# PREVALENCE OF HEPATITIS B VIRUS INFECTION AND ASSOCIATED FACTORS AMONG PREGNANT WOMEN ATTENDING ANTENATAL CARE AT KISUGU HEALTH CENTER III.

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**AN UNDERGRADUATE RESEARCH REPORT SUBMITTED TO THE INSTITUTE OF ALLIED HEALTH SCIENCES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF A BACHELOR'S DEGREE IN MEDICAL LABORATORY SCIENCES OF CLARKE INTERNATIONAL UNIVERSITY.**

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## DECLARATION

I, **NAKKUNGU VIOLET,** hereby testify that the work in this research report is my original work and has never been submitted to any other institution of higher learning for an academic award. Where work related to the topic has been referred to, the source has been acknowledged.

**Signature:** ……. **Date:** .....…

## APPROVAL

This research report is submitted with my approval;

**Signature:**  …… **Date:** 21/02/2022

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## DEDICATION

I dedicate this report to my dad Mr. MUGAMBE STEVEN for the financial support and his encouragement towards my success, Mrs. MUGAMBE JULIET for her sincere efforts and unending support towards my well-being and my mum, Ms. NAKAYEMBA TEDDY for her moral support and all her prayers towards my success.

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I appreciate the Kisugu Health Centre III team for their support during my research project. I also appreciate the Clarke International University staff for the administrative, technical and moral support offered to me during my period of stay at the university. I thank my family who have supported me financially and all my friends who helped me academically.

I’m very grateful to my supervisor Mr. Taremwa Ivan Mugisha whose professional guidance has made it possible for me to understand every aspect of my work.

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## LIST FOR THE DEFINITIONS OF OPERATION TERMS

**Acute:** it is a condition that develops suddenly and lasts a short time.

**Antibody:** it is a large, Y-shaped glycoprotein produced by the immune system in response to exposure of antigens.

**Antigen:** it is a substance or molecular structure (such as that may be present on the exterior of a pathogen), that binds specifically to an antibody or B-cell receptor.

**Chronic:** it is a condition that develops slowly and may worsen over a long period of time.

**Gravidity:** it is the number of pregnancies of a woman.

**Horizontal transmission:** it is the transmission of disease from one person to another.

**Independent variable:** it is the variable that influences the dependent variable and accounts for variations in the dependent variable.

**Perinatal transmission:** it is mother to child transmission also known as vertical transmission.

**Seromarkers:** they are biochemical markers specific for an infection.

**Hepatitis B surface antigen:** It is a hepatitis B virus marker that presents in people who are currently infected with Hepatitis B virus.

**Prevalence:** Is the number of cases of a disease in a specific place at a specific time.

## LIST OF ABBREVIATIONS

**ANC:** Antenatal Care

**CI:** Confidence Interval

**ELISA:** Enzyme Linked Immunosorbent Assay

**HBcAg:** Hepatitis B core Antigen

**HBeAg:** Hepatitis B envelope Antigen

**HBsAg:** Hepatitis B surface Antigen

**HBV:** Hepatitis B Virus

**HIV:** Human Immuno-deficiency Virus

**MTCT:** Mother-to-Child Transmission

**WHO:** World Health Organization

## ABSTRACT

**Background:** Infection with Hepatitis B virus (HBV) is life-threatening both to the pregnant woman and the fetus. Consequently, there is growing need to explore the status of the pregnant woman and avert the potential risk of perinatal transmission. Additionally, understanding the associated factors is critical for infection prevention and control. The aim of this study was to determine the prevalence of hepatitis B virus infection and associated factors among pregnant women attending antenatal care (ANC) at Kisugu Health Centre III.

**Methods:** A cross sectional study was carried out among pregnant women attending antenatal care at Kisugu Health Centre III between September and October, 2021. Blood samples were collected in red tops by venipuncture and analyzed for the presence of Hepatitis B surface Antigen (HBsAg) using ASTRACARE HBsAg Rapid Test strips and positive samples were confirmed using Enzyme-linked Immunoarbsorbent assay (ELISA). A researcher administered questionnaire was used to obtain sociodemographic characteristics and the associated factors. Data was analyzed using Statistical Package for the Social Sciences (SPSS) Version 20.

**Results:** Four hundred pregnant women were enrolled. Their age ranged from 15 to 40 years with a mean age of 24.93 years. Prevalence of HBsAg was 3.5% (95% CI 1.7 – 5.3). Also, 64.3% were single pregnant women and majority (38.3%) were in the age category of 22-26 years. The variables of age group (OR = 1.838, 95% CI 0.026 – 0.033, p value = 0.019), gravidity (OR = 0.869, 95% CI 0.066 – 0.076, p value = 0.045) and history of dental procedures (OR = 2.914, 95% CI 0.004 – 0.007. p value = 0.004) showed a statically significant association with the risk of HBV infection.

**Conclusion:** There is a low-intermediate prevalence of Hepatitis B virus infection among the study population at Kisugu Health Centre III, and the risk was associated with the history of dental procedure, gravidity and age group. To this, there is an urgent need to avert the likely risk of perinatal transmission.

# CHAPTER ONE: INTRODUCTION

## 1.0 Introduction

This chapter presents the background, problem statement, objectives, research questions, significance and conceptual framework of the study.

## 1.1 Background

Hepatitis B virus (HBV) is a viral infection of the liver that causes acute and chronic infection globally. The World Health Organization (WHO) estimated that about 257 million people were living with chronic HBV infection worldwide; defined as hepatitis B surface antigen (HBsAg) positive (WHO, 2018) and 900,000 people died mostly due to chronic complications such as liver cirrhosis and hepatocellular carcinoma (WHO, 2020).

The chronic HBV infection health burden varies geographically with regions such as Europe, America and Australia lowly burdened (>2%) compared to regions like Asia and Sub-Saharan Africa (SSA) that are highly burdened (>8%) (WHO, 2017). Uganda, being part of SSA has a high prevalence of HBV reported at 10% (Manga *et al*., 2017) with regional variations such as northern Uganda with the highest risk of 24.3% and 17.6% in Gulu district (Ochola *et al*., 2013). Furthermore, according to a recent national serosurvey conducted by the Uganda Population-based HIV Impact Assessment (UPHIA) throughout 2016-2017, the HBV infection prevalence among Ugandan adults was 4.3% with the northern region of the country having the highest prevalence (4.6%) and the southwest the lowest at 0.8% (UPHIA, 2016).

In such highly endemic areas, most HBV-associated deaths among adults are secondary to infections acquired at birth or in the first five years of life as people above the age of 5 years rarely develop the chronic condition if infected. Mother-to-child transmission (MTCT) of HBV contributes to nearly half of the transmission routes estimated in 2020 at 1% - 5% (Kayondo *et al*., 2020) of all chronic HBV infections (WHO, 2020). This has led to pregnant women constituting an important sub-population towards the HBV spread due to the risk of MTCT of HBV (Ringelhan *et al*., 2017). Acute infection is associated with a higher incidence of low birth weight and prematurity than in the general population (Halota *et al*., 2017; Kayondo *et al*., 2020). In pregnancy, the immune response against hepatitis B is less effective. With HBV, the incidences of

preterm birth are high. Gestational diabetes and antepartum hemorrhage are also associated with chronic HBV infections (Safir *et al*., 2010). It is estimated that approximately 90% of the HBeAg-seropositive women (with high viral load) transmit HBV infection to their babies compared to the 10-20% of the HBeAg-seronegative women (WHO, 2015).

The risk of MTCT is very high in the absence of prophylaxis, varying with the hepatitis B envelope antigen (HBeAg)/anti-HBe status of the pregnant women: 70%–90% for HBeAg positive women, 25% for HBeAg-negative/hepatitis B envelope antibody (HBeAb)-negative women and 12% for HBeAg-negative/anti-HBe-positive women (WHO, 2018).

Two recent systematic reviews and meta-analysis revealed that the overall prevalence of hepatitis B infection among pregnant women in Ethiopia ranged between 5% to7% (Kinfe *et al*., 2021). The prevalence of HBV among pregnant women in Gambia was estimated at 9.20% (Bittaye *et al*., 2019). In Northern Uganda, the prevalence of HBV among pregnant women was found to be around 11.8% (Bayo *et al*., 2014). The prevalence of HBV among the antenatal population of Mulago Hospital was estimated at 0.9% (Namirembe *et al*., 2017). Also, Kayondo *et al*., in their study state that the latter study had several limitations concerning participant recruitment and estimation of MTCT risk thus conducting another study among the antenatal population at Mulago hospital which estimated the prevalence of HBV at 2.9% (Kayondo *et al*., 2020).

Efforts to alleviate the HBV burden in Uganda exist, for example, the Uganda National Expanded Program on Immunizations (UNEPI) initiative which integrated hepatitis B vaccine at 6-weeks to prevent MTCT of HBV (MOH, 2008). However, the 6 weeks window limits the efficacy of the vaccine in the prevention of vertical transmission (Bayo *et al*., 2014) and also allows for the potential transmission of HBV through close contacts (WHO, 2017). Additionally, there is no evidence that this initiative can prevent vertical transmission if one is vaccinated after more than 7 days after birth (Namirembe *et al*., 2017).

Healthier approaches have been recommended that necessitate the screening of pregnant women for HBV and infants born to women who test HBV positive to receive hepatitis B vaccine at birth which provides over 95% protection against the development of chronic infection (Namirembe *et al*., 2017). Timely antenatal HBV detection to prevent MTCT HBV transmission should result in

reduced disease incidence and consequently, prevalence (Yelemkoure *et al*., 2018). Despite these recommended approaches, the present practice at Kisugu Health Center III antenatal clinic neither tests for HBV nor vaccinates at birth; consequently, there is not enough data to expound the HBV burden, safety against perinatal transmission and associated factors.

## 1.2 Problem statement

The current practice at Kisugu Health Centre III antenatal care clinic neither tests for HBV among pregnant women nor vaccinates at birth hence leaving room for MTCT transmission of HBV at birth and increasing the risk of horizontal transmission to care takers. Emphasis is put on HIV testing and other sexually transmitted infections such as syphilis in the antenatal care package.

In order to alleviate the HBV burden, HBV testing should be made mandatory among pregnant women to reduce the risk of MTCT and such that HBV vaccine is administered at birth to the babies whose mothers test positive. The risk of developing chronic hepatitis B for babies born to women with hepatitis B is greater than 90%, if not identified and treated at birth (WHO,2018). It is therefore imperative for pregnant women to know their hepatitis B status through testing (WHO,2018). Pregnant women who test positive for both HBsAg and HBeAg have 70 – 90% risk of transmitting the infection to their newborn infants and about 10 – 40% risk if they test positive for only HBsAg (WHO, 2018).

Despite the global concerted efforts to address the HBV perinatal effects and eventual vertical transmission risk, limited studies have focused on the assessment of this. At Kisugu Health Centre III, HBV screening is not routinely done among pregnant women, and the associated factors are not known.

## 1.3 Objectives of the study

### 1.3.1 General objective

To determine the prevalence of hepatitis B virus infection and associated factors among pregnant women attending ANC at Kisugu Health Centre III.

### 1.3.2 Specific objectives

i. To determine the prevalence of hepatitis B virus infection among pregnant women attending ANC at Kisugu Health Centre III.

ii. To assess the associated factors of HBV infection among pregnant women attending ANC at Kisugu Health Centre III.

## 1.4 Research questions

i. What is the prevalence of hepatitis B virus infection among pregnant women attending ANC at Kisugu Health Centre III?

ii. What are the factors associated with HBV infection among pregnant women attending ANC at Kisugu Health Centre III?

## 1.5 Significance of the study

The results of this study will show the importance of HBsAg testing among pregnant women as an intervention towards the reduction of hepatitis B transmission. Pregnant women that test positive will be informed about their statuses and appropriate measures of treatment and ways of preventing MTCT implemented. The results of the study will be used as a future reference to those interested in the similar study. The final report is a requirement for the partial fulfilment of the requirements for the award of a Bachelor's degree in Medical Laboratory Sciences of Clarke International University.

## 1.6 Conceptual framework

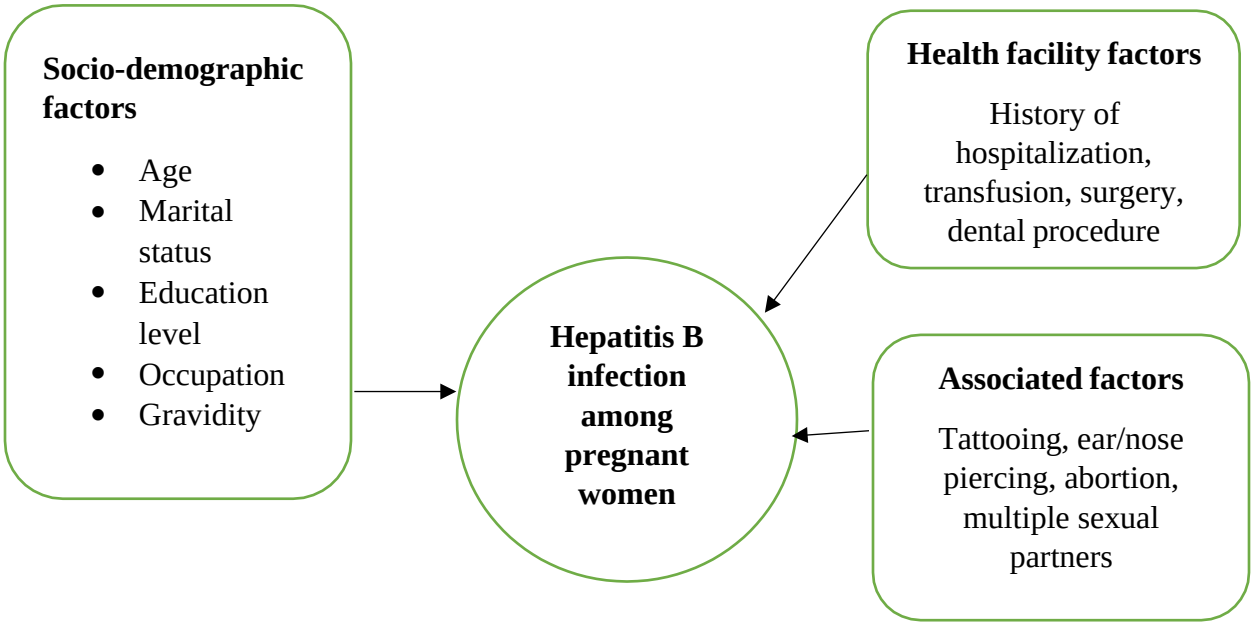


***Figure 1; A conceptual frame work showing dependent and independent variables.***

### Interpretation of conceptual framework

The conceptual frame work presents the interrelationships among the dependent and independent variables. HBV infection is related to factors for instance age, education level, occupation, income and gravidity of the pregnant women. The associated factors for acquiring HBV infection include; tattooing, ear/nose piercing, history of abortion and having multiple sexual partners. Hospital factors such as; dental procedure, surgery and blood transfusion are associated with the risk of HBV infection.

# CHAPTER TWO: LITERATURE REVIEW

## 2.0 Introduction

This chapter presents the review of literature published about the study from previous scholars. This has been structured into the following sub-headings:

## 2.1 Overview of HBV infection

HBV infection is the commonest and severest infection of the liver caused by the hepatitis B virus which is known to attack and harm the liver (WHO, 2015). HBV is a small partially double-stranded circular Deoxyribonucleic acid (DNA) virus that belongs to the family Hepadnaviridae. The infectious HBV virion has a spherical, double-shelled structure of about 42 nm in diameter, consisting of a lipid envelope containing Hepatitis B surface antigen (HBsAg) which surrounds an inner nucleocapsid composed of Hepatitis B core antigen (HBcAg) complexed the viral DNA genome. HBV is classified into eight genotypes (A to H) with each one having different geographic distribution (Kilonzo *et al*., 2018).

The main seromarkers of HBV are the Hepatitis B surface antigen and antibody (HBsAg and HBsAb) and Hepatitis B virus envelope antigen and antibody (HBeAg and HBeAb) (WHO, 2017). If any of these markers shows positivity, it signifies that the person has had or has the infection, but if only HBsAg, HBeAg and HBcAb test positive it means that hepatitis B virus is replicating actively and the person is infectious (WHO, 2017). The HBsAb is produced in response to the HBV infection by the immune system of the body. The HBeAg is a portion of the core antigen and appears in blood when the HBcAg has degraded in the serum (Maucort-Boulch *et al*., 2018). The Centers for Disease Control and Prevention (CDC) states that when HBeAg marker tests positive in serum, it is equivalent to a positive HBcAg meaning the person is infectious (CDC, 2018). HBsAg is the hallmark of HBV infection and is the first serological marker to appear in acute hepatitis B, and persistence of HBsAg for more than 6 months suggests chronic HBV infection.

Hepatitis B Virus is known to be transmitted in ways similar to Human Immunodeficiency Virus (HIV), but HBV has been reported to be more infectious (Dionne-Odom *et al*., 2016). HBV is known to be transmitted by percutaneous or mucosal exposure to the blood or body fluids of an infected person, infected woman to her newborn during childbirth, through close contact with

infected individuals within households or the community, through unscreened blood transfusion and unsafe injections in health centers when receiving treatment, through injection drug use and from sexual contact with an infected person (CDC, 2018). Hepatitis B is also spread by needlestick injury, tattooing, piercing and exposure to infected blood and body fluids, such as saliva, menstrual, vaginal, and seminal fluids. Sexual transmission of hepatitis B may occur, particularly in persons with multiple sex partners (WHO, 2020).
In addition, infection can occur during medical, surgical and dental procedures, or through the use of razorblades and similar objects that are contaminated with infected blood (WHO, 2020).

## 2.2 Prevalence of Hepatitis B Virus Infection

Globally, there were 1.34 million deaths in 2015 due to viral hepatitis, a number comparable to deaths caused by tuberculosis and higher than those caused by HIV (Lavanchy & Kane, 2016). However, the number of deaths due to viral hepatitis is increasing over time (WHO, 2020). Most viral hepatitis deaths in 2015 were due to chronic liver disease (720,000 deaths due to cirrhosis) and primary liver cancer (470,000 deaths due to hepatocellular carcinoma). Hepatitis B prevalence is highest in the WHO Western Pacific Region and the WHO African Region, where 6.2% and 6.1% of the adult population is infected respectively. In the WHO Eastern Mediterranean Region, the WHO South-East Asia Region and the WHO European Region, an estimated 3.3%, 2.0% and 1.6% of the general population is infected, respectively. And in the WHO Region of the Americas, 0.7% of the population is infected (WHO, 2020).

A study in Nigeria estimated the prevalence of HBV among pregnant women to be 6.7% (Mustapha *et al*., 2020). A study carried out in Ghana found the prevalence of HBV among pregnant women to be 3.3% (Kwadzokpui *et al*., 2020). A study carried out at Juba Teaching Hospital in South Sudan documented that the prevalence of HBV among pregnant women attending ANC was 11% (Kirbak *et al*., 2017). A study carried out in Rwanda estimated the prevalence of HBV among pregnant women to be 3.7% (Mutagoma *et al*., 2017). A study done in a tertiary hospital in Mwanza, Tanzania reported the prevalence of HBV among pregnant women to be 3% (Geffert *et al*., 2020). A study carried out in Northern Uganda reported a prevalence of 11.8% among pregnant women (Bayo *et al*., 2014). A prevalence of 0.9% was estimated among pregnant women at Mulago Hospital (Namirembe *et al*., 2017). Also, Kayondo *et al*., in their study state that the latter study had several limitations concerning participant recruitment and estimation

of MTCT risk thus conducting another study among the antenatal population at Mulago hospital which reported a prevalence 2.9% (Kayondo *et al*., 2020).

Hepatitis B is known to be highly endemic in Uganda with the rising annual cases (Ministry of Health Uganda, 2016). A meta-analysis investigating the risk of perinatal transmission of HBV in Sub-Saharan Africa showed that in HBeAg-positive women, the pooled risk of transmission was 38.3% (95% CI: 7.0–74.4%) compared to only 4.8% (95% CI: 0.1– 13.3%) in HBeAg-negative women (Shimakawa, 2016).

### 2.3 Factors associated with Hepatitis B Virus Infection

Numerous factors associated with HBV infection have been reported. The risk of developing clinical hepatitis is 22-31% if the source is both HBsAg and HBeAg positive (Maucort Boulch *et al*., 2018). Also, certain types of behavioral factors increase the risk for contracting HBV such as; use of contaminated needles during acupuncture, intravenous drug abuse, ear piercing and tattooing, sexually active individuals (having more than one sexual partner in the last 6 months), infants/children in highly endemic areas, infants born to infected women, health care workers, haemodialysis patients, blood transfusion (Essam, 2014).

The sociodemographic factors associated with HBV infection were; age, marital status, educational level, occupation and income. In a study done at Mbarara Regional Referral, 44.5% of the participants were found to have attended secondary education level (Kabajulizi *et al*., 2019). In a study done at Mulago hospital by Namirembe *et al*., the prevalence of hepatitis B was noted to be higher among younger women of the age categories of <20, 21-24 and 25 – 29 years. Also, biological and social factors including unemployment and little formal education contributed significantly to a higher prevalence of hepatitis B. The study also demonstrated that history of sharing sharp objects could predispose one to HBV infection (Namirembe *et al*., 2017). This is similar to a study done by Kayondo *et al* which discovered that most of the participants (76.7%) had a secondary education and above while 52.4% were employed. It also reported that 65.3% were of low socioeconomic status, earning less than 500,000 Uganda shillings per month (Kayondo *et al*., 2020).

A study done in Ethiopia revealed that educational status, having history of admission to the hospital, dental procedure, surgery, abortion and tattooing were statistically significantly associated with the prevalence of hepatitis B virus infection among the pregnant women (Kinfe *et al*., 2020). Another study done in Bahrain reported that 37.2% of the participants were infected through dental procedures, 35.6% through surgical operations, 24.6% through blood transfusions while sexual contact and intravenous drug use were reported to be the least possible sources of infection (Essam, 2014). A study done in Rwanda reported that the prevalence of HBV was higher among women aged 15-24 years compared to those women aged 25-49 years, women with more than two pregnancies were potentially having the infection compared to those with two or less (Mutagoma *et al*., 2017). A study done in Mwanza, Tanzania reported that 61.6% of the pregnant women were multigravidae with a higher prevalence of active HBV infection compared to those who were primigravidae (Mirambo *et al*., 2016). These results are similar to a study done in Kenya which reported that 57.8% of the pregnant women were employed while 42.2% were house wives, 98.1% of the women had classroom-based education, 87.8% women were married, 3.1% were cohabiting with a male partner, 9.1% were single and participants were almost equally distributed among multigravidae (53.3%) and primigravidae (46.6%) gravidity (Ngaira *et al*., 2016).

## 2.4 Laboratory diagnosis of Hepatitis B Virus Infection

There are many laboratory tests that determine if an individual has the HBV presently, had it in the past and cleared it off naturally (making them immune) or if the individual is immune due to immunization (Dionne-Odom *et al*., 2016). If HBsAg tests positive over a period longer than six months, this indicates that the person is a chronic carrier of HBV infection and can possibly transmit the virus to others (Song & Kim, 2016). Not all cases of Hepatitis B produce the HBeAg, but people who test positive for HBeAg have higher replication rates of the HBV and are highly infectious to others (Song & Kim, 2016).

Other tests measure the Hepatitis B viral load or the presence of the Hepatitis B genetic material (HBV DNA). ELISA tests can be used to confirm HBV antigens and antibodies. Liver Function Tests are also recommended and should be carried out if the individual is first diagnosed with HIV and/or diabetes mellitus (Puri *et al*., 2017). Tests such as elastography or pathological examination of liver biopsies are recommended to determine the liver damage extent in chronic patients (CDC. 2018).

# CHAPTER THREE: METHODOLOGY

## 3.0 Introduction

This chapter presents the study design, study population, study area, inclusion criteria, sample size determination, sampling procedures, study variables, data collection tools and techniques, data analysis, quality control measures and ethical consideration of the study.

## 3.1 Study design

This was a cross-sectional facility-based study of Hepatitis B infection and associated factors among pregnant women attending antenatal care at Kisugu Health Centre III. It is a method for collecting information from the whole sample population at a single point in time as it does not involve any follow up. The study used quantitative data collection approach. Data about the infection status of HBV was collected using laboratory methods while data about the associated factors was collected using a questionnaire.

## 3.2 Study area

The study was carried out at Kampala City Council Authority (KCCA) Kisugu Health Centre III located in Kisugu one of the suburbs of Kampala District; Makindye division. The facility is a 20-bed facility offering free antenatal care services and it receives approximately one thousand pregnant women per month.

## 3.3 Study population

The study population was pregnant women attending ANC at Kisugu Health Centre III.

## 3.4 Inclusion and exclusion criteria

### 3.4.1 Inclusion criteria

Only pregnant women attending ANC at Kisugu Health Centre III and consented to take part in the study were recruited.

### 3.4.2 Exclusion criteria

Pregnant women attending antenatal care at Kisugu Health Centre III who were in labor, those in obstetric emergency and those who declined consent were excluded from the study.

## 3.5 Sample size determination

The sample size was determined using Kish &Leslie formula (1965). 95% confidence interval and 5% marginal error was considered. Given as;

$$N = \frac{Z^2 p(q)}{e^2}$$

Where;

N = the study population size required.

p = assumed true population prevalence of HBV infection among pregnant women (8.3%) (Katamba *et al*., 2019)

q(1-p) = estimated proportion of non-infected population

e = marginal error at 95% level of confidence which is 5%.

Z = the confidence level at 95% confidence which is 1.96

Therefore;

$N = [1.96^2 \text{ X } 0.083(1-0.083)]/0.05^2 = [3.8416\text{X}0.083\text{X}0.917]/ 0.0025$

N = 117

Anticipated non response rate/drop out percentage =10%

Final Sample Size = (Non response rate * N) + N

Final Sample Size = (10% * 117) + 117

Final Sample Size = 128

Therefore, the study enrolled a minimum of 128 pregnant women.

### 3.6 Sampling procedures

The study participants were chosen using simple random sampling technique; a sampling technique in which pregnant women were chosen randomly from the population until the sample size was acquired.

### 3.7 Study variables

#### 3.7.1 Dependent variable

The dependent variable for the study was HBV infection among pregnant women attending ANC at Kisugu Health Centre III which was measured as HBsAg positivity and a positive HBsAg ELISA value.

#### 3.7.2 Independent variable

The independent variables for the study were the socio demographic factors (like; age, marital status, gravidity), associated factors (like; ear piercing, tattooing, multiple sexual partners) and health facility factors (like; history of hospitalization, transfusion, surgery, dental procedure) of the pregnant women attending ANC at Kisugu Health Center III.

### 3.8 Data collection tools

#### 3.8.1 Questionnaire

A structured questionnaire was used for data collection and the tool helped to collect data on socio-demographic factors, associated factors and health facility factors of HBV infection among pregnant women attending ANC at Kisugu Health Centre III.

#### 3.8.2 Laboratory methods

The study used laboratory methods to collect data on the HBV virus infection status of the pregnant women attending ANC at Kisugu Health Centre III as explained below;

##### 3.8.2.1 Sample collection

Two milliliters (mLs) of venous blood were drawn from the participants using a 2ml syringe and needle and transferred into a labelled red top vacutainer. A tourniquet was applied on the upper

arm of the participant 4 inches above the collection site to make the vein prominent. The venipuncture site was disinfected in a circular motion starting from the center outwards using 70% alcohol swabs. Carefully, the needle was inserted into the vein with the bevel facing up and blood collected. The tourniquet was quickly removed after collection of the blood sample and pressure immediately applied on the venipuncture site with cotton wool so as to stop the bleeding. The blood was allowed to clot meanwhile the needle used was carefully disposed into the sharp's container. The blood was allowed to clot, then centrifuged at 40,000 resolution per minute for 5 minutes and serum was picked using a sterile pasteur pipette. For the positive samples, an aliquot of the serum was transferred and stored in a cryotube at $-20^0$C until confirmed using ELISA.

#### 3.8.2.2 Sample analysis

Samples were analyzed for the presence of HBsAg using ASTRACARE HBsAg Rapid Test strips that have regions for test and control bands. Procedures for analysis were carried out using the manufacturer's manual. Specifically, 60µl of serum were added on the test region of the strip, and the sample was allowed to migrate for 15 minutes. Then, bands were interpreted as follow; two red lines (bands), that is to say, one in the test region and the other in the control region were indicative of a positive test for HBsAg, one red line (band) in the control region and a blank test region was indicative of a negative test for HBsAg and a negative result with a blank control was rendered invalid. Those that tested positive for HBsAg were confirmed using ELISA that was done at Lancet laboratories using ARCHITECT HBsAg assay that is installed on the Abbott ARCHITECT *i* system.

### 3.9 Data analysis

Data collected was cleaned to ensure consistency, completeness, correctness and any possible errors were removed before it was analyzed. The cleaned data was entered in Statistical Package for Social Sciences (SPSS) version 20.0 for analysis. The numerical results were presented as frequencies and percentages. The prevalence of HBV infection was estimated as a proportion of the total number of study participants who tested positive for HBsAg to the total number of study participants. To assess associated factors with HBV infection in pregnancy, bivariate analysis was performed and adjusted Odds Ratio (AORs) were computed at 95% Confidence Intervals (CIs). Statistical association was considered for variables with a p-value less than 0.05.

### 3.10 Quality control

The quality of laboratory results was ensured through strict adherence to the standard operating procedures (SOPs) from the manufacturer's test kit insert. Known positive and negative samples for HBsAg from Kisugu Health Centre III were included daily as controls. Environmental safety was ensured through proper disposal of samples and testing kits after analysis. All samples that tested positive using the RDT were confirmed using ELISA. The ARCHITECT HBsAg Positive Control 1, HBsAg Positive Control 2 and Negative Control were run once every 24 hours at Lancet Laboratories.

### 3.11 Ethical consideration

Ethical review and clearance were obtained from Clarke International University Research Ethics Committee (CIU-REC). Additionally, administrative permission to conduct the study was sought from the authorities at Kisugu Health Center III. The study participants (pregnant women) were informed about the study in the language that was clear and well understood (English or Luganda). Only those that were willing to take part in the study were enrolled. There was no coercion and confidentiality of the participants (including responses and findings) was upheld. Laboratory results were reported to the antenatal care clinic and those pregnant women who tested positive for HBsAg were managed appropriately by the attending obstetrician.

### 3.12 Plan for dissemination

A copy of the research report will be presented to Clarke International University for the award of a Bachelor's degree in medical laboratory sciences and for future reference by other students interested in a similar study. Another copy will be presented to Kisugu Health Centre III so that administrators will be able to evaluate completed and ongoing hospital projects in relation to Hepatitis B virus infection.

# CHAPTER FOUR: RESULTS

## 4.0 Introduction

This chapter presents the findings got from the study intended to determine the prevalence of Hepatitis B virus infection and associated factors among pregnant women attending antenatal care at Kisugu Health Centre III.

## 4.1 Socio-demographic characteristics of study participants

The study enrolled a total of four hundred pregnant women with a response rate of 100%. Their reported varied sociodemographic characteristics were as indicated below;

**Table 1. Sociodemographic characteristics of the participants (n=400)**

| Variable | Categories | Frequency (N) | Percentage (%) |
|---|---|---|---|
| Age group (Years) | ≤ 21 | 116 | 29.0 |
| | 22-26 | 153 | 38.3 |
| | 27-31 | 92 | 23.0 |
| | 32-36 | 27 | 6.8 |
| | ≥ 37 | 12 | 3.0 |
| Educational level | None | 07 | 1.8 |
| | Primary | 119 | 29.8 |
| | Secondary | 214 | 53.5 |
| | Tertiary/University | 60 | 15.0 |
| Marital status | Married | 143 | 35.8 |
| | Not in marital union | 257 | 64.3 |
| Occupation | Civil servant | 62 | 15.5 |
| | Trader | 145 | 36.3 |
| | Farmer | 10 | 2.5 |
| | Unemployed | 170 | 42.5 |
| | Student | 13 | 3.3 |
| Gravidity | Primegravidae | 130 | 32.5 |
| | Multigravidae | 270 | 67.5 |

Of the study population, 64.3% (257/400) were single pregnant women. Majority of the study participants were aged 22-26 years (38.3%) and 1.8% had not attained any education. Most of the

women were unemployed (42.5%) and a high percentage were multigravidae (67.5%).

### 4.2 Prevalence of HBV

Of the 400 study participants, 14 tested positive for HBsAg test giving a prevalence of 3.5% (95% Confidence Interval: 1.7 – 5.3), details indicated in Fig. 2. The HBV infection was recorded most among women who were not in marital union, those aged ≤ 21 years as well as those who had a history of Ear-Nose piercing and a history of dental procedures as shown in Table 2.

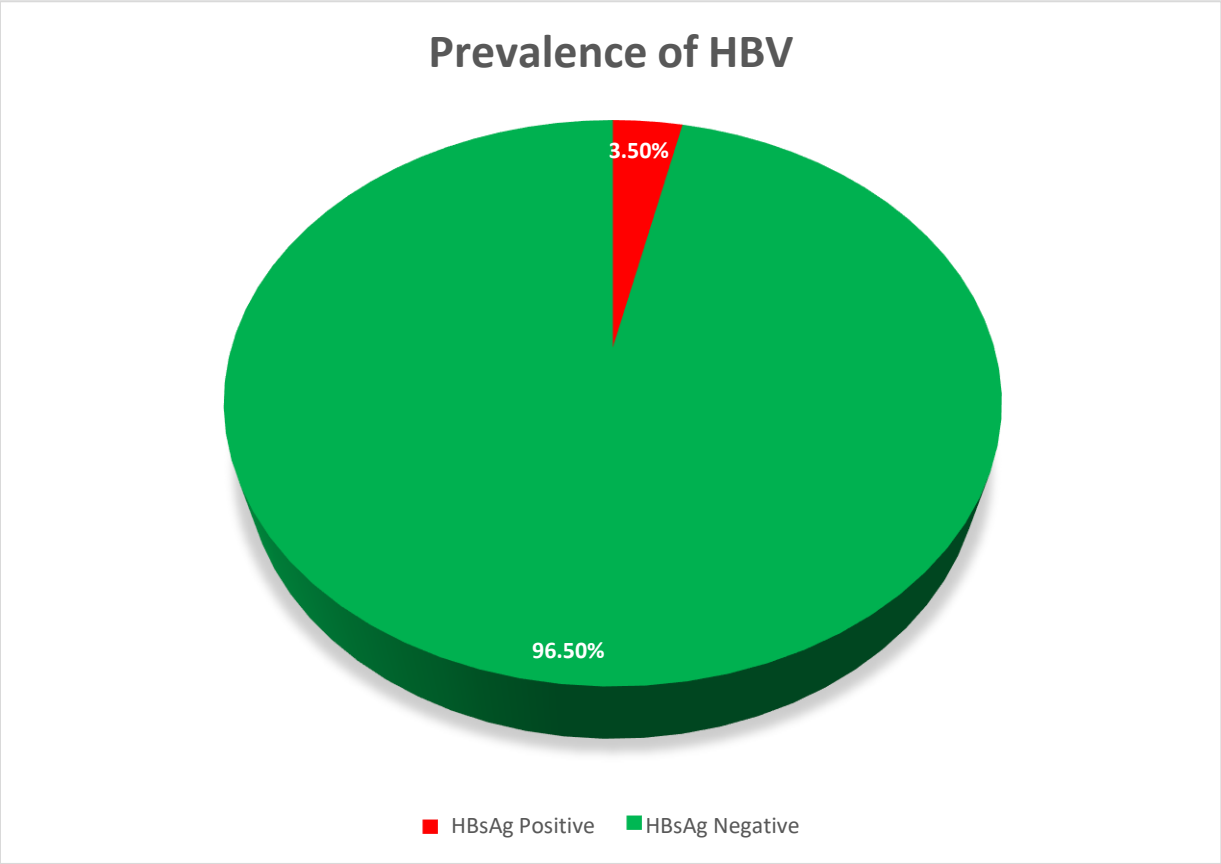


**Figure 2. A pie chart showing the prevalence of HBV among the participants**

**Table 2: Prevalence of HBV among pregnant women (n = 400)**

| Variable | Category | HBV Status | |
|---|---|---|---|
| | | **Positive** | **Negative** |
| Age group (Years) | ≤ 21 | 9 | 107 |
| | 22-26 | 4 | 149 |
| | 27-31 | 0 | 92 |
| | 32-36 | 0 | 27 |
| | ≥ 37 | 1 | 11 |
| Educational level | None | 0 | 7 |
| | Primary | 6 | 113 |
| | Secondary | 7 | 207 |
| | Tertiary/University | 1 | 59 |
| Marital status | Married | 4 | 139 |
| | Not in marital union | 10 | 247 |
| Occupation | Civil servant | 3 | 59 |
| | Trader | 4 | 141 |
| | Farmer | 1 | 9 |
| | Unemployed | 4 | 166 |
| | Student | 2 | 11 |
| Gravidity | Primegravidae | 8 | 122 |
| | Multigravidae | 6 | 264 |
| Ear-Nose piercing/Tattooing | Yes | 11 | 337 |
| | No | 3 | 49 |
| Sexual partners in the past two years | One | 8 | 313 |
| | Two | 5 | 56 |
| | Three or more | 1 | 17 |
| History of sharing sharps | Yes | 3 | 82 |
| | No | 11 | 304 |
| History of blood transfusion | Yes | 1 | 18 |
| | No | 13 | 368 |
| History of surgical procedures | Yes | 1 | 31 |
| | No | 13 | 355 |
| History of dental procedure | Yes | 11 | 154 |
| | No | 3 | 232 |

### 4.3 Associated factors of HBV among pregnant women attending antenatal care at Kisugu Health III

Majority of the pregnant women reported having Ear-Nose piercing (87.0%) while 80.3% had one sexual partner in the previous two years. Of the study population, 78.8% had no history of sharing sharps, 95.3% had no history of blood transfusion, 92% had no history of surgical procedures and 58.8% had no history of dental procedures as shown in Table 3.

**Table 3. Associated factors of HBV**

| Variable | Category | Frequency (N) | Percentage (%) |
|---|---|---|---|
| Ear-Nose piercing/Tattooing | Yes | 348 | 87.0 |
| | No | 52 | 13.0 |
| Sexual partners in the past two years | One | 321 | 80.3 |
| | Two | 61 | 15.3 |
| | Three or more | 18 | 4.5 |
| History of sharing sharps | Yes | 85 | 21.3 |
| | No | 315 | 78.8 |
| History of blood transfusion | Yes | 19 | 4.8 |
| | No | 381 | 95.3 |
| History of surgical procedures | Yes | 32 | 8.0 |
| | No | 368 | 92.0 |
| History of dental procedure | Yes | 165 | 41.3 |
| | No | 235 | 58.8 |

### 4.4 Bivariate analysis of sociodemographic and associated factors of HBV

Using bivariate analysis, the association of the different associated factors to HBV infection was determined as shown in Table 4.

**Table 4. Bivariate Analysis to determine association**

| Variable | $X^2$ | *p* value |
|---|---|---|
| Age group (Years) | 11.730 | **0.019** |
| Educational level | 1.722 | 0.632 |
| Marital status | 0.325 | 0.568 |
| Occupation | 7.915 | 0.095 |
| Gravidity | 4.016 | **0.045** |
| History of Ear-Nose piercing/Tattooing | 0.911 | 0.340 |
| Sexual partners in the past two years | 5.174 | 0.075 |
| History of sharing sharps | 0.000 | 0.987 |
| History of surgical procedures | 0.14 | 0.904 |
| History of blood transfusion | 0.184 | 0.668 |
| History of dental procedures | 8.338 | **0.004** |

*Significance at $p \leq 0.05$.*

The variables that showed a statistically significant association with HBV infections were; age group ($p = 0.019$), gravidity ($p = 0.045$) and history of dental procedures ($p = 0.004$) in Table 4. Using logistic regression analysis, pregnant women who had a history of dental procedures were found to be 0.175 times more likely to test positive for HBV infection than those with no history of dental procedures and women aged between 27 – 31 were 3 times more likely to test positive for HBV as shown in Table 5.

**Table 5. Multivariate Analysis and regression**

| Variable | Categories | *p* value | Odds ratio (OR) |
|---|---|---|---|
| Age group (Years) | 22-26<br>27-31 | 0.894<br>0.398 | 0.852 (0.079 – 9.143)<br>2.766 (0.261– 29.277) |
| Gravidity | Yes | 0.663 | 0.760 (0.221 – 2.612) |
| History of dental procedures | Yes | 0.010 | 0.175 (0.046 – 0.658) |

# CHAPTER FIVE: DISCUSSION

The prevalence of HBV infection was 3.5%. The obtained value falls within the WHO 'intermediate endemicity' category (2%–8%) (Kayondo *et al.,* 2019). The prevalence is similar to 3.5% reported by a study done in Southwest Ethiopia (Chernet *et al.,* 2017). However, it is higher than the 2.9% reported by a study done from Mulago Hospital (Kayondo *et al*., 2020), 0.9% reported by a prior study from Mulago Hospital (Namirembe *et al*., 2017), 3.3% prevalence reported in Ghana (Kwadzokpui *et al*., 2020) and 3% reported in Tanzania (Geffert *et al*., 2020). On the hand, the prevalence is lower than; the prevalence reported in Ethiopia which ranged between 5% to7% (Kinfe *et al*., 2021), 9.20% reported in Gambia (Bittaye *et al*., 2019), 6.7% prevalence reported in Nigeria (Mustapha *et al*., 2020), 11% prevalence reported in South Sudan (Kirbak *et al*., 2017) and 3.7% reported in Rwanda (Mutagoma *et al*., 2017). This variation might be due to differences in sampling methods, geographical variation, cultural and behavioral differences regarding possible associated factors of HBV infection and differences in the test methods employed to detect HBV infection. The central region of Uganda is a low prevalence area, compared with other regions such as the north and east (Kayondo *et al.,* 2019). The intensification of hepatitis B prevention programs over the last few years in Uganda may also have contributed to a reduction in prevalence of hepatitis B in the general population and among pregnant women, that is to say; the Ministry of Health embarked on phase 4 of the Hepatitis B control activities in 31 districts including Kampala Metropolitan Area on 19$^{th}$ February, 2021 (Ministry of Health, 2021).

The highest cases of HBV infection were recorded among the age categories of ≤ 21 and 22 – 26 years. This finding is similar to what was reported in Mulago hospital (Namirembe *et al*., 2017) and Rwanda (Mutagoma *et al*., 2017). This could be attributed to the likelihood of women in those age groups to be involved in high risky sexual behavior. Likewise, this is the age where most participants may commence unprotected sexual interaction (Manyahi *et al.,* 2017). The prevalence rate was higher in women who were not in marital union (3.90%) compared to those who were married. This is likely because women who were not in marital union had no stable partner and this increases the risk of having contracted hepatitis B via risk-taking sexual behaviour. Similar results were reported from a study done at Mulago Hospital (*Kayondo et al., 2019*).

The study has demonstrated that history of Ear – Nose piercing and history of dental procedures could predispose one to HBV infection. Similar results were reported in Ethiopia (Kinfe *et al*., 2020) and Bahrain (Essam, 2014). This might be attributed to poor practices of infection prevention and control. Such modes of transmission could be significantly reduced by having high standards for sterilization, disinfection, screening and training (Essam, 2014). There was a significantly high number of women who had their ears or noses pierced as compared to those who did not indulge in the practice. Age group (p value = 0.019), gravidity (p value = 0.045) and history of dental procedure (p value = 0.004) were significantly associated with HBsAg infection in this study. Similar results were reported by a study in Ghana (Kwadzokpui *et al*., 2020), a study done in Ethiopia (Gedefaw *et al.* 2019) and another study done in Bahrain (Essam, 2014). Other factors identified as statistically significant in other studies such as; number of sexual partners (Chernet *et al.,* 2017), occupation (Manyahi *et al.,* 2017), marital status (*Kayondo et al.,* 2019), education level (Gedefaw *et al.* 2019), history of sharing sharps (Namirembe *et al*., 2017), history of ear/nose piercing (Umare *et al.,* 2016), history of blood transfusion (Essam, 2014) and history of surgical procedures (Essam, 2014) were not significantly associated with HBV infection in this study. The lack of significance for other characteristics may be due to the small number of HBsAg positive cases that could conceal significant results in the logistic regression.

Pregnant women who were aged between 27 – 31 years were about 3 times more likely to test positive for hepatitis B virus infection (AOR = 2.766, CI 0.261– 29.277) as compared to other age categories. The same results were reported in a study done in Nigeria where the odds of HBV infection were higher in younger age groups with the age group 21 – 31 years having the highest odds of infection (AOR = 4.6, CI 2.2 – 9.5) (Talla *et al.,* 2021). The reason for this may be because this is the age group in which most women are most likely to get married and become pregnant. It is also the age when they are likely to present for the first time to the ante-natal care clinic. Hence, those positive to HBsAg are likely to be picked up when screened as was noted from this study.

# CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

## 6.0 Introduction

This chapter presents the conclusion, limitations and recommendations of the study.

## 6.1 Conclusion

There is a low-intermediate prevalence of Hepatitis B virus infection among pregnant women attending antenatal care at Kisugu Health Centre III. The risk was associated with the history of dental procedure, gravidity and age group. Thus, there is an urgent need to avert the likely risk of perinatal transmission.

## 6.2 Recommendations

As HBV infection befalls endemic in Uganda, routine HBsAg screening of all pregnant women during antenatal visits is recommended because of the asymptomatic nature of HBV. All pregnant women who test positive for HBV must be treated to reduce the viral loads and their newborns vaccinated at birth with the single doze hepatitis B vaccine to break the cycle of MTCT. I also recommend another study that includes tests for viral load and HBeAg. This will yield more important information regarding risk of vertical transmission.

## 6.3. Limitations

Regrettably, this study did not screen HBsAg positive women for HBeAg that would inform determination of risks (probability) of vertical transmission. Another potential limitation of the study is that it was carried out on pregnant women attending ANC in a lower health center and thus results may not accurately reflect the situation in higher health settings such as; national referral and private hospitals. The limited number of hepatitis B positive participants in the study also leads to increased uncertainty regarding the magnitude of risk conferred by each factor studied. A less sensitive serological test for HBsAg was used, maybe if it was a Nucleic Acid Amplification Test, the detection would be higher.

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## APPENDICES

## APPENDIX I: CONSENT FORM

I am asking you to take part in a research study called:

Prevalence of hepatitis B virus infection and associated factors among pregnant women attending antenatal care at Kisugu Health Center III.

The person who is in charge of this research study is Nakkungu Violet. The research will be conducted in Kampala District of Uganda.

**Purpose of the study**

The purpose of this study is to:

**i.** To determine the prevalence of hepatitis B virus infection among pregnant women attending ANC at Kisugu Health Centre III.

**ii.** To assess the associated factors of HBV infection among pregnant women attending ANC at Kisugu Health Centre III.

**Study Procedures**

You are being asked to participate in this study, as you are a pregnant woman who can help me to better understand the prevalence of hepatitis B virus infection and associated factors among pregnant women attending antenatal care at Kisugu Health center III.

If you take part in this study, you will be asked to:

- Take some time and fill out a one-time, structured questionnaire that will enable me fulfill the purpose of the study.

- To give 2mls of your blood which will be collected from the vein on your arm, then it will be put in a vacutainer and a hepatitis B test will be carried out.

**Benefits/ compensation**

You will be able to know your hepatitis B status through your participation in the study, the

information you will provide will be useful in knowing more about HBV, its causes, what predisposes you to it and how to control it that is to say, you will be informed about the causes, signs, symptoms, management and control of the disease.

**Risks or Discomfort**

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

**Compensation**

No research participants will be compensated. Participation into the study will be completely voluntary and you will be free to either participate or withdraw at any time without any consequences.

**Privacy and Confidentiality**

I will keep your study records private and confidential. Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are: The research team, including the Principal Investigator and those involved with the study**.** I may publish what I have learnt from this study. If l do, l will not include your name. l will not publish anything that would let people know who you are.

**Voluntary Participation / Withdrawal**

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

**You can get the answers to your questions, concerns, or complaints**

If you have any questions, concerns or complaints about this study, or experience an adverse event or unanticipated problem, contact the researcher on 0783635958. If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you

want to discuss with someone outside the research, call the CIUREC Chairperson Dr. Samuel Kabwigu on (0312307400) & the executive secretary of UNCST on (0414-705500) respectively.

**Assessment of understanding**

Please check which box best describes your assessment of understanding of the above informed consent document:

□ I have read the above informed consent document and understand the information provided to me regarding participation in the study and benefits and risks. I give consent to take part in the study and will sign the following page.

□ I have read the above informed consent document, but still have questions about the study; therefore, I do not give yet give my full consent to take part in the study.

_____

Signature/Thumbprint of Person Taking Part in Study Date

Nakkungu Violet

## Consent form in Luganda

Nkusaba okwetaba mu kunonyereza okuyitibwa;

Obunji bwo bulwadde bwa Hepatitis B ne byongeza enkwatibwa yobulwadde buno mu bakyala ab'embuto abafuna obujaajabi bwa Antenatal ku dwaliro lya Kisugu Health Centre III.

Nze agenda okukola okunonyereza kunno nze Nakkungu Violet. Okunonyenyereza kugenda kukorebwa mu Kampala district Uganga.

**Omugaso gw'okunonyereza**

Omugaso gw.okunonyereza kunno guli;

- Okunonyereza kuno kugenderedwamu okuzuula obuunji bw' obulwadde bwa Hepatitis B mu bakyala abalina embuuto abafuna obujanjabi bwa antenatal ku Kisugu Health Centre III.

- Okunonyereza kugenda kuzula ebimu ku bibuleeta Hepatitis B n'ebimu kubiteka abakyala mubulabe bwo'kofuna Hepatitis B mu bakyala abalina embuuto abafuna obujanjabi bwa antenatal ku Kisugu Health Centre III.

**Etambula y' okunonyereza kuno**

Nkusabwe okwetaba mu kunonyereza kunno kubanga oli omu ku bakyala abali olubuto era nga osoboola okunyamba okutegera obuunji bw' obulwadde bwa Hepatitis B mu bakyala abalina embuuto abafuna obujanjabi bwa antenatal ku Kisugu Health Centre III.

Wonetaba mu kunonyereza kuno, njakusaba;

- Ojjuze mu ebibuzo ku lupapula ebinanyamba okokola omugaso gw'okunonyereza kunno.

- Omusaayi mutono kujja kugibwaako ela gukebelebwe mu laboratory okufuna obutundutundu obulaga obulwadde obuletebwa akawuka Hepatitis B.

**Obulungi obuli mu Kunonyeleza kuno**

Ojja kufuna omukisa okumanya ennyo ku bulwadde buno, ekyibuleeta, obubonera obulagaobulwadde buno ate saako n' engeri y'okubwewala nga ogaseeko n'obujanjabi bwabwo. Ate ebinaava mu kukeberebwa bijja kuweebwa.

**Obulabe obubiyinza okutukawo**

Okunnonyereza kunno sikwabulabe nyo ela tewali kyabulabe kijja kuakako.

**Okusasula kw'abaneetaba mu kunonyereza**

Tewali kintu kyona kijja kuweebwa banetaba mu kunonyereza kuno. Okwetaba mu kunonyereza kuno kujja kubeela kwa kyeyagalire ela omukyaala yeena ajjakuba wa ddembe okukwetabamu oba okukuvaamu wona wayagalira ela tewajja kubaawo buzibu bwona.

**Ebyekyama**

Nja kuteleka byoona ebikukwatako nga byakyama. Abantu abaamu bajja kulaba ebikukwatako naye nga bajja bikuma nga byakyama.

**Okwetaba mu kunonyereza/ okuvaamu kwa kyeyagalire**

Okwetaba mu kunonyereza kuno kujja kubeela kwa kyeyagalire ela omukyaala yeena ajjakuba wa ddembe okukwetabamu oba okukuvaamu wona wayagalira ela tewajja kubaawo buzibu bwona.

**Osoobola okuffuna obuyambi bwoba oyina ebibuuzo**

Bwoba oyina ebibuuzo byonna osoboola onkukubira ku 0783635958 oba okubire chairman wa CIUREC Dr. Samuel Kabwigu ku (0312307400) ne secretary wa UNCST ku (0414-705500).

**Okukebeera oba okitegedde**

Njakusaba osse tick mu ka box akalaga oba ottegedde foomu enno:

□ Nsomye ela ntegedde omugasso na buli kimu ekili mu lupapula luno, ela nzikiriza okwetaba mu kunonyereza kuno.

□ Nsomye naye sitegedde omugasso na buli kimu ekili mu lupapula luno, ela siikiriza kwetaba mu kunonyereza kuno.

_____ _____

Signature/Ekinkumu

Nakkungu Violet

## APPENDIX II: QUESTIONNAIRE

I, NAKKUNGU VIOLET, a student of Clarke International University, in partial fulfillment of the requirements of the award of a Bachelor's degree in Medical Laboratory Sciences, am conducting research on the "PREVALENCE OF HEPATITIS B VIRUS INFECTION AND ASSOCIATED FACTORS AMONG PREGNANT WOMEN ATTENDING ANTENATAL CARE AT KISUGU HEALTH CENTER III."

I kindly request for your answers and this research information is to be kept confidential and used for academic purposes. Please tick the best alternative

**SECTION A: Sociodemographic factors**

**1.** What is your age? …….

≤ 21 ☐ 22–26 ☐ 27–31 ☐ 32–36 ☐ ≥37 ☐

**2.** What is your marital status?

Married ☐ Not in marital union ☐

**3.** What is your highest education level?

None ☐ Primary ☐ Secondary ☐ Tertiary/University ☐

**4.** What is your occupation?

Civil servant ☐ Trader ☐ Farmer ☐ Unemployed ☐ Student ☐

**6.** Is this your first pregnancy?

Yes ☐ No ☐

**Section B: Associated factors**

**1.** History of tattooing, ear-piercing or nose pricking?

Yes ☐ No ☐

**2.** How many sexual partners have you had in the past two years?

One ☐ Two ☐ Three or more ☐

**3.** History of sharing sharps?

Yes ☐ No ☐

**Section C: Health facility factors**

**1.** History of blood transfusion?

Yes ☐ No ☐

**2.** History of any surgery procedures?

Yes ☐ No ☐

**3.** History of a dental procedure?

Yes ☐ No ☐

**Questionnaire in Luganda**

Nze, NAKKUNGU VIOLET, omuyinzi okuva ku Clarke International University. Nga obumu ku bukwakulizo bw'okufuna essomo lya Bachelor's degree in Medical Laboratory Sciences, ndi mu kukola okunonyereza ku bunjji bwo bulwadde bwa Hepatitis B mu bakyala ab'embuto abafuna obujaajabi bwa Antenatal ku dwaliro lya Kisugu Health Centre III.

Mu buwombeefu nsaba oddemu ebibuuza bino. Byona ebikukwatako no okuddamu kwo bijja kukumibwa nga byakyama ela nga bijja kukoma mu kunonyereza kuno. Nkusaba oteeke akasaze mu kyona kyoba olonze.

**SECTION A: Ebikukwatako mu bulamu obwa bulijjo**

**1.** Oyina emyaaka emekka? ……

≤ 21 ☐ 22–26 ☐ 27–31 ☐ 32–36 ☐ ≥37 ☐

**2.** Oli mukyaala mufumbo?

Mufumbo ☐ Simufumbo ☐

**3.** Watuuka wa mukusoma kwo?

Sassoma ☐ Essomo erisoka ☐ Essoma elwokubiri ☐ Essomo lyawagulu ☐

**4.** Okola mulimu ki?

Mukozi wa govumenti ☐ Musubuzi ☐ Mulimi ☐ Silina mulimu ☐ Nkyasoma ☐

**6.** Luno lwe lubutto lwo olusoose?

Yee ☐ Nedda ☐

**Section B: Ebisoboola okuleeta obulwadde**

**1.** Wali wekubizaako Tattoo, okuwumula amattu oba enyindo?

Yee ☐ Nedda ☐

**2.** Obadde n'abagalwa bameka mu myaaka ebbiri egyiyise?

Omu ☐ Babiri ☐ Basatu nokusobamu ☐

**3.** Wali ogabanyeko ebintu ebifumita?

Yee ☐ Nedda ☐

**Section C: Eby'ekuusa ku by'obulamu**

**1.** Wali ofuunyeko omusaayi nga oli mu dwaliro?

Yee ☐ Nedda ☐

**2.** Wali olongosebwa ko?

Yee ☐ Nedda ☐

**3.** Wali ofunyeeko ku bujanjabi bw'amannyo?

Yee ☐ Nedda ☐

## APPENDIX III: INTRODUCTORY LETTER

CLARKE INTERNATIONAL UNIVERSITY
LEAD · INNOVATE · TRANSFORM
ALLIED Institute of Allied Health Sciences

(+256) 0312 307400
deansallied@ciu.ac.ug
www.ciu.ac.ug

Kampala, Monday 16th August 2021

To;
LAB MANAGER
KISUGU HEALTH CENTRE III

Dear Sir/Madam,

**RE: ASSISTANCE FOR RESEARCH**

Greetings from Clarke International University formerly known as International Health Sciences University.

This is to introduce to you **Nakkungu Violet** Reg. No. **2017-BMLS-FT-AUG-002** who is a student of our University. As part of the requirements for the award of a Bachelors Degree of Medical Laboratory Sciences of our University, the student is required to carryout research in partial fulfillment of her award.

Her topic of research is: **PREVALENCE OF HEPATITIS B VIRUS INFECTION AND ASSOCIATED FACTORS AMONG PREGNANT WOMEN ATTENDING ANTENATAL CARE AT KISUGU HEALTH CENTRE III.**

This therefore is to kindly request you to render the student assistance as may be necessary for her research.

I, and indeed the entire University are grateful in advance for all assistance that will be accorded to the student.

Yours sincerely,

for

Dr. Okiria John Charles (PhD)
**Professor / Dean IAHS**
**(0772409126 /0752409126)**

#Make a Difference

Kawagga Close, off Kalungi Road, Muyenga
Block 244 | Plot 8244 Bukasa Kyadondo
P.O.Box 7782 Kampala-Uganda

## APPENDIX IV: RESEARCH ETHICS COMMITTEE APPROVAL LETTER

CLARKE INTERNATIONAL UNIVERSITY
LEAD · INNOVATE · TRANSFORM
RESEARCH ETHICS COMMITTEE

(+256) 0312 307400
rec@ciu.ac.ug
www.rec.ciu.ac.ug

25/09/2021

To: Nakkungu Violet

Clarke International University
0783635958

**Type:** Initial Review

**Re: CLARKE-2021-160: Prevalence of Hepatitis B virus infection and associated factors among pregnant women attending antenatal care at Kisugu Health Center III., 1, 2021-08-18**

I am pleased to inform you that at the **22nd** convened meeting on **22/09/2021**, the Clarke International University REC, committee meeting, etc voted to approve the above referenced application.
Approval of the research is for the period of **25/09/2021** to **25/09/2022.**

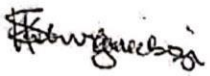
As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the REC for re-review and approval **prior** to the activation of the changes.
3. Reports of unanticipated problems involving risks to participants or any new information which could change the risk benefit: ratio must be submitted to the REC.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by participants and/or witnesses should be retained on file. The REC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Continuing review application must be submitted to the REC **eight weeks** prior to the expiration date of **25/09/2022** in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study.
6. The REC application number assigned to the research should be cited in any correspondence with the REC of record.
7. You are required to register the research protocol with the Uganda National Council for Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

The following is the list of all documents approved in this application by Clarke International University REC:

| No. | Document Title | Language | Version Number | Version Date |
|---|---|---|---|---|
| 1 | Protocol | English | 1 | 2021-08-18 |
| 2 | Risk management plan | English | 1 | 2021-08-21 |
| 3 | Informed Consent forms | Luganda | 1 | 2021-08-21 |
| 4 | Informed Consent forms | English | 1 | 2021-08-21 |
| 5 | Data collection tools | Luganda | 1 | 2021-08-18 |
| 6 | Data collection tools | English | 1 | 2021-08-18 |

Yours Sincerely



Samuel Kabwigu
For: Clarke International University REC

## APPENDIX V: CORRESPONDENCE LETTER

KCCA
KAMPALA CAPITAL CITY AUTHORITY
*For a better City*

KISUGU HEALTH CENTRE
KCCA-IDI PROJECT
BOX 7010 KAMPALA
30th-SEP-2021

**Ms.NAKKUNGU VIOLET**

**Reg.No:2017-BMLS-FT-AUG-002**

**Re: Approval toconduct researchat Kisugu H/C III-KCCA on the Research Topic "Prevalence of Hepatitis B virus infection and associated factors among pregnantwomen attending Antenatal care at Kisugu Health Centre III".**

This is to acknowledge that the above student's research topic has been approved to be conducted at our facility with hope that the findings of this study will positively impact on the quality of health care offered to our expectant mothers.

The approval covers the protocol and the accompanying documents listed below

- Informed consent form
- Questionnaire
- Lab Data collection

This approval is subjected to the following terms and conditions.

1.The study will be monitored by the Laboratory supervisor /Manager at all times to ensure that the ethical concerns are followed.

2.No changes will be made and implemented in the protocol and study documents until they are revised and approved by the management and research supervisors.

3. You will abide by the regulations governing research in the country as set by the Uganda national council for science and Technology.

4.You will include Kisugu H/C III-KCCA in your acknowledgements in all your write ups /publications.

Wishing you the best in your Research.

Yours

Emmanuel Amalai

Lab-supervisor KCCA-Makindye

Lab Manager Kisugu H/C III KCCA

KCCA-KISUGU H/C III LAB
30 SEP 2021
P. O. BOX 7010, KAMPALA
TEL: 0772 484937

P. O. Box 7010 Kampala- Uganda
Plot 1-3 Apollo Kaggwa Road
Tel: 0414 231 446 / 0204 660 000
Web: www.kcca.go.ug, Email: info@kcca.go.ug
f: facebook.com/kccaug, t: @KCCAUG

## APPENDIX VI; SOP FOR HBsAg TESTING

1. Allow the specimen and test kits to get to room temperature before testing.

2. Open the pouch and remove the strips. Place the strip on a flat, clean surface. Use test immediately after opening.

3. Using a dropper, transfer 60 µl of serum to the sample well on the strip. Avoid trapping air bubbles.

4. Read results at 15 minutes.

5. Results read after 20 minutes are considered invalid. Dispose of the strip safely after testing.

**Interpretation of results**

Two red lines (bands), that is to say, one in the test region and the other in the control region will be indicative of a positive test for HBsAg, one red line (band) in the control region and a blank test region will be indicative of a negative test for HBsAg and a negative result with a blank control will be rendered invalid.

## COVID 19 RISK MANAGEMENT PLAN

**Introduction**

The coronavirus disease 2019 (COVID-19) is a communicable respiratory disease caused by a new strain of coronavirus that causes illness in humans. COVID-19 can be spread by person to person through respiratory droplets expelled from the nose and mouth when an infected person coughs or sneezes. It can also be transmitted when people have contact with hands or surfaces that contain the virus and touch their face, mouth or nose with the contaminated hands. Due to the rapidly increasing number of cases in the country, there is a great danger posed among

communities to have cross infection from either symptomatic or asymptomatic individuals if mitigation measures are not observed properly. Protecting the safety and well-being of volunteers who participate in the study is of critical importance. Of equal importance is protecting the researcher who conducts this research. Therefore, careful planning is critical to mitigate risk.

This Plan is designed to ensure the health and safety of the researcher, support staff and participants against COVID-19. To ensure the protection of study participants and the researcher, the following protocol will be observed;

1. All people involved in the study will put on face masks covering the mouth and the nose properly and consistently. Pregnant women without masks will not be recruited in the study.
2. Hand washing will occur frequently during the study. If hand-washing is not possible, alcohol-based hand sanitizer will be used.
3. Physical distancing of at least 2 meters will be encouraged among the participants and the researcher during data collection.
4. All research participants will be screened using the questions; Have you tested positive for COVID 19 with in the past 10 days? Do you have any signs and symptoms of COVID 19? Have you been in contact with someone who has COVID 19 in the past 14 days?

   Pregnant women will not be involved in the study if they: Have current symptoms of COVID-19, tested positive within the past 10 days or have been exposed to someone with COVID-19 in the past 14 days.
5. There will be no hand shaking or sharing of pens during data collection with the study participants

## APPENDIX VII: SOP FOR ELISA

1. The ARCHITECT HBsAg Reagent Kit is loaded once on the ARCHITECT *i* system.
2. Spin the samples to obtain serum, load the samples on the ARCHITECT *i* system and press RUN.
3. The ARCHITECT *i* System performs the following functions:

- Moves the sample carrier to the aspiration point and loads a reaction vessel into the process path.
- Aspirates and transfers sample into the reaction vessel.
- Advances the RV one position and transfers microparticles into the reaction vessel.
- Mixes, incubates, and washes the reaction mixture.
- Adds conjugate to the reaction vessel.
- Mixes, incubates and washes the reaction mixture.
- Adds Pre-Trigger and Trigger Solutions.
- Measures chemiluminescent emission to determine the presence of HBsAg in the sample.
- Aspirates contents of reaction vessel to liquid waste, unloads reaction vessel to solid waste and calculates the result.

**Interpretation of Results**

- Specimens with concentration values < 0.05 IU/mL are considered nonreactive by the criteria of ARCHITECT HBsAg.
- Specimens with concentration values ≥ 0.05 IU/mL are considered reactive by the criteria of ARCHITECT HBsAg.
- All initially reactive specimens should be retested in duplicate. If both retest values are nonreactive, the specimen must be considered nonreactive for HBsAg. If either of the retest values is reactive, the specimen must be considered repeatedly reactive for HBsAg by the criteria of the ARCHITECT HBsAg.

- Repeatedly reactive samples should be tested by a neutralizing confirmatory test. Samples which are confirmed by neutralization with human anti-HBs must be considered positive for HBsAg.