

**UTILIZATION OF PREVENTION OF MOTHER-TO-CHILD TRANSMISSION  
OF HIV (PMTCT) AT JUBA TEACHING HOSPITAL-(SOUTH SUDAN)**

**THESIS SUBMITTED TO THE UNIVERSITY OF NAIROBI, DEPARTMENT OF  
OBSTETRICS AND GYNAECOLOGY IN PARTIAL FULFILMENT FOR THE  
AWARD OF MASTER DEGREE OF MEDICINE IN OBSTETRICS AND  
GYNAECOLOGY**

SUBMITTED BY

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## DEDICATION

I dedicate this book to my Husband Lobor, my son Wani and my daughter Diko whose everlasting and unwavering love filled me with patience, courage and commitment to pursue my study.

To all the people working in the field of HIV/AIDS and specifically on PMTCT.

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DECLARATION

This is to certify that this proposal is my original work and has not been presented elsewhere. References to the work done by others are clearly indicated.

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## **CERTIFICATE OF SUPERVISION**

This is to certify that Dr. Idyoro J. Ojukwu researched this thesis under my guidance and supervision and this book is submitted with my approval

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## **LIST OF ABBREVIATIONS**

AIDS	ACQUIRED IMMUNE DEFICIENCY SYNDROME
ANC	ANTENATAL CLINIC
ART	ANTI-RETROVIRAL THERAPY/TREATMENT
ARV	ANTI-RETROVIRAL
AZT	ZIDOVUDINE
BCG	BACILLUS CALMETTE-GUE'RIN
BFHI	BABY FRIENDLY HOSPITAL INITIATIVE
CD4	CLUSTER OF DIFFERENTIATION 4
DNA	DEOXYRIBONUCLEIC ACID
GOSS	GOVERNMENT OF SOUTH SUDAN
HIV	HUMAN IMMUNO-DEFICIENCY VIRUS
MCH	MOTHER AND CHILD HEALTH
MOH	MINISTRY OF HEALTH
MTCT	MOTHER TO CHILD TRANSMISSION
NVP	NEVIRRAPINE
OIs	OPPORTUNISTIC INFECTIONS
OPV	ORAL POLIO VACCINE
PCR	POLYMERASE CHAIN REACTION
PLWHIV	PEOPLE LIVING WITH HIV

PMTCT PREVENTION OF MOTHER TO CHILD TRANSMISSION  
SD-NVP SINGLE DOSE NEVIRAPINE  
SRH SEXUAL AND REPRODUCTIVE HEALTH  
SVD SPONTANEOUS VERTEX DELIVERY  
UNAIDS UNITED NATIONS PROGRAMME ON HIV/AIDS  
UNGASS UNITED NATIONS GENERAL ASSEMBLY SPECIAL SESSION  
UNICEF UNITED NATION CHILDREND'S FUND  
WHO WORLD HEALTH ORGANIZATION

## **DEFINITION OF TERMS**

**Comprehensive PMTCT package:** Refers to HIV counselling and testing, knowing the HIV test results, use of HAART for those tested positive, infant ARV prophylaxis, safe infant feeding and use of family planning.

**HIV free survival:** Refers to infants born to HIV positive mothers who are alive and without HIV infection.

**Mixed feeding:** Refers to breastfeeding while also giving other fluids and/or foods.

## **ABSTRACT**

**Background:** Mother-to-child transmission (MTCT) of HIV is the most common route of infection in paediatrics HIV acquisition. It contributes to more than 90% of paediatrics HIV infections. Vertical transmission of HIV virus can occur during pregnancy, labour, delivery and even breastfeeding. Without any interventions the risk of a HIV exposed infant acquiring HIV is 20-45% but with interventions the risk can be reduced to less than 2%.

**Objective:** To determine the utilization of PMTCT services by mothers attending postnatal services at Juba Teaching Hospital.

**Study Design:** Cross-sectional study.

**Study area:** The study was conducted at the mother and child health (MCH) clinic at Juba teaching Hospital.

**Study population:** All consenting mothers who attended the clinic at six weeks to nine months after delivery for immunization.

**Methodology:** The data was collected using a structured questionnaire through direct interview of the participants.

**Results:** A total of three hundred (300) women were recruited in the study at the mother and child health (MCH) clinic at Juba Teaching Hospital. All of them had at least one antenatal care visit and 246 (82%) received antenatal counselling for HIV whereby 201(67%) got tested. The HIV prevalence was found to be 7.5%. Of the fifteen (15)

mothers who tested positive for HIV, 85.7% delivered in a health facility. None of the HIV positive mothers had a CD4 test result. Only 20% of the mothers were put on single dose Nevirapine, and 13.2% were on more efficacious ARV combination otherwise the rest did receive neither antenatal nor intrapartum ARV intervention. Ten (66.7%) of HIV exposed infants received Nevirapine after delivery. Polymerase chain reaction/Deoxyribonucleic acid (PCR/DNA) was not done to all the HIV exposed babies. Six (40%) of these babies were on exclusive breastfeeding for the first six months with 26.7% and 33.3% on formula and mixed feeding respectively. Six (6[50%]) of the eligible mothers for family planning were not using any mode of family planning, while 16.6% used condoms, IUCD (16.6%) and 16.6% used dates(natural) method.

**Conclusion:** Although majority of the mothers received HIV counselling during the antenatal period yet less than 70% got tested for HIV. CD4 count testing was not routinely done for PMTCT and the use of HAART and other more efficacious ARV combination was very low among HIV positive mothers. DNA/PCR was not routinely done for HIV exposed infants. Safe infant feeding practices were however limited. A great majority of those with HIV positive partners did not practice safe family planning methods.

## **1.0 BACKGROUND AND LITERATURE REVIEW**

### **1.1 INTRODUCTION**

It is estimated that at the end of 2011 there were 34.0 million people living with HIV globally. Each year around 2.5 million people become infected with HIV and 1.7 million die from AIDS related causes worldwide. UNAIDS have estimated that 69% of people living with HIV are in Sub-Saharan Africa where 23.5 million people are infected with the disease. There is around 3.1 million women age 15 to 24 years living with HIV in sub-Saharan Africa accounting to three quarters of all infected women worldwide<sup>1</sup>. The difference in prevalence by sex is more marked among young people aged 15-24 years with 3 out of 4 people living with HIV in that age group being female<sup>2</sup>. In South Sudan, with adult population of 6.9 million in 2007, an estimated 214,000 adults were living with HIV<sup>3</sup>.

The United Nations general assembly special session on HIV/AIDS (UNGASS) declaration adopted in 2001 committed the member countries to reduce the number of infants infected by HIV/AIDS by 20% in 2005 and by 50% in 2010, by ensuring that 80% of pregnant women receive HIV information, counseling, testing, interventions to prevent vertical transmission and other HIV prevention services<sup>4</sup>. The strategy towards universal elimination of mother-to-child transmission of HIV includes seven principal strategic directions which include<sup>5</sup>:

- Strengthening commitment and leadership for achieving full coverage of PMTCT services
- Provision of technical guidance to optimize HIV prevention, care and treatment services for women and children

- Promote and support integration of HIV prevention, care and treatment services within maternal, newborn and child health and reproductive health programmes
- Ensuring reliable and equitable access for all women including the most vulnerable
- Promotion and support of health systems interventions to improve the delivery of HIV prevention, care and treatment services for women and children
- Tracking programme performance and impact on mother-to-child transmission of HIV rates and on maternal and child health outcomes
- Strengthening global, regional and country partnerships for providing HIV prevention, care and treatment for women, infants and young children and advocate for increased resources

PMTCT provides an opportunity for preventing new paediatric HIV infections as well as reaching the 20-30% of HIV positive pregnant women who meet WHO eligibility criteria for initiating ART for their own health. Acute HIV infection is characterised by a transient and rapid decrease in CD4 lymphocyte count and thus high viral loads and these when occur during pregnancy pose the greatest risk for mother-to-child transmission (MTCT) of HIV to the unborn baby. ARV prophylaxis as well as treatment in these situations is very crucial.

To effectively address MTCT of HIV requires a comprehensive approach that includes the following strategic components –the WHO prongs;

- Primary prevention of HIV infection among women of child bearing age.
- Preventing unintended pregnancies among women living with HIV.
- Preventing HIV transmission from women living with HIV to their infants.

- Providing appropriate treatment, care and support to mothers living with HIV and their children and families.

The WHO guidelines recommend all mothers diagnosed as HIV positive during pregnancy should begin a triple antiretroviral regimen immediately irrespective of their CD4 count and should remain on the same regimen throughout pregnancy and continuing for life. Infants born to HIV positive mothers should receive daily NVP or AZT from birth until age 4-6 weeks regardless of infant feeding method<sup>6</sup>.

Almost all infants HIV infection occur in low and middle-income countries and more than 90% are the result of mother-to-child transmission during pregnancy, labour and delivery, or breastfeeding. Without interventions, there is a 20-45% chance that a baby born to an HIV-infected mother will become infected<sup>7</sup>. With implementation of recommendation for universal prenatal HIV counseling and testing, Anti-retroviral treatment and combination prophylaxis, MTCT of HIV has decreased to <2% in resource rich countries<sup>8</sup>. This low MTCT level has not been attained at national levels in Sub-Saharan countries due to inaccessibility to highly active antiretroviral therapy (HAART), prelabour interventions and other logistics constraints.

Antenatal care is a key factor in reduction of mother-to-child transmission of HIV. With regular antenatal HIV testing, women who are HIV positive can be identified and be put on either antiretroviral therapy or prophylaxis. In HIV infected women, the initiation of ART for their own health is recommended when the CD4 cell count is less than or equal to 350 cells/mm<sup>3</sup>, irrespective of WHO clinical staging and for all those with WHO clinical stage 3 or 4 irrespective of CD4 cell count. Prophylaxis interventions should be provided solely for the prevention of mother-to-child transmission and be stopped after transmission risk has ceased

since most pregnant HIV positive women are asymptomatic<sup>9</sup>. PMTCT interventions should still be offered to those identified as HIV infected and presenting in the third trimester, during labour and even after delivery. Programmes should therefore seize every opportunity to offer testing to women of unknown HIV status. Retesting of women who were previously negative should be done three months later in case they have since become infected since the transmission would be higher in places where the prevalence is high<sup>10</sup>.

Involvement of the male partner in PMTCT programme helps improving PMTCT service uptake. If couples are counselled and tested together then there is less potential for blame and recrimination. The man's responsibility for protecting the health of his partner and family should be emphasized during counselling, and thus promote the use of PMTCT and other services, resulting in much higher up-take rates in terms of adherence to treatment and safe infant feeding. Possible ways to increase male participation include hand delivered invitations and routine testing for men who accompany their partners. Unfortunately, it is usually far from easy to persuade men to attend what they regard as women's clinics dealing with women's issues<sup>8</sup>.

Appropriate mode of family planning can be offered to couples during the antenatal period<sup>11</sup>. This will help reduce risks of unwanted pregnancies and HIV transmission to uninfected partner in case of discordant couple when condoms are used. Strengthening the link to family planning services and condom access for dual protection offers a chance to further prevent MTCT<sup>6</sup>.

The WHO recommends that all mothers who are known to be HIV-infected and whose infants are HIV uninfected or have unknown HIV status should exclusively breastfeed their infants for the first six months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first twelve months of life and stop breastfeeding only if nutritionally

adequate and safe diet without breast milk can be provided<sup>12</sup>. Several studies have shown that the gaining of ARV prophylaxis in preventing in-utero and intrapartum transmission is eroded in breastfeeding population due to postnatal acquisition through breast milk and morbidity associated with mixed feeding. Other studies also demonstrated that mixed feeding carries a higher risk of HIV transmission than exclusive breastfeeding. It has also been shown that the risk of HIV transmission is double when mixing breastfeeding and formula feeding and eleven times higher when mixing breastfeeding and solids. In a study done in Botswana, comparing children who were exclusively formula fed or breastfed and given AZT daily until six weeks after birth, there was no difference in 18 months HIV-free survival between the two groups. Again another study in Botswana on diarrhoeal disease outbreak showed increased severe diarrhea and increased mortality among formula fed children, not associated with HIV status. Early cessation of breastfeeding has been associated with diarrhoea and mortality in HIV-exposed children<sup>13</sup>.

The goal of the Ministry of Health – Government of Southern Sudan (MOH-GOSS) National PMTCT Program is in line with the goal set out at the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) in 2001 to reduce the proportion of infants infected with HIV. These guidelines are based on a public health approach to care, taking into consideration issues of feasibility and acceptability, in addition to efficacy and cost-benefit in different settings. The guidelines for prevention of mother to child transmission (PMTCT) in South Sudan 1<sup>st</sup> edition was developed in 2010, and was implemented in mid-2010. It is expected to improve the uptake, quality and effectiveness of PMTCT services in the country. The PMTCT Guidelines has proposed a four-pronged approach for the prevention of HIV transmission that targets non-pregnant and pregnant women, mothers and their children as per WHO recommendations<sup>10</sup>.The

guidelines advocate that all HIV positive mothers should be put on prophylactic ARVS depending on the CD4 count which is as follows;

- CD4 < 250 cells/mm<sup>3</sup> –AZT (TDF) + 3TC (FTC) + NVP
- CD4 250-350 cells/mm<sup>3</sup>- AZT + 3TC + LPV/r or ABC + 3TC + LPV/r
- CD4 > 350 cells/mm<sup>3</sup>- AZT + 3TC + LPV/r or ABC + 3TC + LPV/r, and EFV can replace NVP in the second and third trimester <sup>10, 30</sup>.The guidelines also advocate for vaginal delivery instead of caesarian section and prefer breastfeeding to formula feeding in promoting PMTCT <sup>10, 24</sup>. In non-breastfeeding infants, prophylactic AZT or NVP should be given for six weeks after birth and for the breastfeeding ones prophylactic daily NVP be given from birth till one week after breastfeeding is completely stopped.

## **2.0 JUSTIFICATION**

Impact and utilization of PMTCT services has not been studied in South Sudan, as it has just been recently introduced. The results from this study will generate data for planning and decision making for the government of South Sudan.

The indicators for the HIV epidemic in South Sudan are generally limited and not conclusive and thus the data from this study may be used to help inform policy regarding effectiveness of PMTCT implementation.

## **2.1 RESEARCH QUESTION**

What is the uptake of PMTCT services by mothers attending MCH services at Juba Teaching Hospital?

## **3.0 STUDY OBJECTIVES**

### **3.1 BROAD OBJECTIVE**

To determine the utilization of PMTCT services among women seeking MCH services at Juba Teaching Hospital.

### **3.2 SPECIFIC OBJECTIVES**

1. To determine the proportion of women attending postnatal services who underwent HIV counselling and testing at ANC, intrapartum and postpartum.
2. To determine the proportion of women testing positive who had CD4 count, clinical staging and ART treatment
3. To determine the proportion of mothers who tested HIV positive, delivered in a facility and were practicing safe infant feeding.
4. To determine the proportion of those tested positive with no pregnancy intention that had initiated family planning methods.

## **4.0 MATERIALS AND METHOD**

### **4.1 STUDY DESIGN:**

This was a cross-sectional study whereby all consenting and eligible mothers who attended the MCH clinic at Juba Teaching Hospital during the period of the study were enrolled in the study. A questionnaire was then filled by the investigators through direct interview on their antenatal HIV counselling and testing and other PMTCT services offered.

### **4.2 STUDY AREA:**

The research was conducted at the Juba teaching hospital Mother and child health unit (MCH).

Juba Teaching Hospital is one of the three referral hospitals in South Sudan. It is also the teaching hospital and is located in the center of Juba town the capital city of South Sudan. It has 518 beds out of which the obstetric unit has 30 beds and the gynaecology unit has 30 beds. A total of 15 to 25 deliveries are conducted daily. The ANC attendance for 2010 ranged from 700 to 1000 clients per month. The MCH clinic is preferred by most mothers for vaccination and family planning and it receives an average of 30 to 60 clients per day and some of them attending the MCH clinic having not attended its antenatal clinic attendance of the same. The MCH clinic offers maternal antenatal and postnatal and babies' health services such as immunization. The turnover of patients at the clinic is estimated to be 40 to 60 clients per day. Most of the postnatal mothers enrolled in this study attended the MCH clinic for immunization purpose which is scheduled as follows:

- BCG and polio (o dose) at birth
- At six weeks (DPT1 + polio1 and BCG if not given at birth)
- At ten weeks (DPT2 + polio2)
- At fourteen weeks (DPT3 + polio3)
- At nine months (measles)

#### **4.3 STUDY POPULATION:**

The study population comprised of postnatal mothers bringing their children for immunization at the MCH clinic up to nine months after delivery.

#### **4.4 INCLUSION CRITERIA:**

1. Mothers who were attending the MCH clinic 6 weeks to nine months post-delivery at Juba Teaching Hospital.
2. Consented for the study.

#### **4.5 EXCLUSION CRITERIA:**

-The mothers and/or mothers of infants who were too sick and required emergency care.

#### **4.6 ACTUAL SAMPLE SIZE: 300**

#### **4.7 SAMPLE SIZE DETERMINATION: <sup>14</sup>**

In order to estimate the uptake of PMTCT services a sample of postnatal mothers was estimated using the formula below;

$$n = [z^2 \times p (1-p)] / [m^2]$$

$$n = [(1.96^2) \times 0.5 (1-0.5)] / [0.06^2]$$

$$n = [3.8416 \times 0.5 (0.5)] / 0.0036$$

$$n = 0.9604 / 0.0036$$

$$n = 267$$

#### **Where:**

n = 267: Minimum required sample size of postnatal mothers

z = 1.96: Standard deviation for a 2 tailed at 95% confidence interval

p = 50%: The estimated uptake of counseling in the antenatal clinic

m = 6%: The margin of error in measuring counseling services

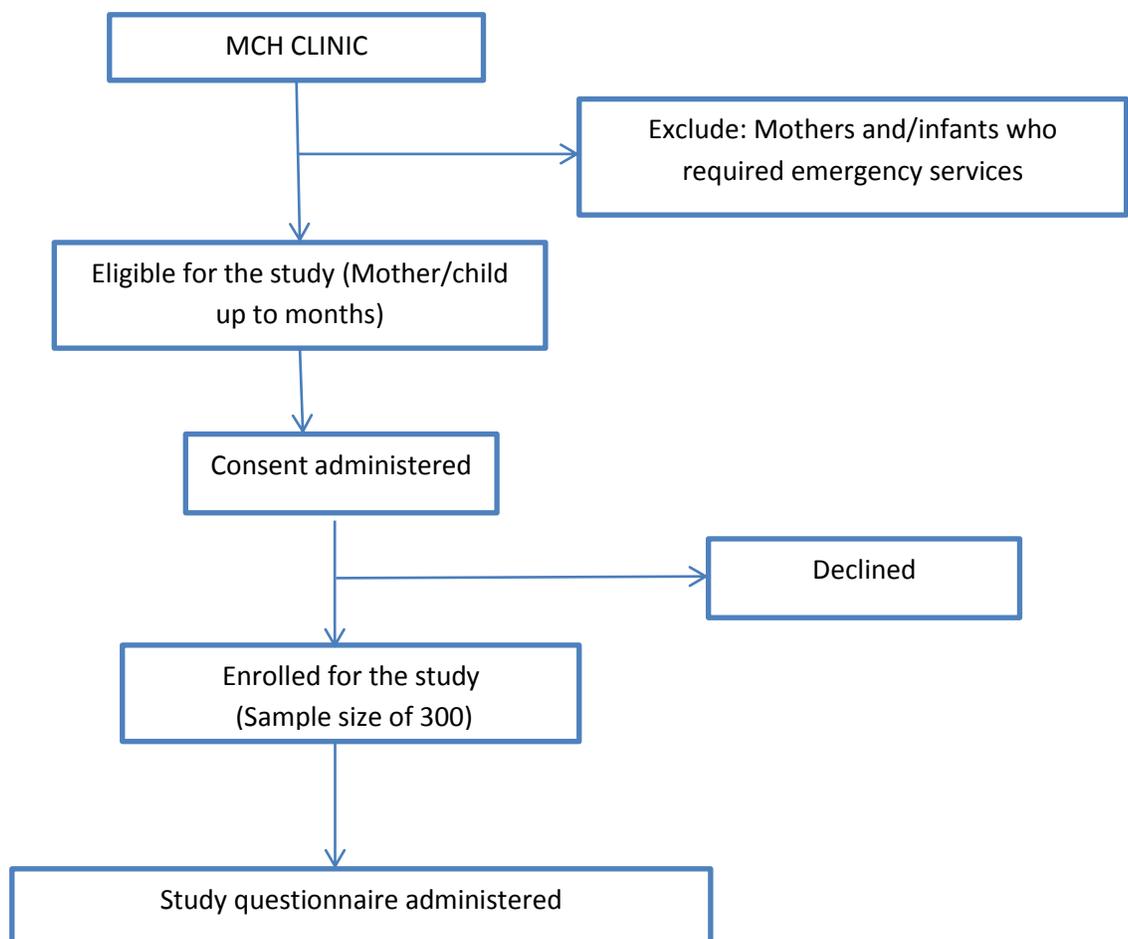
#### 4.8 SAMPLING PROCEDURES:

Purposive sampling where by all the mothers who attended the MCH clinic during the period of the study were asked to join the study, those who accepted were given the consent form and explanation for those who could not read, then those who consented were enrolled in to the study.

#### 4.9 DATA COLLECTION:

The data was collected using a structured questionnaire through direct interview of the participants

#### ENROLMENT FLOW CHART



#### **4.9.1 DATA COLLECTION TOOLS:**

Data was collected by means of a structured questionnaire.

The main parts of the questionnaire included:

1. Socio-demographic data
2. Obstetric history
3. Counselling and testing results, CD4 count, disease staging, OI prophylaxis and ARVs provision
4. Place of delivery
5. Mode of delivery
6. Mode of infant feeding
7. HIV status of the husband

#### **4.9.2 DATA MANAGEMENT:**

Research assistants were trained by the principal investigator before the start of data collection. They were trained on the enrolment algorithm and privacy of participants' information. They were also trained on ethical issues in regards to this study. The questionnaire was then administered after the enrolled mothers got their services at the clinic. After filling the questionnaire at the end of each day, the research assistance sat to sort out the questionnaires, made sure all relevant information was filled correctly and then stored in a secured drawer inside the obstetrics and gynaecology department at Juba Teaching Hospital where confidentiality was also ascertained. The data was then entered in to the computer hard drive in a clean set for analysis.

## **5.0 DATA ANALYSIS AND PRESENTATION OF RESULTS:**

Data management was done using MS Access 2007 (Microsoft Corp, Seattle, USA) while statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS 17.0, SPSS Inc. Chicago). Descriptive statistics was used to analyze the data. Women with single ANC visit, HIV counseling services received, uptake of HIV tests, women testing HIV positive and those who received CD4 count test and clinical staging, health facility delivery and infant feeding practices was analyzed and presented as proportions. The study findings were presented in form of tables and graphs. Chi square test was used for categorical variables, t-test for means, and odds ratios with 95% confidence interval (CI) as estimates of relative risk.

## **6.0 ETHICAL CONSIDERATION**

Clearance was obtained from both University of Nairobi and Kenyatta National Hospital research and ethical committee as well as Ministry of Health Government of South Sudan research and ethical committee.

Confidentiality was our priority; none of the participant's information was shared with another participant or with other members who are not part of the research team. Confidentiality for every participant was upheld.

The consent form was the only document that had the participant's name. Otherwise the questionnaire contained study number.

Consent forms were given to each participant after enrolment in to the study. We provided consent forms both in English and Arabic for those who could read, and to those who could not read consent was obtained by a thumb print after explanation of the procedure.

Participants were informed that they could discontinue with the questionnaire whenever they felt verbal information provided uncomfortable and this did not jeopardise them from accessing services further. Those with unknown HIV status were linked with the nurses to undergo counseling and testing.

## **7.0 STUDY LIMITATIONS**

This study was however, limited by the fact that it was conducted in only one hospital which is a referral hospital and it could not represent the whole population of those living in Juba. Also it could be bias because it only targeted the population who were able to access the facility when some mothers who would have been eligible for study might have attended health centers nearest to them for immunization purposes.

## **8.0 RESULTS OF THE STUDY**

Three hundred (300) postnatal mothers were interviewed at the MCH clinic in Juba Teaching Hospital. The mean age of the mothers was 25.4 years ( $\pm 5.3$  years) with youngest being 13 years and the oldest 42 years. Majority (95%) was married and 99% said their husbands were alive. As reported by the mothers, the mean age of their husbands was 33.9 years ( $\pm 8.8$  years) ranging from 13 to 65 years. Majority of the men (65%) had single wives while the rest had more than one wives. The mothers had a median parity of 2.0 (IQR 1.5-4.0) ranging from 1 to 10.

Literacy level was high with majority of the mothers having primary (34.3%) and secondary (30.7%) levels of education while the illiterate group made up 20.7% of all the mothers. Education level was even higher among the partners with majority having secondary (39.3%) and college/university (36.9%) levels of education. Illiteracy was significantly lower among the partners with 4.7% having no education.

In relation to occupation, 69% of the mothers were unemployed reporting that they were housewives (Table 1).

**Table 1: Socio-demographic characteristics for all the mothers and their partners**

<b>Characteristics</b>	<b>Frequency (%)</b>
<b>Age</b>	
Mean (SD)	25.4 (5.3)
Median (IQR)	25 (22-28)
Min - Max	13-42
<b>Level of education of the mothers</b>	
Not educated	63 (21)
Primary	102 (34)
Intermediate	5 (1.7)
Secondary	92 (30.7)
College/university	38 (12.7)
<b>Employment status of the mothers</b>	
House wife/unemployed	207 (69.0)
Employed	93 (31)
<b>Parity</b>	
Mean (SD)	2.9 (1.8)
Median (IQR)	2.0 (1.5-4.0)
Min-Max	1-10
<b>Marital status</b>	
Not married	11 (3.7)
Married	285 (95.0)
Divorced / Separated	4 (1.3)
<b>Husband alive</b>	
Yes	297 (99.0)
No	3 (1.0)
<b>Age of husband</b>	
Mean (SD)	33.9 (8.8)
Median (IQR)	32.5 (28-38)
Min - Max	13-65
<b>Educational level of the husband</b>	
None	14 (4.7)
Primary	46 (15.3)
Intermediate	11 (3.7)
Secondary	118 (39.3)
College/university	111 (37.0)
<b>Number of wives husband has</b>	
1	196 (65.0)
>2	104 (35.0)
<b>Employment status of husband</b>	
Unemployed	26 (8.7)
Employed	274 (91.3)

**Table 2: Comparison of characteristics between HIV positive and HIV negative women**

Characteristics	HIV status		OR(95% CI)	P value
	Positive Frequency (%)	Negative Frequency (%)		
Age (years), mean ( $\pm$ SD)	29.9 (4.6)	25.1 (4.9)	-	<0.001
<b>Level of education</b>				
None	2 (13.3)	29 (16.0)	0.9 (0.2-4.4)	0.863
Primary/Intermediate school	6 (40.0)	64 (35.4)	1.2 (0.4-3.7)	0.777
Secondary/College/University	7 (46.7)	88 (48.6)	1.0	
<b>Marital status</b>				
Not married	2 (13.3)	6 (3.3)	1.0	
Married	13 (86.7)	175 (96.7)	0.2 (0.0-1.2)	0.117
<b>Mother's employment status</b>				
Employed	5 (33.3)	53 (29.3)	1.0	
Unemployed	10 (66.7)	128 (70.7)	0.8 (0.3-2.5)	0.772
Parity, mean (SD)	3.5 (1.7)	2.7 (1.7)	-	0.130
<b>Husband alive</b>				
Yes	14 (93.3)	176 (98.3)	0.2 (0.0-2.4)	0.277
No	1 (6.7)	3 (1.7)	1.0	
Age of husband, mean (SD)	38.5 (8.5)	32.5 (7.1)	-	0.002
<b>Level of education of husband</b>				
<Secondary	2 (13.3)	31 (17.5)	0.9 (0.2-4.9)	0.906
Secondary school	8 (53.3)	76 (42.9)	1.5 (0.5-4.7)	0.514
College / university	5 (33.3)	70 (39.5)	1.0	
<b>Husband's employment</b>				
Employed	15 (100.0)	164 (90.6)	-	0.371
Unemployed	0 (0.0)	17 (9.4)		
<b>Wives husband have</b>				
1	6 (40.0)	120 (66.7)	1.0	
More than 1	9 (60.0)	60 (33.3)	3.0 (1.0-8.8)	0.038

## **PMTCT SERVICES INTERVENTION**

### **HIV counseling and testing**

Of the two hundred and forty six (246) mothers reported receiving HIV counseling, 201 (67%) reported being tested for HIV and 2% said they did not know if they were tested. The prevalence of HIV infection was found to be 7.5% among those tested while 2.5% did not know their HIV status even after reporting being tested. All the HIV positive mothers had no CD4 test result (Figure 1).

### **ARV/ART intervention**

Of the fifteen 15 women who were HIV positive, only 5 (33.3%) received antiretroviral drugs for PMTCT, 3 (20%) received single dose Nevirapine and 2 (13.3%) had highly efficacious antiretroviral regimen (Table 3).

### **Partner involvement**

Of the 300 mothers, 124 (41.3%) had their partners tested for HIV, 114 (38%) of the partners were not tested, and 62 (20.7%) were unaware of their partners having been tested for HIV. One hundred and fourteen (114) of the partners who received HIV test were tested negative for HIV (91.9%), 7 (5.6%) tested positive for HIV while 3 (2.4%) were not aware of their partners HIV test results (Table 3).

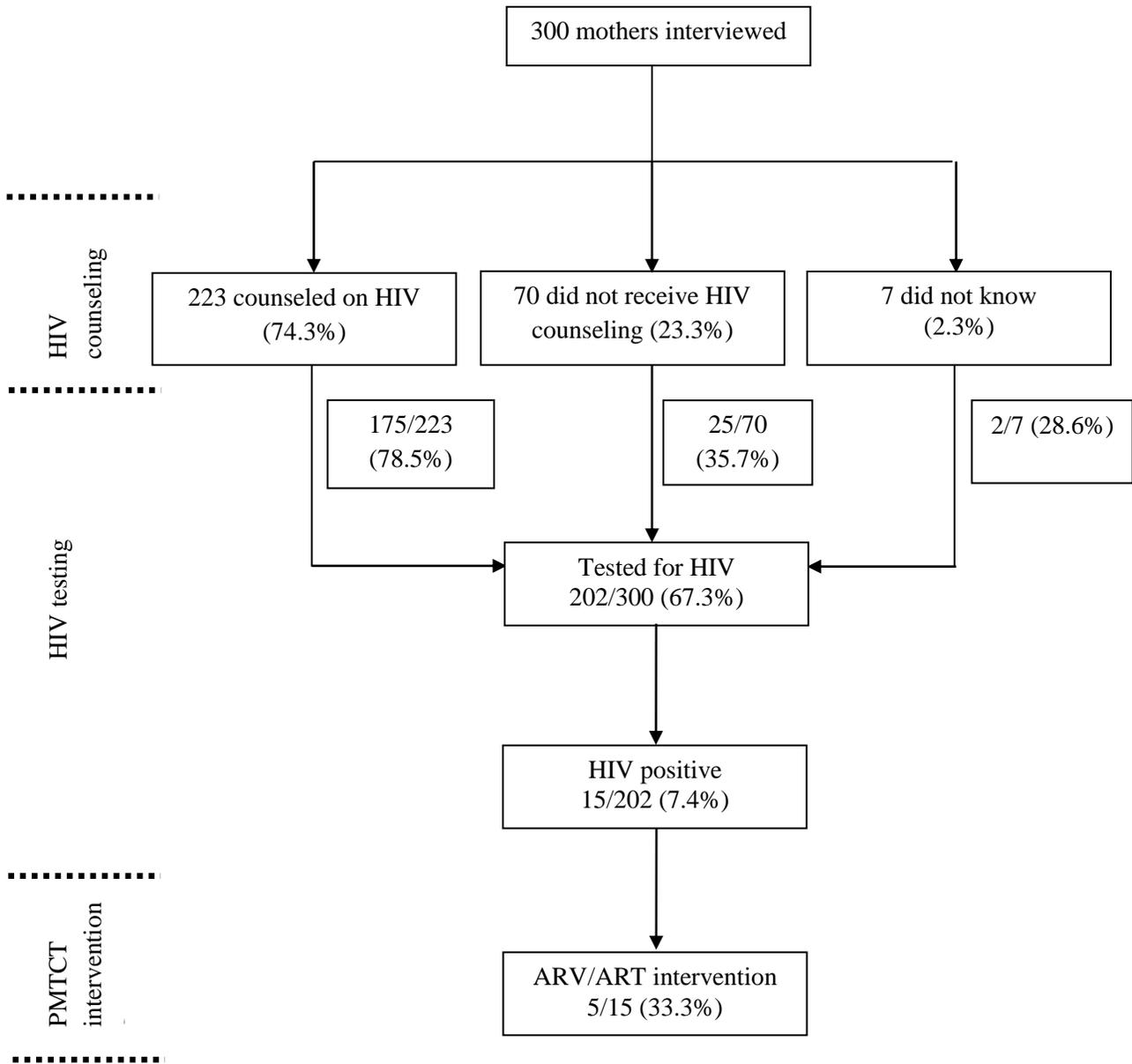
Disclosure of HIV status to partners among the HIV positive mothers were 7 (46.7%) and 8 (53.3%) did not reveal their HIV status to their partners. Among the fifteen (15) HIV positive mothers; the partners status was positive for 7 (46.7%), negative for 2 (13.3%) and 6 (40%) did not know their partners status.

None of the HIV positive partners were reported to have been initiated on ARV/ART treatment; 3 (42.8%) their drugs were not known by the mothers, 2 (28.6%) were on co-trimoxazole, 1(14.3%) was on multivitamins alone and 1(14.3%) was not on any type of medication (Table 3).

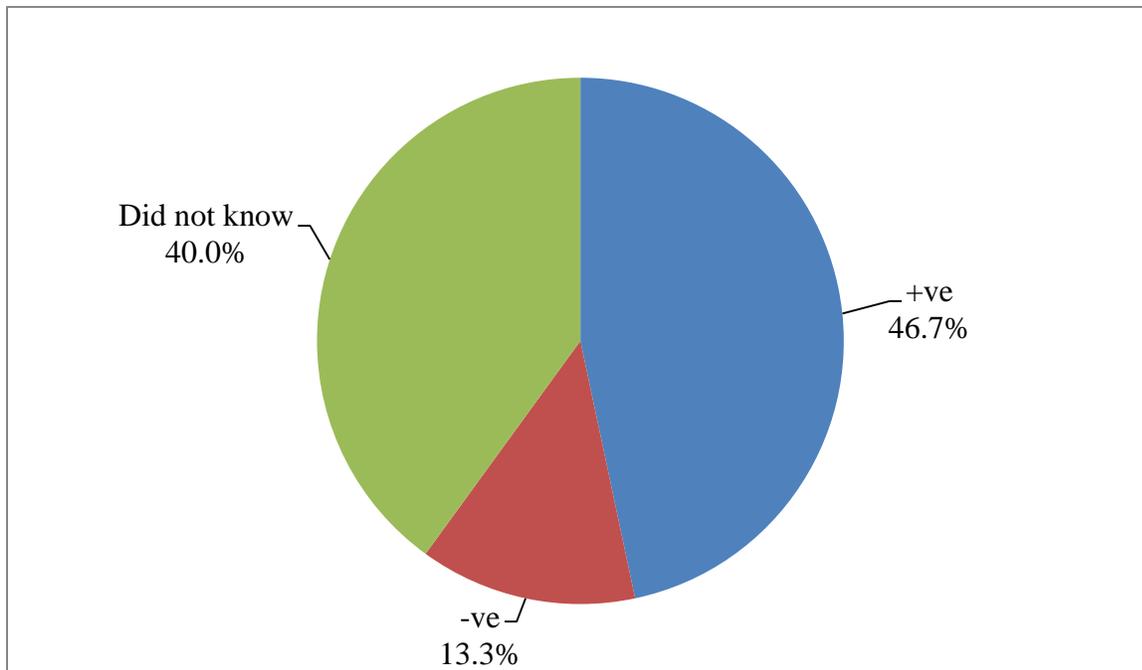
**Table 3: PMTCT services intervention given to the mothers and their partners**

<b>Variable</b>	<b>Frequency (%)</b>
<b>Mothers Counseled for HIV test(n=300)</b>	
Yes	246 (82.0)
No	48 (16.0)
Did not know	6 (2.0)
<b>Mothers Tested for HIV</b>	
Yes	201 (67.0)
No	93(31.0)
Did not know	6 (2.0)
<b>Mothers Result for HIV(n=201)</b>	
Positive	15 (7.5)
Negative	181 (90.0)
Did not know	5 (2.5)
<b>Mother's CD4 test done for PMTCT</b>	0 (0%)
<b>Did not know</b>	15 (100.0)
<b>ARV/ART intervention among HIV positive mothers</b>	
Yes	5(33.3)
No	10 (66.7)
<b>Regimen used for HIV positive mothers</b>	
Sd NVP	3 (20.0)
AZT+3TC+NVP	1 (6.7)
AZT+3TC+LPV/r	1 (6.7)
Co-trimoxazole	5 (33.3)
Multivitamin	1 (6.7)
Nothing	3 (20)
Don't know the drug	1 (6.7)
<b>Disclosure of HIV+ status to partner(n=15)</b>	
Yes	7 (46.7)
No	8 (53.3)
<b>Partners tested</b>	
Yes	124 (41.3)
No	114 (38.0)
Did not know	62 (20.7)
<b>Partners HIV results (n=124)</b>	
Positive	7 (5.6)
Negative	114 (91.9)
Did not know	3 (2.4)
<b>Partners intervention</b>	
Co-trimoxazole	2 (40.0)
Did not know	3 (60.0)

**Figure 1: PMTCT services intervention given to the mothers and their partners**



**Figure 2: Partners HIV status among HIV positive mothers (n = 15)**



### **INFANT PMTCT INTERVENTION**

Ten (10) of the mothers (66.7%) reported that their babies received NVP after delivery while 5(33.3%) did not have any intervention. Seven (9) of those who had Nevirapine (90%) used it during the first six months and 1(10%) used it for only one month.

PCR/DNA testing was not routinely done and none of the 15 (100%) HIV exposed babies received testing despite the fact that most of them (10) [66.7%] were around nine months of age (Table 4).

Exclusive breastfeeding for the first six months was practiced by 6 (40%) of the mothers while 5(33.3%) practiced mixed fed and 4(26.7%) formula fed their babies (Table 4).

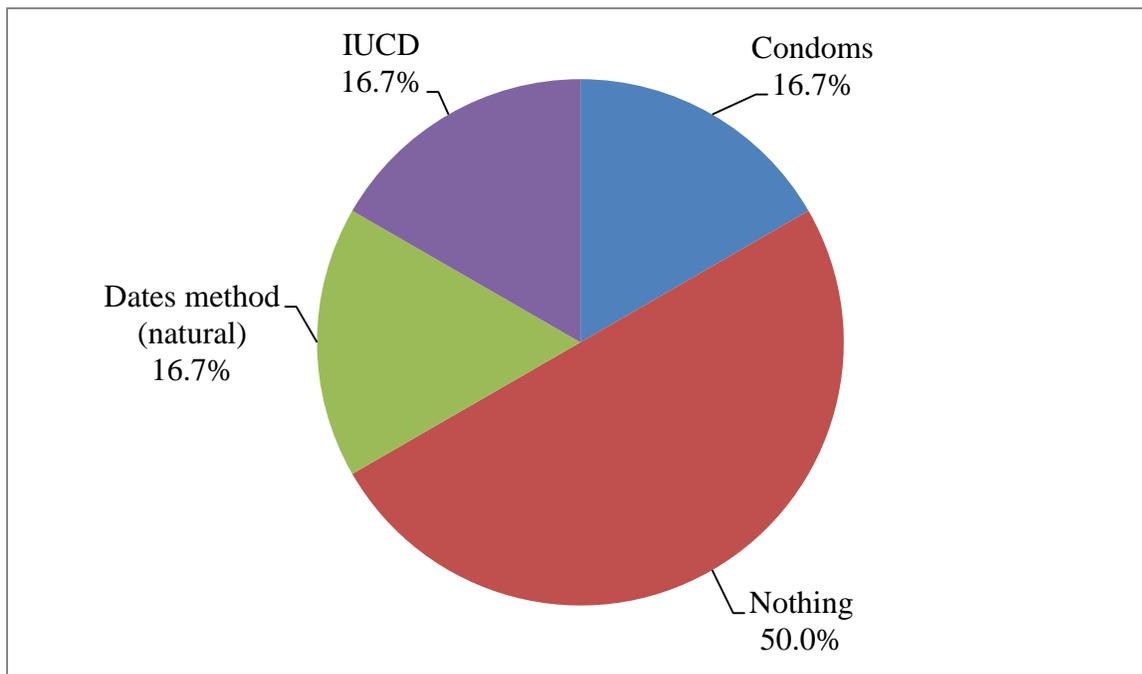
**Table 4: PMTCT intervention given to the babies of HIV positive mothers**

<b>Variable</b>	<b>Frequency (%)</b>
<b>Baby received NVP after delivery</b>	
Yes	10 (66.7)
No	5 (33.3)
<b>Duration of NPV treatment</b>	
Still on treatment	7 (70.0)
For one month	1 (10.0)
More than six months	2 (20.0)
<b>PCR/DNA done to exposed baby</b>	0 (0%)
No	15(100%)
<b>practiced mode of infant feeding option for the first six months</b>	
Exclusive breastfeeding	6 (40)
Formula	4 (26.7)
Mixed feeding	5 (33.3)

### FAMILY PLANNING AMONG HIV POSITIVE PARTNERS

Only six (6) of the HIV positive mothers were more than six weeks postnatal period and so were eligible for family planning. Three (3) (50%) of them were not using any mode of family planning, 1(16.7%) used condoms, 1(16.7%) IUCD and 1 (16.7%) used dates methods (Fig 3).

**Figure3: Mode of family planning with HIV+ partners**



## **9.0 DISCUSSION**

This research evaluated the utilization of PMTCT services by postnatal mothers who attended the MCH clinic at Juba Teaching Hospital for immunization purpose; it was not specific on the site of antenatal clinic attended.

Of the 300 enrolled mothers, 21% had not gone to school while 79% had at least primary education. Two hundred and seven (69%) of the mothers are unemployed as compared to 91.3% of their partners reported to have an employment thus, majority of them totally depend on their partners. Comparing their socio demographic characteristics according to their HIV status; of those tested HIV positive, 86% had at least primary education compared to 84% of those tested HIV negative and this implies that level of education is not a risk factor for contracting HIV. Unemployment was 66.7% for the HIV positive mothers and even higher 70.7% for those who tested HIV negative. All the partners (15[100%]) of those who were HIV positive had an employment and this can contribute greatly to PMTCT in terms of affordability to safe infant feeding.

While antenatal counselling and testing is so crucial in PMTCT, in this study 82% received counselling during their antenatal clinic follow, comparing to Kenya where antenatal testing and counselling up take is more than 90%<sup>15</sup>. The reasons for this low uptake could be attributed to either lack of provider initiation or inappropriate integration of PMTCT services in to the antenatal care systems or lack of perception of the importance of HIV testing during pregnancy.

As this study showed 31% of the mothers had not received HIV testing, carries a great risk of missed opportunity for those who would have been HIV positive but not detected and in turn

could be a risk for infant HIV infection. A study done in Kenya on uptake of PMTCT interventions showed an uptake of 92.1% for antenatal HIV testing which is much higher than the 82% in this study, some of the reasons attributed to mothers who attended ANCs and were not tested were due to unavailability of services or failure of staff to offer testing, and slow service provision. Personal factors included need to consult partner, fear of results, no perceived need due to previous negative test, and cost when mothers visited private antenatal clinics<sup>11</sup>.

According to the global HIV/AIDS response report 2011, the estimated number of pregnant women who had received an HIV test in Sub-Saharan Africa was found to be 9% in 2005 and 42% in 2010.<sup>16, 158</sup>

Of the 201 mothers who received antenatal HIV test, the prevalence of HIV was 7.5% as compared to the prevalence of 6% out of 299 found in a study done in South Sudan among antenatal mothers in Juba Teaching Hospital<sup>10, 22</sup>; this difference could be due to the smaller sample in this study.

Antenatal intervention for HIV positive mothers is the cornerstone in reducing mother-to-child transmission rate of HIV; these include testing for CD4 count, clinical and laboratory staging, initiation of antiretroviral therapy and counselling on mode of infant feeding. None of the fifteen (15) HIV positive mothers had undergone CD4 testing or WHO clinical staging, which effectively reflects lack of adherence to guidelines and could also be as a result of lack of equipment for CD4 testing or unawareness of importance for testing since the WHO PMTCT guideline recommends all HIV positive pregnant women be initiated on ARVs based on their CD4 count. Another cohort study on effectiveness of antiretroviral therapy in South Africa has shown that each month of HAART is associated with increase in CD4 cell count of 15.1 cells/ $\mu$ l which in turn further reduces MTCT of HIV<sup>17</sup>.

The uptake of ARV/ART was generally low among the fifteen(15) HIV positive mothers; 10(66.7%)were not on any antiretroviral drugs and 5(33.3%) were on ARVs. Of the five (5) mothers who were on ARVs 3(60%) received single dose Nevirapine (which is recommended for women who present late for ANC and/or had no CD4 count), 1(20%) was on combination regimens of AZT, 3TC, NVP and another 1(20%) was on AZT, 3TC, LPV/r. This translates to more than 60% of the HIV positive mothers having not been on ARV/ART intervention which in turn could lead to high MTCT rates, this could be attributed to shortage in drugs or health facility factors such as lack of proper counselling on adherence. In 2011, 59% of pregnant women living with HIV had received antiretroviral therapy or prophylaxis during pregnancy and delivery in Sub-Saharan Africa<sup>18</sup>. In this study only 40% of the mothers received either co-trimoxazole or multivitamins. On average MTCT rates are 15% for Sd NVP, 6.5% for more efficacious dual regimens and 2.4% for three-drug ARV combination<sup>10, 31</sup>.In sub-Saharan Africa the coverage of antiretroviral medicine for preventing mother-to-Child transmission of HIV in 2010 was 50% for the effective regimens and 10% for single dose Nevirapine<sup>16</sup>.

Health facility delivery helps to reduce missed opportunity for HIV testing during the antenatal period and provides both intrapartum and immediate postpartum HIV testing which in turn will help in early infant intervention in terms of prophylactic antiretroviral drugs. Health facility delivery was more common among the HIV positive mothers, (85.7% Vs.83.8% p= 1.000). This shows that PMTCT intervention at the facility level could have still been achieved during delivery and thus reduced the number of untested mothers and thus those who tested positive could have still been put on ART/ARV.

Though caesarian section reduces the chances of mother-to-child transmission (MTCT) of HIV, the South Sudan PMTCT guidelines do not indicate caesarian section for PMTCT due lack of facilities and human resource.

While a study in Kenya showed 90% of exposed infants being on antiretroviral drugs<sup>11</sup>, in this study only 10(66.7%)of the infants born to the HIV positive mothers received NVP after delivery and 5(33.3%) did not receive any intervention and this could result in high MTCT rate through breastfeeding. At the time of the interview 7(70%) of the babies who were at 6 months of age were still on Nevirapine syrup, 2(20%) were more than six months and were still continuing with the Nevirapine syrup while 1(10%) only used Nevirapine for one month and she was still breastfeeding. This shows an improper counselling on use of the medicine and could also be attributed to health system factors. The South Sudan PMTCT guideline 2010 recommends that every HIV positive mother be given Nevirapine syrup to take home in case delivery happens outside a health facility and should be given to the baby within 72 hours of delivery and continued till one week after breastfeeding stops<sup>10, 30-35</sup>.

All the exposed infants enrolled did not have DNA/PCR done; and they were still receiving prophylaxis, this could mean that some of the babies could be receiving prophylaxis instead of treatment for HIV if diagnosis for HIV was made earlier. Every HIV exposed infant should be screened for DNA/PCR as soon as possible, preferably after six weeks of age to determine if the baby is already infected or not, this improves service delivery by providing appropriate management to the infant at the right time. Early infant diagnosis (age 0 to 18 months) in Kenya showed a prevalence of 8.4%<sup>14</sup>. In the South Sudan PMTCT guidelines, all children born to HIV infected mothers should be seen in the health care facility within 1-2 weeks of delivery and their HIV status established as early as possible and appropriate intervention done. Early infant

diagnosis should be provided at six weeks using DNA-PCR testing and follow up visits recommended through 2 years. Where possible, visits should be linked to the immunization and growth monitoring visits<sup>10, 38, 49</sup>.

Exclusive breastfeeding for HIV exposed infants is advisable for the first six months unless replacement feeding is AFASS and mothers should be supported to provide optimal infant feeding and particularly to avoid mixed feeding. The WHO 2010 guidelines recommend that “mothers known to be HIV–infected and whose infants are HIV infected or of unknown HIV status should exclusively breastfeed their infants for the first six months of life, introducing appropriate complementary foods thereafter and continue breastfeeding for the first twelve months of life”. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided<sup>19</sup>. In this study exclusive breastfeeding was practiced by 6 (40%) of the HIV positive mothers whereas 5(33.3%) used mixed feeding and 4(26.7%) formula fed their babies during the first six months.

Extended antiretroviral prophylaxis during the entire breastfeeding period reduces postnatal transmission of HIV in breastfed infants. The Kesho Bora study found that giving HIV positive mothers a combination of 3 antiretroviral drugs reduces transmissions during breastfeeding by 54%<sup>20</sup>.

Knowing HIV status of one’s partner is critical and forms an important entry point for establishing prevention with positive programs among couples as well as providing access to prevention, care and treatment services for the whole family<sup>10</sup>. Disclosure of HIV positive status helps to improve mode of infant feeding in case the mother had preferred exclusive breastfeeding or formula feeding, it will also support the mother to adhere to antiretroviral drugs both for her and her baby without fear. Providers should encourage couple counselling, testing, disclosure

and positive living among HIV infected women. This study have shown that out of the 15 HIV positive mothers; only 7(46.7%) disclosed their HIV status to their partners while 8(53.3%) did not. Seven (7) of them (46.7%) had HIV positive partners, 2(13.3%) their partners were HIV negative and 6(40%) did not know their partners status. The prevalence of HIV among the partners who were tested (n=124) was found to be 5.6%.

Family planning services are among the core interventions of PMTCT provided to help women determine future child bearing patterns including the prevention of HIV-infected births. Counselling among HIV positive couples should include other family planning methods emphasizing on partner involvement and dual protection methods to avoid unwanted pregnancy, new infection, other sexually transmitted infections and further transmission. Only 6 out of the 15 HIV positive mothers (40%) were at more than six weeks postnatal period and were eligible for family planning. Three (50%) were not using any mode of family planning; 1(16.7%) used condoms, 1 (16.7%) used dates method and 1 (16.7%) used IUCD. This low uptake of family planning puts majority of the HIV positive couples at increased risk of getting unwanted pregnancy, susceptibility to getting other sexually transmitted infections and opportunistic infections, this could also mean that the mothers being more than six weeks postnatal period, they had already come for postnatal follow up and the facility/provider had failed to initiate family planning at the earliest opportunity.

## 9.1 CONCLUSIONS

1. Although counselling and testing is offered to majority of pregnant women, still more than 30% of those counselled were not tested for HIV
2. All the mothers who tested HIV positive did not have CD4 results and thus response to treatment and disease progression could not be detected early
3. Majority of the HIV positive women used co-trimoxazole/ multivitamins and Sd NVP but the use of HAART and other more efficacious combination is limited and this could increase MTCT of HIV rates
4. The use of recommended antiretroviral regimens for HIV exposed infants was not as per the WHO guidelines and this will in turn increase the incidence of children HIV infection.
5. All HIV exposed infants did not have PCR/DNA done, there is high possibility that some of the infants are still on prophylaxis when they could actually be put on treatment
6. Standard mode of infant feeding among exposed children is not well adhered to
7. Majority of the HIV positive mothers did not disclose their status to their partners and partner involvement in PMTCTC is negligible.
8. Use of condoms is limited among HIV positive partners and thus even those who were in a discordant relationship are at increased risk of HIV infection

## **9.2 RECOMMENDATIONS**

1. All women should be encouraged on testing for HIV during pregnancy and be encouraged on partner's disclosure
2. CD4 count should be mandatory and routinely done to all HIV positive mothers
3. All exposed children should have their HIV status established as early as possible
4. Use of more efficacious ARVs or HAART should be done to all mothers for PMTCT
5. A research at the national level involving more health facilities needs to be done to evaluate PMTCT services offered.

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## 11.0 APPENDICIES

### Appendix 1: Study eligibility checklist

Date: DD. MM [ ] [ ] [201....]

Data collector's initial: .....

Client code No: .....

**Inclusion criteria** (If any inclusion criteria is marked "NO", the patient is not eligible for enrollment)

1. Delivered around nine months ago Y [ ] N [ ]
2. Consented for the study Y [ ] N [ ]

**Exclusion criteria** (If any exclusion criteria is marked "YES", the patient is not eligible for enrollment)

1. Did not consent for the study Y [ ] N [ ]
2. Mother or infant too sick and require emergency care Y [ ] N [ ]

- Is the patient eligible for the study? Y [ ] N [ ]

## Appendix II: Data collection form

1. Age  years

2. Level of education

(a) Did not go to school

(b) Primary school

(c) Intermediate

(d) Secondary school

(e) College/university

3. Marital status

(a) Not married

(b) Married

(c) Divorced/separated

(d) Widow

4. Employment status

(a) House wife

(b) Employed with government

(c) Private

(d) NGO

(e) Military

(f) Police

5. Is your husband alive? Yes  No

6. Age of husband  years

7. Level of education of husband

(a) Did not go to school

(b) Primary school

(c) Intermediate

(d) Secondary school

(e) College/university

8. Husband's employment

(a) Employed with government

(b) Private

(c) NGO

(d) Military

(e) Police

(f) Not employed

9. How many wives does your husband have?

(a) 1

(b) 2

(3) 3

(4) > 3

10. Parity

11. How many weeks' postnatal  weeks

12. Mode of delivery

- (a) Caesarian section
- (b) Normal spontaneous vaginal delivery
- (c) Vacuum extraction
- (d) Forceps' delivery

13. Place of delivery

- (a) Health Facility
- (b) Home
- (c) Road
- (d) Others.....Specify.....

14. If delivered at home, who attended the delivery?

- (a) Doctor
- (b) Midwife
- (c) Nurse
- (d) Clinical officer
- (e) TBA
- (f) Neighbors
- (g) Others.....Specify.....

15. Were you counseled for HIV test during antenatal clinic?

- (a) Yes
- (b) No

(c) I don't know

16. If yes, did you get tested for HIV?

(a) Yes

(b) No

(c) I don't know

17. If tested, what was the result?

(a) +ve

(b) -ve

(c) Do not know (Cannot remember)

18. If +ve, did you receive ARV/ART

(a) Yes

(b) No

19. If yes, which regimen?

(a) sd NVP

(b) Co-trimoxazole

(c) Multivitamins

(d) AZT + 3TC + NVP

(e) AZT + 3TC + LPV/r

(f) AZT + 3TC + ABC

(g) ABC+3TC+LPV/r

(h) AZT+3TC +EFV

20. If tested positive, what was your CD4 count (cells/mm<sup>3</sup>) \_\_\_\_\_

21. If you are positive, did your baby receive NVP after delivery?

(a) Yes

(b) No

22. If yes, how long after delivery?

(a) Within the first 24 hours

(b) Within the first 48 hours

(c) After 3 days

(d) After 7 days

23. If positive, did you tell your husband?

(a) Yes

(b) No

24. Was your husband tested?

(a) Yes

(b) No

25. If tested, what was the result?

(a) +ve

(c) Do not Know

(b) -ve

26. If your husband was tested +ve, was he put on ARV/ART?

(a) Yes

(c) Do not Know

(b) No

27. If yes, what is the regimen?

- (a) Co-trimoxazole
- (b) Multivitamins
- (c) AZT + 3TC + NVP
- (d) AZT + 3TC + LPV/r
- (e) AZT + 3TC + ABC
- (f) ABC+3TC+LPV/r
- (g) AZT+3TC +EFV
- (h) Do not know

28. If your husband was tested +ve, what was your mode of family planning

- (a) Condom
- (b) Nothing
- (c) Dates method (natural)
- (d) Oral contraceptives pills
- (e) IUCD
- (f) Norplant
- (g) BTL

29. Is there any affected child?

- (a) Yes
- (b) No

30. How many children?

31. If yes, are they on treatment?

(a) Yes

(b) No

32. If you are positive, what was your preferred mode of infant feeding option?

(a) Exclusive breastfeeding

(b) Formula

(c) Mixed feeding

(d) Others.....specify.....

### **Appendix III: Inform Consent explanation**

#### **UNIVERSITY OF NAIROBI DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**

Consent form to participate in a study to evaluate the utilization of comprehensive PMTCT package during the antenatal period among postnatal women in Juba Teaching Hospital.

**Study title:** Utilization of PMTCT services during the antenatal period at Juba Teaching Hospital.

**General Information:** This consent form contains information about the research mentioned above. It is provided to you so that we are sure that you had been informed about the research. You are therefore allowed to read the form or read to (in case of inability to read) before signing your consent. The researcher will explain and answer all your questions concerning this study. In case of unfamiliar words please don't hesitate to ask the researchers.

This study is guided by research ethics and rules. Approval is here in given by the Ethics and Research committee of Kenyatta National Hospital and University of Nairobi as well as the Ethics and Research committee in the Ministry of Health Government of South Sudan.

**Purpose of the Study:** Mother-to-Child transmission is the most common way of infant and childhood infection by HIV virus. Over 90% of HIV infection in children is due to MTCT. PMTCT provides an opportunity for preventing new paediatric HIV infections as well as for reaching the 20-30% of HIV positive pregnant women who meet WHO eligibility criteria for initiating ART for their own health. Without any intervention, up to 40 percent of HIV positive women will transmit the infection to their children during pregnancy, labour and breastfeeding. PMTCT program is a newly established program in South Sudan to help combat MTCT as in other countries around the world. The ministry of health has developed guidelines for PMTCT, and this study is designed to look on how best you received information on that during your

antenatal clinic follow up. This study will also help us know our deficiency and how we'll improve in providing a better PMTCT service.

**How the Study will be conducted:** The study will be conducted on ..... women who will be attending the Mother and Child Health Clinic during the period of the study. If you accept to take part in the study you will be asked some questions which will include your age, marital status, the number of children you have, your antenatal clinic attendance card and whether you know your HIV status or not. If you don't know your status at that time we will encourage you to test and if you are HIV positive we will ask you more on your mode of delivery, mode of infant feeding and your preferred mode of family planning. Also we'll ask some questions concerning your husband and the number of wives he has.

**Your role in participating:** If you accept to be recruited in the study then our research assistants will ask you to fill a structured questionnaire by taking you through it. Parts of the questions have already been explained above.

**Risks and Benefits of the Study:** There are no risks associated with this study. You may not benefit directly from this study. However, if you don't know your status we will encourage you to go for testing and those who are already positive will benefit from more information which will be provided by the research assistants on safe infant feeding which reduces the risk of you transmitting the virus to your child and safe sex practices which on the other will help reduce your viral load. The results of this study will be made available to the Ministry of Health in the Government of South Sudan and Juba Teaching Hospital in particular and can be used to improve PMTCT services.

**Confidentiality:** We will make sure that we protect all information about your taking part in the study to the best of our ability. Your name will not be written on the research form and will not appear after the final report is published.

**Compensation:** There is no payment of any kind for participating in this research. However, you will receive all the necessary care you deserve in the clinic.

**Refusal/Withdrawal:** You are free to withdraw from the study if you feel that you can't continue. This will not affect the services being offered to you at the clinic.

**Contacts for Rights and Complains:** If you have any complain about your taking part in the study or you have more inquiries please do not hesitate to contact Dr Idyoro Ojukwu, mobile numbers-+249-912973884,+254-728738607 or e-mail [idyoro2001@yahoo.com](mailto:idyoro2001@yahoo.com).

Any inquiries concerning your rights in the study you may contact the research and ethics committee in the MOH/GOSS chair Dr. Richard Laku

**Appendix IV: Inform consent**

I have read this informed consent form. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study as a volunteer.

\_\_\_\_\_  
Name and Signature or Finger print of study volunteer      Date and Time when signed

I was present during the consent PROCESS AND signing of this agreement above by the study volunteer.

\_\_\_\_\_  
Name and Signature of witness      Date and time when signed  
(Required if consent is presented orally)

**I ASSURE THAT I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER, THE NATURE AND PURPOSE, PROCEDURES, THE RISK AND BENEFITS OF THIS STUDY.**

\_\_\_\_\_  
Signature of researcher      Date and Time signed