART) initiation for those testing positive, as early cessation of breastfeeding is associated with poor health outcomes for HIV-exposed babies (WHO, 2014b). Current guidelines support continued breastfeeding in conjunction with extended infant prophylaxis with Nevirapineand re-testing of the exposed baby at least 6 weeks after cessation of breastfeeding(USAID, 2013). Also, included within the guidelines are recommendations for infant feeding in the context of HIV, which stress that carers need to be educated about the importance of exclusive breastfeeding in the first 6 months of life (Manji et al., 2018). All these guidelines necessitate continued follow-up of exposed babies to ensure their full participation in the postnatal care cascade. Yet despite advances in knowledge of effective interventions to save lives of HIV-

exposed infants, many infants do not access the full package of services because of loss to follow-up (Adane, 2012).

Regular follow-up is the backbone of caring for HIV-exposed and infected (HEI) children as itensures optimal health care and psychosocial support to the family but also evaluation of the definitive outcome of such efforts potentially guide policy interventions. The HEI should receivecare together with their mother in the mother-baby care point in the MCH setting until theinfant is 18 months of age. The HEI and the mother should consistently visit the healthfacility at least nine times during that period. The mother-baby pair should be supported toadhere to the visit schedule(Ade et al., 2016).

Because of long commuting distances to access such services in Western Uganda, clients may be lost to follow up which can significantly impact on the overall HIV outcome for the exposed child. This research seeks to document to what extent loss to follow-up is a burden and document the definitive HIV serological status outcome of such babies at 18 months of the mandatory follow-up(Sidze et al., 2015).

The WHO guidelines recommend that all HIV-exposed infants should be identified, the HIV status of the mother documented in the child health card and mothers' passport. Infants whose HIV status is not documented or is unknown should be offered rapid HIV testing; including those whose mothers did not receive eMTCT services or have become newly infected after pregnancy(WHO, 2014b). The entry points for identification of HIV-exposed infants include outpatient department, pediatric wards and outreaches. Special attention is paid during immunization both at static and outreach areas to ensure that all children have their exposure status ascertained (WHO, 2014b).

The infant testing algorithm is followed to test and the test result interpreted.The first Polymerase Chain Reaction (PCR) is done within 6–8 weeks or the earliest opportunity thereafter, the 2ndPCR is done 6 weeks after cessation of breastfeeding. Dried Blood Spot (DBS) is done for confirmatory DNA PCR for all infants who test positive on the day they start ART, a DNA PCR test for all HEI who develop signs/symptoms suggestive of HIV during follow-up, irrespective of breastfeeding status is done. A rapid HIV test is done at 18 months for all infants who test negative at 1st or 2nd PCR(Ngemu et al., 2014).

All HIV-infected and exposed children should be immunized as per EPI immunization schedule. Health workers should review child immunization status at every visit. Some special

considerations/modifications for HIV-exposed childrenWhen considering BCG vaccination at a later age (re-vaccination for no scar or missed earlier vaccination), exclude symptomatic HIV infection. Children with symptomatic HIV infection should not receive BCG.Although the measles vaccine is a live vaccine, it should be given at six and nine months even when the child has symptoms of HIV (WHO, UNICEF, 2016).

The guidelines further emphasize the importance of providing Nevirapine(NVP) syrup to HEI from birth until six weeks of age. For high-risk infants, NVP syrup should be given from birth until 12 weeks of age. (Isoniazid) INH is also given for six months to HEI who are exposed to TB after excluding TB disease. For newborn infants, if the mother has TB disease and has been on anti-TB drugs for at least two weeks before delivery, INH prophylaxis should not be given. All HEI and HIV-infected children should receive insecticide treated nets and CTX.

If all that is set within the guidelines is followed to the letter, the chances of mother-to-child transmission of HIV will be significantly reduced (Ngemu et al., 2014).

1.2 PROBLEM STATEMENT

HIV can be transmitted from an HIV-positive woman to her child during pregnancy, childbirth and breastfeeding. Mother-to-child transmission (MTCT), which is also referred to as vertical transmission accounts for the vast majority of new infections in children (World Health Organization, 2018).

The many benefits of breastfeeding are well documented however, because of the risk of MTCT of HIV from an HIV infected mother to her infant, there is considerable concern over the practice especially in developing countries(Nyirenda, 2013). Several studies have been done that showed that vertical transmission of HIV remains a challenge, especially in rural Uganda(The Uganda HIV/AIDS Knowledge Management and Communications Capacity Initiative, 2015). Only a few of such studies have been done in Bushenyi despite the high prevalence of HIV/AIDS in Bushenyi(Uganda Ministry of Health, 2015). The purpose of this study was to assess the effectiveness ofnevirapine and cotrimoxazole prophylaxis and outcome of breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi District.

1.3 STUDY OBJECTIVES

1.3.1 GENERAL OBJECTIVE

To determine the effectiveness of Nevirapine and Cotrimoxazole prophylaxis and outcome of breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district.

1.3.2 SPECIFIC OBJECTIVES

1. To determine the effectiveness of nevirapine prophylaxis in breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district.
2. To determine the effectiveness of cotrimoxazole prophylaxis in breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district.
3. To determine factors associated with adverse outcome of nevirapine and cotrimoxazole prophylaxis in breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district

1.4 RESEARCH QUESTION

1. What is the effectiveness of nevirapine prophylaxis in breastfed babies born to HIV positivemothersin selected hospitals in Bushenyi district?
2. What is the effectiveness of cotrimoxazole prophylaxis in breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district?
3. What factors are associated with poor outcome of nevirapine and cotrimoxazole prophylaxis in breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district?

1.5 SCOPE OF THE STUDY

1.5.1 SUBJECT SCOPE

This study focused on the effectiveness of Nevirapine and Cotrimoxazole prophylaxis and factors influencing the outcome of breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district.

1.5.2 GEOGRAPHICAL SCOPE

The study was carried out in selected hospitals in Bushenyi district, including Kampala International University Teaching Hospital,Ishaka Adventist Hospital, Comboni hospital and Bushenyi Health Center IV. These hospitals and health center offer maternal and child health care services including antenatal care, HIV/TB clinics, normal deliveries, caesarean sections, pediatric and general medical wards.

1.5.3 TIME SCOPE

The study analyzed the problem from delivery of HIV exposed infant to 18 months when the last confirmatory test should be performed.

1.6 STUDY JUSTIFICATION

The study will enrich the researchers with knowledge on the effectiveness of Nevirapine and Cotrimoxazole prophylaxis and outcome of breastfed babies born to HIV positive mothers. It will also add knowledge which will enable health workers to diagnose HIV infection in infants early and treat. The study will add knowledge on child survival interventions to prevent early death from preventable childhood illnesses. It will help attract development partners to invest more resources in the prevention of HIV through mother to child transmission. The findings of this study will help policy makers establish other measures that target prevention and control of HIV infection through mother to child transmission.

1.7 CONCEPTUAL FRAMEWORK

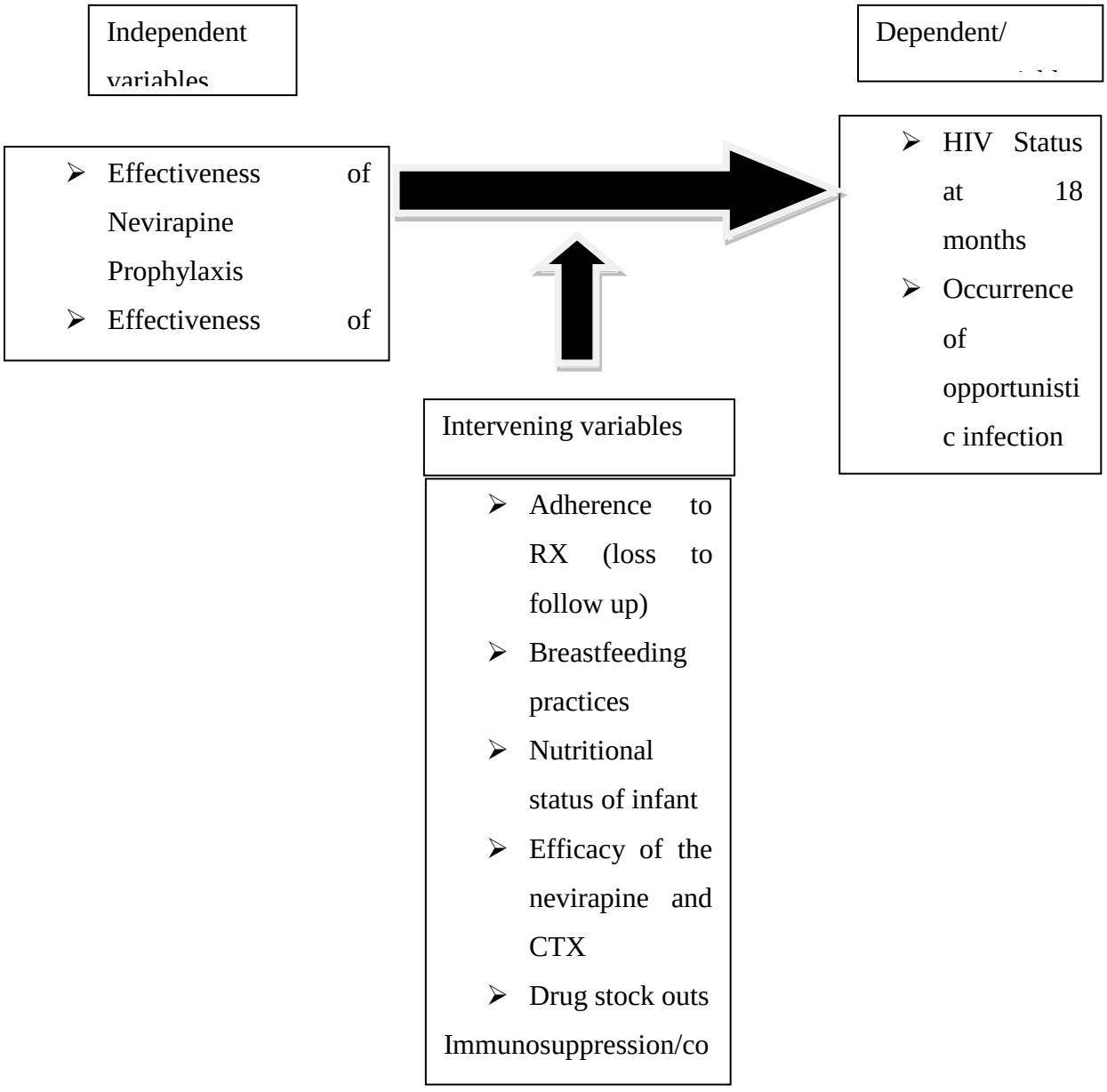


Figure 1: conceptual Framework on Effectiveness of Nevirapine&Clotrimoxazole and Outcome in HIV-exposed and positive children

CHAPTER TWO: LITERATURE REVIEW

2.0. INTRODUCTION

The following chapter deals with the literature reviewed on the effectiveness of Nevirapine and Cotrimoxazole prophylaxis in breastfed babies born to HIV positive mothers.

2.1 Effectiveness of nevirapine prophylaxis in breastfed babies born to HIV positive mothers

Single-dose Nevirapine for mothers and newborns at delivery is the simplest prevention strategy for vertical HIV-1 transmission and hence widely used in resource-constrained settings(Children & Aids, 2010). HIV-1-positive mothers and newborns received single-dose nevirapine in a prevention of mother-to-child HIV-1 transmission (PMTCT) program in Uganda. In the investigation, breast milk and plasma samples of mothers and newborns were collected. The plasma-placenta transfer could be quantified, revealing a transfer fraction of 11% to 25% (with a significant influence of time span between maternal nevirapine intake and birth) and a high transfer rate constant from maternal drug administration. Inter-individual variability was moderate between mothers and high between newborns. Simulations revealed that newborns born early (<1 hour) after maternal nevirapine intake would benefit from a 3-fold higher nevirapine dosage (6 mg/kg) after birth for analogous protective plasma concentrations over the first 2 weeks. In contrast, postnatal nevirapine dosage seemed to be dispensable for newborns born late (>24 hours) after maternal nevirapine intake. These dosing recommendations should be evaluated in prospective studies, including additional antiretroviral drugs in accordance with current PMTCT guidelines.(Frank, Harms, Kunz, & Kloft, 2013)

Nevirapine given once-daily for the first 6, 14, or 28 weeks of life to infants exposed to HIV-1 via breastfeeding reduces transmission through this route compared with single-dose nevirapine at birth or neonatally(Murthy & Krishnamurthy, 2011). The study conducted aimed to assess incremental safety and efficacy of extension of such prophylaxis to 6 months. Following receipt of nevirapine from birth to 6 weeks, infants without HIV infection were randomly allocated to receive extended Nevirapine prophylaxis or placebo until 6 months or until breastfeeding cessation, whichever came first. The primary efficacy endpoint was HIV-1 infection in infants at 6 months and safety endpoints were adverse reactions in both groups(Murthy & Krishnamurthy, 2011).

In Kaplan-Meier'sanalysis, infants who received extended nevirapine developed HIV-1 between 6 weeks and 6 months compared with 24 of controls, equating to a 54 reduction in transmission(Fowler et al., 2015). However, combined HIV infection and mortality rates did not differ between groups at 6 months. Infants given extended nevirapine and controls had serious adverse events, but frequency of adverse events, serious adverse events, and deaths did not differ significantly between treatment groups. Nevirapine prophylaxis can safely be used to provide protection from mother-to-child transmission of HIV-1 via breastfeeding for infants up to 6 months of age(Fowler et al., 2015).

In resource-limited settings, mothers infected with human immunodeficiency virus type 1 (HIV-1) face a difficult choice: breastfeed their infants but risk transmitting HIV-1 or not breastfeed their infants and risk the infants dying of other infectious diseases or malnutrition(Nyirenda, 2013). Recent results from observational studies and randomized clinical trials indicate daily administration of nevirapine to the infant can prevent breast-milk HIV-1 transmission(Frank et al., 2013). Cox regression models with nevirapine as a time-varying covariate, stratified by trial site and adjusted for maternal CD4 cell count and infant birth weight, indicated that nevirapine reduces the rate of HIV-1 infection by 71% and reduces the rate of HIV infection or death by 58%. Extended prophylaxis with Nevirapine or with nevirapine and zidovudine significantly reduces postnatal HIV-1 infection. Longer duration of prophylaxis results in a greater reduction in the risk of infection(Banwat et al., 2014).

Prevention of mother-to-child transmission through the use of antiretroviral (ARV) prophylaxis has been identified as one of the ways of reducing prevalence of HIV/AIDS in children and many centers are implementing it. A study to assess the use and effectiveness of antiretrovirals in the prevention of mother-to-child transmission (PMTCT) in a treatment center in Jos, Nigeria, was carried out. The prophylaxis given to HIV positive mothers and their babies were reviewed over a 20 months' period and the outcome of the intervention was assessed. The study revealed that 221 babies were given post exposure prophylaxis of single dose nevirapine at birth followed by 7-day course of zidovudine (AZT). Out of these babies 96.4% (213) returned negative Polymerase Chain Reaction (PCR) test results for HIV. The breast feeding options showed that 35.5% were on mixed or exclusive breastfeeding; 21% were on infant formula. The antiretroviral prophylaxis to the mothers and infants was given in accordance with recommended guidelines

and was effective in reducing the perinatal transmission of HIV to the babies.(Banwat et al., 2014).

2.2 Effectiveness of cotrimoxazole prophylaxis in breastfed babies born to HIV positive mothers

WHO recommends cotrimoxazole prophylaxis for children born to HIV-infected mothers from 6 weeks of age until breastfeeding cessation and exclusion of HIV infection(WHO, 2014b). Studies have reported on the protective efficacy and safety of CTX prophylaxis in these children when continued beyond breastfeeding cessation to age 4 (WHO, 2014a). A study was done in Eastern Uganda, an area of high HIV prevalence, malaria transmission intensity and anti-folateresistance. Throughout follow-up, malaria incidence was lowest among HIV-infected children who received continuous CTX prophylaxis and highest among HIV-negative unexposed children who never received CTX prophylaxis. There was no evidence of malaria incidence rebound in the year following discontinuation of CTX at age 2 or 4, but incidence increased significantly from age 4 to 5 among children who stopped CTX at age 4(Sandison et al., 2011). These results were reproduced in a study conducted in the same study population by Homsy and colleagues in 2014. Results of this study indicated that continuing cotrimoxazole prophylaxis beyond the period recommended by WHO is safe and efficacious in protecting HIV-exposed children living in malaria endemic areas even in the presence of high anti-folate resistance.(Homsy J. et al., 2014)

The influence of cotrimoxazole prophylaxis on incidence of lower respiratory tract infections (LRTIs) and diarrhoea has been documented. In multivariate analysis controlling for breast-feeding status, number of clinic visits and HIV infection status, HIV infected infants with access to CTM prophylaxis had a significantly lower incidence of LRTI (82%) than those without access to prophylaxis (Onakpoya, Hayward, & Heneghan, 2015). However, in HIV-uninfected infants, this was not the case. CTM prophylaxis was associated with a non-significant increased risk for diarrhea in both infected and uninfected infants. This observational study confirms current thinking that CTM prophylaxis is protective against LRTIs in HIV-infected children. However, because of a possible association between CTM prophylaxis and an increased risk of diarrhoea(Eh, Nm, Azman, Mcleod, & Gw, 2010), HIV status of infants should be determined as early as possible in order to prevent unnecessary exposure of uninfected infants to CTM

prophylaxis, while further studies to quantify both beneficial and adverse effects of CTM prophylaxis are undertaken (Onakpoya et al., 2015).

In a study to evaluate the protective efficacy of co-trimoxazole prophylaxis against malaria in HIV exposed children (uninfected children born to HIV infected mothers) in Africa, Tororo district, rural Uganda, an area of high malaria transmission intensity, Co-trimoxazoleprophylaxiswas given from enrollment until cessation of breast feeding and confirmation of negative HIV status. The incidence of malaria, calculated as the number of a Co-trimoxazole prophylaxis was moderately protective against malaria in HIV exposed infants when continued beyond the period of HIV exposure despite the high prevalence of Plasmodium genotypes associated with antifolate resistance (Sandison et al., 2011).

According to WHO, Cotrimoxazole (CTX) prophylaxis significantly reduces the incidence and severityof *Pneumocystis jiroveci*pneumonia. It also offers protection against common bacterial infections, toxoplasmosis and malaria (Charles F. Thomas, Jr,MD, Andrew H Limper, 2018).

2.3 Outcome of breastfed babies born to HIV positive mothers

A study was conducted in Togo to analyze the fate of children born to HIV-positive mothers and to determine the impact of feeding options on the HIV status of the children in preventing mother-to-child transmission (PMTCT). It was found in the study that the antiretroviral prophylaxis most used in the mothers and/or the children was nevirapine in 86% of the cases. The transmission rate in the group of children breastfed was 5.9% (six children infected out of 102) and 8.5% in the group of children fed by formula milk (seven children out of 82). Death occurred in half of the cases during the first two months of life. Follow-up was the major issue in monitoring children born to HIV-infected mothers. The HIV transmission rate is very high, irrespective of the feeding method (Lawson-Evi et al., 2010).

A study to determine proportions and factors associated with intra-facility linkage to HIV care and Early Infant Diagnosis care (EID) to inform strategic scale up of PMTCT programs was conducted in Uganda. In the study, HIV-infected pregnant mothers, identified through routine antenatal care (ANC) and HIV-exposed babies were evaluated for enrollment in HIV clinics by 6 weeks post-delivery. Linkage of mother-baby pairs to HIV chronic care and EID was in rural and in urban health facilities. Within rural facilities, ANC registration <28 weeks-of-gestation was associated with mothers' linkage to HIV chronic care and mothers' multi-parity was associated with baby's linkage to EID. Stigma, long distance to health facilities and vertical PMTCT

services affected linkage in rural facilities, while peer mothers, infant feeding services, long patient queues and limited privacy hindered linkage to HIV care in urban settings. Post-natal linkage of HIV-infected mothers to chronic HIV care and HIV-exposed babies to EID programs was low. Barriers to linkage to HIV care vary in urban and rural settings. The study recommended targeted interventions to rapidly improve linkage to antiretroviral therapy for elimination of MTCT.(Mugasha et al., 2014).

Data comparing survival of formula-fed to breast-fed infants in programmatic settings are limited. A study compared mortality and HIV-free status of breast and formula-fed infants born to HIV-positive mothers in a program in rural, Rakai District Uganda. Infants born to HIV-positive mothers were followed at one, six and twelve months postpartum. 41% were formula-fed while 59% were breast-fed. Exclusive breast-feeding was practiced by only 25% of breast-feeding women at one month postpartum. The cumulative 12-month probability of infant mortality was 18% among the formula-fed compared to 3% among the breast-fed infants. There were no statistically significant differentials in HIV-free survival by feeding choice. Formula-feeding was associated with a higher risk of infant mortality than breastfeeding in this rural population (Kagaayi et al., 2008).

In yet another study the rates and timing of mother to infant transmission of HIV associated with breast feeding in mothers who seroconvert postnatally, and their breast milk and plasma HIV loads during and following seroconversion, compared with women who tested HIV positive at delivery were studied. Mother to child transmission of HIV, and breast milk and maternal plasma HIV load during the postpartum period. Breastfeeding associated transmission is high during primary maternal HIV infection and is mirrored by a high but transient peak in breast milk HIV load. Around two thirds of breastfeeding associated transmission by women who seroconvert postnatally may occur while the mother is still in the "window period" of an antibody based test, when she would test HIV negative using one of these tests (Humphrey et al., 2010).

CHAPTER THREE: METHODOLOGY

3.0. INTRODUCTION

This chapter deals with the methodology used in the study such as the study design, technique, population, sample size determination, ethical considerations, information dissemination among others.

3.1 STUDY DESIGN

This study employed a retrospective cohort study design. This design was chosen because we already had a group of exposed babies and some of whom we already had the outcome to assess the effectiveness of nevirapine and cotrimoxazole prophylaxis and outcome of breastfed babies born to HIV positive mothers.

3.2 STUDY POPULATION

The study population comprised of babies born to HIV positive mothers in selected hospitals in Bushenyi district.

Bushenyiis a district in western Uganda which is bordered by Rubirizi district in the northwest, Buhweju district to northeast, Sheema district to the east, Mitooma district to the south and Rukungiri district to the west. The largest town in the district is Ishaka located 75 kilometers by road northwest of Mbarara.

3.2.1 SAMPLING TECHNIQUE

Systematic random sampling technique of every Nth file corresponding to even numbers was used to select files of HIV exposed babies in 2015. A total of 18 files were selected from 2015 from each hospital. The first 18 files of 2015 were selected.

3.2.2 SAMPLE SIZE

A total of 73 files were selectedas per the sample size according toKeish&Leisely formula, 1965 $n=Z^2P(1-P)/E^2$,

Where,

n is the desired sample sizeZ is the standard deviation taken as 1.96 at a confidence interval of 95%.

P is the proportion of the target population estimated to have similar characteristics=5%

(Keish&Leisely, 1965)

E is the degree of accuracy= 0.05.

Therefore, $n= 1.96^2$ X0.05 (1-0.10)/ $(0.05)^2= 73$

3.3 DATA COLLECTION

Data was collected by use of a checklist.

3.4 INCLUSION CRITERIA

All babies born to HIV positive mothers who were enrolled in care in the selected hospitals in Bushenyi district in 2015and all those who were exclusively breastfed.

3.5 EXCLUSION CRITERIA

All babies born to HIV positive mothers not enrolled in care in the selected hospitals in Bushenyi district and those who were not born in 2015nor exclusively breastfed.

3.6 ETHICAL CONSIDERATION

Permission to carry out research was obtained from Kampala International University IREC, an introductory letter from the faculty administrator school of clinical medicine and dentistry (IRB letter dated 03/01/2018) and permission from the selected hospital administrations were also obtained to ensure proper protocols were observed and for easy search of required data. Unique numbers were used instead of client names

3.7 DATA ANALYSIS AND PRESENTATION

The data was analyzed using SPSS 20.0. In order to achieve objective one, percentages were computed for HIV exposed infants who turned positive at 18 months. Inorder to achieve objective 1, percentages were computed for seroconverted infants who had acquired at least an opportunistic infection while enrolled on cotrimoxazole prophylaxis during the year 2015. To achieve objective 2, Chi-square test was conducted for binary data and multivariate logistic regression analysis to determine factors significantly associated for seroconversion and subsequent opportunistic infections. Analysis was conducted at 95% confidence interval, regarding $p<0.05$ as significant.

3.8 DATA QUALITY CONTROL

Use of knowledgeable research assistants who were staff working with HIV clinics attached to PMTCT intervention under close supervision were provided by the principal researcher. The research assistants were trained and taken through the data collection tool at the beginning of data collection. Completeness and appropriateness of the data was checked before leaving the field. Unique client numbers were used to avoid duplication.

3.9 LIMITATIONS

Being a retrospective cohort study, there was likely to be incompleteness of records since they were not collected to suit the current study tool. In the event a file had incomplete records, next file corresponding to an even number was considered. Only files with complete records were considered for analysis

3.10 DISSEMINATION OF FINDINGS

1. After the work copies of the research will be sent to KIUTH library and university library.
2. A hard copy of the report will be sent to the offices of Bushenyi district and the different selected hospitals.
3. The research findings will be published in medical journals and also presented in conferences.

CHAPTER FOUR: STUDY FINDINGS

4.0. INTRODUCTION

This chapter deals with analysis and presentation of the study findings in form of tables, charts and graphs. A total of 73 checklists were analyzed giving a response rate of 100%. The information derived span a total period of 2 years, i.e. from birth of a HEI to 18 months of age when the final serological test was done, plus an allowance of six months for delayed visits.

4.1. MOTHER INFORMATION

4.1.1. SOCIO-DEMOGRAPHICS

Table 1: Socio-demographic Characteristics of the Mothers (N=73)

VARIABLE		FREQUENCY (No.)	PERCENTAGE (%)
Age	Less than 18 years	10	13.70
	18 – 40 years	57	78.08
	Above 40 years	6	8.22
Marital status	Single	16	21.92
	Married	35	47.95
	Separated	4	5.48
	Widowed	18	24.66
Employment Status	Employed	22	30.14
	Unemployed	51	69.86

Majority (78.08%) of the mothers fell between the ages of 18 years and 40 years, with most (47.95%) being married and unemployed (69.86%).

4.1.2. HEALTH AND RISK INDICATORS

4.1.2.1. ANC Attendance and HIV status of mother at First ANC visit

All the 73 mothers had at some time attended ANC though numbers of attendance varied widely. At the first ANC attendance, the HIV status of the mothers were as follows; 22 unknowns, 4 negative and 47 positive (figure 2). Of the 47 HIV positive mothers at first ANC visit, 30 (63.83%) were already on ART while 17 (36.17%) were not yet on ART (figure 3). All of 17 who were not on ART were initiated. In the third trimester and delivery, all the 73 mothers had tested positive including those whose status was unknown or negative at first visit, and all of them had been put on ART.

Figure 2: HIV Status of Mothers at First ANC Visit (N=73)

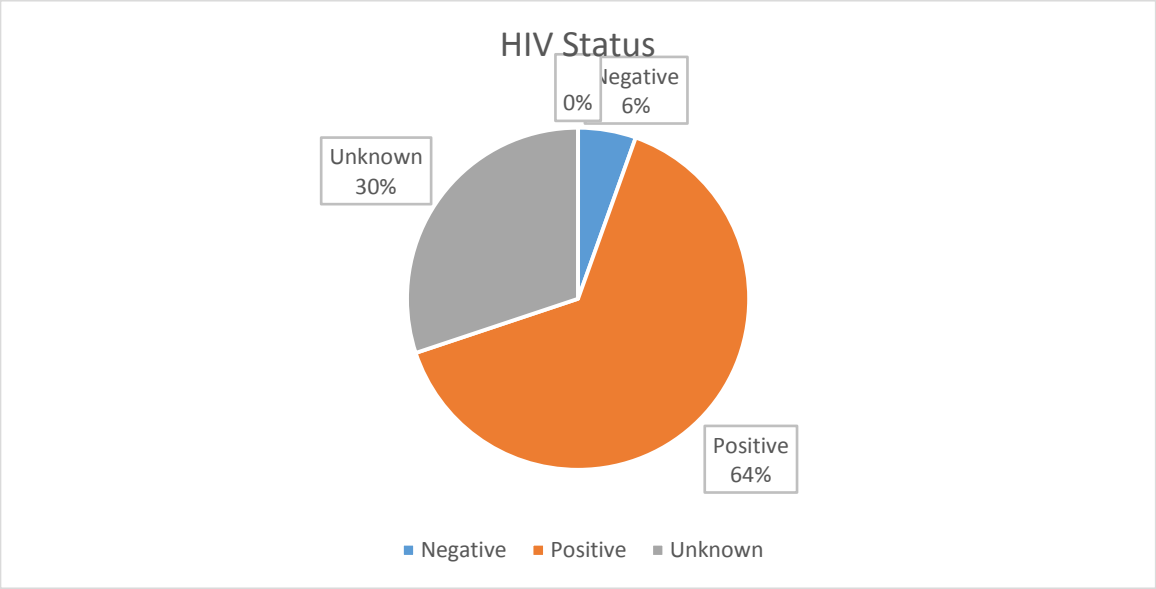
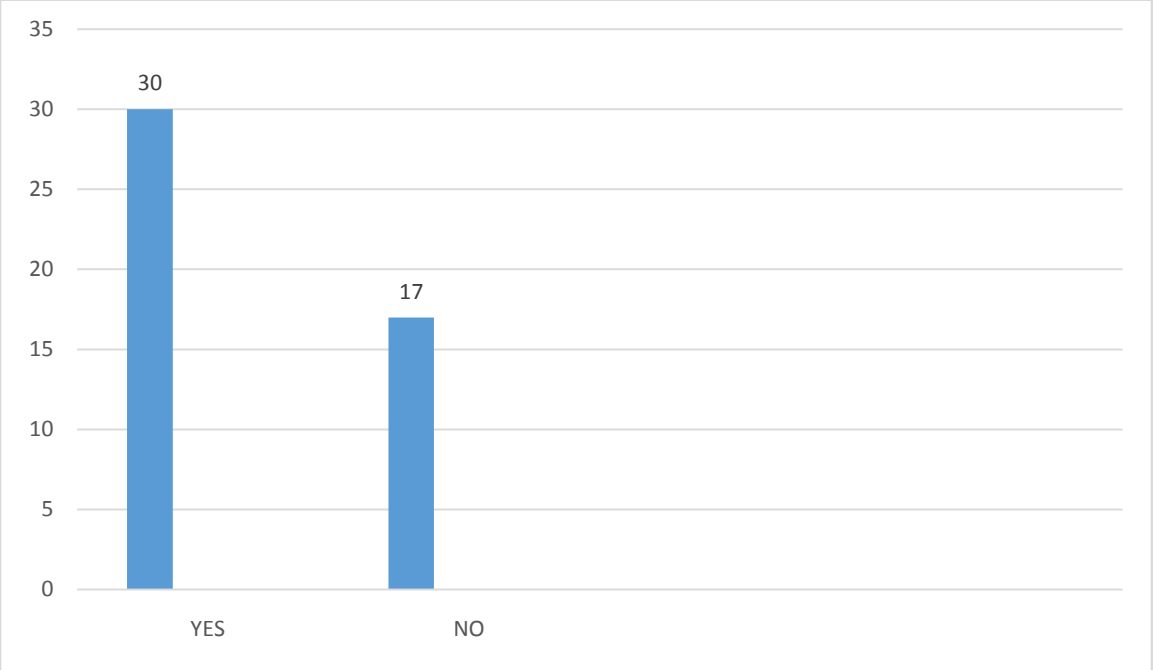


Figure 3: ART Treatment Status of HIV Positive Mothers at First Visit (N=47)



4.2. INFANT INFORMATION

4.2.1. Exposure Status of Infant

4.2.1.1. Place of Delivery and Nevirapine Syrup at Birth

58(79.45%) of the mothers delivered in a health facility under the assistance of skilled health professional while 15(20.55%) delivered at home. For this reason, those that delivered in any other setting apart from a

health facility, were categorized as to be of high risk in transmitting HIV to the child and the child viewed as highly exposed whereas those delivered at a health facility were viewed as not highly exposed. All of those infants delivered in a health facility were initiated on Nevirapine at birth or shortly after while of those delivered elsewhere were not immediately put onNevirapine syrup; 2 were taken to a nearby health facility immediately after birth, while for 13, it was not done immediately but at the earliest first contact. (Table 2)

Table 2: Place of Delivery and Nevirapine Syrup Initiation at Birth (N=73)

Place of Delivery		**Nevirapine Syrup at Birth**	
Health Facility	58	YES: 58	NO: 0
Home	15	YES: 2	NO: 13
TOTAL	**73**	**60**	**13**

4.2.1.2. Six Months Exclusive Breastfeeding and total Breastfeeding Duration

Only 31(42.47%) of the infants were exclusively breastfed for six months, the other 42 were not.14 mothers opted to totally refrain from breastfeeding their infants and give only formula milk, 28 breastfed but not exclusively for a full six months. For the total duration of breastfeeding, most infants, who were not on formula milk, stopped breastfeeding between one year and two years. None were stopped before reaching one year.

4.2.2. HIV Status of HIV-exposed infants

6(2.22%) of the 73 HIV-Exposed infants contracted the disease via MTCT. All had turned positive by the first DNA-PCR done and were immediately initiated on ART. 4 (66.67%) of those that turned positive had been fed on formula milk only while only 2(33.33%) had been breastfed. They were also initiated on cotrimoxazole together with those who had turned out negative by both first and second DNA-PCR. Those who turned negative by 18 months had stopped contrimoxazole while those positive had continued. None of the mothers complained of any adverse effectsexperienced by their infant upon medication initiation.

Table 3: 2 by 2 Table showing the Odds of Turning Positive among HEI on different feeding modes (N=73)

HIV-exposed	**Turned HIV +ve**	**Turned HIV -ve**	**TOTAL**
On Formula Milk	4	10	14
Breastfed	2	57	59
TOTAL	**6**	**67**	**73**

As shown in table 3 above, HEIs on formula milk were more likely to turn out positive compared to their breastfed counterparts (OR=11.4, CI = 95%, p = 0.05).

4.2.3. Outcomes of Nevirapine and Cotrimoxazole Prophylaxis and Associated Factors

Over the follow-up period, no significant complain in as far as drug adverse effects were reported although one infant who had tested positive succumbed. On further follow-up, it was noted that the child belonged to the group that hadn't been born at a health facility so initiation of prophylaxis was significantly delayed, and had not been exclusively breastfed for 6 months. The child had been admitted thrice over this period, one time on account of malaria, one on severe acute malnutrition and one time due to pneumonia. 4(5.48%) of the total 73 were malnourished on their last visit.

CHAPTER FIVE: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.0. INTRODUCTION

This chapter deals with the discussion of the findings, conclusions arrived at and recommendations made.

5.1. DISCUSSION OF STUDY FINDINGS

5.1.1. Effectiveness of Nevirapine HIV-exposed breastfed infants

From the study, we find that only 6(2.22%) of the 73 HEIs tested positive for HIV after DNA-PCR testing. This shows a significant protection conferred by Nevirapine prophylaxis against MTCT of HIV. These low transmission rates agree with the WHO stand and also with findings in Jos, Nigeria by (Banwat et al., 2014) that showed that Nevirapine prophylaxis markedly reduced HIV transmission in HEIs; out of 221 HEIs, only 9 (3.6%) returned positive DNA-PCR tests.

5.1.2. Effectiveness of Cotrimoxazole in HIV-exposed breastfed infants

Among the HEIs breastfed infants put on cotrimoxazole prophylaxis, none of the breastfed infants developed significant opportunistic infections, malaria or pneumonia. Malaria and pneumonia were reported only in one infant who had been exclusively on formula milk and who later succumbed. Among the HEIs who later turned out negative, none had problems of opportunistic infections or malaria over the duration they were on septrin prophylaxis. These findings agree with (Homsy J. et al., 2014) that Septrin prophylaxis reduces incidence of OIs and malaria in HEIs.

5.1.3. Outcomes in Breastfed Babies born to HIV-Positive Mothers

From our study findings, we see that of the six babies that tested positive, 4 (66.67%) had been fed exclusively on formula milk whereas only 2 (33.33%) had been breastfed. This indicates that breastfed HEIs have a significantly lower transmission risk compared to those on formula milk. Our findings mirror those of (Lawson-Evi et al., 2010) that also found a significantly lower transmission rate among breastfed HEIs (5.9%) compared to those on formula milk (8.5%).

Only one of the HEIs who had turned out positive succumbed. The infant was among those who had been fed exclusively on formula milk. None of the breastfed had succumbed. Similar findings were reported in Rakai District, Uganda whereby higher mortality was reported amongst HIV positive infants on formula milk (18%) compared to those who were breastfed (3%) (Kagaayi et al., 2008).

5.2. CONCLUSIONS

Nevirapine and Cotrimoxazole prophylaxis are effective against MTCT of HIV and OIs and malaria respectively among breastfed HEIs. Transmission and mortality risk are lower among breastfed HEIs compared to those on formula milk. The study findings highlight the importance and effectiveness of NRP and Septrin prophylaxis in the current eMTCT strategy and the battle against the HIV/AIDS scourge in general.

5.3. RECOMMENDATIONS

5.3.1. To the HIV Positive Mothers

1. Try as much as possible to exclusively breastfeed their children for six months.
2. Ensure delivery at a health facility so that appropriate measures can be instituted as early as possible so as to minimize chances of MTCT of HIV.

5.3.2. To Concerned Health Provision Bodies

1. Step up efforts in advocating for early ANC attendance, early diagnosis and delivery at a health facility for HIV positive mothers.

5.3.3. Area for further research

Further research is recommended on the effect of six months' exclusive breastfeeding and the total duration of breastfeeding on MTCT of HIV.

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APPENDIX I: DATA COLLLECTION TOOL

A CHECKLIST FOR EFFECTIVENESS OF NEVIRAPINE AND COTRIMOXAZOLE PROPHYLAXIS AND OUTCOME OF BREASTFED BABIES BORN TO HIV POSITIVE MOTHERS IN SELECTED HOSPITALS IN BUSHENYI DISTRICT.

CHECKLIST NUMBER……..

IPNo. ……..

FACILITY……..

Section A: Mother information

1. Age(<18 years) ☐ 18-40years ☐ Above 40years ☐

2. Maritral status

Single ☐…. Married ☐ separated ☐ widow ☐..

3. employment status

Employed ☐ unemployed ☐

4. Did she attend ANC

YES ☐ NO ☐

5. HIV status of mother during first ANC visit

Negative ☐ Positive ☐ Unknown status ☐

6. If positive, was she already on ARVs?

YES ☐ NO ☐

7. If positive and not on medication was she initiated on ARVs?

YES ☐ NO ☐

8. HIV status of mother during third trimester and on delivery

Negative ☐ Positive on ART ☐ Positive not on ART ☐

SECTION B

Infant information

1. Exposure status

Highly exposed ☐ not highly exposed ☐

2. Was baby initiated on Nevirapine syrup at birth?

YES ☐ NO ☐

3. Age at iniation of Nevirapine ……

3. Was baby exclusively breastfed for the first 6months?

YES ☐ NO ☐

4. Was the first DNA PCR positive?

YES ☐ NO ☐

5. If yes was baby initiated on ART immediately?

YES ☐ NO ☐

6. If yes was the baby initiated on cotrimoxazole prophylaxis?

YES ☐ NO ☐

6. Was the second DNA PCR positive?

YES ☐ NO ☐

7. How long was the child breastfed?

6months ☐ 1year ☐ >1year ☐

8. Did mother report ant worrying side effects to the nevirapine?

YES ☐ NO ☐

If yes, specify……

9. Did the baby suffer from any opportunistic infections?

YES ☐ NO ☐

10. If yes, specify…….

11. Was HIV rapid test done at 18months?

YES ☐ NO ☐

12. If YES, what was the result?

Positive ☐ Negative ☐

13. Age at which infant was enrolled……

14. Gestational age at which mother was enrolled into care

……..

15. Number of visits

…….

16. Lost to follow up

YES ☐ NO ☐

17. Nutritional status of infant on the last visit

…….

.

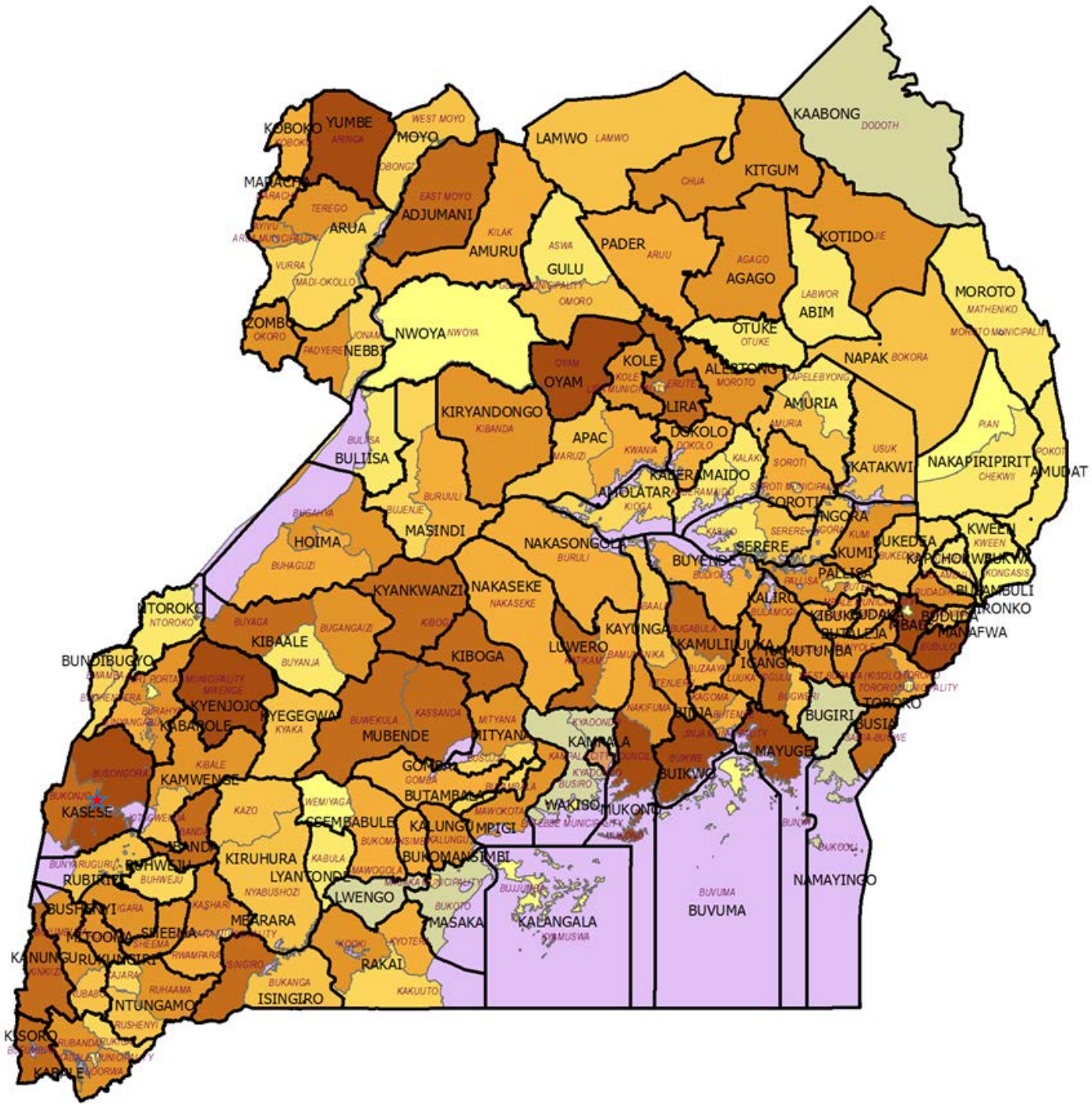
APPENDIX II: BUDGET

ITEM	QUANTITY	UNIT PRICE @	AMOUNT
STATIONARY	1 Reams of photocopying paper	15000	15,000
	6 pens	500	3, 000
	Binding and printing	30000	30,000
	2 Staples	1000	2,000
	5 Clear bags	1400	7,000
Facilitation	Water, food, transport	50000	50,000
Data management	Data entry and analysis		50,000
Miscellaneous			50,000
Grand Total			207,000

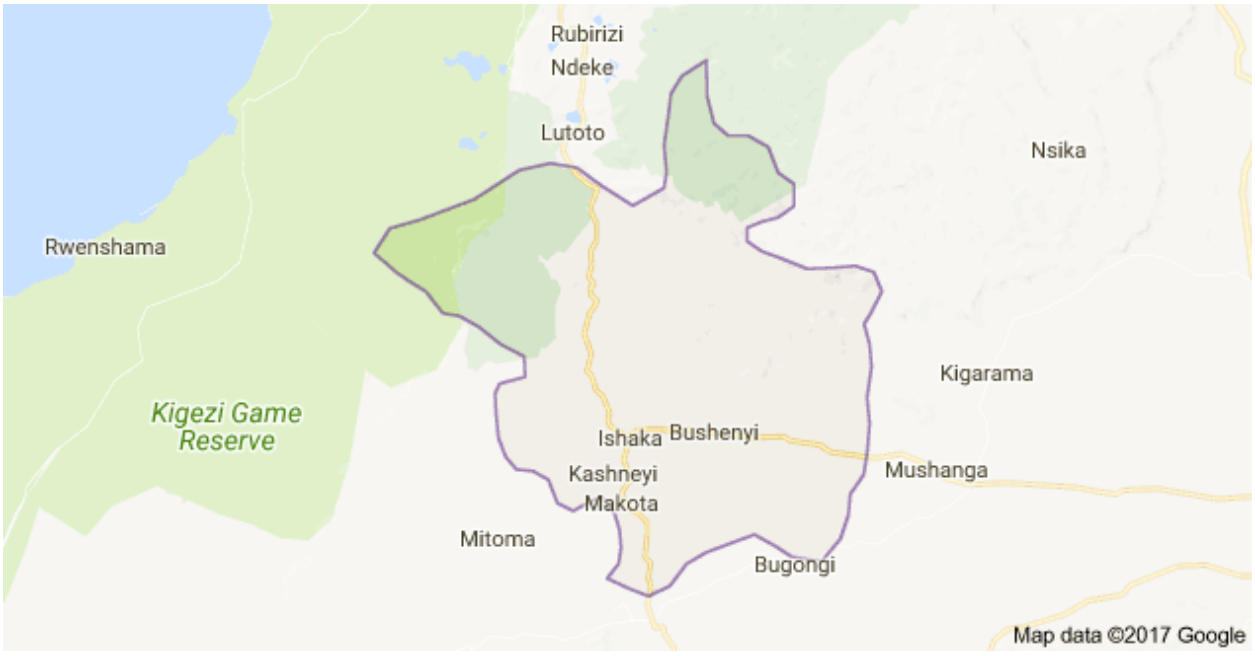
APPENDIX III: WORK PLAN

OBJECTIVES	ACTIVITIES	TIME FRAME 2017				
		SEPT	SEPT	OCT	NOVE	Responsible person
Administrative Requirements	Choosing & Presentation of the research topic for approval					Supervisor Researcher
Proposal Writing	Writing a proposal and preparing research tools Typing and binding the proposal Handing the proposal to the supervisor					Supervisor Researcher
Gathering data	Distribution of research tools and collection					Researcher
Data analysis	Making sense of the collected information Compiling the analyzed information Discussing, finagling, the findings. Writing the report.					Data analyst and Researcher
Dissemination of information	Copies of the dissertation presented to DON, KIU library and conferences					Researcher

APPENDIX V: MAP OF UGANDA SHOWING THE LOCATION OF BUSHENYI DISTRICT (RED STAR)



APPENDIX VI: MAP OF BUSHENYI DISTRICT & ISHAKA TOWN



APPEDIX:VII INTRODUCTORY LETTER

KAMPALA INTERNATIONAL UNIVERSITY – WESTERN CAMPUS

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Tel: +256 200923534
www.kiu.ac.ug

OFFICE OF THE DEAN
FACULTY OF CLINICAL MEDICINE & DENTISTRY

05/01/2018

TO WHOM IT MAY CONCERN

RE: MPANGA MARY (BMS/0090/133/DU)

The above named person is a fifth year student at Kampala International University pursuing a Bachelor of Medicine, Bachelor of Surgery (MBChB) Programme.

She wishes to conduct her student research in your community.

Topic: Effectiveness of nevirapine and cotrimazole prophylaxis and outcome of breastfed babies born to HIV positive mothers in selected hospitals in Bushenyi district

Supervisor: Dr. Lule Herman

Any assistance given will be appreciated.

K.I.U TEACHING HOSPITAL
05 FEB 2018
W.Campus
DEDI ASSOCIATE DEAN FCM&D

Dr. Akib Surat O
Assoc Dean FCM&D