SEROPREVALENCE OF HEPATITIS B SURFACE ANTIGEN AND IT'S ASSOCIATED FACTORS AMONG HIV POSITIVE PREGNANT WOMEN IN JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL, KISUMU, KENYA.

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DECLARATION

This thesis is my own original work and has not been submitted or presented for any award of a degree or examination at any other university, either in part or as a whole.

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DEDICATION

This work is passionately dedicated to my dear wife Olivia, my daughters Imani, Zoelani, Njambi, my parents and my entire family for their overwhelming support, prayers and encouragement from the very beginning to completion of this project. May our good Lord bless you abundantly.

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ABBREVIATIONS

AIDS: Acquired Immunodeficiency Syndrome

AMREF: African Medical and Research Foundation

ANC: Antenatal Clinic

ANOVA: Analysis of Variance

ART: Antiretroviral Therapy

ARVs: Antiretrovirals

BSN: Bachelor of Science in Nursing

CD4: Cluster of Differentiation

CDC: Center for Disease Control

DNA: Deoxyribonucleic Acid

EIA: Enzyme Immuno Assay

FANC: Focused Antenatal Care

HAART: Highly Active Antiretroviral Therapy

HBeAg: Hepatitis B 'e' antigen which is a protein from HBV that circulates in infected blood when the virus is actively replicating.

HBsAg: Hepatitis B Surface Antigen

HBsAg: Hepatitis B –Surface Antigen

HBV: Hepatitis B Virus

HCV: Hepatitis C Virus

HIV: Human Immunodeficiency Virus

JOOTRH: Jaramogi Oginga Odinga Teaching and Referral Hospital

KDHS: Kenya Demographic Health Survey

KNH/UoN-ERC: Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

KNH: Kenyatta National Hospital

MDGs: Millenium Development Goals

MSN: Master of Science in Nursing

NASCOP: National AIDS and STI Control Program

PLHIV: People Living with HIV

SPSS: Statistical Package for Social Sciences

STI: Sexually Transmitted Infections

SVD: Spontaneous Vertex Delivery

UNAID: United Nations Program on HIV/AIDS

USA: United States of America

WHO: World Health Organization

OPERATIONAL DEFINITIONS

Acquired Immunodeficiency Syndrome: A condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive.

Chronic Hepatitis B: Persistence of hepatitis B surface antigen positively for more than six months.

Co-infection/Dual Infection: Concurrent infection of an organism with two different microorganisms. In this study concurrence is between HIV/Hepatitis B.

Hepatitis B Surface Antigen (HBsAg): The "surface antigen" is part of the hepatitis B virus that is found in the blood of someone who is infected. If this test is positive, then the hepatitis B virus is present.

Hepatitis B Virus: An infectious disease caused by the hepatitis B virus (HBV) which affects the liver. It can cause both acute and chronic infections.

Hepatocellular Carcinoma: A primary malignancy of the liver that results in liver cancer.

Human Immunodeficiency Virus: A lentivirus that causes the Acquired Immunodeficiency Syndrome (AIDS) in humans.

Mentor Mothers: These are HIV-positive women who serve as peer counselors for PMTCT clients, provide guidance and support in keeping appointments and promoting antiretroviral adherence and retention-in-care.

Opportunistic Infections: An infection that occurs because of a weakened immune system.

Pregnant Woman: A woman expecting to deliver a child.

Puerperium: The period of adjustment after childbirth during which the mothers reproductive system returns to its normal pre-pregnant state.

Referral Hospital: A hospital in which health care providers at lower levels of the health care system, who lack the skills, the facilities, or both to manage a given clinical condition, seek the assistance of providers who are better equipped or specially trained to guide them in managing a clinical condition of a patient

Seroconversion: The development of detectable antibodies in the blood that are directed against an infectious agent.

Seropositive: The presence of antibodies or other immune markers in serum that indicate prior exposure to a particular organism or antigen.

Seroprevalence: The frequency in a population that have a particular element in their blood serum.

ABSTRACT

Introduction: Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) are among the leading causes of infectious disease deaths worldwide. The two viruses are highly endemic in sub-Saharan Africa. Pregnant women who are co-infected with HBV and HIV are highly viremic for HBV and may be at a high risk of transmitting HBV to their infants. The prevalence of HIV in pregnant women aged 15-49 years in Kenya is 5.6%. Nyanza region of Kenya has the highest prevalence of HIV at about 15.1% compared to other regions in Kenya. Adult prevalence (15-64 years) in 2013 was 23.7% for males and 27.4% for females in Homabay County, 17.8% and 20.6% respectively in Kisumu and 21.8% and 25.3% respectively in Siaya Counties. With these statistics it is clear that more females than males in the same age group are infected with HIV in the region. Therefore, females in the same age bracket including pregnant women could be co-infected with HBV more than males. This study sought to establish seroprevalence of hepatitis B surface antigen and its associated factors among HIV positive pregnant women in Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in Kisumu. Approval for conducting the study was obtained from KNH/UoN-ERC and JOOTRH's hospital administration.

Study Design: The study utilized a descriptive cross sectional design that sought to establish seroprevalence of hepatitis B surface antigen and its associated factors among HIV positive pregnant women in JOOTRH.

Study Population: The study population was composed of pregnant women living with HIV/AIDS aged between 15-49 years.

Sampling Procedure: Purposive sampling (homogenous) was use in this study. Potential study participants who met the inclusion criteria were purposively sampled.

Data Collection: Data was collected for a period of one month using structured questionnaires to identify the demographic characteristics and risk factors to HBV infection in the study participants. Determination of HBsAg status was done through laboratory screening of blood serum using *Onsite Rapid Test kit manufactured by CTK Biotec, Inc USA*. HIV status was ascertained using the antenatal record booklet issued to all pregnant women during their first visit to the ANC.

Data Analysis Procedures: Filled questionnaires were checked for completeness and data entry commenced. Accuracy of entry was ascertained. Data was summarized in percentages and measures of central tendency. Analysis was done using chi-squire tests and analysis of variance (ANOVA). Results were presented in tables, graphs, charts and text narratives.

Findings: Seroprevalence of HBsAg was 1% among study participants. Social demographic factors (age, marital status, level of education, religion and occupation) were found not statistically significant with HBV/HIV co-infection with $p>0.05$. Similarly, there was no statistical correlation between presumed risk factors to HBV/HIV co-infection and HBsAg status as follows. (Blood transfusion $p=0.753$, body tattooing $p=0.859$, body piercing for medicinal purpose $p=0.751$, circumcision $p=0.901$ and dental procedure $p=0.673$ at 95% confidence interval.

Conclusion: Findings of this study revealed a low seroprevalence rate of HBsAg of only 1% among study participants. However this finding does not necessarily reflect the real picture of co-infection in the entire region. Based on the current statistics of HIV/AIDS in Nyanza region, the rate of HBV/HIV co-infection could be different.

Recommendations: More attention should be focused on screening for HBsAg among HIV cases to identify demographics that show higher prevalence and to make informed decision on routine screening.

CHAPTER ONE

1.0. Introduction

Human immunodeficiency virus (HIV) is a type of two lentiviruses types 1 and 2 (HIV-1 and HIV-2) that cause Acquired Immunodeficiency Syndrome (AIDS) in humans. AIDS was first described in 1981, when previously healthy young adults living mainly in urban areas of the United States of America became ill with opportunistic infections previously unknown for their age group. Similar infections were soon described in Africa, the Caribbean and Europe. In 1983, Professor Luc Montagnier and others discovered a retrovirus tropic for the CD4 cells which was later called HIV (WHO, 2003).

HIV/AIDS has become a serious health issue around the world with some countries including Kenya having declared it a national disaster. Globally about 35 million people were living with HIV as of 2013 and approximately 2.1 million new cases of HIV infection worldwide in the same year were reported. Further an estimated 5 million people died from AIDS related illnesses in 2013 and another approximately 39 million have died from AIDS related illnesses in the world since the epidemic begun (WHO, 2014) In Africa, the sub-Saharan region is the most affected with about 24.7 million people living with HIV/AIDS in 2013 accounting for approximately 70% of the global total of new HIV infections in the same year (WHO, 2014).

HIV prevalence among pregnant women aged 15-49 years attending ANC clinics varies in different countries in Africa. The median HIV prevalence among pregnant women aged 15-49 years attending ANC in selected African countries were as follows. In 2010 Kenya had a prevalence of 6.2%, Tanzania had 5.1% in 2011, Uganda had 7.1% in 2007 and South Africa in 2011 showed a prevalence of 29.5% (WHO, 2013). Overall, the median HIV prevalence rate among ANC attendees aged 15-49 years declined from 9.5% in 1999-2000 to 3.4% in 2007-2008

and 3.5% in 2010-2012 in the WHO African Region. In Kenya for instance, there was a decline in prevalence to 6% in 2013 compared to 2010 (WHO, 2013 & NASCOP 2014).

HIV/AIDS can result in many opportunistic infections including tuberculosis, kaposi sarcoma, pneumonia and meningitis among others. Co-infection of HIV/AIDS and other diseases is widely documented. For instance, Hepatitis B Virus (HBV) is one condition likely to infect a person who is also infected with HIV/AIDS. According to Hoffman & Thio (2007), HIV-infected people are three to six times more likely to develop a chronic or long-term hepatitis B infection because of their weakened immune system than individuals without HIV. Both HIV and HBV have common routes of transmission and endemic areas, but HBV is about 100 times more infectious (Torantola et al, 2006). Studies by Thio CL et al, (2002) showed that up to two thirds of all HIV-infected people have a blood marker of past or present HBV infection.

Liver disease caused by chronic HBV infection is an important cause of morbidity and mortality among HIV infected individuals in the western world. Co-infection with both viruses is frequently seen world over. Most co-infected individuals live in sub-Saharan Africa and in the far East. In western countries, the prevalence of chronic HBV infection is overall 10-fold higher among HIV-positive individuals than in the general population (Lar et al, 2013).

1.1. Background Information

HBV infection is a global health problem with an estimated 400 million people infected, with majority of cases occurring in regions of Asia and Africa where the virus is endemic (Lar et al, 2013).

HBV is transmitted through blood or body fluids of an infected person, unprotected penetrative sexual contact, blood transfusion, drug injections, tattoos, skin piercing activities and health care

occupational risks. The world's predominant mode of HBV transmission is perinatal accounting to 35-50% of all carriers (Yao, 1996). If a pregnant woman is a carrier of HBV and is also hepatitis B e antigen (HBeAg)-positive her newborn baby is 90% likely to be infected and becoming HBV carrier. About 25% of such newborns will die in adult life from chronic liver disease or liver cancer (Liaw et al, 2010).

Among people at risk of developing HBV infection are pregnant women and those already infected with HIV/AIDS. Other groups of people at risk include homosexuals and intravenous drug users. Center for Disease Control (CDC) recommends that all pregnant women be screened for the marker of active hepatitis B surface antigen (HBsAg) particularly those already infected with the HIV/AIDS, to prevent perinatal transmission. In developed countries, screening for HBsAg is routine in pregnancy. In most African countries for example Nigeria, screening for HIV in pregnancy is routine. However, screening for HBV is not routinely done in some African countries despite the two infections having similar modes of transmission.

In sub-Saharan Africa vertical transmission is the most common mode of acquiring HBV infection while in Asia early childhood exposure plays a major role. HIV/HBV co-infection in pregnant women increases the risk for increased morbidity and mortality.

Mother to child transmission of HIV/HBV occurs in-utero or through exposure to blood or blood contaminated fluids or at birth. According to Bohidar (2004), vertical transmission of HBV occurs in about 10% of neonates during the first trimester and 60-90% in the third trimester. Complications associated with HBV are well documented. In order to prevent these complications and transmission of HBV to the fetus and neonates WHO recommends routine screening for pregnant women before delivery (Rashid, 2014).

1.2. Problem Statement

HBV has been found to be high among people infected with HIV. Previous studies on the prevalence of HIV/HBV co-infection in pregnant women have revealed an increased incidence of co-infection.

Generally Kenya has seen a continued decline of HIV prevalence among adult population from late 1990's to 2008 with estimated prevalence rate of 6% among people aged 15-49 years in 2013. In the same year, the total number of people living with HIV (PLHIV) in Kenya was estimated to be 1.6 million. Among this an estimated 58 %(815630) of all adults aged 15 years and above were women (NASCOP, 2014).

It is widely known that the Nyanza region leads in the prevalence of HIV infection in Kenya. According to NASCOP (2014), Counties with the highest adult HIV prevalence in 2013 included; Homabay at 25.7%, Siaya at 23.7%, Kisumu at 19.3% and Migori at 14.7%.

As earlier noted, HIV and HBV share similar modes of transmission and risk factors. For this reason it is likely that the rate of HBV infection is also high in the Nyanza region owing to the high prevalence of HIV.

1.3. Study Justification

Studies have established that the rate of HIV infection is directly proportional to the rate of HBV infection due to their similar modes of transmission. HIV infection in Kenya was declared a national disaster in the year 1999. The National AIDS/STI Control Program (NASCOP) was established to coordinate all issues related to HIV/AIDS in the country. According to NASCOP (2014) the current prevalence of HIV stands at 7% in women and 4% in men with varying rates of infection in different counties.

HIV epidemic in Kenya is diverse geographically. Nyanza region has the highest prevalence of 15.1% compared to 0.2% in North Eastern region (NASCOP, 2014). Nyanza region is among the leading in the prevalence of HIV in Kenya. As earlier noted, Counties with the highest adult HIV prevalence include Homa Bay at 25.7%; Siaya at 23.7%; Kisumu at 19.3%; Migori at 14.7% and Kisii at 8%.

In developed countries such as the United States of America (USA), testing for HBsAg is recommended for every pregnant woman regardless of previous testing or vaccination. CDC in one of its weekly report recommends that pregnant women who have not been tested and those with risk factors for HBV infection should be tested when they appear for delivery. WHO also recommends screening of pregnant women for HBV infection (Rashid, 2014). However, this is not the case in Kenya. With the highest number of new HIV infections coupled with the highest number of people living with HIV/AIDS, Nyanza region is likely to have higher co-infection rates in women than in men. More pregnant women in this region particularly those living with HIV/AIDS could be HIV/HBV co-infected. The prevalence of HBV and that of HIV/HBV co-infection among pregnant women in the region is undocumented. Therefore, this study aimed to establish the seroprevalence of HBsAg and its associated factors among HIV positive pregnant women in Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in Kisumu.

1.4. Research Question

What is the seroprevalence of HBsAg and its associated factors among HIV positive pregnant women in JOOTRH?

1.5. Study Objectives

1.5.1. Broad Objective

To determine seroprevalence of HBsAg and its associated factors among HIV positive pregnant women in JOOTRH.

1.5.2. Specific Objectives

1. To describe the social demographic profiles of HIV positive pregnant women in JOOTRH.
2. To determine the seroprevalence of HBsAg among HIV positive pregnant women in JOOTRH.
3. To establish factors associated with HIV/HBV co-infection among pregnant women in JOOTRH.

CHAPTER TWO

LITERATURE REVIEW

2.0. Introduction

HIV/AIDS has been and remains a major health concern worldwide because of the high mortality and morbidity that has been witnessed in different parts of the world. Highly Active Antiretroviral Therapy (HAART) has had a positive impact in improvement of overall morbidity and mortality for the life threatening opportunistic infections. However, other similar conditions that co-infect HIV positive patients are reversing the gains of lowered morbidity and mortality. Chung at al, (2001) notes that in place of the usual HIV-associated opportunistic infections, morbidity and mortality due to the sequelae of hepatitis B and hepatitis C infections have taken on a leading role in HIV infected individuals.

HIV, HBV and Hepatitis C Virus (HCV) are the three most common chronic viral infections all over the world. However, co-infection with HBV and HIV is more common than that with HCV and HIV (Piliero & Faragon 2002).

Kourtis et al, (2012) established that HBV and HIV type 1 are among the leading causes of infectious disease deaths worldwide. According to Dusheiko (2006), HIV/HBV co-infection affects a significant number of people worldwide and in many settings approximately 90% of HIV infected persons have evidence of previous (inactive) HBV infection.

Barth et al, (2010), notes that HIV and HBV are highly endemic in sub-Saharan Africa, where infection with both viruses is frequent. He further states that 13% of HIV-infected pregnant women also have HBV in sub-Saharan Africa. According to Jonas (2009), few reports of HIV/HBV co-infection in pregnant women are available in sub-Saharan Africa. Pregnant women

who are co-infected with HIV/HBV tend to be highly viremic for HBV (Anderson et al, 2012) and may be at heightened risk of HBV transmission to their infants (Burk et al 1994).

2.1. Hepatitis B Infection

Hepatitis B is a potentially life threatening liver infection caused by HBV. It results in chronic liver disease, chronic infection and liver cancer. Of the estimated 350 million people chronically infected with HBV worldwide Africa has 65 million people infected (WHO, 2004).

Alter, (2003) adds that of the estimated 350 million cases at least 50% acquired their infections perinatally or in early childhood, especially in countries where HBV is endemic. This is attributed to the high rates of HBeAg-positive infections in women of child-bearing age. World prevalence of HBV ranges from 0.1% to 20% (McMahon, 2005 & Custer et al, 2004). According to Hoffman & Thio (2007), it is the leading cause of chronic liver disease and a leading cause of death, accounting for up to half of all cases of liver cirrhosis and hepatocellular carcinoma. Goldstein et al, (2005) declares that out of a total of 400 million hepatitis B infected people worldwide, 620,000 die annually from complications of chronic hepatitis B. Thio et al, (2002) further states that in settings of HIV co-infection, the mortality rate from chronic hepatitis B is increased compared to that of either infection.

Studies by Elinav et al, (2006), Ornoy & Tenenbaum (2006), Tse et al, (2005) and Dafallah et al, (2003) concur that viral hepatitis during pregnancy is associated with a high risk of maternal complications, high rate of vertical transmission causing fetal and neonatal hepatitis and has been reported as a leading cause of maternal mortality.

Prevalence of HBV during pregnancy varies worldwide. For, instance in the USA, the prevalence of viral hepatitis during pregnancy is 0.14–6% (Airoldi & Berghella, 2006). In sub Saharan

Africa the virus if hyperendemic at above 8% with the exception of Kenya, Senegal, Ivory Coast and Sierra Leone which are regions of intermediate endemicity at about 2-8%. The prevalence of chronic HBV infection among pregnant women reflects the same pattern. (Okoth et al, 2006, Akani et al, 2005). WHO classifies Kenya as a highly endemic area with a prevalence of more than 8%.

HBV generally occurs during the third trimester, with 1% of cases resulting in fulminant disease. Beyond liver-related complications, pregnant women with viral hepatitis may be at an increased risk for pregnancy complications (Lao et al, 2007). Gambarin (2007) notes that during pregnancy HBV is associated with preterm birth and antepartum hemorrhage.

2.2. HIV/HBV Co-infection in Pregnant Women

Co-infection of HIV with HBV represents a major global public health threat as each virus affects the other's natural history and response to therapy. For instance, the influence of HIV on the course of HBV include;- increased rate of liver related mortality, increased rate of occult HBV infection, more severe liver disease with increased rate of cirrhosis and hepatocellular carcinoma, higher rates of chronicity after acute HBV infection and increased rate of HBV DNA replication.

On the other hand, chronic hepatitis B with evidence of HBV replication might act as a co-factor for HIV disease progression. HBV might accelerate HIV disease progression indirectly, enhancing immune activation. However, no definitive proof for the role of HBV on HIV disease progression has been reported so far (Soriano et al, 2005). The prevalence of HBV among HIV infected pregnant women is widely varied and in some instances data is not available on the same. In Europe for instance, few studies have addressed the issue of co-infection with HBV in HIV-infected pregnant women to date and in particular, there are no data on the prevalence of

HIV/HCV or HIV/HBV co-infection in antenatal populations in Europe (Santiago-Munoz et al, 2005, Rouet et al, 2004, Simpore et al, 2006 & Hershow et al, 2005).

Studies in Africa indicate that pregnant women are three times as likely as HIV negative pregnant women to test positive for HBV Deoxyribonucleic Acid (DNA) and twice as likely to test positive for HBeAg. However there is scanty information regarding HIV/HBV co-infection in Africa. According to Hoffman & Thio (2007), very few studies have addressed co-infection with HBV among HIV infected pregnant women. In other parts of the world, studies on HIV/HBV co-infection in pregnant women have been done to some extent. In India for example of 689 HIV-infected pregnant Indian women, 4.6% (32) had HBV co-infection. HBV DNA was detectable in 64% (18) of 28 HIV-HBV co-infected women (Mave et al, 2014). Sub-Saharan Africa carries high rates of co-infection of HIV-1 and HBV as it is home to about 29.4 million HIV infected people. In Uganda for instance, out of a sample size of 164 HIV infected antenatal mothers screened for HBsAg, 4.9% turned positive and in Rwanda of the 82 HIV infected antenatal mothers, 2.4 % tested positive for HBsAg (Pirillo et al, 2007). In Zambia out of 214 HIV reactive antenatal mothers screened, 31.3% had a marker for HBsAg (Kasolo et al, 2003). In Nigeria, Ezegbudo et al, (2004) established that co-infection of HIV/HBV was 0.7% out of a sample of 1120 pregnant women while in Kenya out of 378 HIV positive females, 6.1% were positive for HBsAg (Harania et al, 2008). Similarly data from KNH and eight provincial hospitals suggested a persistent high prevalence of HBsAg among pregnant women with figure of 9.3% in 2001-2002 (Okoth et al, 2006).

The epidemic of HIV prevalence in Kenya is diverse geographically. Nyanza region as already noted is among the leading in the prevalence of HIV. Counties with the highest adult HIV prevalence in 2013 included Homa Bay at 25.7%; Siaya at 23.7%; Kisumu at 19.3%; Migori at

14.7% and Kisii at 8%. The county with the lowest prevalence was Northeastern region at 0.2% (NASCOP 2014).

From the reviewed literature it is evident that gaps exist in the trends of HIV/HBV co-infection particularly among pregnant women in Kenya. For cases of new HBV to be captured, screening for HBV at the time of diagnosis of HIV will have potential benefits both for the pregnant woman and for public health programmes (Kew et al, 2011). Early diagnosis of the co-infection allows assessment of the requirement for specific anti-HBV treatment. Early identification of co-infected women and appropriate counseling will alert them to the need for targeted HBV interventions for their babies, should they be chronically infected and identification of HBV seronegative HIV-infected individuals will facilitate an option of vaccination against HBV (Kew et al, 2011). Pregnant women are a special group in regard to this topic because of the risk of perinatal transmission of HBV which according to the literature is the leading mode of HBV transmission to children. The study sought to establish seroprevalence of HBsAg and its associated factors among HIV positive pregnant women in JOOTRH.

CHAPTER THREE

RESEARCH DESIGN AND METHODS

3.0. Study Design

The study utilized a descriptive cross sectional study design that sought to determine seroprevalence of HBsAg among pregnant women infected with the HIV/AIDS. Purposive sampling was used to get the desired sample size and to capture all eligible and potential study participants.

3.1. Study Area

The study was conducted at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in Kisumu County. It is the major teaching and referral hospital in Nyanza regions and parts of Western Kenya. The hospital is approximately 350 kilometers from Nairobi city and about 5 kilometers from the Kisumu International Airport located along Busia road. JOOTRH is located along the Kakamega road heading towards Kondele market just after Kibuye market. It is adjacent to The Regional Blood Transfusion Center to the left and Kibuye market to the right as one enters the main gate of the hospital. The hospital serves as a referral facility in neighboring counties including, Homa Bay, Siaya, Kisii, Kakamega, Vihiga and Kericho counties. It has a total bed capacity of 501. It offers many health care related services including Child Welfare Clinic (CWC) services, family planning, dialysis, Comprehensive Care Centre (CCC) for HIV/AIDS cases, palliative care, surgical, medical, pediatric, maternity, newborn care, laboratory services, critical care services and many more. The Maternity and Baby Unit is located towards the left as one enters the main gate of the hospital and houses labor ward on the ground floor, newborn unit on the first floor and postnatal ward adjacent to labor ward. Labor

ward has a capacity of 17 beds with 5 delivery couches. The postnatal ward has a bed capacity of 60 beds while the newborn unit has a capacity of 15 beds and 21 baby cots. The study took place in labor ward, antenatal ward and clinic. Labor ward has four spacious rooms. Two of the rooms are delivery rooms which are further subdivided into two sections each having two delivery couches. For the other two rooms, one serves as an observation room for women after delivery and the other as first stage for those in latent phase of labor. On average about 400 deliveries are conducted per month excluding cesarean section. This is according to the hospital statistics. Antenatal ward is a small section of the postnatal ward. It has a bed capacity of twenty beds.

3.2. Study Population

The study population was all pregnant women infected with HIV/AIDS attending the maternity unit of the hospital including antenatal clinic. To ascertain HIV status of potential study participants, ANC record booklet was evaluated. All pregnant women who visit health facilities are tested for HIV among other infections. Dates for the tests and signature of the HIV counselor are included. More so majority of pregnant women who attend ANC and have been tested, know their HIV status.

3.3. Study Sample

The sample encompassed pregnant women newly diagnosed with HIV and the known positive cases either on ART or not. All potential study participants who consented to participate in the study and met the inclusion criteria were considered.

3.3.0. Inclusion Criteria

- All consenting pregnant women infected with HIV evident on the ANC record booklet.
- All pregnant women aged between 15-49 years. This is the reproductive age bracket according to WHO.
- All pregnant women positive for HIV whether on ART or not. This is to capture all potential study participants to achieve the objectives of the study.

3.3.1. Exclusion Criteria

- Non-consenting pregnant women.
- Pregnant women who are HIV negative.
- Pregnant women whose age is not within the reproductive age bracket.

3.4. Sample Size Determination

Sample size was determined using the following formula: $N=\frac{Z^2\ pq}{d^2}$ (Mugenda & Mugenda 2003)

Where:

N is the desired sample if the target population is >10,000.

Z is the standard normal deviation at the required confidence interval (1.96) which corresponds to 95% confidence interval. P is the proportion in the target population estimated to have characteristics being measured. In this case the prevalence of hepatitis B and HIV in pregnant women in Kenya. q =1-p, d is the degree of accuracy/precision expected i.e. 0.05 and $N=1.96^2$ According to KEMRI researchers, the prevalence rate of HBV is about 10% among pregnant women who attend their clinics.

Therefore; p=0.1

$$N=\frac{Z^2\,pq}{d^2}$$

$$N=\frac{1.96^2(0.1)\,(0.9)}{(0.05)^2}$$

$$N=\frac{3.8416\times0.09}{0.0025}$$

$$\frac{0.345744}{0.0025}$$

$$= 138.2$$

$$= 139$$

Therefore the minimum sample size was 139 potential study participants.

3.5. Sampling Method

Purposive sampling (homogeneous) was used in this study whereby potential study participants were selected based on their HIV positive status. This sampling method was used in order to capture all eligible study participants who met the inclusion criteria.

3.6. Recruitment of Potential Study Participants

With the help of the unit managers of maternity and ANC clinic the principal researcher was introduced to two mentor mothers who work in the respective units to counsel and test pregnant women for HIV. Their work involved recruiting potential study participants into the study by checking all ANC booklets and referring those positive for HIV to the counseling room where two research assistants were stationed. Those who had not been tested were counseled and testing done.

The principal researcher trained two research assistants in establishing rapport and climate setting and administering the study questionnaire. The research assistants were nurses working in labor ward and antenatal ward including ANC clinic with a minimum qualification of bachelors' degree in nursing (BScN). They were selected through the help of the unit managers who were familiar with their qualifications and competence. They were able to speak and understand dholuo which is the local language. The principal researcher explained study objectives to them including emphasis on ethical considerations and consenting process. Potential study participants in labor ward and antenatal ward included HIV positive clients who were admitted while in ANC clinic they included newly diagnosed cases of HIV and those on routine visits. The research assistants evaluated their ability to take part in the study including determination of whether they met the inclusion criteria for the study. Those who met the inclusion criteria and were willing to participate in the study were taken through the contents of the ethical considerations and the consent form and were expected to understand and ask any questions or clarifications before signing the consent.

3.7. Data Collection Process

Structured questionnaires were prepared and pre-tested for validity before the data collection. The research assistants helped in pre-testing the questionnaire which took place in the ANC clinic. They ensured that they understood the questionnaire in their local dialect to increase the response rate in cases where study participants could not understand English. Each questionnaire was labeled with a different serial number that corresponded with the one labeled on the red-topped vacutainer blood collection tube. One research assistant administered the questionnaires study participants who were admitted in labor ward and antenatal ward in the counseling room situated next to the ultrasound room as one enters labor ward. The room is labeled on the door

and entry is restricted when a session is going on. This ensured privacy. The work of the counselor was not interfered with. The principal researcher ensured that clients who were to be counseled were given priority to occupy the room. Collection of blood specimen followed after the questionnaires were filled. Blood samples were collected by laboratory personnel and were put in red-toped vacutainer collection tubes and were labeled with serial numbers similar to the ones in each questionnaire filled for the day and were ready to be transported to the laboratory. The other research assistant worked in ANC clinic and similarly the counseling room was used. The room was a bit busy than the one in labor ward though clients who were to be counseled were given fast priority. Just like the other side, a mentor mother help to identify and recruit potential study participants and referred them one by one to the research assisted who established rapport and set the climate for data collection. After filling the questionnaire, blood samples were drawn from each client and put in the collection tubes ready to be taken to the laboratory. All collected blood samples for the day were taken to the laboratory in company of the principal researcher for screening. Results were entered on each questionnaire by the principal researcher. All used material was discarded accordingly.

3.8. Laboratory Screening for HBsAg

Laboratory screening for HBsAg were performed with the help of two laboratory technicians working in the main laboratory of the hospital. With the help of the laboratory manager the two individuals were selected based on their qualifications and competence. The principal investigator briefed them on the objectives of the study and provided all relevant information about the study. Study participants were provided with all the information regarding the procedure of blood specimen collection and the importance of the study. They were expected to ask questions or seek clarifications from the principal investigator or the laboratory technicians.

After understanding all that was expected they were voluntarily asked to sign the consent form. Two milliliters of blood specimen was collected aseptically using a sterile syringe and put in red-topped vacutainer blood collection tube. Each vacutainer collection tube was labeled using a specific serial number corresponding to each questionnaire. The blood specimen was then centrifuged at a speed of 3000 revolutions per minute for three minutes to separate serum from plasma. Determination of the presence of HBsAg on the serum was carried out using the *Onsite Rapid Test kit manufactured by CTK Biotec, Inc USA.* The screening test kits were sourced from the main laboratory of the hospital and were validated for use on serum. Test strips were dipped in the serum for about ten seconds and the results were ready within 15 minutes.

3.9. Interpretation of Results

A positive result was indicated by two distinct red bands appearing one in the test (T) region and the other in the control (C) region.

A negative result was indicated by a single red band appearing in the control (C) region. No apparent red or pink band appears in the test (T) region.

An invalid result was indicated when control (C) band failed to appear meaning improper testing procedure or malfunction of the test strip. In this study no invalid results occurred.

3.9.1. Quality Assurance

JOOTRH being a major teaching and referral hospital in Kenya has all its functions and services approved by the Ministry of Health in the country. The hospital's medical laboratory operates under the requirements and guidance of The Quality Policy Manual for Medical Laboratory Services in Kenya of 2011 developed by the Ministry of Medical Services and Ministry of Public Health and Sanitation, Kenya and partners including the United States Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), Kenya and

Laboratory Programme of the African Medical and Research Foundation (AMREF). The laboratory is categorized under the district and provincial hospital laboratories. The quality manual clearly defines the laboratory Quality System Essentials and documents the policies and procedures needed to implement continuous laboratory service improvements towards meeting international accreditation standards such as ISO 15189. The manual is also a source of invaluable information offering guidance to both laboratory and non-laboratory staff in improving quality of laboratory services through evidence-based practices. According to the laboratory director, JOOTRH's medical laboratory is guided by the Quality Policy Manual for Medical Laboratory Services in Kenya and its own internal quality control.

3.9.2. Quality Assurance for Data Collection Tool

The data collection tool was first pre-tested before actual data collection. After filling each questionnaire research assistants checked for completeness. This was counter checked by the principal researcher. Each questionnaire had a specific serial number written on which corresponded to the one labeled on each vacutainer collection tube. This ensured anonymity and accuracy recording of results in each questionnaire. The principal researcher was always present in the laboratory when screening was done and he was the one who entered the results in each questionnaire. After data entry all questionnaires were put in safe custody by the principal researcher.

3.9.3. Ethical Considerations

The study was conducted following approval by The Joint University of Nairobi and Kenyatta National Hospital Ethics and Research Committee (KNH/UoN-ERC). The researcher obtained approval from KNH/UoN-ERC before data collection. Permission was sought from Jaramogi Oginga Odinga Teaching and Referral Hospital administration as well as from the Reproductive

Health Unit Manager and Nurse Managers for labor ward and antenatal ward as well as for antenatal clinic. Written informed consent was obtained from all study participants after explanations and all necessary information had been provided to them by the principal researcher and research assistants**.** Confidentiality was highly observed in this study. HIV positive status and HBV positive status of study participants were not disclosed to anybody without consent of the study participant. Privacy was provided during collection of blood samples which were coded to ensure anonymity. Participation in this study was voluntary. A participant was free to withdraw from the study at any point and no services were denied to such participants if they choose not to participate. Anonymity of study participants was ensured through coding of questionnaires with serial numbers that corresponded to those in the vacutainer collection tubes. Data base systems were password protected and study findings would be made public in different forums for utilization accordingly.

All the documents including filled questionnaires were not shared to other people and neither were they destroyed. After data analysis they were kept under lock and key and would be stored for at least five years. Study participants' names were not required in any of the questionnaires or any other documents so as to ensure anonymity. Full information on the purpose of the study, any foreseen risk, benefits and compensation or lack of them were given to the participants to ensure voluntary informed consent and participation. No harm to both the participant and unborn baby were anticipated. All procedures including blood sample collection and screening were done aseptically under sterile conditions.

3.9.4. Dissemination Plan

The study findings would be disseminated to the University of Nairobi and JOOTRH. Further dissemination would be done through seminar presentations and workshops.

The principal researcher would make efforts to publish the findings in journals.

3.9.5. Time Line and Budget

The study was conducted from September 2015 to October 2015. The budget for the study was approximately one hundred and seventeen thousand Kenya Shillings. (Kshs. 117,000).

3.9.6. Limitations of the Study

- The subjectivity and non-probability nature of sample selection used in this study (purposive sampling) may have resulted in less representativeness of the sample.
- The study being observational did not permit much intervention to be carried out on study participants who were positive for HBsAg though the client who turned positive was referred for ELISA.
- Translation of the questionnaire to the local dialect and back to English may have interfered with understanding of some questions in the questionnaire.

3.9.7. Data Management, Analysis and Presentation

Data analysis started after all the questionnaires were complete with test results indicated there in. All questionnaires were reviewed for completeness before data entry was commenced. They were kept in a lockable cabinet in the principal researcher's office during data collection and in the statistician's office during data entry and analysis. Data was entered into a password protected Microsoft Access Database accessible only to the Data Manager, Data Clerk and the Principal researcher. Once data entry was complete, the Principal researcher performed comparison of the hard copy questionnaires with the entered data to assess accuracy of entry.

Descriptive data analysis was then carried out to identify inconsistencies and extreme values. While describing the study population and seroprevalence of HBsAg and its associated factors among study participants, categorical variables were summarized as counts and percentages by use of frequency tables while continuous variables were summarized using measures of central tendency and dispersion. (Mean and Standard Deviation). In order to determine seroprevalence of HBsAg among study participants, Pearson Correlation Tests were carried out where the predictor was a categorical variable and analysis of variance (ANOVA) tests was carried out where the predictor was continuous. This was followed by multiple regressions to determine seroprevalence of HBsAg and its associated factors among the study participants. Results were presented using tables, graphs, charts and text narratives.

CHAPTER FOUR

STUDY RESULTS

4.0. Introduction

This chapter presents results of the study. A descriptive cross sectional design was utilized to establish seroprevalence of HBsAg among HIV positive pregnant women attending JOOTRH. Structured questionnaires were administered to 125 consenting study participants and the results of the analysis presented as detailed below.

4.1. Participants Response Rate

The study targeted 139 participants out of which 125 respondents consented participation. Questionnaires were administered to the 125 study participants and determination of their HBsAg status was done.

Figure 4.1 Response return rate.

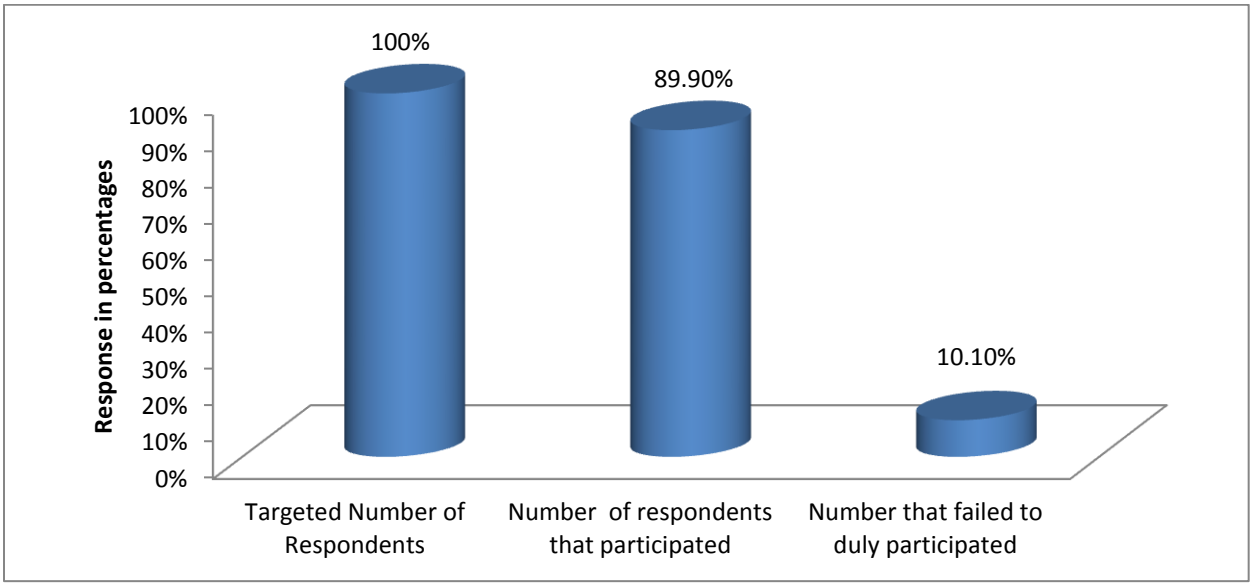


Figure 4.1 shows the response return rate where by 89.9% (125) response rate was achieved while 10.1 %(14) potential study participants declined participation.

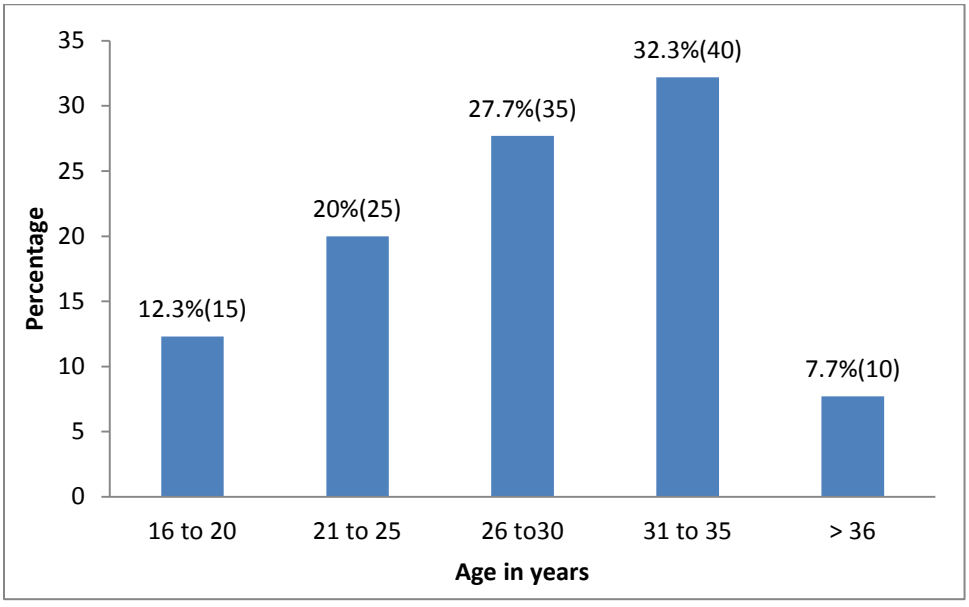
4.2. Social Demographic Profiles

Findings from the descriptive analysis of social demographic profiles of the respondents were as follows.

4.2.1. Age

Analysis of the age revealed an average age group of 31 to 35 years. Thus majority of the respondents were aged between 31 to 35 years accounting for 32.3 %(n=40) followed by age bracket of 26-30 accounting for 27.7% (n=35). Those aged 16 to 20 years accounted for 12.3 %(n=15) while those aged 21 to 25 accounted for 20 %(n=25). Only 7.7% (n=10) were above 36 years. This is shown in figure 4.2.

Figure 4.2 Age distribution of study participants.



4.2.2. Marital Status

Majority of respondents were married i.e. 72% (n=90) while 21.5% (n=27) reported to be single, 4.6 %(n=6) were separated and only 1.5% (n=2) reported to have divorced. This is presented in table 4.1.

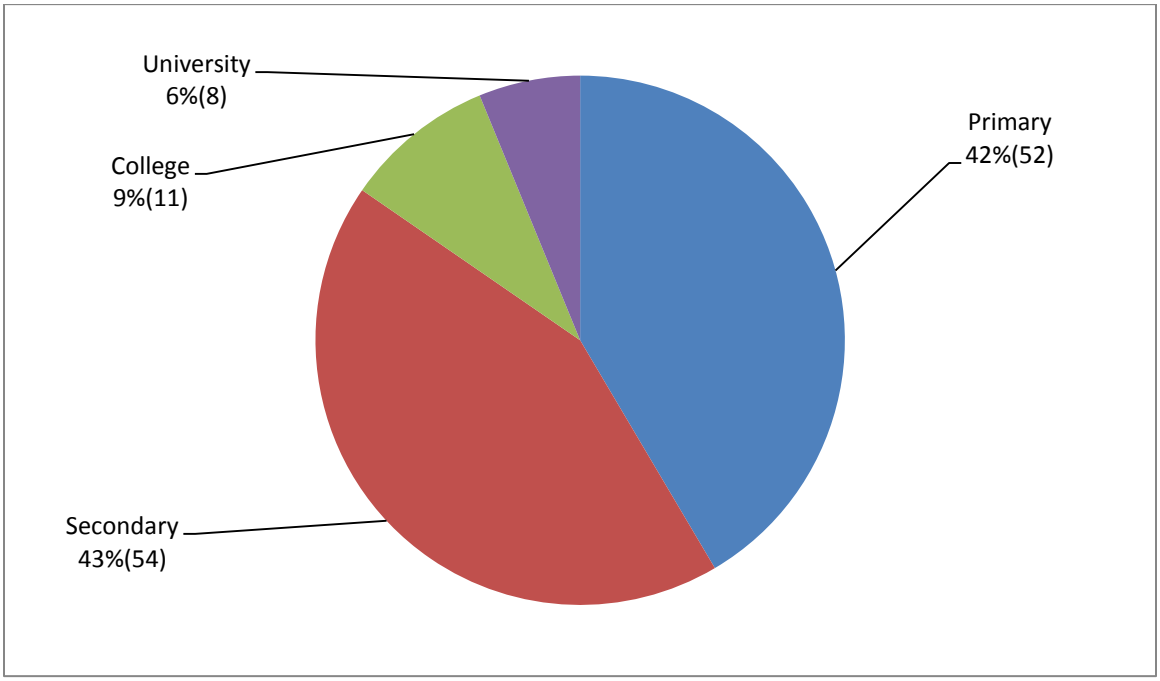
Marital status	Number	Percentage (%)
Single	27	21.6
Married	90	72
Separated	6	4.8
Divorced	2	1.6
Total	125	100

Table 4.1 Marital status of study participants.

4.2.3. Level of Education

As shown in figure 4.3, majority of the respondents had either secondary or primary education i.e. 43% (n=54) and 42 %(n=52) respectively. Those with college education accounted for 9 %(n=11) while those who had reached university were 6 %(n=8).

Figure 4.3 Level of education of study participants.



4.2.4 Occupation and Religion

Table 4.3 displays the occupation and religious affiliation of study participants. As shown, housewives accounted for 29.6% (n=37). Those without any form of employment accounted for 16.8 %(n=21). Study participants in business, casual laborers and self employed showed similar percentages i.e. 15.2% (n=19), 11.2% (n=14) and 12% (n=15) respectively. Only 1.6 %(n=2) reported to be students. On the other hand, Christianity was the main religion at 95.2% (n=119). Muslims and atheists accounted for only 3.2% (n=4) and 1.6% (n=2) respectively.

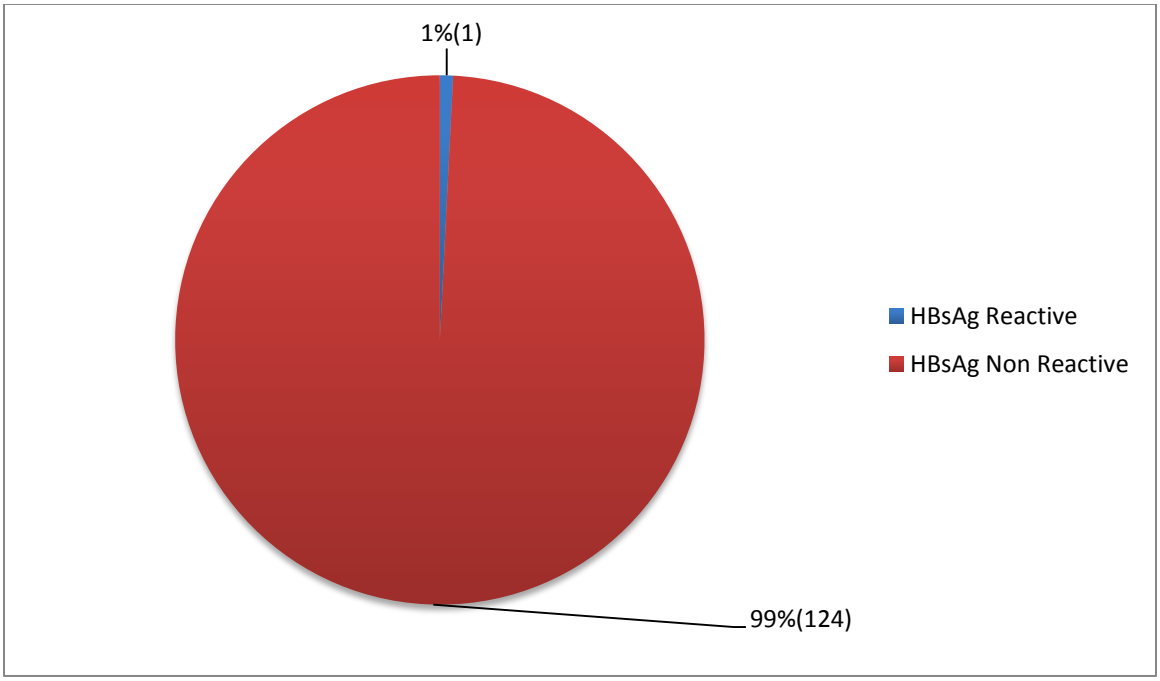
Table 4.2 Occupation and religious affiliation of study participants.

Occupation	**Number**	**Percentage (%)**
Employed	17	13.6
Business	19	15.2
Casual	14	11.2
Self Employed	15	12
Housewife	37	29.6
Unemployed	21	16.8
Student	2	1.6
Total	125	100
Religion		
Christian	119	95.2
Muslim	4	3.2
Atheist	2	1.6
Total	125	100

4.3. Seroprevalence of HBsAg among Study Participants

The researcher sought to establish seroprevalence of HBsAg among study participants. Out of a total of 125 respondents, only 1% (n=1) tested positive for HBsAg while 99% (n=124) tested negative as shown in figure 4.4 below.

Figure 4.4 Test results for HBsAg among study participants.



4.4. Socio-Demographic Characteristics and HBV/HIV Co-infection

Table 4.3 Demographic characteristics correlations

Demographic Factor	Test		HBsAg Test result
Age	Pearson Correlation	(r)	.003
	Sig. (2-tailed)	(p)	.979
Marital Status	Pearson Correlation	(r)	-.031
	Sig. (2-tailed)	(p)	.804
Education	Pearson Correlation	(r)	.118
	Sig. (2-tailed)	(p)	.348
Religion	Pearson Correlation	(r)	.016
	Sig. (2-tailed)	(p)	.902
Occupation	Pearson Correlation	(r)	-.083
	Sig. (2-tailed)	(p)	.513

** Correlation is significant at the 0.01 level (2-tailed).

Table 4.3 shows Pearson correlation analysis between various socio-demographic factors and HIV/HBV co-infection. The results revealed no correlation for the demographic factors and HIV/HBV co-infection. For age, there was low correlation (r=0.003) which is not significant as p=0.979 (where p >0.01 and p>0.05). This does not satisfy the significance at 99% and 95% confidence interval. Therefore age of respondents was not a predictor of HIV/HBV co-infection among study participants. Similarly marital status (r = -0.031 with p = 0.804) showed a weak negative correlation which is not significant at either p > 0.01or p > 0.05. The level of education of the participant (r = 0.118, p = 0.348), religion (r = 0.016, p = 0.902) and occupation (r = -0.083, p = 0.513) are equally not significant thus show weak correlation. In summary none of the above factors showed any correlation with HIV/HBV co-infection.

4.5. Obstetrics/ Gynecology History

Obstetrics/gynecology history combined several factors which the researcher sought from study participants. The results are presented below.

4.5.1. Number of Living Children among Study Participants

From figure 4.5 below, most of the participants had between 1-3 children. This accounted for 57% (n=71). This was followed by primigravida at 28 %(n=35). Those who reported to have 4-6 children accounted for 15 %(n=19).

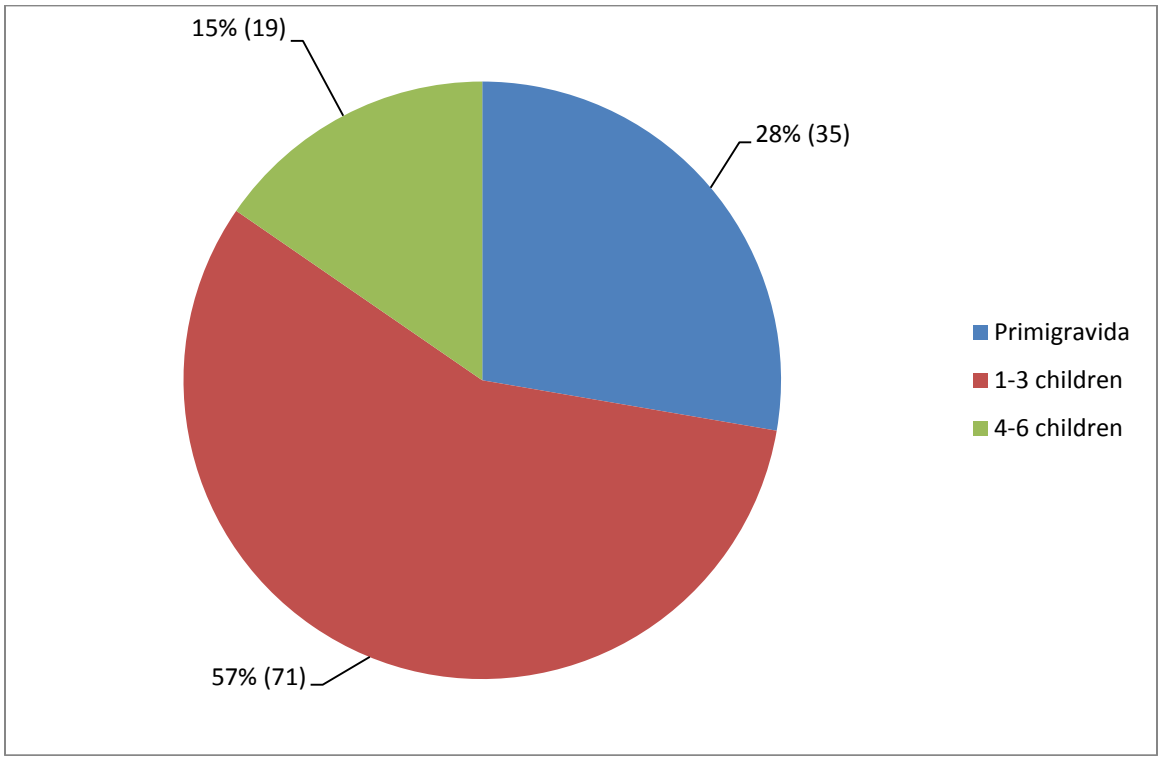


Figure 4.5 Number of living children among study participants

4.5.2. Mode of delivery

Majority of the respondents delivered through SVD i.e. 81.1% (n=73). Only 18.9 %(n= 17) of the respondents reported to have had a cesarean section as shown in figure 4.6.

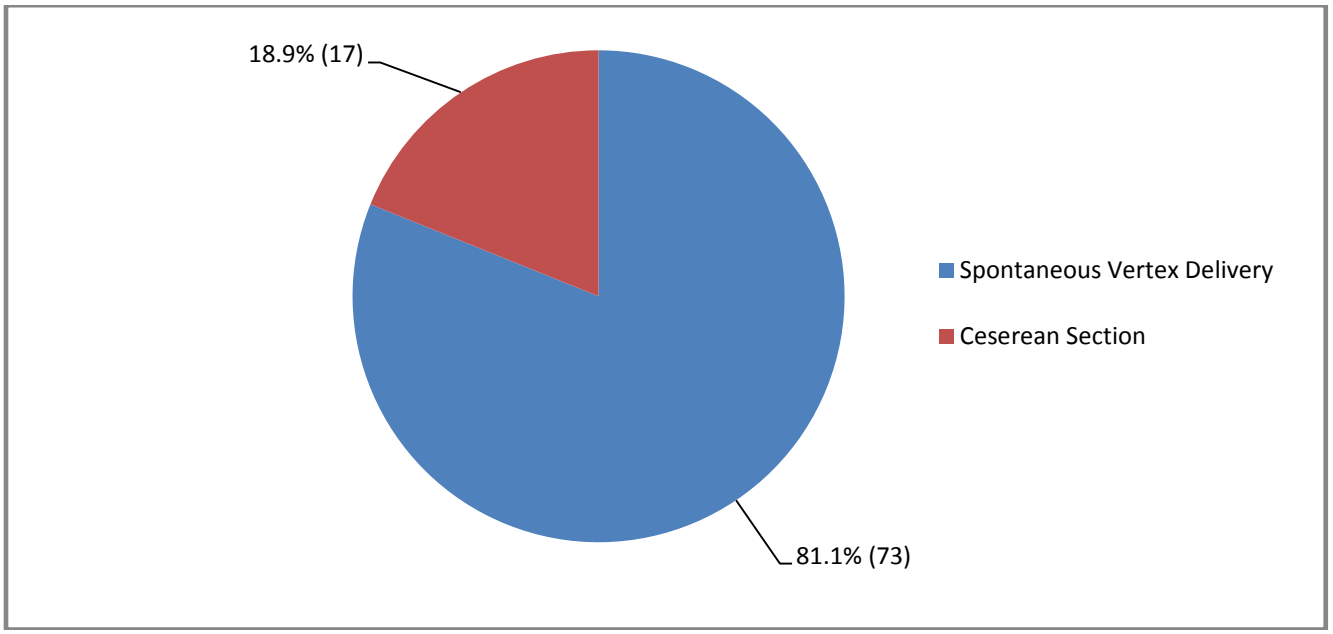


Figure 4.6 Mode of delivery among study participants.

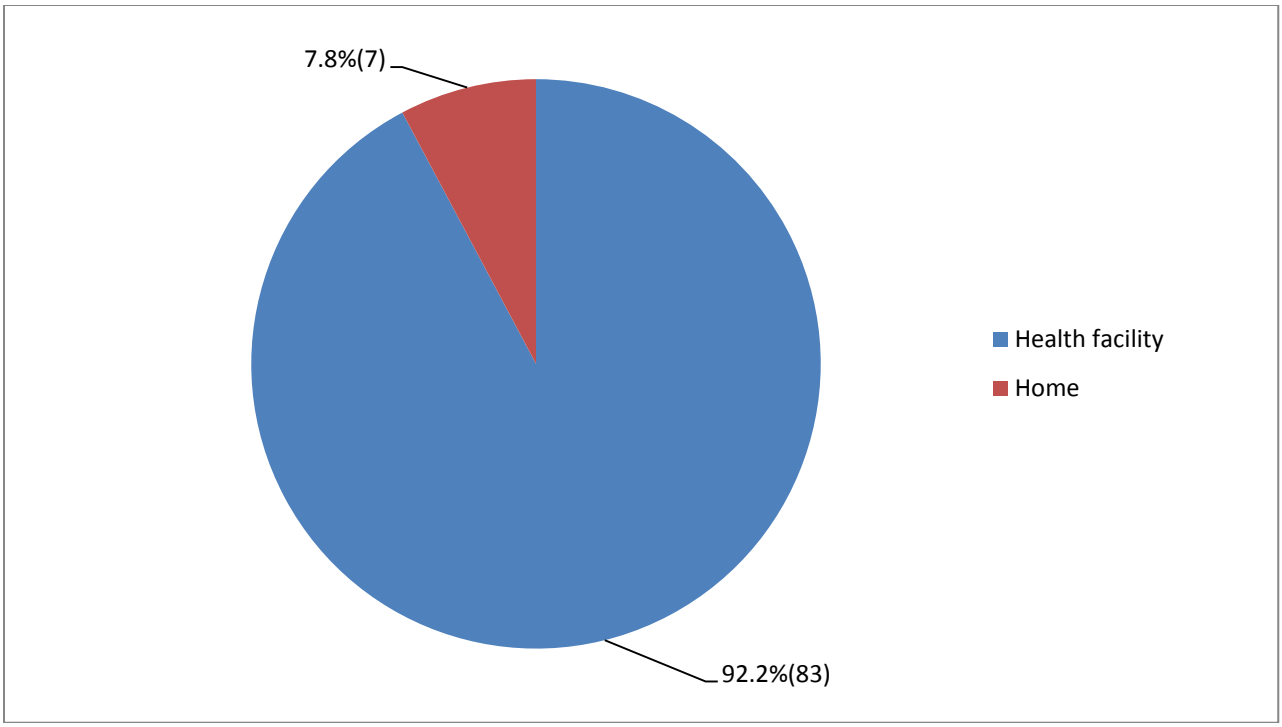


Figure 4.7 Place of delivery preferred by study participants

4.5.3. Place of Delivery

Majority of the respondents opted to deliver in health facilities 92.2 %(n=83) with only 7.8% (n=7) delivering at home as shown in figure 4.7.

4.5.4. Other Obstetrics/Gynecology Factors

Respondents who had previous history of perineal tears/episiotomy during delivery accounted for 30 %(n=27) with the majority 70 %(n=63) reporting no such history. History of abortion/miscarriage among study participants revealed a majority having no such history 92 %(n= 115). However, those who had previously experienced an abortion, it occurred at 23-28 weeks gestation accounting for 60 %(n=6)). Most of the respondents did not have a history of death of children in their family i.e.78.9 %(n=71)). Only 21.1 %(n=19) had lost their children

who were aged between 2-4 years 60 %(n=6) and reported pneumonia as the main cause of death 50 %(n=5) as seen in table 4.4.

Table 4.4 Other factors in the obstetrics/gynecology history.

Factor/Characteristic	Category	Frequency	Percent
Perineal tears/ Episiotomy	Yes	27	30.0
	No	63	70.0
	Total	**90**	**100.0**
Ever had Abortion or Miscarriage	Yes	10	8
	No	115	92
	Total	**125**	**100.0**
No of Abortions/ Miscarriages	1	10	100.0
	Total	**10**	**100.0**
Gestation when had Abortion/Miscarriage	17-22 Weeks	2	20
	23-28 Weeks	6	60
	35-40 Weeks	2	20
	Total	**10**	**100.0**
Any Dead Children	Yes	19	21.1
	No	71	78.9
	Total	**90**	**100.0**
Age of Dead Children	6 - 12 Months	3	30.0
	2-4 Years	6	60.0
	>5 Years	1	10.0
	Total	**10**	**100.0**
Cause of Death of child/children	Malaria	4	40.0
	Pneumonia	5	50.0
	Typhoid	1	10.0
	Total	**10**	**100.0**

4.6. Factors Associated With HBV Infection among HIV Positive Pregnant Women

In order to establish how risk factors associated with HBV infection, predict infection among study participants, a one way ANOVA between the presumed factors and HBsAg test result was run to determine how significantly the factors could predict infection. This is presented in table 4.7. History of blood transfusion compared with the HBsAg test result shows a significance p value of 0.753 (Table 4.7) which shows that blood transfusion did not predict HBV infection among study participants. Similarly, body tattooing (p = 0.859), body piercing (p = 0.751)

circumcision (p=0.901) and dental procedures (p = 0.673) do not significantly predict HBV infection at 0.05 confidence interval as in all cases p is greater than 0.05 (p>0.05). This is shown in table 4.7.

Table 4.5 ANOVA analysis of factors associated with HBV infection

		Sum of Squares	df	Mean Square	F	Sig.
Blood Transfusion	Between Groups	.009	1	.009	.100	.753
	Within Groups	5.438	124	.086		
	Total	**5.446**	**125**			
Body tattooing	Between Groups	.001	1	.001	.032	.859
	Within Groups	1.937	124	.031		
	Total	**1.938**	**125**			
Body Piercing for Medicinal Purpose	Between Groups	.009	1	.009	.102	.751
	Within Groups	5.429	124	.088		
	Total	**5.438**	**125**			
Undergone Circumcision	Between Groups	.000	1	.000	.016	.901
	Within Groups	.984	124	.016		
	Total	**.984**	**125**			
Undergone Dental Procedure	Between Groups	.024	1	.024	.179	.673
	Within Groups	8.438	124	.134		
	Total	**8.462**	**125**			

Significance at p>0.05 at 95% confidence interval.

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.0. Introduction

This chapter presents the discussion, conclusion and recommendations of the study findings. The purpose of the study was to determine seroprevalence of HBsAg and its associated factors among HIV positive pregnant women in JOOTRH.

5.1. Social Demographic Profiles

Results revealed that age of study participants showed a low correlation (r=0.003) which was not significant (p=0.979).Thus age was not a predictor of HIV/HBV co-infection. In a similar study in Nigeria Lar et al, (2013) found out that pregnant women between 36-40 years had the highest rate of co-infection of HIV/HBV while women between the age range of 16-20 had no co-infection. Results in this study agree with findings of a similar study in Ethiopia which established no correlation between prevalence of HBsAg and age among pregnant women (Awole & Gabre-Selassie, 2005). Level of education in this study showed no correlation with HBsAg status though participants with secondary education were the majority at 43.1%. This contradicts findings from a similar study in Nigeria which established that pregnant women with only secondary education had highest prevalence of co-infection of HIV/HBV (4.4%), while those with no formal education had the lowest prevalence rate of 0.7% (Lar et al, 2013). In this study results showed no correlation between occupation of study participants and HBsAg status. Though housewives were the majority, they had negative results for HBsAg. This is not consistent with findings of Lar et al, (2013) in Nigeria that showed a significant association between occupation and HIV/HBV co-infection whereby housewives demonstrated higher rate

of infection (8.8% at $p<0.05$) than study participants with other forms of occupation. It is likely that housewives in the study done in Nigeria may have engaged in more risky sexual behavior than their counterpart in this study. In terms of marital status, majority of study participants in this study were married though no correlation existed with HIV/HBV co-infection. However in Anambra State of Nigeria, Ezegbudo et al, (2004) established a paltry 0.4% co-infection among married women which was not statistically significant. To some extend these two findings are similar. The study in Anambra State also revealed HIV/HBV co-infection being highest among the widowed/divorced at 11.1% followed by the unmarried group. In this regard a conclusion can be made that the widowed/divorced women may have engaged in risky sexual behavior thus exposing them to dangers of HIV/HBV co-infection.

5.2. Seroprevalence of HBsAg

Findings of this study revealed a low seroprevalence of HBsAg of only 1% among study participants. In other parts of the world different seroprevalence rates have been reported. In India for instance Mave et al, (2014) studied 689 HIV infected pregnant women of which 4.6 %(n=32) had HIV/HBV co-infection. Compared to this study the results are not consistent despite the difference in sample sizes. In Sub Saharan Africa several studies have yielded different results. In Uganda, Pirillo et al, (2007) established that out of a sample of 164 HIV infected antenatal women screened for HBsAg 4.9% turned positive. This is a higher prevalence compared to findings in this study though the settings were different. Similarly in Rwanda, of the 82 HIV infected pregnant women screened, 2.4% tested positive for HBsAg (Pirillo et al, 2007). Though the sample size was smaller, the rate was still higher than seen in this study. Kosolo et al (2003) established that out of 214 HIV reactive antenatal women screened, 31.3% had a marker for HBsAg. With a slightly larger sample size the rate was much higher compared to this study.

In Nigeria researchers seeking to establish Prevalence and Immune status of HIV/HBV Co-infection found out that 11.8%(n=16) of pregnant women examined were seropositive for HIV/HBV co-infection out of a sample size of 135 study participants (Lar et al, 2013). Compared to the findings of this study, there is a big discrepancy in the results though in both cases the sample size was similar. This can be attributed to the different settings and time when the two studies were conducted. Similarly Ezegbudo et al, (2004), established a seroprevalence rate of 0.7 %(n=8) of HIV/HBV among 1120 pregnant women over a period of one year in Anambra State of Nigeria. Compared to this study the findings are similar though the study in Nigeria had a larger sample size (1120 participants) and a longer duration of one year. If this study was to be replicated in a wider area of Nyanza region within same study period as the Anambra state one, probably findings would be different. In Jimma Southern Ethiopia, Awole and Gabre-selassie (2005), established seroprevalence of HIV/HBV co-infection of 3.7 %(n=18) of 493 sera that was tested among pregnant women. Results from this study are contradicting the findings of the Jimma study though the sample size was larger. The settings of the two studies were not the same. Jimma was composed of a more cosmopolitan population. In Kenya Okoth et al (2006) reviewed data from Kenyatta National Hospital (KNH) and eight provincial hospitals which revealed a high prevalence of HBsAg among pregnant women of 9.3% in 2001 to 2002. This means on average each province yielded a similar rate to the one established in this study. Worth noting is the number of years between the two studies and the different settings of the study areas.

5.3. Factors Associated with HBV Infection

Several factors were analyzed to determine if they had an influence on HBsAg status among study participants. Majority of study participants reported not to have any history of

abortion/miscarriage with only a few reporting such history. Though the study could not determine correlation between history of abortion/miscarriage and HBsAg status, the study participant who turned positive for HBsAg did not have such history. This finding albeit from a smaller sample size, contradicts findings from Ethiopia which found out that pregnant women who had experienced abortion had a higher prevalence of HBsAg (7.3%). (Awole & Gabre-Selassie 2005). This can be attributed to few participants in this study who reported no history of abortion/miscarriage compared to a higher percentage who had past history of abortion/miscarriage in the study in Ethiopia. Other factors such as history of dental procedures, history of cesarean section and tattooing were associated with HBsAg positive status in the study done in Ethiopia. However findings of this study did not associate any of these factors with HBsAg positive status. The reason could be that this study was done in one hospital while the other study included a whole state (Jimma), which was more cosmopolitan with people from different backgrounds. Majority of the study participant in this study were from one community with relatively low socioeconomic status. Thus they may have been more conservative than their counterparts in the Jimma study.

5.4. Limitations

The study was done in only one hospital. Though it is a major teaching and referral hospital in the region, there are other public and private hospitals around with relatively many clients seeking health services.

The sample size was 139 potential study participants though 125 consented to participate thus the findings may not be generalized owing to the small sample size.

5.5. Conclusions

Findings of this study revealed a low seroprevalence rate (1%) of HBsAg among the study participants. However this may not have reflected the real picture of HIV/HBV co-infection in this region that has more people living with HIV/AIDS than other parts of the country. The researcher still believes the rate could be different owing to high numbers of people living with HIV/AIDS and the shared modes of transmission of the two viruses. With better screening equipment and different setting such as the whole county, a replicated study may yield different results.

Known risk factors for HIV/HBV co-infection included in this study were not associated with seroprevalence of HBsAg among study the participants. Majority of the study participants were married housewives with a significant number unemployed and having primary or secondary education and were Christians. This is evidence that most of them were from low socioeconomic background and as Christians may not have restrained from engaging in risky behavior that would predispose them to HIV/HBV co-infection.

Findings also showed the number of hospital deliveries having gone up compared to home deliveries. This can be attributed to the free maternity services introduced in the country in all public health facilities. Hospital deliveries are largely safe compared to home deliveries. This may have had a positive impact of reducing chances of acquiring infections such as hepatitis B. among the study participants.

Though the study did not determine the number of HIV pregnant women on ART, there is evidence that in Kenya the number of those on ART has increased over the years. Therefore a significant number of study participants may have been on ART which may have covered for

other co-infections of HIV including HBV. However, more needs to be done to curb new infection rates of HIV in Nyanza region and other parts of the country in a bid to prevent co-infections of HIV and mortality associated with the same.

5.6. Recommendations

With the low seroprevalence rate of HBsAg among study participants as determined in this study, the principal researcher recommends more attention to be focused by relevant authorities on screening for HBsAg among HIV/AIDS cases in Nyanza region to identify demographics that show higher prevalence and to make informed decisions regarding policy on routine HBV screening.

5.7. Suggestions for Further Studies

A similar study should be replicated in a wider geographical area in Nyanza region to clearly ascertain HIV/HBV co-infection rate among pregnant women.

A similar study focusing on newly diagnosed cases of HIV infection in pregnant women not yet on ART should be explored by upcoming researchers to determine prevalence of HBV.

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APPENDICES

Appendix i: Study Questionnaire

Title: Seroprevalence of Hepatitis B surface antigen and its associated factors among HIV positive pregnant women in Jaramogi Oginga Odinga Teaching and Referral Hospital.

Serial number…… **Date……**

Instructions to the respondents

Please respond to the following questions by answering in the spaces provided. Try to be as honest as possible. Do not write your name anywhere. When you are through with the questions please hand the questionnaire back to the principal researcher or research assistants.

Part A: Demographic data

Please put a tick (√) inside the box to indicate your response. For example [√]

1. How old are you? (Please indicate in your age in years under the age brackets given).

< 15 [ ] 16 to 20 [ ] 21 to 25 [ ] 26 to 30 [ ] 31 to 35 [ ] >36 [ ]

2. What is your marital status? Single [ ] Married [ ] Separated [ ] Divorced [ ]
Widowed [ ]

3. What is your level of education? Primary [ ] Secondary [ ] College [ ]
University [ ]

4. What is your religion? Christian [ ] Muslim [ ] Hindu [ ] Buddhist [ ]
Atheist [ ]

Other (specify)……

5. What is your occupation? Employed ☐ Business ☐ Casual ☐

Self employed ☐ Housewife ☐ Other (specify)……..

Part B: Obstetrics/Gynecology History

6. Gestation (weeks) ……. (To be filled by the research assistant) 24-29 ☐

30-35 ☐ 36-40 ☐ >41 ☐

7. How many living children do you have? None (primigravida) ☐ 1-3 ☐ 4-6 ☐

>7 ☐

8. What was your mode of delivery for your children? Spontaneous vertex delivery (SVD) ☐

Cesarean section (CS) ☐

9. Where did you give birth? Health facility ☐ Home ☐

10. Did you have tears or episiotomy? Yes ☐ No ☐

11. Have you ever had an abortion/miscarriage? Yes ☐ No ☐

If Yes, specify the number……

12. What was your gestation (weeks) when you had an abortion/miscarriage? <16 ☐

17-22 ☐ 23-28 ☐ 29-34 ☐ 35-40 ☐ >41 ☐

13. Have any of your children died? Yes ☐ No ☐

If yes, at what age? 0-1 month ☐ 6 months-1year ☐ 2-4 years ☐

>5years ☐

What was the cause of death? ……

14. Which family planning method do you use? None ☐ Natural ☐ Injection ☐

Pills ☐ Implants ☐ Barrier ☐

15. Have you ever undergone circumcision or female genital mutilation? Yes ☐

No ☐

Part C: Social History

16. Have you ever had any form of injuries Yes ☐ No ☐

If yes, specify type of injury……..

17. Do you smoke? Yes ☐ No ☐

18. Do you consume alcohol? Yes ☐ No ☐

19. Have you ever used any drugs of abuse? Yes ☐ No ☐

If Yes specify which ones……

20. Has your body been pierced for medicinal purposes? Yes ☐ No ☐

21. Has any part of your body been tattooed? Yes ☐ No ☐

Part D: Past Medical/Surgical History

22. Do you have a history of hepatitis B? Yes ☐ No ☐

23. Has any of your family members suffered from hepatitis B? Yes ☐ No ☐

24. Have you ever been transfused? Yes ☐ No ☐

25. Have you ever donated blood? Yes ☐ No ☐

26. Have you ever undergone dental procedures? Yes ☐ No ☐

27. Have you ever had any surgery? Yes ☐ No ☐

If yes, please indicate type of surgery……

Thank you for your time.

Appendix ii: Budget

COMPONENT	ACTIVITY DESCRIPTION / COST	ITEM	UNIT OF MEASUREMENT	UNIT COST (KSH)	TOTAL (KSH)
Research proposal/Stationary	Stationery	Foolscaps	3 reams	@500	1,500
		Photocopy papers	3 reams	@500	1,500
		Photocopy charges	300 pages	@2	600
	Printing charges	First draft	40 pages	@10	400
		Second draft	40 pages	@10	400
		Third draft	40 pages	@10	400
Subtotal					**4,800**
Research tool pretesting	Research assistant	Responsibility allowance	5 days	500	2,500
	Questionnaires	Typing and Printing questionnaires	20 copies	@10	200
		Photocopy of questionnaires	2000 pages	@2	4000
	Data collection/laboratory charges for testing HBV	Research assistants (2) sustenance	20 days	@500	20,000
		Reagents, lab fee	139 subjects	@500	69,500
		Miscellaneous	-	-	5,000
Sub –total					**101,200**
Reports/Thesis	Draft reports (3)	Printing	50 pages(3)	@10	1,500
		Photocopying	8 copies of 50 pages by 3=1200	@2	2,400
	Final reports	Correction and Printing	60 pages	@ 10	600
		Photocopying	8 copies	@ 300	2,400
		Binding	8 copies	@ 500	4,000
Sub-total					**10,900**
Grand total					**116,900**

Appendix iii: Time Frame

FROM OCTOBER 2014 TO NOVEMBER 2015													
ACTIVITY	Dec 2014	Jan 2015	Feb 2015	Mar 2015	Apr 2015	May 2015	June 2015	Jul 2015	Aug 2015	Sep 2015	Oct 20 15	Nov 20 15	Dec2 015
TOPIC IDENTIFIC ATION													
PROPOSAL WRITING													
ETHICS RESEACH COMMITT EE REVIEW													
DATA COLLECTI ON													
DATA ANALYSIS													
THESIS WRITING													
THESIS EXAMINA TION													
DEFENCE OF THESIS AT SONS													
REFINING THESIS													
PUBLISHIN G/DISSEMI NATION													

Appendix iv: Consent Information.

Title: Seroprevalence of Hepatitis B surface antigen and its associated factors among HIV positive pregnant women in Jaramogi Oginga Odinga Teaching and Referral Hospital.

Principal Researcher: Joseph .N. Ngerecia, MSN student at School of Nursing Sciences of the University of Nairobi.

I am a student pursuing Master of Science in Nursing at the School of Nursing Sciences of the University of Nairobi. I am conducting a research on Seroprevalence of Hepatitis B surface antigen and its associated factors among HIV positive pregnant women admitted in labor ward of Jaramogi Oginga Odinga Teaching and Referral Hospital. You are being requested to voluntarily participate in this study. You can only participate at your own free will. Note that whether you decide to participate or not will not affect the usual care that you are entitled to receive in this health facility. This is a consent form that gives you information about the purpose, procedure, risks, benefits, confidentiality/privacy and the process that will be expected during the study.

Purpose

The purpose of this study is to establish seroprevalence of HBV and its associated factors among HIV positive pregnant women in JOOTRH. The findings of this study will be used to improve the management of pregnant women who have HBV/HIV co-infection to prevent complications.

Procedures

You will be expected to participate by answering a researcher administered questionnaire.
Your ante-natal record will be used to get more information regarding your pregnancy and previous tests particularly for HIV done on you.

Blood samples to be used for screening for HBsAg will be collected aseptically and will be labeled not with your name but a serial number that will match your questionnaire. You will get the result after the test and depending on your status, necessary information will be provided to you. A repeat procedure may be required if the test result is invalid.

Risks

There is no harm or risk anticipated for participating in this study. There may be a possibility that some of the equipment and reagents for carrying out various tests may fail or yield false results. The principal researcher and his team will ensure all the equipment and reagents are up to date for the task. Some discomfort during collection of blood specimen is anticipated though the principal researcher will ensure those involved in the collection of the specimen will be qualified for the task and the discomfort will not result in any complications.

Benefits

The benefits are there but not monetary. The research participants will benefit from knowing their status of HBV co-infection. This will enable the medical team to start treatment immediately to avoid any further complications.

Voluntary participation and withdrawal

Your participation is in the study is entirely voluntary. Should you change your mind, you have the right to drop out at any time.

Confidentiality

All the results of any tests that will be performed on you will not be shared with any other person. The results will also not be linked to individual participant. However for the wellbeing of the study participant and the fetus, those who turn positive for the HBV will be informed and necessary action taken to avoid any complications.

Contact Persons

You will be given a card to take with you containing contact information of the principal researcher, the lead supervisor and the secretariat of KNH/UON Ethics and Research Committee. Should you have any questions, queries or concerns please feel free to contact them at any given time. This research has been reviewed and approved by the KNH/UoN Ethics and Research Committee in order to protect study participants.

Principal Researcher: Joseph Ngerecia MSN student, College of Health Sciences, School of Nursing Sciences of the University of Nairobi. Phone Number: 0723140177, Email address: josaacnjenga@yahoo.com

Lead Supervisor: Dr. Sabina Wakasiaka PhD, MPH, BScN. Senior Lecturer, School of Nursing Sciences, University of Nairobi. Phone Number: 0727438358, Email address: swakasiaka@gmail.com

KNH/UoN-ERC Secretariate: The Secretary, KNH/UoN Ethics and Research Committee. Kenyatta National Hospital P.O Box 20723-00202, Telephone: 020-726300-9, Fax: 725272, Email address: uonknh_erc@uonbi.ac.ke

Appendix v: Consent Form

The following are the contact persons for this study:

1. **Principal Researcher:** Joseph Ngerecia MSN student, College of Health Sciences, School of Nursing Sciences of the University of Nairobi. Phone Number: 0723140177, Email address: josaacnjenga@yahoo.com

2. **Lead Supervisor:** Dr. Sabina Wakasiaka PhD, MPH, BScN. Senior Lecturer, School of Nursing Sciences, University of Nairobi. Phone Number: 0727438358, Email address: swakasiaka@gmail.com

3. **KNH/UoN-ERC Secretariate:** The Secretary, KNH/UoN Ethics and Research Committee. Kenyatta National Hospital P.O Box 20723-00202, Telephone: 020-726300-9, Fax: 725272, Email: uonknh_erc@uonbi.ac.ke

Respondents' statement and signature/thumb print

I the undersigned have been explained to and understood the above information and voluntarily

accept to participate in the study.

Accepted……. Declined……

Signature/thumb print……

Patient/Next of kin telephone (Patient)…… Next of kin……

Researcher…….. Telephone……

Signature……. Time……Date…….

Appendix vi: Kiswahili Consent Information Form

Kichwa cha utafiti:

Mtafiti: Joseph. N. Ngerecia

Shule: Chuo Kikuu cha Nairobi

Utangulizi

Nachukua fursa hii kukukaribisha kushiriki kwenye utafiti huu unaofanywa na Joseph Ngerecia ambaye ni mwanafunzi katika chuo kikuu cha Nairobi.Utafiti wenyewe utafanyika katika Hospitali ya JOOTRH kitengo cha wamama wajawazito ambao wamekuja kujifungua. Utafiti huu utafanyika kati ya mwezi Juni na Julai mwaka huu wa 2015. Madhumuni ya utafiti huu ni kuchunguza kuwepo kwa ugonjwa wa Homa ya maini (Hepatitis B) kati ya wamama wajawazito ambao wameathirika na virusi vya ugonjwa wa ukimwi.

Nakualika kushiriki kwenye utafiti huu maanake ungojwa wa homa ya maini pamoja na ule wa ukimwi zikiwa ndani ya mwili wa mwanamke mjamzito ni hatari kwa afya yake pamoja na mtoto ambaye hajazaliwa. Utahitajika kujibu maswali katika fomu utakayo pewa na mtafiti mkuu au msaidizi wake itakuchukuwa dakika kama thelathini hivi. Baada ya hayo utahitajika kuithinisha utoaji wa damu kiasi kidogo ili kupima kuwepo kwa ugonjwa wa homa ya maini kwenye mwili wako.

Lengo la Utafiti

Utafiti huu una jukumu la kutathmini kuwepo kwa ugonjwa wa homa ya mapafu kati ya wamama wajawazito ambao wameathirika na ugonjwa wa ukimwi. Iwapo mtu atapatikana kuwa na maraghi hayo mawili kwa wakati mmoja, juhudi zitachukuliwa na hospitali pamoja na mchunguzi mkuu ili kutoa matibabu kwa manufaa ya afya ya mama pamoja na mtoto.

Hatari za kushiriki

Kwa ujumla hakuna hatari kubwa itakayo athiri mtu yeyote anayeshiriki katika uchunguzi huu.Utahitajika kujibu maswali kadhaa ambayo yanaweza kukukera. Kama utakabiliana na maswali kama hayo una haki ya kutoyajibu. Pia utahisi uchungu kiasi kidogo wakati wa kuchukua damu kotoka kwa mshipa wa mwili wako.

Utaratibu

Utapewa daftari na naibu wa mtafiti ambayo ina maswali yenye utahihajika kujibu. Baada ya hayo muuguzi wa maswala ya homa ya mapafu atachukua kiasi kidogo cha damu kutoka mwilini mwako. Utahisi uchungu kidogo wakati damu itakuwa ikitolewa. Kasha damu hio itapimwa na utapata kujua majibu baada ya muda wa saa moja hadi mbili.

Usiri

Hautahitajika kuandika jina lako mahali popote na matokeo ya damu yako hayataambatanishwa na mtu bibafsi. Pia hakuna mtu yeyote atakaye jua matokeo ya damu yako n aitakuwa vigumu kutambuliwa kama ulihusika na utafiti huu. Lakini kwa wale watakaopatikana kuwa na virusi vyote viwili, watapewa mawaidha na wanaweza kutibiwa ama kuelekezwa kwa wauguzi maalum ambao wamesomea taaluma hio.

Zawadi/Malipo

Hakutakuwa na malipo yoyote kwa wale watakao shiriki katika utafiti huu. Kushiriki ni hiari ya mtu.

Haki ya kujiondoa katika utafiti

Wale watakao shiriki kwenye utafiti huu wana haki ya kuondoka kwa hiari yao. Hakuna hatua yoyote itakayochukuliwa mtu ambaye atjiondoa kwenye utafiti huu.

Kusambaza matokeo ya utafiti

Matokeo ya utafiti huu yataenezwa kwa daftari la hospitali na huenda yakachapishwa kwenye magazeti ya kisayansi na kielimu.

Mawasiliano

Utapewa kadi ambayo itakuwa na majina kamili ya mtafiti mkuu pamoja na anwani na nambari yake ya simu. Pia kadi nyingine itakuwa na maelezo kuhusu Mkurugenzi wa Maadili kuhusu utafiti katika Kenyatta National Hospital na Chuo Kikuu cha Nairobi.(KNH/UON ERC). Tafadhali kuwa huru kuwasiliana nao moja kwa moja. Majina na anwani pamoja na nambari ya simu ni kama ifuatavyo:

1. **Mtafiti Mkuu:** Joseph Ngerecia. Nambari ya simu 0723140177, Barua pepe josaacnjenga@yahoo.com

2. **Mkurugenzi wa Maadili kuhusu utafiti (Director of KNH/UON ERC):** Professor A. N Guantai. S.L.P 20723-00202, Nairobi, Nambari ya simu, 726300-9, Fax: 725272, Barua pepe: uonknh_erc@uonbi.ac.ke

Appendix vii: Fomu ya Kudhibitisha Idhini

Nimesoma maelezo ya idhini na nimeelewa maudhui yake. Nimepewa fursa ya kujadili maswala yangu yote na mtafiti. Hivyo basi nimekubali kushiriki kwa hiari yangu pasipo na kulazimishwa na mtu yeyote.

Ridhaa ya kushiriki

Nimetoa idhini kwa hiari**:** Ndio…….. La…….

Sahihi /kidole cha gumba ……..

Jina la mshiriki/Msaidizi ……..

Nambari ya simu ya mshiriki…… Tarehe……

Taarifa ya mtafiti

Mimi niliyetia sahihi hapo chini nimetoa maelezo kikamilifu kuhusu utafiti huu kwa muhusika na nina hakika kwamba ametoa idhini ya kushiriki kwa hiari.

Mtafiti mkuu…… Tarehe…….. Sahihi……..…..

Mtafiti msaidizi……Tarehe…… Sahihi……..

Appendix viii: Letter to KNH/UoN-ERC

Joseph .N. Ngerecia.

School of Nursing Sciences,

University of Nairobi.

P.O. Box 19676,

Nairobi.

The Director,

KNH/UoN Ethics and Research Committee,

P. O. Box 20723 - 00202

Nairobi.

Dear Sir/Madam,

RE: REQUEST FOR AUTHORIZATION TO CONDUCT STUDY

I am a second year postgraduate student pursuing Master of Science in Nursing (obstetrics/midwifery) at the School of Nursing Sciences, University of Nairobi. I humbly request for permission to conduct a study on Seroprevalence of Hepatitis B surface antigen and its associated factors among HIV positive pregnant women admitted in Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), Kisumu.

At the completion of this study, pregnant women who will be found to be HIV/HBV co-infected will be treated particularly thereby preventing complications associated with the co-infection. On the other hand, babies born to such women will be managed effectively to prevent perinatal transmission of HBV. This will go a long way to improve both maternal and newborn health as part of the objectives of the MDGs.

Your kind consideration will be highly valued as it will also go a long way to facilitate completion of study and subsequent award of the degree. Thank you.

Yours faithfully,

Joseph .N. Ngerecia.

(Cell phone number: 0723140177).

Appendix ix: Letter to Jaramogi Oginga Odinga Teaching and Referral Hospital

Joseph .N. Ngerecia

The University of Nairobi

School of Nursing Sciences

P.O Box 19176

Nairobi.

The Medical Superintendent,

Jaramogi Oginga Odinga Teaching and Referral Hospital,

P.o Box 849-40100

Kisumu.

Dear Sir/Madam,

RE: REQUEST FOR AUTHORIZATION TO CONDUCT STUDY

I am a second year postgraduate student pursuing Master of Science in Nursing (obstetrics/midwifery) at the School of Nursing Sciences, University of Nairobi. I humbly request for permission to conduct a study on Seroprevalence of Hepatitis B surface antigen and its associated factors among HIV positive pregnant women in Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) Kisumu.

At the completion of this study, pregnant women who will be found to be HIV/HBV co-infected will be treated effectively thereby preventing complications associated with the co-infection. On the other hand, babies born to such women will be managed effectively to prevent perinatal transmission of HBV. This will go a long way to improve both maternal and newborn health as part of the objectives of the Sustainable Development Goals.

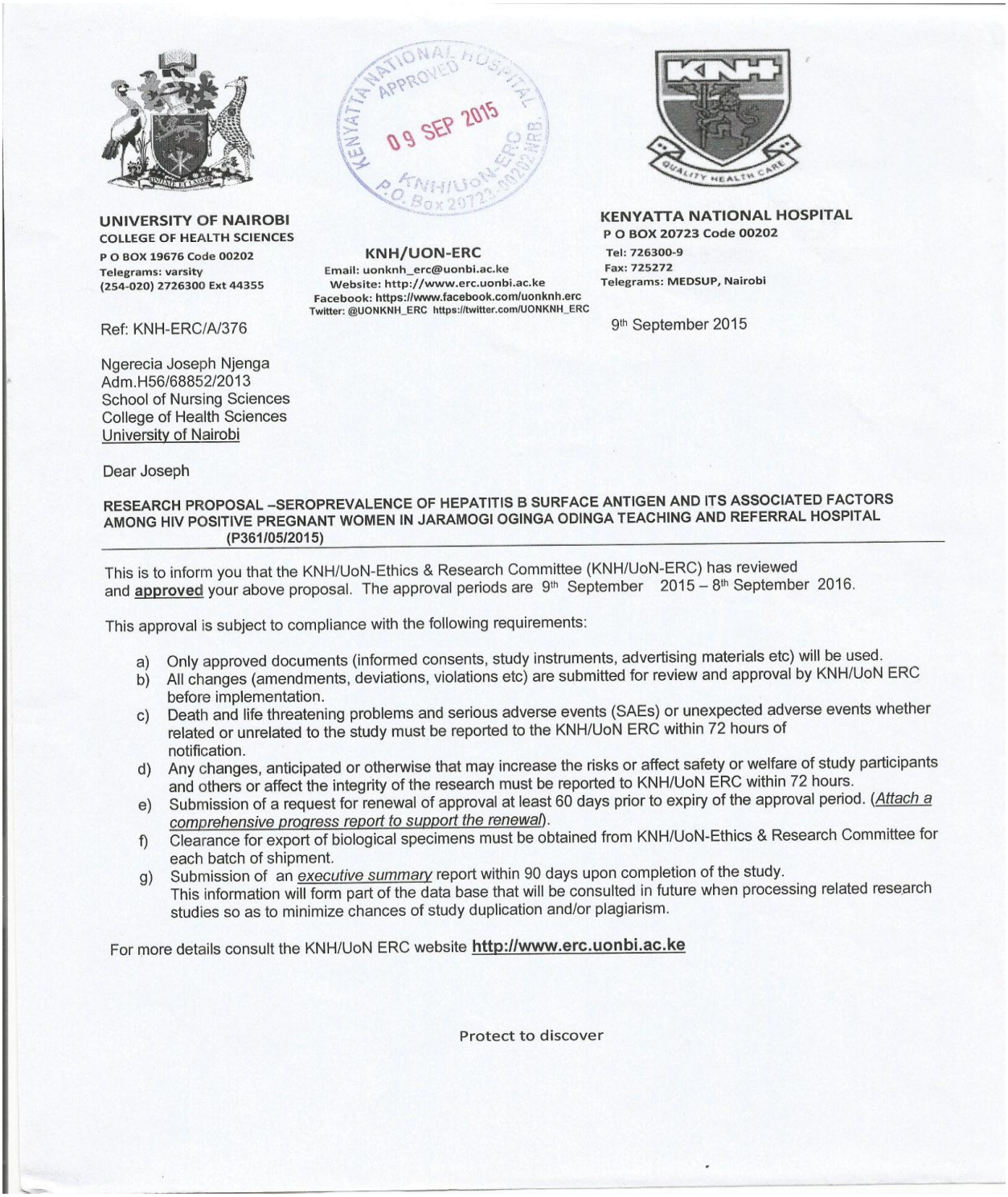
Your kind consideration will be highly valued as it will also go a long way to facilitate completion of the study and subsequent award of the degree.

Yours Faithfully,

Joseph .N. Ngerecia.

(Cell phone number: 0723140177).

Appendix x: Letter of Approval KNH/UON- ERC



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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
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Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 09 SEP 2015 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

Ref: KNH-ERC/A/376

9th September 2015

Ngerecia Joseph Njenga
Adm.H56/68852/2013
School of Nursing Sciences
College of Health Sciences
University of Nairobi

Dear Joseph

RESEARCH PROPOSAL –SEROPREVALENCE OF HEPATITIS B SURFACE ANTIGEN AND ITS ASSOCIATED FACTORS AMONG HIV POSITIVE PREGNANT WOMEN IN JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL (P361/05/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 9th September 2015 – 8th September 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,

PROF. A.N. GUANTAI
CHAIRPERSON, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Director, School of Nursing Sciences, UoN
Supervisors: Dr.Sabina Wakasiaka, Dr. Kivuti Bitok, Dr.Jennifer Oyieke

Appendix xi: Letter of Approval from JOOTRH

MINISTRY OF HEALTH

Telegrams: "MEDICAL", Kisumu
Telephone: 057-2020801/2020803/2020321
Fax: 057-2024337
E-mail: ercjootrh@gmail.com
When replying please quote

JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL
P.O. BOX 849
KISUMU

ERC.1B/VOL.I/223
Ref: .....

7th October, 2015
Date .....

Ngerecia Joseph Njenga,
Reg. No. H56/68852/2013,
UNIVERSITY OF NAIROBI.

Dear Joseph,

RE: FORMAL APPROVAL TO CONDUCT RESEARCH ENTITLED:
"SEROPREVALENCE OF HEPATITIS B SURFACE ANTIGEN AND ITS ASSOCIATED FACTORS AMONG HIV POSITIVE PREGNANT WOMEN IN JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL"

The JOOTRH ERC (ACCREDITATION NO. 01713) has reviewed your protocol and found it ethically satisfactory. You are therefore, permitted to commence your study immediately. Note that this approval is granted for a period of one year (7th October, 2015 to 8th October, 2016). If it is necessary to proceed with this research beyond the approved period, you will be required to apply for further extension to the committee.

Also note that you will be required to notify the committee of any protocol amendment(s), serious or unexpected outcomes related to the conduct of the study or termination for any reason.

Finally, note that you will also be required to share the findings of the study in both hard and soft copies upon completion.

The JOOTRH ERC takes this opportunity to thank you for choosing the institution and wishes you the best in your endeavours.

Yours sincerely,

JOOTRH ETHICS & REVIEW COMMITTEE
P. O. Box 849 - 40100
KISUMU

DR. ALLAN OTIENO,
CHAIRMAN –ERC,
JOOTRH – KISUMU.

Noted.
D/C to start
7/10/15.