KNOWLEDGE AND RISK FACTORS OF HEPATITIS B DISEASE AMONG WOMEN ATTENDING ANTENATAL CARE AT ARUA REGIONAL REFERRAL HOSPITAL, ARUA, UGANDA

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DECLARATION AND APPROVAL

Declaration by student

This thesis is my original work and has not been presented for a degree in any other University or for any other award.

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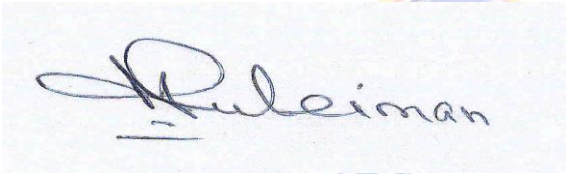
Approval by the supervisor

I confirm that the work reported in this project was carried out by the candidate under our supervision.

Signature: ……  ……. **Date:** …31st January 2023

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DEDICATION

I dedicate this work to my parents who have tirelessly provided for my needs since childhood. I appreciate you for all the sacrifices made.

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Special thanks to the Lord for this journey, for it is Your Will that I am at this stage. Without forgetting my entire family of whom my parents Mr. and Mrs. Kagoro Bonifance and Susan Komugisha, Patritia Birungi and Lawrence Byamukama for they have been there for me throughout the journey this far. Emmauel Manenga for the great help as a research assistant and the entire Arua team for the help and warm reception. Not forgetting my friends Manzi Mbabazize Gerald, Christopher Sekandi, Andrew Nyanja, Henry Oundo and Racheal Kemigisha for the support rendered. Not forgetting my workmates Kasule Timothy, Mrs. Dr. Ssebbagala Victoria Nannono, Moses Lubale and Lule Falisy for the constant encouragement and reviews of my work. I am blessed to work with a team of good people like you. I appreciate my supervisors Prof. Mbaruk A. Suleiman and Dr. Owino Alfred Odongo who has always endlessly reviewed my work while giving me all the necessary comments to improve my work.

ABSTRACT

Hepatitis B is a highly infectious disease with a prevalence of 4.3% among people aged 15-64 years, with a prevalence of 5.6% in men compared to 3.1% in women in Uganda. Mother-to-child transmission accounts for nearly 50% of new cases per year, and infants who acquire hepatitis B disease before 5 years have a 90% chance of progressing to chronic hepatitis B infection. The study assessed the knowledge and risk factors of hepatitis B disease among women attending antenatal care (ANC) at Arua Regional Referral Hospital (ARRH), Uganda. A cross-sectional study was carried out at Antenatal care unit of Arua Regional Referral Hospital. Convenience sampling was used, and a sample size of 384 was calculated. Each participant was screened for HBsAg using commercial rapid test kits and evaluated using a structured questionnaire and. A hepatitis B basic knowledge summary score was used to assess the of knowledge of the participants on hepatitis B. Data analysis was carried out using MICROSOFT EXCEL-2013 and STATA version 14 packages. Poor knowledge levels of hepatitis B disease stood at 17.9%, while 82.1% of the pregnant women had adequate knowledge. A prevalence of 2.05% was obtained from the participants in the study. None of the assessed risk factors was significantly associated with HBsAg positivity. The study participants were knowledgeable to a great extent about hepatitis B disease, with 82.1% exhibiting good knowledge of hepatitis B disease. There are gaps in knowledge, especially among the low educated groups, which need to be addressed to improve knowledge levels of hepatitis B disease among these categories in the community. The results show a relatively healthy population given the low prevalence of 2.05% seen in the participants of the study. The absence of a risk factor associated with hepatitis B disease in this study does not imply that there are no risk factors in the community around Arua Regional Referral Hospital. Further studies are recommended to assess more risk factors for hepatitis B disease in the community.

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LIST OF ABBREVIATIONS AND ACRONYMS

ANC:	Antenatal Care
ARRH:	Arua Regional Referral Hospital
CVI:	Content Validity Index
DNA:	Deoxyribonucleic acid
EDTA:	Ethylenediaminetetraacetic acid
ELISA:	Enzyme-linked immunosorbent assay
ERC:	Ethics Review Committee
HBsAg:	Hepatitis B Surface Antigen
HBV:	Hepatitis B Virus
HCIV:	Health center four
HCC:	Hepatocellular Carcinoma
HCV:	Hepatitis C Virus
HIV:	Human Immunodeficiency Virus
IERC:	Institutional Ethics Review Committee
IRB:	Institutional Review Board
MOH:	Ministry of Health
MTCT:	Mother-to-Child-Transmission
SCT:	Social Cognitive Theory
STD:	Sexually Transmitted Disease
STI:	Sexually Transmitted Infection
TASO:	The AIDS Support Organization

UNCST:	Uganda National Council of Science and Technology
UPE:	Universal Primary Education
VHT:	Village Health Teams
WHO:	World Health Organization.

CHAPTER ONE: INTRODUCTION

1.0 Introduction

This chapter embraces the introduction of the study under investigation; it contains background information, study purpose, problem statement, and study objectives, more so, in this chapter the reader will find; the research questions, justification, scope and finally the operational definitions adopted in the research.

1.1 Background of the study

Hepatitis refers to a condition where the liver is inflamed. It may be caused by a variety of agents, including alcoholism, the Hepatitis virus, autoimmune disorders, toxic chemicals, and other infectious and non-infectious diseases. Whereas hepatitis B, hepatitis C, and hepatitis D are mostly spread by contact with infected bodily fluids, Hepatitis A and Hepatitis E diseases are spread through intake of intoxicated water and food ingredients. Hepatitis B virus (HBV) and hepatitis C virus (HCV) are the most common causes of liver cirrhosis and liver cancer in people with hepatitis disease (World Health Organisation, 2017) , (Schweitzer, Horn, Mikolajczyk, Krause, & Ott, 2015) , (Hwang & Cheung, 2011) .

Infection with the HBV affects people worldwide and has greatly contributed to the development of cancerous cells among the people across the globe (World Health Organisation, 2017) . According to a World Health Organization (WHO) survey conducted in 2015, over 200 million people worldwide are infected and living with HBV type infections, resulting in over 887,000 deaths (World Health Organisation, 2017) . Worldwide, the Western Pacific is the most afflicted region, followed by the African continent, with around 6.2% and 6.1% of the total infected individuals, respectively, with the adult age group taking center stage. (World Health Organisation, 2017) . In Africa, there are approximately 50 million people living with hepatitis B disease (C F Kiire, 1996) . In the East African region, pooling the prevalence of HBV by country, Kenya had the highest prevalence rate of 8.54%, followed by Uganda (8.454%) and Tanzania (5.16%), and finally Rwanda with the lowest prevalence (4.1%) (Kafeero, et al., 2021) .

According to the most current Uganda Population-Based Human Immunodeficiency Virus (HIV) Impact Assessment, the prevalence of hepatitis among persons aged 15 to 64 years is 4.3%, with a slightly higher prevalence of 5.6% in males compared to 3.1% in women. Regional diversity in disease prevalence, with the North providing the greatest prevalence (4.6% in the mid north, 4.4%

in the North East, and 3.8% in West Nile areas) , should be used to direct national response (ICAPU, Uganda, 2016), (Ministry of Health, 2018) . The disease has a higher mortality rate among women aged 15-19 years compared the same age group of men (Teo E-K & Lok, 2009) .

HBV causes acute hepatitis with visible signs such as jaundice of the eyes and skin, dark yellow urine output, severe vomiting-like sensations, and extreme stomach pains. This causes acute liver failure usually experienced in the chronic stage, which leads to death (Thio, Guo, Xie, Nelson, & Ehrhardt, 2015) .

The primary cause of chronic liver infections that have led to the cirrhosis- related cancer hepatocellular carcinoma is hepatitis B virus (Fattovich, Bortolotti, & Donato, 2008) . Age during virus acquisition has a significant impact the progression into the chronic stage of disease. When infected before their first year of life, infants have a high possibility of getting chronic hepatitis B (90%), but children under the age of 6 and children beyond the age of 6 have 30%-50% and 5%-10% chances of doing so, respectively. The likelihood of getting chronic hepatitis in adults is the lowest, at less than 5% (Vodkin & Patton, 2014) . With this, mother to child transmission accounts to more than 50% of new chronic hepatitis B disease cases seen in the world today from children who progress to the chronic stage earlier in life.

The likelihood of an uninfected individual contracting hepatitis B rises when they come into touch with contaminated bodily fluids such as blood, saliva, and semen that have high viral concentrations (Parry, Godfrey, Mabey, & Gill, 2009) . Some of the risk factors for hepatitis B illness include unsafe abortion procedures, conventional tattooing, and body piercing, having a lot of sexual partners, using condoms inconsistently, having Sexually Transmitted Disease (STD) infections, and blood transfusions using donors unscreened blood (Parry, Godfrey, Mabey, & Gill, 2009) .

Most patients with hepatitis B don't know they have it and frequently show up at hospitals and clinics with severe liver damage (World Health Organization, WHO, 1990) . This is because the body will try to fight the virus during the acute stage of disease hence mild symptoms like headaches, vomiting and nausea might be noticed. Other symptoms like jaundice might show up but only for a limited time as the body will in most cases fight the virus in 95% of adults. These symptoms are much like other diseases which are common hence it is very easy to miss diagnosis. By the time the patients seek medical attention, they are most likely in the chronic phase with

extensive liver damage caused by liver cirrhosis or liver cancer. At the chronic stage, treatment is very expensive, and the chances of survival are limited hence death in most of the patients who seek treatment in this stage.

In areas with low resources, testing among vulnerable populations, especially mothers, is still subpar, which increases the risk of infecting the baby during or right after birth. Availability of hepatitis B immunoglobulin which is key in preventing infection of a newly born child born on of a hepatitis B positive mother is low and very expensive which puts the newly born babies at risk of acquiring disease. Also, availability of the hepatitis B vaccine at birth for newly born children is not done and in Uganda, this has recently been added to the vaccination schedule by the ministry of health to further protect newly born babies from acquiring hepatitis B disease in the first years of life. This information gap might accelerate the transmission and development of illness of hepatitis B disease among the population (World Health Organization, WHO, 1990) .

1.2 Problem statement

The prevalence of hepatitis B disease globally remains high with over 200million people infected with the disease. Over 50 million people are infected in Africa with the pooling prevalence of the East African region at an average of 6.1% with Rwanda having the lowest prevalence (4.1%), followed by Tanzania (5.16%), Uganda (8.45%) and then Kenya (8.54%) (Kafeero, et al., 2021). The Northern region in Uganda have the highest prevalence of about 4.6% followed by West Nile region at 3.8% (Ministry of Health, 2018) where Arua district is the regional hub.

The chances of progression to chronic liver disease are increased if HBV is acquired early in life. Infants who acquire disease during pregnancy or after birth (Mother-To-Child-Transmission) from mothers suffering from or exposed to hepatitis B disease have a 90% chance of progressing to chronic hepatitis B infection compared to 30-50% and <5% chronicity when acquired by horizontal transmission before 6years of age and when infected in adulthood respectively (World Health Organisation, 2017) , (Gambarin-Gelwan, 2007) , (Lai, Ratziu, Yuen, & Poynard, 2003) , (McMahon, 2010) .

Nearly 16,000 children under the age of five still pass away every day, the majority from conditions that may be prevented, such as hepatitis B. (UN, 2021) . This transmission is preventable if women are aware of risk factors associated with and the measures required for prevention hepatitis B disease. However, recent studies reported that women in developing countries including Cameroon

and China have limited knowledge on hepatitis B disease (Andreas, Julius, Peter, & Peter, 2014) , (Zhenyan, Zhang, Erhardt, & Chloe, 2017) .

Although worldwide HBV vaccination numbers in children has greatly improved, most new hepatitis B virus infections in Uganda are still transmitted from mother to child, even though vaccination was introduced in 2002 as part of the country's standard vaccination schedule for children to reduce on the risk of Mother-to-child-Transmission (MTCT). Mother-to-child-transmission contributes to around 50% and a third of new infections, respectively, in high and low epidemic nations (Vodkin & Patton, 2014) , (Thio, Guo, Xie, Nelson, & Ehrhardt, 2015) .

Although the hepatitis B vaccine is available both in private and public hospitals and health centers in Uganda, several people do not get vaccinated at all or do not complete the whole course of vaccination schedule for hepatitis B disease which usually involves getting three doses at zero, one month and six months respectively. This poses a major health risk of not fully been vaccinated hence the body cannot fully fight off the infection once exposed. Ministry of health in Uganda conducted a mass vaccination campaign for hepatitis B disease in

The risk factors associated to hepatitis B disease have not been identified among women in Uganda among various populations making it hard to have targeted interventions to reduce spread of the disease.

1.3 Purpose of the study

The main purpose of the study was to explore available knowledge and risk factors associated with hepatitis B disease among women attending antenatal care (ANC) at Arua Regional Referral Hospital (ARRH).

1.4 Objectives

1.4.1 General objective

The main objective of the study was to assess the level of knowledge and risk factors associated with hepatitis B disease among women attending antenatal care at Arua Regional Referral Hospital.

1.4.2 Specific objectives

1. To determine the percentage of women attending antenatal care at Arua Regional Referral Hospital who are knowledgeable about hepatitis B disease.

2. To determine the prevalence of HBsAg among women attending antenatal care at Arua Regional Referral Hospital.
3. To determine the risk factors of hepatitis B disease among women seeking antenatal care at Arua Regional Referral Hospital.

1.5 Research questions

1. What is the percentage of women attending antenatal care at Arua Regional Referral Hospital who are knowledgeable about hepatitis B disease?
2. What is the prevalence of HBsAg among women attending antenatal care at Arua Regional Referral Hospital?
3. What are the risk factors associated with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital?

1.6 Justification of the study

West Nile region in Uganda has the 2nd highest prevalence of hepatitis B disease lying at 3.8% compared to the national prevalence of 4.3% in people aged 15-64 years. The West Nile region's regional center is Arua, which has a population of about 782,077 people (UBOS, 2017) . Arua Regional Referral Hospital was the only regional referral hospital serving the region until recently when Yumbe Regional Referral Hospital was upgraded from a General hospital to a Regional Referral status.

Currently, there is limited data available on level of awareness, knowledge and justifiable risk factors within different populations that are associated with hepatitis B positivity especially in developing countries that are faced with many vulnerable young populations with high mortality rate including Uganda. With the long term and severe indications of hepatitis B disease, prevention through vaccination is the ultimate cost-effective solution to this growing epidemic especially in low-income countries like Uganda. Although the vaccine is available both in private and public hospital and health centers, risk factors associated to hepatitis B disease have not been identified among the women.

There is need to identify the factors that expose women to HBV infection (risk factors) in that setting to address the problem better. This will facilitate design of preventative measures targeted to people in each setting. In addition, depending on results of identified knowledge gaps policy makers especially Ministry of Health (MOH) will be guided in development of health promotion

and education programs/materials that will help increase awareness of hepatitis B in this population.

1.7 Scope of the study

Generally, this was limited to under themes of content, geographical and time scopes as explained further below.

1.7.1 Context scope

The study was focused on hepatitis B disease. Emphasis was on assessing knowledge and risk factors that are associated with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital.

1.7.2 Geographical scope

The study was conducted at only Arua Regional Referral Hospital, a hospital located in Northwestern part of Uganda in Arua town in West Nile region.

1.8 Study limitation

Sampling was done only for women attending antenatal care at Arua Regional Referral Hospital which might not be representative of the entire population.

HBsAg test was used in the study is best to understand if the person has chronic hepatitis B disease. There are more specific tests that could have been used in the study including the enzyme-linked immunosorbent assay (ELISA) and Polymerase chain reaction (PCR) test although these are very expensive and there is limited equipment in Uganda.

1.9 Delimitations

Only pregnant women attending antenatal care at Arua Regional Referral Hospital were included in the study. All other pregnant women seeking other services at the facility were never included in the study.

1.10 Assumptions of the study

The risk factors of pregnant women attending antenatal care at Arua Regional Referral Hospital represent the risk factors of the pregnant women in Arua district and the West Nile region.

The perceived knowledge obtained in the study from the participants attending antenatal care at Arua Regional Referral Hospital represents the knowledge of the pregnant women in Arua district and the West Nile region.

1.11 Operational definitions of key terms

Horizontal Transmission: This is the spreading of infections either between or among the members belonging to the same genus not in a parent-child relationship.

Occurrence: This is the number of times or frequency of something happening.

Prevalence: The percentage of persons who are affected by the disease at a given time.

Risk Factors: Everything that makes a person more likely to contract a disease or sustain harm, such as a trait or exposure, falls under this category.

Socio-demographic characteristics: Participant characteristics with regards to their wellbeing for example age, race, ethnicity, income, level of education and language.

Vaccination: The administration of antigenic material to improve immunity to a particular disease.

Vertical transmission: Spread of disease usually before or after birth from mother to baby.

CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

This chapter looks at the available literature that provides documented insights and gaps which this research sought to potentially provide answers. The chapter contains a summary of the theoretical, conceptual, and actual review of literature.

2.1 Empirical literature

Approximately 257 million people worldwide live with the HBV and is considered one of the life-threatening infections. According to data from a World Health organization survey, it is predicted that by 2015, HBV-type infections had caused approximately 88,000 fatalities globally. (World Health Organisation, 2017) .

When one acquires the infection, they usually will take one to three months without any visible symptoms or just mild symptoms. This is the acute phase of the disease progression. The likely symptoms may include fever, jaundice, passing of dark urine, headaches, and malaise. During this time, an adult may completely recover, and the infection may sometimes resolve completely.

The acute phase has 3 stages which have various symptoms. The earliest phase is called the prodromal phase and one can have symptoms like fever, loss of appetite, nausea and vomiting, rash, and pain in the joints. This is usually after incubation of the hepatitis B virus between 6 weeks and 6 months after getting infected. Once the symptoms in the prodromal phase start reducing, the individual usually will progress to the Icteric phase.

During the icteric phase the infected individual will have symptoms like dark urine, yellow color in the pigments like the eyes and palms. These symptoms are familiar to those of acute liver failure and detection of the virus can be easily missed and confused with acute liver failure due to other causes. The liver at this phase is not breaking down the bilirubin causing the yellow coloration in the eyes and urine. The liver enzymes will have high titer values in the serum of tested. This phase usually will peak in about one or 2 weeks after which all symptoms will be resolved, and the individual will normally gain back their well- being.

The convalescence phase of the acute phase is the period when one usually fully recovers from the disease. The body usually fights the virus and recovery is mostly certain. Although some very few individuals usually will progress to the chronic phase.

Information available presupposes that most of the infected persons take long to develop disease like symptoms of the infection, some might have yellowing of mucosal surfaces, abdominal pain and extension, dark colored urine, nausea and vomiting, extreme fatigue, and acute hepatitis in a few cases which might lead to death. During the chronic phase, liver cirrhosis and liver cancer are likely to happen (World Health Organisation, 2017) . This is because the virus can be integrated in the human genome and can mutate and replicate in the body since it is a Deoxyribonucleic acid (DNA) virus (World Health Organization, Training workshop on screening, diagnosis and treatment of Hepatitis B and C, 2022).

The virus usually does not cause harm to the liver as the harm is usually caused by the host human immune system. In a bid to fight the virus the host immune system and cytokines will damage the hepatocytes hence the liver injury. If the host immune system is intolerant to the virus, there will be liver injury. However, the host immune system is sometimes tolerant to the virus as seen in the immune tolerant phase in children where there is no injury despite the high viral load in the blood (World Health Organization, Training workshop on screening, diagnosis and treatment of Hepatitis B and C, 2022) .

The chronic stage of hepatitis B disease has majorly 4 stages/phases namely the immune tolerant phase, immune active phase, immune control phase, and the immune clearance phase. In most children who acquire disease through mother to child transmission (MTCT), they will show all phases at intervals after birth. For most adults, it is hard to know which phase they are at when 1st diagnosed with disease. Following them up for 6 months will help determine which phase of the chronic stage they are at (World Health Organization, Training workshop on screening, diagnosis and treatment of Hepatitis B and C, 2022) .

During the immune tolerant phase, there is high viral load in the blood since the host immunity if the body is weak to fight the virus. The virus will multiply hence the high viral load. There is however no damage to the hepatocytes. The ration of aspartate transaminase (AST) and alanine transaminase (ALT) enzymes (AST/ALT) which are found in the blood at low levels that help to metabolize amino acids are usually low in this phase.

The immune active phase the ratio of aspartate transaminase (AST) and alanine transaminase (ALT) enzymes (AST/ALT) usually increases. The host immunity also kicks in to defend the virus and infected hepatocytes which causes liver damage. The viral load in the body will decrease in

this phase due to the body defending itself. Treatment is needed in this phase to increase the ability of the body to fight off the virus.

The immune control phase is when the body host immunity has gained control of the viral load. The host immunity is now stronger than the virus. The viral load in the blood is now reducing and in control.

In the immune clearance phase, the alanine transaminase (ALT) enzymes are moderate, and the viral load is lowest amongst all the four stages of the chronic phase. There is no need for treatment during this phase as the body has the virus under control.

A reactivation phase can usually occur in some individuals. This is usually due to a weakened immune system especially due to taking immune suppressive agents or other causes of immune suppression like illness including HIV. The viral load will increase in this phase. There is need for treatment in this phase.

Individuals who are infected with hepatitis B virus and are in the chronic phase will only need treatment in the Immune active phase, the reactivation phase and if they show signs of liver cirrhosis at any of the phases. The anti- viral treatment is free of charge in all accredited public facilities in Uganda including Arua Regional Referral Hospital.

Of the 250 million cases worldwide in 2016, only 10.7% (27 million) were aware of their disease and of those diagnosed of hepatitis B disease, only 4.5 million were on treatment (World Health Organization, Hepatitis B fact sheet, 2020) . This clearly shows the extent of lack of knowledge of hepatitis B disease from the infected patients as they seek health care.

The highest prevalence of chronic disease has been observed to be transmitted by vertical transmission compared to horizontal transmission (World Health Organisation, 2017) . A previous study conducted in Gambia shows that individuals who acquired the disease by vertical transmission are more likely to develop cancer of the liver compared to those who acquired the disease by horizontal transmission. Hence if there are interruptions in spread by vertical transmission there would be a reduction of liver disease caused by hepatitis B infections (Shimakawa, Bottomley , Njie, & Mendy, 2014) .

Prevention of hepatitis B disease has been mainly by vaccination. This averts the development of complications which include liver cirrhosis and liver cancer as seen in the chronic stages (World Health Organization, Hepatitis B fact sheet, 2020) . There is a vaccine available worldwide which is safe and effective offering 98%- 100% protection (World Health Organization, Hepatitis B fact sheet, 2020) . Global coverage of hepatitis B vaccination at birth lies at 43% worldwide however this is still widely uneven in the various parts of the world with African region only at 6% coverage (World Health Organization, Hepatitis B fact sheet, 2020) . In Uganda this vaccination has adapted and included in the vaccination schedule of infants with the first monovalent dose administered at birth, second and third following the standard developed schedule as per World Health Organization (MOH, 2015) .

Testing of hepatitis B disease has remained to be poor especially in low-income countries including Uganda. World Health Organization recommends testing of all pregnant women during the antenatal visits since they are part of high-risk groups (World Health Organization, Hepatitis B fact sheet, 2020) . Screening of hepatitis B for the eligible pregnant women at antenatal care alongside the prevention of Mother-to-child-Transmission of HIV and congenital syphilis screening services is key in identifying new cases as well (World Health Organization, Hepatitis B fact sheet, 2020) .

The World Health Organization has gone ahead to publish a guideline “Prevention of Mother-to-child-Transmission of hepatitis B virus: Guidelines on antiviral prophylaxis in pregnancy” to guide health workers in how to handle cases of hepatitis B disease in pregnancy (World Health Organization, Hepatitis B fact sheet, 2020) .

Development of hepatitis B disease is highly dependent on the knowledge of the disease, traditional beliefs, and cultural practices of the communities. Lack of knowledge of how the disease is spread leads to engagement in several practices that might expose the non-infected person to the disease. Hepatitis B infection is commonly linked to traditional activities including nose and ear piercing, tattoos, and scarification, which expose people to the disease outside of pregnancy in certain zones (Dwivedi, et al., 2011) . Due to these dynamic characteristics of populations, each population has its unique risk factors associated to hepatitis B disease.

People usually present with advanced disease because of knowledge gap of hepatitis B disease. (World Health Organisation, 2017) . From studies carried out in Cameroon, Nigeria, China and

Hong Kong, there is insufficient knowledge about hepatitis B disease by women (Chan, Lao, Suen, & Leung, 2012) . The continuous spread of hepatitis B disease from infected mothers to infants may be due to the attitude of mothers or lack of knowledge about the disease (Zhenyan, Zhang, Erhardt, & Chloe, 2017) . In a study in Cameroon, the knowledge levels of hepatitis B disease were 16% from the participants (Andreas, Julius, Peter, & Peter, 2014) . These poor levels of awareness and knowledge lead to participants engaging in activities/risk factors which further expose them to hepatitis B disease.

A previous study conducted in Cameroon shows no significant association between the assessed risk factors including past surgeries, blood transfusion, tattoos, abortions, scarification, number of sexual partners, piercing, condom use and past urinary tract infections with HBsAg positivity (Andreas, Julius, Peter, & Peter, 2014) .

Previous research from Mexico showed only blood transfusion was significantly associated with HBsAg positivity (Cisneros, Hernández, Ibarra, Fernandez, & Escobedo, 2001) .

According to similar study conducted in Nigeria, a big percentage of childbirth, polygamy, a series of sexual partners one has had since he / she started engaging in sexual activities and previous led to Sexually Transmitted Infection (STI) were some of the major risk factors (Obi , Onah, & Ezugwu, 2006) . Another study in Nigeria identified only three risk factors associated with HBsAg positivity which included Sexually Transmitted Infection (STI) history, having sex with a person with multiple sexual partners and early age starting to engage in sexual activities (Rabiu, Akinola, & Adewunmi, 2010) .

Although there are existent generic risk factors for hepatitis B disease, from the results of research on the risk factors of hepatitis B disease conducted worldwide, it has proven that every community has specific risk factors for the hepatitis B virus infection. Identifying these risk factors for each community is key in coming up with specific interventions that will address the gaps.

2.2 Theoretical framework

Health outcomes and how the public uses health services are highly linked to the health seeking behaviors of the population (Babar & Juanita, 2005) . Health seeking behaviors are affected by several factors including the perception of the public, the knowledge of the public about the intervention, social pressures and financial barriers that will affect the seeking of interventions.

The social cognitive theory (SCT) explains health seeking behavior as an interaction of three ways-personal factors, environmental factors and behavioral factors continuously interacting. The social cognitive theory explains that people learn through their own experiences and by the results of the actions of other people. Higher expectations for associated outcomes are most likely going to be associated to individuals with higher self-efficacy.

An individual is more likely to have high expectations for the outcomes of an activity if they have a greater level of self-efficacy for that action. They also experience more social and physical support and participate in more positive self-regulatory actions than people with poor self-efficacy. Success with the behavior fuels self-efficacy, especially when it happens in the face of difficulty. Self-efficacy is directly influenced by one's physiological state. (Rejeski WJ & Fanning, 2019) .

To further explain the social cognitive theory in the aspect of hepatitis B disease, most of the people will continue to participate in unsafe activities or risk factors because they have not enough knowledge to influence their decisions. Often time, when there are no immediate consequences in participating in a risk factors of hepatitis B disease since the signs are not immediate and they manifest later in life. This lack of a negative consequence immediately will encourage people to continue as they feel they are safe conducting these activities.

Some of these risk factors are because of the cultural norms of the communities like body piercings and tattoos, inconsistent condom use, having many sexual partners etc. These are part of the environmental factors which lead to the spread of hepatitis B disease. The Madi in West Nile region consider having tattoos and body piercings as a form of beauty especially among the women. A man having only one sexual partner in the African setting and some cultures and religions is considered as a sign of weakness. This will encourage men to have several sexual partners which will in turn increase the chances of acquiring hepatitis B disease.

Some of the women participate in these risk factors as a personal factor. Engaging in unsafe abortions especially among the young girls is to avoid the shame of being seen pregnant by the community before marriage. These will be willing to perform unsafe abortions to avoid the embarrassment and judgement of being pregnant at such a young age.

According to the human belief model, the population's impression of how serious a disease is likely to be and/or the chance of contracting a disease has a significant impact on the perceived danger

of a disease. Age, general understanding of the disease, how it spreads, and risk factors, as well as gender, all influence the risk of engaging in disease-causing behaviors. It is then compared to one's views about the likelihood of receiving care, benefits, and barriers to care, as well as one's abilities to seek and obtain care, to encourage care-seeking, treatment, and prevention behavior. (Nankya-Mutyoba, Aizire, Makumbi, Ocama, & Kirk, 2019) .

Since hepatitis B disease information has not been relatively communicated compared to other sexually transmitted diseases like HIV/AIDS, there is perceived low knowledge among the public on the risk factors, signs and symptoms, and preventative measures. Also, the fact that the signs and symptoms of hepatitis B disease will show up later in life and not immediately will further limit the linkage of participation in the risk factors to the spread of disease. This will make the public have a perception that hepatitis B disease is not a serious disease and that participation in the risk factors of hepatitis B disease is not in any way harmful to them since the consequences are not immediate and signs of disease show over time.

Hepatitis B virus prevention among pregnant women has been hampered in most low- and middle-income countries, including Uganda, due to a number of problems, including inadequate awareness of hepatitis B virus and its prevention, as well as risk factors for hepatitis B disease underdeveloped health-care institutions that are ill-equipped to provide screening, and a lack of peer and community support. Hepatitis B illness treatment and prevention, as well as insufficient information on pregnant women's attitudes toward the disease. Because there are so many false conceptions of hepatitis B disease in the population, it has a negative impact on the behavioral responses that are built up to deal with it. (Abdulai, Baiden, Adjei, & Owusu-Agyei, 2016) , (Ngaira, et al., 2016) , (Ma, et al., 2007) , (Bond & Nolan, 2011) .

The knowledge gap about hepatitis B disease and its impact on participating in risk behaviors that lead to hepatitis B disease are best explained by the human belief model. Once one is not aware of the risk factors, it is eminent that they will most likely engage in activities that put them at risk to acquire disease. For example, a woman who is not aware of the risk of having many sexual partners to cause sexually transmitted diseases like hepatitis B will most likely engage in unsafe sexual activities with inconsistent condom use. This will put her, her unborn baby, and the sexual partners at risk of acquiring hepatitis B disease. The ability to acquire knowledge of hepatitis B disease will

cognitively have the same woman practicing safer sex using condoms with less sexual partners compared to when she had little or no knowledge on hepatitis B disease.

2.3 Conceptual framework

The poor knowledge levels on the signs and symptoms have led to many people not seeking care early enough before the disease progresses to advanced stages. This has led to the high numbers of people seeking care with advanced liver disease (World Health Organization, WHO, 1990) . The low levels of knowledge can also attribute to the population engaging in many risk factors like piercings and tattoo rituals which further exposes them to disease.

High amounts of the virus are present in bodily fluids including semen, vaginal secretions, blood, and saliva, which are how the extremely dangerous hepatitis B illness is transmitted. (Parry, Godfrey, Mabey, & Gill, 2009) . Engaging activities that expose one to such fluids increases their chances of acquiring disease.

Low levels of knowledge of hepatitis B disease as reported by the various studies are a contributor to hepatitis B disease. Once the population has insufficient knowledge, they will most likely seek health care later in life with advanced disease. They will also engage in activities which put them at risk of acquiring infection.

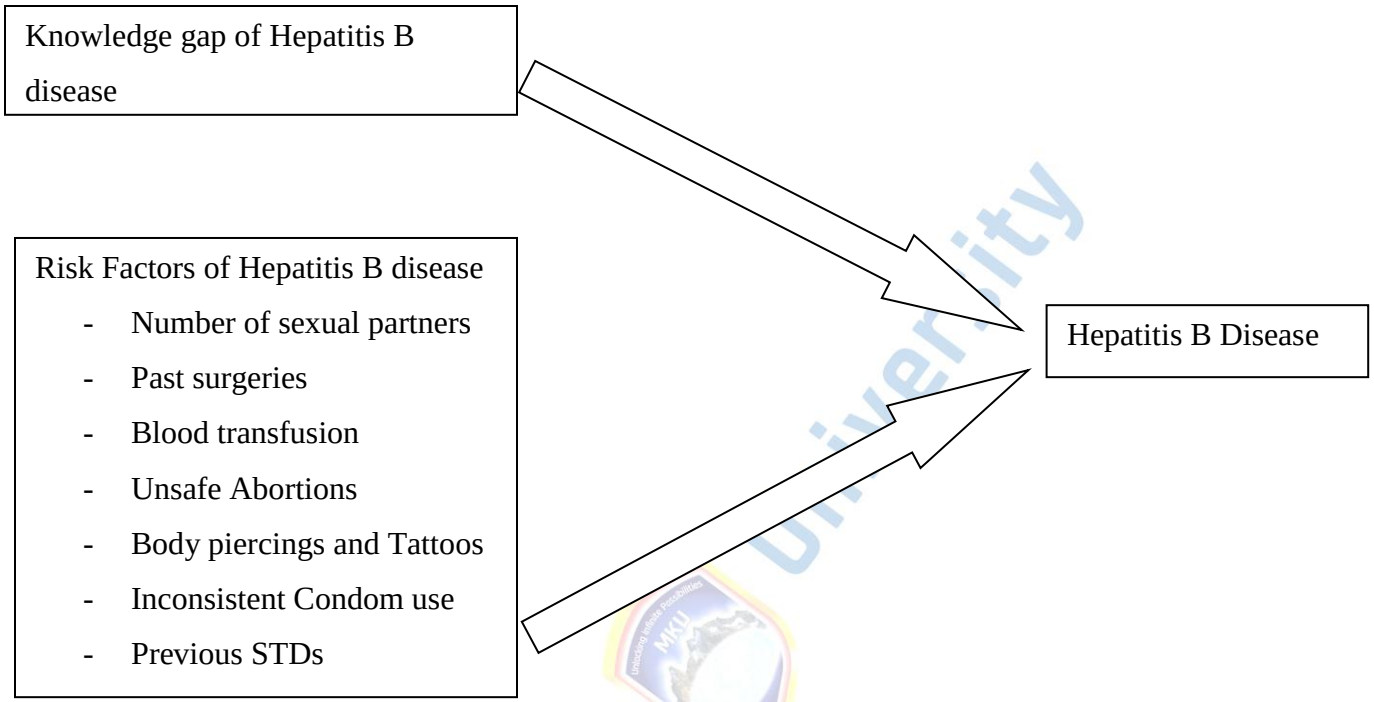
Blood once contaminated will exposed one to hepatitis B disease due to the very high concentrations of hepatitis B virus. Activities like unsafe surgeries, unsafe abortions as seen in most traditional settings, traditional body piercings and tattoos using unsterilized needles will expose uninfected people to hepatitis B disease.

Having many sexual partners and inconsistent condom use are some of the risk factors that expose one to either vaginal secretions or semen that contain high concentrations of hepatitis B virus. Once these secretions are contaminated, there are higher chances of acquiring hepatitis B disease.

Risk factors of Hepatitis B disease and the poor knowledge of hepatitis B disease are the independent variables in this study. Dependent variable in the study is acquiring hepatitis B disease. Poor knowledge of hepatitis B disease is a contributor of hepatitis B disease transmission since it influences the engagement of uninfected persons in risk factors that put them at risk of acquiring disease. Just like in the human belief model, knowledge on how disease is spread, and the risk factors influence the risk of engaging in disease-causing behaviors.

Figure 1*:*

The graphical model of the variable relationship of hepatitis B disease.



Hepatitis B disease is majorly spread by contact of body fluids that have a high concentration of the virus from a person who is infected to one who is not. Body fluids with high concentrations include semen, vaginal secretions, blood and sometimes saliva if the person has open sores in the mouth.

Activities where one is in contact with these body fluids will expose them to increased risks of acquiring disease hence an increase in the chances of a mother transmitting the virus to the baby either at birth or during the 1st years of life which currently accounts to more than 50% of new hepatitis B infections worldwide.

There are a number of risk factors associated with hepatitis B disease and some include having traditional body piercings and tattoos, inconsistent condom use, having many sextual partners, drug abuse especially when using injections, unsafe abortions, unsafe blood transfusion using untested or inconsistently tested blood, having many sexual partners as well as having previous sexually transmitted infections. Spread can also occur when one reuses contaminated needles and syringes which can occur in the community setting during rituals like piecing's and tattooing,

among drug users who inject themselves or even in the health setting through accidental needle pricks (World Health Organization, Hepatitis B factsheet, 2022) .

The study assessed only 8 risk factors of hepatitis B disease which included number of past sexual partners, if the participant has had any past surgeries, if the participant has had blood transfusion, if the participant has had unsafe abortions, if the participant has had body piercings and tattoos, if the participant has had inconsistent condom use and if the participant has had any previous sexually transmitted diseases in the last one year.

The number of past sexual partners expose one to greater chances of acquiring hepatitis B disease. There is a strong association of having many sexual partners to acquiring a sexually transmitted infection including hepatitis B disease. Women with 5 or more sexual partners are said to have an 8-fold chance of having acquired a sexually transmitted infection compared to those who have had just one sexual partner (Joffe, et al., 1992) . The prevalence is increased if one has more casual sexual partners and the age of the initial sexual activity. (Rabiu, Akinola, & Adewunmi, 2010) .

Having many casual sexual partners increase one's chances of acquiring a sexually transmitted infections including hepatitis B disease. Adults who are unvaccinated and have multiple sexual partners or sexual partners of people who are in the chronic stage of hepatitis B infection have an increased risk of acquiring hepatitis B disease compared to those who have fewer sexual partners. Having multiple sexual partners as seen in female sex workers will increase the spread of hepatitis B disease not only among the female sex workers but also their clients. A study conducted in the Hawassa city of Ethiopia showed the prevalence of hepatitis B disease among the sex workers as 9.2% which was higher than the national prevalence in Ethiopia (Deresse , Getahun, & Demissie , 2022) .

Hepatitis B disease usually spread through sexual contact where either vaginal secretions or semen from an infected person is exchanges. Condom use is one of the major ways to avoid this form of spread as it acts as a barrier to prevent infection. It should be noted that using condoms consistently and correctly is one of the major ways of preventing sexually transmitted infections to up to 99%.

The study in Ethiopia highlights that female sex workers who did not use condoms were six and two times more at risk to acquire hepatitis B disease than those who used condoms regularly or

those who had incidences of condom breakage during sexual intercourse (Deresse , Getahun, & Demissie , 2022) .

In some African cultures including the Lugbara and Madi who predominantly reside in the Arua district, body tattoos and body piercings among the women is regarded as a sign of beauty. Commonly these are performed by elders who use sharp needles to draw different designs on the hands, or face of the women or to create holes on the ears and nose where rings are inserted. There is an increased risk of acquiring hepatitis B disease from such traditions since most of the time the sharp needles used during the tattooing and body piercings are not sterilized at all or even disposable. Most of the needles are used from one person to another which increases the risk of hepatitis B disease transmission. There is risk to have infected blood from one person to another during this process which will increase the risk of spreading and acquiring hepatitis B disease from these traditional rituals.

Unsafe abortions are also a risk factor to hepatitis B disease since they expose one to contaminated blood which might lead to spread of hepatitis B disease. Teenage pregnancy is so common in Uganda with almost 25% of all women aged fifteen to nineteen years of age have given birth or are pregnant with their first child before the age of 18 years according to a Uganda Bureau of Statistics report of 2018. Most of these teens who get pregnant are unmarried which creates a lot of undesired incidences of unsafe abortions since in most African settings, they expect only pregnant women to be married. The fear of dropping out of school by these pregnant teens or forced to get married has fuelled the unsafe abortions. Most of these unsafe abortions are performed by inexperienced persons by inserting sharp objects in the woman's reproductive parts to open the cervix inducing abortion. The risk of using the same unsterilized objects among different women increases the risk of acquiring hepatitis B disease.

Presence of recent or past sexually transmitted diseases (STDs) is a risk of acquiring hepatitis B disease. Since both sexually transmitted diseases and hepatitis B disease are spread by unprotected sexual contact, people with current or past STIs are evaluated to have a highest risk of hepatitis B infection. A study conducted in Rakai, Uganda showed that HIV status and serologic syphilis were significantly associated with hepatitis B virus infection (Lara, et al., 2011) .

Past surgeries especially the non-medical surgeries performed for cultural and religious purposes expose one to hepatitis B disease since there is a high possibility of sharing unsterilized sharps which are used in the surgeries. Most of these surgeries are conducted in the different cultures and religions put the recipients at risk of acquiring infection since there is frequent use of the same sharp instruments among different people which get in contact with blood hence the spread of hepatitis B disease. It is important to note that in most cases, these surgeries are not carried out with disposable sharp instruments but rather these are shared among different people.

2.4 Recap of literature review

High amounts of the virus are present in bodily fluids including semen, vaginal secretions, blood, and saliva, which are how the extremely dangerous hepatitis B illness is transmitted. Globally, over 275 million people are infected with the virus and over 880,000 deaths occur annually.

Vertical transmission accounts to nearly 50% of new chronic cases worldwide. Mother to Child Transmission being one of the leading methods of transmission is majorly due the attitude of mothers or lack of knowledge about the disease. The lack of knowledge leads to engaging in risk factors like unsafe abortions, piercings, and tattooing, having many sexual partners among others which expose one to infection. These low levels of knowledge of hepatitis B disease have been reported in various studies as a contributor to the spread of the hepatitis B virus.

Different studies have shown different risk factors which are associated with hepatitis B disease amongst various populations. The study assessed only eight risk factors associated with hepatitis B disease including presence of body tattoos and body piercings, past STIs, consistent condom use, number of past sexual partners, past unsafe abortions, past blood transfusions, and past surgeries. It is important to understand the risk factors associated to hepatitis B disease since these might differ depending on the different population cultural and religious backgrounds which affect the behaviors of the populations.

CHAPTER THREE: RESEARCH METHODOLOGY

3.0 Introduction

This chapter considers the research methodology, techniques, and design of the study. The estimation of sample size, sampling methods, techniques and data collection procedures, methods, and research tools and instruments used in the study are thoroughly taken care of in this section.

3.1 Research design

An analytical cross-sectional study design was used to assess the knowledge of hepatitis B and its associated risk factors among women attending antenatal care at Arua Regional Referral Hospital. The prevalence of hepatitis B disease in the sample population was also determined using the findings of the HBsAg test.

3.1.1 Location of the study

The research was carried out at the Arua Regional Referral Hospital's general antenatal care clinic in Arua district in Uganda's Northwestern region.

Arua Regional Referral hospital is the only regional referral hospital that serves 12 districts in Uganda's West Nile area namely Pakwach, Nebbi, Zombo, Madi Okollo, Arua, Terego, Maracha, Koboko, Yumbe, Moyo, Obongi, and Adjumani. Since it is the regional referral hospital in the region, the hospital offers specialized services in the region hence the facility with the most qualified health work force in the region comprising of medical consultants, medical doctors, clinical officers, pharmacists, nurses, and many other professionals employed in the facility.

The hospital is a public hospital that is Government owned and funded. Given that it offers free services to the public, most of the patients visiting the facility are low-income earners from all the 12 districts served by the facility.

3.1.2 Target population

Women seeking antenatal care services at Arua Regional Referral Hospital were the study's target demographic. Only after consenting to participate in the study, the women attending antenatal care at Arua Regional Referral Hospital. were eligible to take part. A total of 341 pregnant women seeking antenatal care services at Arua Regional Referral Hospital agreed to participate in the study and were chosen at random.

3.1.2.1 Inclusion Criteria

1. All participants who attended antenatal care at Arua Regional Referral Hospital and consented for the study.

3.1.2.2 Exclusion Criteria

1. Participants who sought antenatal care services at Arua Regional Referral Hospital but were critically ill.
2. Participants who had earlier consented but chose to withdraw from the study.
3. Pregnant women seeking other services apart from antenatal care at Arua Regional Referral Hospital.

3.1.3 Sampling procedure and techniques

The sampling method of convenience sampling (Elfil & Negida, 2017) was used where all women attending antenatal care at Arua Regional Referral Hospital were eligible until the sample size is obtained. Participants who attended antenatal care sessions during the allocated time of data collection by the Arua Regional Referral Hospital REC were considered during the study. Only participants who consent by signing the consent form to be part of the study were included as part of the sample until the required number was achieved.

3.1.4 Sample population

Using formula for sample size estimation (Kish, 1965) , for cross sectional surveys with categorical outcomes, $n= [(Z^2 PQ) \div \delta^2]$

Where, Z = 1.96 (standard error of mean), P = 10%, i.e., 0.1, (estimated prevalence of the hepatitis B in Uganda is 10%), (Macro., 2004-2005)

Q = 1-P =0.9, δ = 3%, i.e., 0.03. Therefore, n=384.

The desired sample size was 384 pregnant women however only 89% (341) pregnant women participated in the study given available resources and time allocated by Arua Regional Referral Hospital Research and Ethics Committee (REC) to conduct the study. Data collection was also halted by the COVID 19 virus lockdown which happened in March 2020 in Uganda. The COVID 19 virus lockdown halted all travels of the data collection team to Arua Regional Referral Hospital.

3.2 Construction of research instruments

The structured questionnaire was designed with sections that cover demographic data, social status, facts on hepatitis B to assess knowledge and a section to assess participant's risk factors of hepatitis B. The questionnaire was adapted from a World Health Organization protocol for designing hepatitis B assessment tools and it included both open and closed ended questions (World Health Organization, WHO, 1990) .

The questionnaire was administered to each woman who attended antenatal care on a one-on-one basis. The participant was required to have a written consent before the interview on the questionnaire is started. For participants who could read and write in English, a research assistant was available to interpret the entire questionnaire to them in local languages and have consent through a thumb print.

Blood tested for hepatitis B had results tagged to the respective questionnaire by using same code indicated on both the questionnaire and sample. This is to have confidentiality of the results since only unique numbers were used for every client.

3.3 Testing for validity and reliability

The research instrument was verified for appropriateness through pre-test techniques and expert judgment by my supervisors at Mount Kenya University, various Research and Ethics Committee representatives and other subject matter experts. Prior to data collection process, my supervisors and subject matter experts who gave their input which was in cooperated, and changes made. A pre-test with the aim of identifying questions that were poorly structured and to also estimate average questionnaire fill time was further conducted among randomly 40 selected respondents at Oli health center IV in Arua located about 3km from Arua Regional Referral Hospital. The pretest was never carried out at the research site as a measure to prevent exposure of the data collection tool to any of the participants in the final data collection site (Arua Regional Referral Hospital), to determine the average time to be spent to conduct data collection as well as to understand the user-friendliness of the data collection tool to which would be key aspects to ensure a successful data collection process.

Furthermore, the content validity index (CVI) which involves judgment issues, scores attained in respective asked questions per used research instrument with available variables under test for reaching a conclusive judgment that is not biased was calculated.

The standard formula for calculating content validity index is below.

CVI= (Number of available valid items) ÷ (Total number of items sampled)

For the instrument to be valid, CVI above 0.7 was considered (Amin, 2005).

The questionnaire was then revised according to the comments received in the pretest and approved by the supervisor.

3.4 Data collection methods and procedures

3.4.1 Administration of the questionnaire

After Examination by a health worker, a standard questionnaire with modifications was administered to all participants who consented.

The questionnaire was divided into sections to assess social demographic data, knowledge on hepatitis B and availability of risk factors of hepatitis B. Participants who could read and write filled in the questionnaire on their own except when they needed clarification. Those who could not read and write were translated to in their local language by a research assistant during face-to-face sessions. Each participant was given ample time to properly answer all questions on the questionnaire.

3.4.2 Hepatitis B screening

The participants would then undergo routine counseling before tested for hepatitis B disease. A brand of Accurate HBsAg strips were used for the study purchased form Joint Medical Stores of Batch number 2019060064 and expiry date of 05/2022 According to the manufacturer specifications, these tests stripes have a clinical Sensitivity of 98.6%, Clinical Specificity of 100% and accuracy of 99.6%, according to the manufacture's specifications.

A qualified laboratory assistant stationed at the antenatal care clinic would then draw 3mls of fresh venous blood from the median cubital vein using a vacutainer needle and Ethylenediaminetetraacetic acid (EDTA) vacutainer tube. Testing involved the using a capillary tube to pick two drops of whole blood sample which were deposed on a corresponding sample section of the HBsAg strips and buffer added. Holding up to for a 5 to 10 minutes as defined by the test strip instructions before reading the test result. If one band appeared in the test strip's control region, the test was ruled negative. When two bands (one in test and another in the control

area of the test strips) showed, it was determined that the test was positive. An inconclusive test was when no band emerged at all or when the control region did not show a band, but one band showed in the test region. Such tests were declared invalid. These tests were rejected, and a repeat test with a new test strip was conducted using the excess blood sample in the vacutainer tube. This repeat test sample was still examined in the same way and the findings were recorded. Depending on the results of the test per participant, the prevalence of hepatitis B disease amongst the participants of the study was established.

Participants who returned negative result for the HBsAg test, post-test counselling was carried out to ensure that they stay negative and do not engage in activities which would expose them to the virus. Participants who returned a positive result for HBsAg were enrolled in the routine hepatitis B care in the hospital which required them to be retested, counseled, and recruited in to care as advised by the Clinicians of the hospital. These were also advised to encourage their recent sexual partners to also conduct a hepatitis B test from an accredited facility.

3.4.3 Quality control and assurance

For quality assurance and control purposes, each new pack of HBsAg rapid test strips had to undergo a quality control test before use. A known positive and negative sample from the hepatitis B clinic earlier confirmed by ELISA (enzyme- linked immunosorbent assay) was run on 2 test strips to verify if the test strips read the same results as the known sample. If they read the same results as the results of the known sample, then the procedure to test the participants would continue. If any of the 2 sample reads a different result, then a 3rd test was to be carried out to verify the results and if it passes the QA test then the pack is usable. If it does not, then the pack was to be discarded and another pack used.

3.5 Data analysis techniques and procedures

The packages MICROSOFT EXCEL-2013, EPI-INFO Version 7.2.2, and STATA version 14 were used to analyze the data collected during the study.

Participants' correct replies were used to determine their specific knowledge about hepatitis B disease. Correctly answered questions received a 1 rating, while "I Don't Know" and improperly answered questions received a 0 rating. Participants with summary scores of 0-2 were regarded to have insufficient information, those with summary scores of 3-5 were considered to have intermediate knowledge, and only those with summary scores of 6-12 were considered

knowledgeable. Participants with insufficient or intermediate understanding of hepatitis B were classified as having poor knowledge of the condition.

The ratio of HBsAg positively tested samples to the total samples tested was the approximate prevalence of hepatitis B among the study population.

Using logistics regression, the potential risk factors to hepatitis B were determined by the risk ratio for each assessed potential risk factor while using the multivalent logistics regression for any risk factors that had significant association with hepatitis B disease. Risk factors were considered statistically significant to hepatitis B disease when $P < 0.05$.

3.6 Ethical considerations

The researcher followed the ethical standards of conduct established by Uganda's relevant review bodies. Mount Kenya University's Institutional Ethical Review Committee (IREC) issued a certificate of Ethical clearance which permitted the researcher to proceed and seek the necessary approvals from the relevant bodies in Uganda to conduct the study. TASO IRB, one of Uganda's recognized Institutional Review Boards which reviews the research protocol for any research that involves human beings reviewed and authorized the study to proceed. The work was later registered with the Uganda National Council of Science and Technology (UNCST) as a requirement by law for research to be conducted in Uganda. Furthermore, the research protocol was reviewed by the Arua Regional Referral Hospital research and ethics committee (REC) as a reassurance that the research protocol was well understood by the administration and protected the welfare of the clients of the hospital prior to data collection. The research and ethics committee of Arua Regional Referral Hospital gave the project the go light to proceed through issuing out an acceptance letter.

Confidentiality was always observed, and random codes were assigned to the respondents to ensure that their identity is not revealed. For respondents who came with their spouses for the antenatal care visits, the spouses were not involved in filling the questionnaires as only the pregnant woman did so.

Consent was sought and obtained for every participant before filling the questionnaire. Participants were allowed to ask any questions to clarify the content of the consent form where they had any inquires. Only participants who signed informed consent questionnaires were allowed to take part

in the study. The consent form highlighted that the study was free, and no monetary incentive would be provided to the participants, confidentiality would be maintained at all cases, no harm was going to be caused to the participant. It also highlighted that the participants had the option to withdraw at any time during the study and accepting to be part of the study was entirely voluntary.

The study was completely free to take part in. To be a part of the study or any tests administered as part of the study, none of the participants paid or were paid any money.

CHAPTER FOUR: RESEARCH FINDINGS AND DISCUSSIONS

4.0 Introduction

This chapter contains the research findings as well as a discussion of the study's findings. This chapter includes the pretest results, participant characteristics, HBsAg prevalence, knowledge of hepatitis B disease, and risk factors associated with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital.

4.1 Research findings

4.1.1 Pretest results

Pretesting of the questionnaire was conducted at Oli health center IV located 3 kilometers from Arua district. A total of 40 participants consented participation in the pretest study. From the 40 questionnaires administered during the pre-test exercise to help revise poorly structured questionnaires, the CVI was calculated for each section of the questionnaire. The CVI for the sections of socio-demographic characteristics, knowledge, and risk factors for hepatitis B disease were 0.970, 0.950, and 0.956, respectively. This showed excellent reliability of the research instruments in all sections of the questionnaire.

4.1.2 Social demographic characteristics of the study participants.

Of the three hundred and forty- one (341) participants who agreed to participate in the study, none was excluded from the study due to incomplete filling of the questionnaire. All participant's information was filled in and the participants sought clarity when they needed to. It should be noted that none of the participant's pulled out of the study after consenting participation.

The study assessed a number of social demographic characteristics which were thought to have an effect either on the knowledge or would expose the participants to the risk factors of hepatitis B disease. These social demographic characteristics include the age, education status, marital status, employment status, gestational stage, and parity stage. Each of the participants was required to give an independent and accurate description of their social demographic characteristics before proceeding to the next section of the questionnaire which regarded the knowledge and risk factors of hepatitis B disease. Participants were free to ask for clarification in case they were not sure of the responses and in some cases, the gestation stage was picked from the participant files where a trained health worker had earlier assessed them and indicated on the client file.

The most common age group was 16-24 years old, which represented 49.3 percent of the participants, followed by 25-34 years old, which represented 43.6 percent of the study's participants. Participants of the age between 35 and 44 years represented 6.7% of the total sample size of those who consented participation in the study. None of the participants was of the age of 45 years.

Regarding the maximum education attained, participants with an education background of primary school were 54.5% while those who attained 29.9% had attained an education up to secondary school while only 11.4% had completed either a tertiary institution or university. Only 4.1% of the participants had not attended school.

The employment status of the participants was evaluated on the fronts of either being employed, unemployed or being a student. Unemployed participants contributed to 76% of the participants of the study while 20.9% of the participants responded to being employed in some form either self-employed or having work. A total of 3.2% of the participants responded to be students and had not yet sought employment at the time due to their occupation.

Majority (69.8%) of the participants were in monogamous relationship with no known other partners from their spouses while 26.4% were in known polygamous relationships. A total of 3.8% of the participants responded to being unmarried in any form either culturally, legally or even cohabiting with their partners.

Regarding the gestational stage of the participants, those who were in the second trimester (14 to 27 weeks pregnant) contributed to a total of 58.7% of the participants in the study. Those in the third trimester (over 28 weeks of pregnancy) contributed to 31.7% of the participants while those in the first trimester contributed to only 9.7% of the participants.

Parity status was to access if participants had been exposed to the antenatal stage before and a total of 46.3% of the pregnant mothers assessed were multigravidas i.e., they had more between 2-4 pregnancies including the one they currently had. Prima gravidas (mothers who had only one conception so far) accounted to 40.2% of the participants while the grand multigravidas (Mothers who had over 5 pregnancies before accounted for 13.5% of the participants.

Table 1:

Participants' social and demographic characteristics in the knowledge and risk factor study among women attending antenatal care at Arua Regional Referral Hospital.

Characteristic	Variable	Frequency, n	Percentage
Age	<15 years	2	0.6%
	16-24 years	168	49.3%
	25-34 years	148	43.4%
	35-44 years	23	6.7%
	> 45 years	0	0.0%
Education Status	Not attended school	14	4.1%
	Primary School	186	54.6%
	Secondary School	102	29.9%
	University/Tertiary Institution	39	11.4%
Employment Status	Unemployed	259	76.0%
	Employed	71	20.8%
	Student	11	3.2%
Marital Status	Unmarried	13	3.8%
	Monogamy	238	69.8%
	Polygamy	90	26.4%
Gestational Stage	1-13 weeks	33	9.7%
	14-27 weeks	200	58.6%
	>28 weeks	108	31.7%
Parity Status	Primipara (1st Child)	137	40.2%
	Multipara (2-4 Children)	158	46.3%
	Grand multipara (>4 Children)	46	13.5%

Note: A total of 341 participants consented participation in the study

4.1.2 Knowledge of hepatitis B disease

The section of knowledge of hepatitis B disease had a total of 12 questions which ranged from questions which included basic questions on knowledge of how hepatitis B disease is spread, the symptoms of hepatitis B disease, questions on the knowledge of the risk factors of hepatitis B

disease and how to prevent the spread of hepatitis B disease. Participants were required to give a response to the questions but had an option of leaving the question blank if they were not sure of the answer. However, all the participants were able to complete the entire set of questions (all 12 questions) in the section to assess the knowledge of hepatitis B disease.

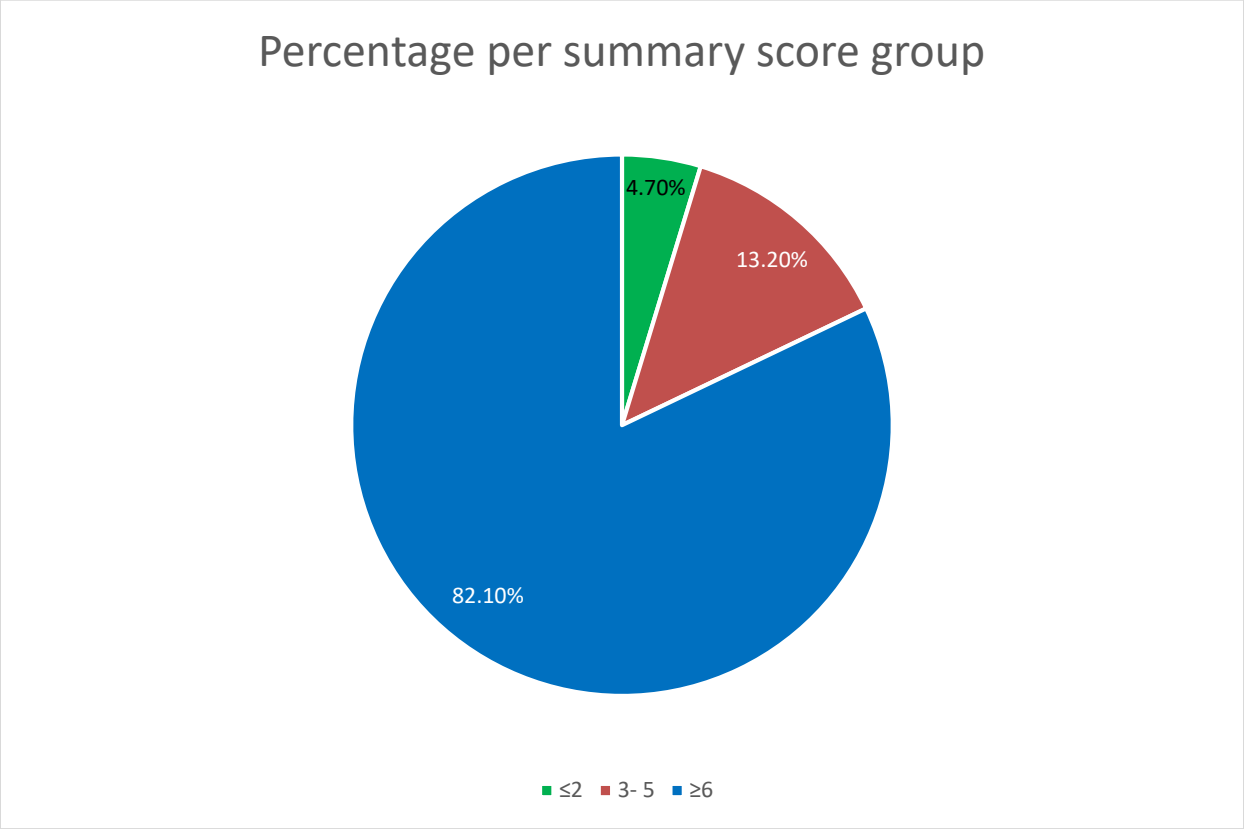
The questions in this section were closed ended questions which required a response or either yes, no or I do not know for each of the questions. Participants who had a correct response were awarded a score of 1 for each score while those who scored a wrong response, or I do not know response were scored zero (0) for that particular question.

Participants were considered knowledgeable if they scored ≥ 6 summary score of the 12 questions in the knowledge section. This accounts to a participant who scored at least 50% in the section to evaluate the knowledge of hepatitis B disease of the participants. Out of the 341 participants in the study, only 16 (4.7%) had inadequate knowledge of hepatitis B disease having ≤ 2 summary score in the section of knowledge while 45 (13.2%) had intermediate knowledge having 3-5 summary score in the section of knowledge in the questionnaire. Two hundred and eighty (280) participants accounting to 82.1% had a summary score ≥ 6 in the section of knowledge. The total of 61 (17.9%) of the 341 participants were hence considered with poor knowledge by adding up those with inadequate and intermediate knowledge scores regarding hepatitis B disease given that they scored < 6 in the section of hepatitis B which is considered the cutoff for being knowledgeable.

Some of the participants were not aware of some basic information including how hepatitis B disease is spread or even the symptoms of hepatitis B disease. The most failed question was the question that evaluated if hepatitis B disease was a virus and most of the participants responded I do not know.

Figure 2:

The percentage per summary score group of a study of knowledge of hepatitis B disease among women attending antenatal care at Arua Regional Referral Hospital.



Note. ≤2 Score =16 participants, 3-5 Score =45 participants, ≥6 Score =280 participants. N= 341

4.1.3 Prevalence of HBsAg

The prevalence of hepatitis B disease was determined by testing for HBsAg from the blood drawn from the participants by a qualified laboratory technician or assistant who was stationed at the antenatal care unit at Arua Regional Referral Hospital. Only participants who showed 2 bands on the test and control part of the test kit were regarded positive. A negative test was when only one band showed on the test part of the test kit while those test kits that showed no band or only one band in the test part and none in the control area of the test kit was considered inconclusive or rejected. It should also be noted that all new packs of the used test kits had a quality control test conducted before mass testing using the same tests using known samples of both negative and positive samples. All test kits pack which were bought passed the quality control tests and were viable to be used.

HBsAg positivity in pregnant women who participated in the study was found to be 2.05 percent. (95% CI: 0.5-3.5). This represents 7 of the 341 mothers who returned a positive test of HBsAg. This is below the national prevalence of 4.3 percent hence representing a relatively healthy population (Ministry of Health, 2018).

Table 2*:*

HBsAg prevalence among women attending antenatal care at Arua Regional Referral Hospital.

HBsAg test result	Frequency, n	Percentage (95% CI)
Positive	7	2.05% (0.5-3.5%)
Negative	336	97.95%
Total	**341**	**100%**

Note: A total of 341 participants consented participation in the study

4.1.4 Risk factors associated with HBsAg.

The final part of the questionnaire assessed the available risk factors of hepatitis B disease among the participants who participated in the study. Risk ratios were used to determine of a risk factor or social demographic characteristics which are associated with hepatitis B disease. This was done in 2 parts by using the responses of the social demographic characteristics which were thought to affect the knowledge to participate in the risk factors. The second part was to assess availability of the risk factors which include if participants had had any past unsafe surgeries, had been exposed to unsafe abortions, had been to unsafe blood transfusion, had body tattoos, had any body piercings, number of past sexual partners, having had a presence of past episodes of having a sexually transmitted infections/diseases and the consistence of condom use.

This section had only eight questions each evaluating the presence of the eight assessed risk factors. Participants were required to respond either open ended or closed ended questions in this section depending on the question that evaluated the risk factor. All participants were able to answer all the required eight questions in this section.

Only social demographic characteristics or risk factors which had a p- value of less than 0.005 were to be considered significantly associated to hepatitis B positivity.

According to the study's findings, the relationship between hepatitis B disease and the assessed social demographic characteristics of age, education status, employment status, marital status,

gestational stage, and parity was found to be above the P value of 0.005. This indicated that none of the characteristics showed a significant statistical relationship with hepatitis B disease.

Table 3:

Association of social demographic characteristics with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital.

Social demographic characteristics	Risk Ratio	P value	95% CI
Age			
<15 years	1.000	Reference	Reference
16-24 years	0.537	0.585	0.057-5.020
25-34 years	0.301	0.336	0.026-3.464
35-44 years	1.000		
> 45 years	1.000		
Education status			
Not attended school	1.000	Reference	Reference
Primary	1.267	0.829	0.148-10.828
Secondary	1.000		
University/Tertiary Institution	1.000		
Employment status			
Unemployed	1.000	Reference	Reference
Employed	0.602	0.641	0.071-5.087
Student	1.000		
Marital Status			
Unmarried	1.000	Reference	Reference
Monogamy	0.496	0.365	0.109-2.260
Polygamy	1.000		
Gestational Stage			
1-13 weeks (1st Trimester)	1.000	Reference	Reference
14-27 weeks (2nd Trimester)	0.714	0.633	0.157-3.251
>28 weeks (3rd Trimester)	1.000		

Social demographic characteristics	Risk Ratio	P value	95% CI
Parity			
Primipara (1st Child)	1.000	Reference	Reference
Multipara (2-4 Children)	0.573	0.545	0.094-3.478
Grand multipara (>4 Children)	2.030	0.446	0.329-12.547

Note: A total of 341 participants consented participation in the study

Although the eight risk factors showed some level of association with hepatitis B positivity, the relationship between hepatitis B disease and of the assessed risk factors in women attending antenatal care at Arua Regional Referral Hospital were not statistically significant since only risk factors with a P<0.005 were considered to have significant association with hepatitis B disease.

Table 4:

Association of assessed risk factors with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital

Risk Factor	Number (%)	Positive, n	Risk Ratio (95% CI)	P-Value
Past Surgery			**0.967 (0.112-8.031)**	**0.960**
Yes	51 (14.96)	1		
No	290 (85.04)	6		
Blood Transfusion			**1.00**	**1.000**
Yes	38 (11.14)	0		
No	303 (88.86)	7		
Abortions			**1.00**	**1.000**
Yes	94 (27.57)	0		
No	247 (72.43)	7		
Body Piercings			**1.032 (0.122-8.756)**	**0.977**
Yes	291 (85.34)	6		
No	50 (14.66)	1		
Tattoos			**0.713 (0.136-3.732)**	**0.689**
Yes	122 (35.78)	2		
No	219 (64.22)	5		

Risk Factor	Number (%)	Positive, n	Risk Ratio (95% CI)	P-Value
Past STIs			**0.473 (0.091-2.474)**	**0.375**
Yes	155 (45.45)	2		
No	186 (54.55)	5		
Sexual Partners			**0.48 (0.196-14.498)**	**0.633**
≥5	31 (9.09)	1		
<5	310 (90.91)	6		
Condom Use			**1.00**	**1.000**
Inconsistently	322 (94.43)	7		
Consistently	19 (5.57)	0		

Note: A total of 341 participants consented participation in the study

4.2 Discussions of results

Given the increased likelihood of an infected child who has acquired the virus via vertical transmission to progress to chronic stages of the disease, understanding the potential risk factors associated with hepatitis B disease in each population is critical. This will enable more targeted interventions by Ministry of Health and hospital management in health promotion and education.

The participant social characteristics showed that most of the pregnant women attending antenatal care at Arua Regional Referral Hospital were aged between 16 to 24 years, the education background was primary school, had an employment status of unemployed, were in monogamous relationships as the marital status, were in the 2nd trimester of pregnancy and the parity status was multi para gravidas (had between 2 to 4 pregnancies) in their lifetime.

The age distribution is consistent with the national census that indicated that most of the Uganda's population are youth between the age of 16 to 35 years and these account for over 78% of the total population. The participants with ages of 16 to 35 years accounted to a total of 92.7% of the total participants in the study.

The ages of 16 to 34 years are when most girls are both fertile and sexually active which further increases the chances of getting pregnant. Given that Arua Regional Referral Hospital is one of the biggest hospitals in the West Nile region, is a specialized regional referral hospital that offers a high range of services including antenatal care and offers free services since it is a government

hospital, it is estimated that it would attract a population that seeks services there that is depictive of the general population of the surrounding districts and its catchment populations.

The results regarding the education background of the participants that show that majority 54.6% of the participants had a maximum education of primary level were consistent with the results disseminated in the annual statistical abstract by the Uganda Bureau of Statistics (UBOS) that show that 8.8 million students in primary school compared to the secondary and tertiary enrollment which lies at 1,371,000 and 259,000, respectively (Uganda Bureau of Statistics, 2020) . This shows more enrollment in primary section than secondary section and/ or the tertiary enrollment. Given the role out of the Universal Primary Education (UPE) system by the government of Uganda to enhance the education system of the country, several primary schools were constructed across the country to enable access to basic education at no cost. This system has further encouraged parents to enroll their children into the Universal Primary Education system to attain the basic education.

Furthermore, due to the successes registered in the Universal Primary Education system, the government of Uganda rolled out the Universal Secondary Education (USE) where free education was provided for students between S1 to S4 in government secondary schools. Participants who had a maximum of an education up to secondary school contributed to 29.9% of the respondents. This is consistent with the annual statistical abstract by the Uganda Bureau of Statistics which shows major declines between the enrollment of primary schools and secondary schools and further to the tertiary institutions of learning.

Most of the participants (76%) who participated in the study also had an employment status of unemployed. Given the high levels of unemployment in Uganda among the youth, a large amount of the pregnant women do not have any formal employment or are self- employed.

The participants in the 2nd trimester (58.6%) and the 3rd trimester (31.7%) contributed to many of the participants compared to those in the 1st trimester (9.7%). The results are also consistent with other similar studies that indicate that pregnant women obtain antenatal care late in pregnancy as shown in a study in Nigeria where 47% sought antenatal care in the third trimester (Karl P, 2005) . Most pregnant mothers seek antenatal care visits late in their pregnancy due to poor health seeking behaviors, as seen in the study, where only 9.7 percent of all participants were in their first trimester. These poor health seeking behaviors are majorly due to lack of knowledge, cultural and religious beliefs amongst different groups of the population. The need to seek antenatal care early

in the pregnancy is beneficial to both the mother and the unborn baby as many tests would be done to prevent the spread of certain diseases through mother to child transmission, health status of both the mother and the unborn baby but as well as much more information and knowledge is passed on to the mothers regarding the nutritional status and recommendations during pregnancy to ensure that they remain healthy.

The study assessed the knowledge levels of the women who attended antenatal care at Arua Regional Referral Hospital in the 2nd part of the questionnaire. The questions assessed general knowledge of hepatitis B disease, the various ways of how hepatitis B disease is spread, the risk factors of hepatitis B disease and the ways to prevent the spread of hepatitis B disease.

This section had twelve (12) closed ended questions which required a "yes", "No" or "I do not know" response by each of the participants. Participants who had a correct response were awarded a score of one (1) for each score while those who scored a wrong response, or I do not know response were scored zero (0) for that question. A total score was finally calculated by adding up the scores for each of the 12 questions.

Participants who scored a total of ≤ 2 out of the 12 possible score, were considered to have inadequate knowledge on hepatitis B disease. Those who scored a total score of three (3) to five (5) were considered to have intermediate knowledge on hepatitis B disease. Both the participants who had inadequate knowledge and those who had intermediate knowledge of hepatitis B disease were considered to have poor knowledge of hepatitis B disease. Only participants who got a total score of 6 or more were considered to have adequate knowledge of hepatitis B disease. These were knowledgeable of hepatitis B disease.

From the study, a total of 280 participants (82.1%) exhibited adequate knowledge of hepatitis B disease given that they scored greater or equal to 6 of 12 questions in the questionnaire in the section of knowledge of hepatitis B. A total of 16 participants (4.7%) obtained a total of less or equal to 2 of the 12 possible score hence they had inadequate knowledge. A total of 45 participants (13.2%) scored between 3 to 5 out if the 12 possible scire hence were regarded to have intermediate knowledge of hepatitis B disease.

This knowledge level amongst women attending antenatal care at Arua Regional Referral Hospital can be attributed the previously conducted mass vaccination of hepatitis B disease in high-risk

areas in Uganda that was rolled out in 2015 which saw 23 million adult and adolescents screened for hepatitis B disease and 17.6 million Ugandans vaccinated against hepatitis B. During this exercise health education/promotion was carried out making the population aware of the disease. (Ministry of Health, 2018) .

During this mass vaccination campaign the Ministry of Health in Uganda used a multi-pronged strategy to improve awareness as well as acceptance of people engaging in hepatitis B vaccination. Some of the strategies included routine radio talk shows by health experts to discuss hepatitis B disease, involvement of political, cultural, and religious leaders to sensitize the public in their various spheres, routine mobilization by the vaccination sites, outreach vaccination to reach more people as well, use of Village Health Teams (VHTs) to mobilize the public among many other strategies. These interventions promoted people who turned up for vaccination who were in turn received health education before or after vaccination which increased the knowledge levels of the public.

A study in Beau Cameroon showed that only 16% of pregnant women were knowledgeable on hepatitis B disease which is the reverse of the findings at Arua Regional Referral Hospital (Andreas, Julius, Peter, & Peter, 2014) . Although the pregnant women attending antenatal care at Arua Regional Referral Hospital were mostly knowledgeable about hepatitis B disease, majority of them failed questions that related to the spread and risk factors of hepatitis B disease. This creates an opportunity for ministry of health to engage in other strategies to improve the knowledge of the population in the West Nile region and Uganda as a whole.

Majority of participants who exhibited poor knowledge of hepatitis B disease were those who had low levels of education. These were either had not attended school or had an education level of primary school. This is expected as the education levels usually will affect the knowledge levels of individuals. More targeted support should prioritize this group of people amongst the communities so that they are informed and acquire knowledge on hepatitis B disease. It was also noted that most of the health promotion material on hepatitis B disease was in the English language which limits the people in the low education levels to acquire this information. The ministry of health can produce targeted messages in local languages to ensure that this category of people with low levels of education equally receive the message as those who are well educated.

The prevalence of HBsAg among the pregnant women who participated in the study of 2.05% was below the national prevalence of 4.3% (Ministry of Health, 2018) . This shows a relatively healthy population given that the prevalence is below the national average.

Of the positive cases, it was found out that 86% were both unemployed. This could have contributed to the prevalence since being unemployed will likely have the participants engage in some of the risk factors of hepatitis B disease like tattooing, piercings among others.

Furthermore 86% of the positive cases had an education background of primary school. This is consistent with findings that suggest that low education levels are directly linked to the possibility of participating in risk factors. This lack of knowledge increases the possibility of acquiring disease. The more educated the people, the more likely they are informed and knowledgeable about the symptoms, causes, risk factors and various preventative ways of acquiring disease. The reverse is true regarding the low educated people. Given that most of the promotional material during the recent hepatitis B vaccination campaign were in the English language, it never targeted the low educated individuals who might not be fluent in reading and writing the English language. This could have also contributed to them not acquiring the information and engaging in activities that lead to the spread of hepatitis B disease.

There is need to have health promotion materials in local languages and local media to ensure awareness of the less educated population. However, this prevalence in the study is not conclusive prevalence of the region as the sample size used in the study was from a confined health facility in one district which does not give the general picture of the entire population in the region. More research with larger sample sizes is needed to determine the prevalence of hepatitis B disease among pregnant women in the region. Furthermore, screening all women seeking antenatal care services for HBsAg is encouraged as it was noticed that at Arua Regional Referral Hospital screening was not done due to shortage of test kits prior to the study. This poses a big risk since most of the infected persons will remain asymptomatic. Screening all women attending antenatal care will be a very efficient tool in early disease detection leading to prompt diagnosis, treatment, and other interventions to promote healthier living.

It is important to note that the study was conducted using HBsAg test strips which have lower sensitivity and specificity compared with other tests like the enzyme- linked immunosorbent assay (ELISA) or the Polymerase chain reaction (PCR) tests which are gold standards for the testing

hepatitis B disease. There is a possibility of having missed some positive cases due to the sensitivity of the test used.

Results of the study showed no significant association of any of risk factors assessed with hepatitis B disease. Although there was some association between the assessed risk factors with hepatitis B disease, the P values obtained were not lower that 0.005 which was the cut off point for significant association.

The risk factors assessed were those that expose one to hepatitis B disease through exposure of body fluids that have the highest concentration of the virus i.e., blood, semen, or vaginal secretions. Unsafe abortions, unsafe surgeries, blood transfusion, piercings, tattooing, expose the person to blood since in most cases sharp instruments are used. These are normally not sterilized and once used on another person, they will expose them to the hepatitis B virus. Inconsistent condom use, number of past sexual partners and history to past STIs will expose one to semen or vaginal secretions which are agents of disease transmission.

The results were consistent with the study carried out in the state of Buea, Cameroon which also did not identify any risk factors associated with hepatitis B disease (Andreas, Julius, Peter, & Peter, 2014) . This could be because of the risk factors assessed were not the ones that are significantly associated with hepatitis B disease. The study also assessed each risk factor independent of the other which further reduces the association.

However other studies around the world have been able to identify at least one risk factor associated with hepatitis B disease. These include early sexual activity engagement, a history of STIs, and a history of multiple sexual partners, as identified in a Nigerian study. (Rabiu, Akinola, & Adewunmi, 2010) . In a study conducted in Mexico, blood transfusion was found to be the only risk factor associated with hepatitis B positivity. (Cisneros, Hernández, Ibarra, Fernandez, & Escobedo, 2001) . In a study conducted in Rakai, Uganda in 2011, HIV status, older age and serologic syphilis were significantly associated with hepatitis B infection (Lara, et al., 2011) . Each population is always perceived to have a specific risk factor to a disease which explain the results in these studies. However, not finding a risk factor to a hepatitis B disease does not mean that there is no risk factor associated with hepatitis B disease.

The failure to identify a potential risk factor associated with hepatitis B disease could be because not all risk factors associated with hepatitis B positivity were evaluated, and none of the evaluated risk factors are associated with hepatitis B disease in this population. Additional to this, the study assessed each of the individual risk factors independently while it could have been possible that the if assessed these were assessed dependently on the other risk factors, the possibility of finding risk factors associated with disease would increase. Furthermore, using a small sample size determined for the use of prevalence rather than identifying risk factors could be one of the reasons why the study could not significantly identify a potential risk factor associated with hepatitis B positivity.

Among women attending antenatal care at Arua Regional Referral Hospital, none of the assessed participants' social demographic characteristics were associated with HBsAg positivity. Results of a similar study in Buea, Cameroon, found no significant association of the participant's social demographic characteristics to hepatitis B disease (Andreas, Julius, Peter, & Peter, 2014) .

Several limitations must be considered when interpreting these findings. The number of participants who agreed to participate in the study (341) was less than the calculated sample size of the study (384). This could have influenced the study's prevalence. Furthermore, the study used HBsAg as a marker for hepatitis B infection, which is unreliable when used alone. Other hepatitis B Virus markers exist and, when combined with HBsAg, would be more reliable.

Furthermore, enzyme- linked immunosorbent assay (ELISA) and Polymerase Chain Reaction (PCR) tests which are more sensitive than rapid tests for hepatitis B disease were not used, which may have resulted in an underestimation of the prevalence of hepatitis B disease. The study also only looked at the prevalence of HBsAg among women who had visited antenatal care at Arua Regional Referral Hospital during the time of data collection.

This does not provide a generalization of the country's prevalence. Given the study's cross-sectional design, it is impossible to rule out any cause-effect relationship between the factors assessed and HBsAg positivity. Additionally, due to social desirability bias and recall bias from self-reported knowledge, this has limitations in and of itself because the information provided by participants cannot entirely be relied on.

CHAPTER FIVE: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.0 Introduction

This chapter includes the summary of the findings of the study, conclusion, and recommendations about the study.

5.1 Summary of results

A total of 341 pregnant women consented to participation which was below the required 384 participants but gave a significant proportion of the sample at 89% participation. Of those who participated in the study, 92.7% were aged 16 to 34 years old, 76% were unemployed, 69.8% were in monogamous relationships, 54% had at most primary level of education, 58.6% were in their 2nd trimester of pregnancy while 46.3% were multi para gravidas.

Poor knowledge of hepatitis B disease was found in only 17.9% of participants of the study who scored less than 6 of the 12 questions in the questionnaire about hepatitis B disease. Most of the participants 82.1% exhibited good knowledge of hepatitis B disease having scored ≥6 of the 12 questions in the questionnaire about hepatitis B disease. Although the participants showed a great extent of knowledge on hepatitis B disease, most of the participants failed the questions regarding risk factors, spread and prevention of hepatitis B disease. Also, most of the participants who had low levels of education failed most of the questions. This lack of knowledge amongst the low educated participants raises more concerns about interventions regarding health promotion and education which need to be interpreted from the usual English language to the local languages which are well understood by uneducated population. Furthermore, the integration of health education of hepatitis B disease in the routine outreaches by the hospital will go a long way in reaching a desired number of people who could still be unaware of disease. The need for health education and promotion materials displayed at strategic points within the hospital and the community in both English and local languages is vital in ensuring that those who have limited knowledge are reached.

An HBsAg prevalence of 2.05% among women attending antenatal care at Arua Regional Referral Hospital was found among the participants. This is below the national prevalence of 4.3% probably because of government interventions of mass immunization and health promotion which were recently conducted in 2017. However, it was realized that 86% of the positive cases were from participants with low education backgrounds (At most primary school). Furthermore, 86% of the

positive cases of HBsAg were unemployed which might have as well contributed to them engaging in activities which promoted the spread of disease. Low education levels might have contributed to the participants engaging in activities that might have put them at risk of acquiring hepatitis B disease. Likewise, being unemployed means having a lot of free time to engage in a lot of activities that could lead to the spread of disease. Although both unemployment and low education levels might have contributed to the spread of disease, they were not significantly associated to the spread of hepatitis B disease in the study population since the P- value was above 0.005 for both. It is important to note that enzyme- linked immunosorbent assay (ELISA) and Polymerase Chain Reaction (PCR) tests which are more sensitive than rapid tests for hepatitis B disease were not used, which may have resulted in an underestimation of the prevalence of hepatitis B disease. The study also only looked at the prevalence of HBsAg among women who had visited antenatal care at Arua Regional Referral Hospital during the time of data collection. This prevalence is not depictive of the prevalence of the entire population as it only considered only women attending antenatal care at Arua Regional Referral Hospital.

It is also important to note that the routine testing of hepatitis B disease amongst the pregnant women attending antenatal care at Arua Regional Referral Hospital was not done due to the unavailability of test kits that are required for testing. This gives a chance for missed opportunities to enroll the positive cases into routine hepatitis B disease routine care hence reducing the chances of mother to child transmission.

The study assessed the association of the social demographic characteristics of the participants with hepatitis B disease. These social demographic characteristics included the age, education status, marital status, employment status, gestational stage, and parity stage of the participants. None of the assessed social demographic characteristics were significantly associated with hepatitis B disease. This was because none had a $P<0.005$ association with HBsAg positivity. Although both unemployment and low education levels might have contributed to the spread of disease, they were not significantly associated to the spread of hepatitis B disease in the study population since the P- value was above 0.005 for both with P- values of 0.641 and 0.829 respectively after analysis.

Among the risk factors studied (presence of body piercings, presence of tattoos, history of unsafe abortions, history of blood transfusion, history of past sexually transmitted infections (STI),

number of past sexual partners, consistent condom use), none of these risk factors was found to be statistically significantly associated with HBsAg positivity in women attending antenatal care at Arua Regional Referral Hospital. This was because none had a P<0.005 association with HBsAg positivity. Not finding a risk factor in the study does not mean that there are no risk factors amongst the population. With the limitations of the study, it is possible that the sample size used was not big enough to identify a risk factor for hepatitis B disease.

5.2 Conclusions

Hepatitis B disease is a global health challenge which has caused significant death and suffering among the population. Most of the people who are infected of hepatitis B disease are not aware of the disease until later in life when then progress to the chronic stage which is fatal stage. If left untreated, it could progress to the chronic stage which is characterized by liver cirrhosis and liver cancer.

Mother to child transmission contributes to over 50% of all new hepatitis B new infections worldwide and children aged below 5 years who often acquire the infection through mother to child transmission or earlier in life have a 90% chance of progressing to the chronic stage compared to those who acquire the disease later in life. Chronic hepatitis B disease which manifests in liver cirrhosis and liver cancer is hard and expensive to treat and most often will lead to death of the patient.

The study assessed the prevalence of HBsAg amongst the participants, the knowledge levels of hepatitis B disease amongst the participants as well as the risk factors of hepatitis B disease amongst the participants who consented to participate in the study.

The study participants were knowledgeable to a great extent about hepatitis B disease with 82.1% of the participants scoring greater or equal to 6/12 of the questions to test knowledge of hepatitis B disease. There are gaps in knowledge especially among the low educated groups which need to be addressed to improve knowledge levels in the community.

The results show a relatively healthy population given the low prevalence of 2.05% as seen in the participants of the study. However, 86% of the positive cases of HBsAg in the study had a maximum education level of primary school. Furthermore, 86% of the positive cases of HBsAg were unemployed which might have as well contributed to them engaging in activities which

promoted the spread of disease. This creates a need to have the specific interventions to target the population with low levels of education and the unemployed group to reduce the spread of hepatitis B disease.

None of the assessed social demographic characteristics were significantly associated with hepatitis B disease. These social demographic characteristics included the age, education status, marital status, employment status, gestational stage, and parity stage of the participants. This is because none of the assessed risk factors had a P- value of less or equal to 0.005 which shows significant association.

None of the assessed risk factors was significantly associated with hepatitis B disease. This is because none of the assessed risk factors had a P- value of less or equal to 0.005 which shows significant association. The absence of a risk factor associated with hepatitis B disease in this study does not imply that there are no risk factors in the community around Arua Regional Referral Hospital. The small sample size could be one of the reasons for the observed results or the fact that not all risk factors of hepatitis B disease were assessed in the study which could have been significantly associated with hepatitis B disease. However, further studies with bigger sample sizes will be required to assess more potential risk factors associated with hepatitis B disease and the prevalence among women attending antenatal care at Arua Regional Referral Hospital.

Ensuring that mother to child transmission which is likely to cause nearly more than 90% of all chronic infections in children is prevented, multi-pronged strategies should be used to increase the knowledge of women in the communities especially the pregnant women on hepatitis B disease which will ensure that they do not engage in activities that expose them to hepatitis B disease hence eventually keeping the prevalence of hepatitis B disease low. Quick identification of the positive cases

5.3 Recommendations

Hepatitis B disease being a highly infectious disease caused by exposure of contaminated fluids from one person to another has contributed to mother to child transmission. The mother to child transmission has contributed to over 50% of cases and children who acquire hepatitis B disease before the age of 5 years have a 90% chance of progressing to chronic hepatitis B disease.

Given that most of the mothers are not aware of their status and lack knowledge on the risk factors, preventative measures, symptoms, the possible ways of getting treatment and vaccination, this has fueled the spread from the mothers to the newly born babies up to the age of 5 years. Chronic hepatitis B disease which manifests in liver cirrhosis and liver cancer is hard and expensive to treat and most often will lead to death of the patient. The study assessed the knowledge and risk factors of hepatitis B disease among the pregnant women attending antenatal care at Arua Regional Referral Hospital.

The study found out the women attending antenatal care were knowledgeable given that 82.1% exhibited good knowledge of hepatitis B disease. The need to keep the pregnant women informed about the various ways of acquiring hepatitis B disease, symptoms of hepatitis B disease and the testing and treatment options available will help the pregnant women empowered not to participate in risk factors of hepatitis B disease hence increasingly preventing Mother to Child Transmission. The results also suggested that majority of the women were having low education levels and unemployed and did not pass the questions regarding risk factors or the spread of hepatitis B disease despite the recent mass vaccination campaign where mass health education and health promotion was carried out. Majority of the material used in the mass vaccination campaign was in the English language and there is a need to have more health education and health promotion activities in local languages to reach the greatest percentage of women who are unemployed and having a low education background. Integrating hepatitis B disease health education in the routine antenatal care visits just like other sexually transmitted diseases including HIV and nutrition is key in building awareness of the pregnant women so that they do not put the unborn baby in danger of acquiring hepatitis B disease through mother to child transmission.

The study found a low prevalence of HBsAg (2.01%) among the women attending antenatal care which was below the national average of 4.3% (Ministry of Health, 2018) . There is need to conduct more studies routinely to determine the prevalence of hepatitis B disease in the community. Ministry of Health needs to set up mechanisms to ensure continued prevention, early testing and detection and treatment of hepatitis B disease amongst the population to ensure low prevalence. However, it was realized that 86% of the positive cases were from participants with low education backgrounds (at most primary school). Furthermore, 86% of the positive cases of HBsAg were unemployed which might have as well contributed to them engaging in activities

which promoted the spread of disease. Low education levels might have contributed to the participants engaging in activities that might have put them at risk of acquiring hepatitis B disease. It is recommended that health education and health promotion is conducted in local languages with this background to reach more women in the community so that they do not engage in risk factors that would put them at risk of acquiring hepatitis B disease.

It is also recommended that routine testing of hepatitis B disease among all pregnant women attending antenatal care is conducted to identify the positive cases of hepatitis B disease to be enrolled into routine hepatitis B disease care and treatment. This will prevent mother to child transmission. Also having the hepatitis B vaccine available and administered at birth to all newly born babies as guided by the Uganda vaccination schedule will go a long way in preventing mother to child transmission.

It is important to note that enzyme- linked immunosorbent assay (ELISA) and Polymerase Chain Reaction (PCR) tests which are more sensitive than rapid tests for hepatitis B disease were not used, which may have resulted in an underestimation of the prevalence of hepatitis B disease. The study also only looked at the prevalence of HBsAg among women who had visited antenatal care at Arua Regional Referral Hospital during the time of data collection. This prevalence is not depictive of the prevalence of the entire population as it only considered only women attending antenatal care at Arua Regional Referral Hospital. Broader studies with bigger sample sizes and more facilities are recommended to ascertain the exact prevalence of hepatitis B disease among the pregnant women attending antenatal in the West Nile region and Uganda as a whole. Finding the prevalence per category and community will help direct resources to inform testing, treatment as well as prevention interventions in Uganda.

The study did not find any of the assessed social demographic characteristics which included the age, education status, marital status, employment status, gestational stage, and parity stage of the participants significantly associated with hepatitis B disease. Although it is known that having many sexual partners is a risk factor to acquiring hepatitis B disease, the study did not find being in a polygamous relationship as a risk factor to hepatitis B disease. The need to evaluate more social demographic characteristics would be key in identifying one or more that are significantly associated with hepatitis B disease.

The study did not find any risk factors of hepatitis B disease that were significantly associated with HBsAg. This does not mean that there are no risk factors associated with hepatitis B disease among women attending antenatal care at Arua Regional Referral Hospital since the study did not investigate all possible risk factors of hepatitis B disease. More studies investigating wider ranges of risk factors using bigger sample sizes are recommended. This will help identify at least one risk factor which is significantly associated with hepatitis B disease.

Similar studies are recommended in other parts of the country to identify various risk factors associated to hepatitis B disease. This is because different populations usually have different risk factors given the different cultural and social beliefs among the communities. This would help identify specific interventions depending on the risk factor to target health education and health promotion. This would also help direct the required resources by the government in the bit to have early detection, testing, prevention, and treatment of hepatitis B disease.

Ensuring that mother to child transmission which is likely to cause nearly more than 90% of all chronic infections in children is prevented, multi-pronged strategies should be used to increase the knowledge of women in the communities especially the pregnant women on hepatitis B disease. Having health education and health promotion material in local languages is key in increasing the knowledge of this population in the communities. Integrating this health education and health promotion of hepatitis B disease in routine antenatal care visits is also a key strategy to increase the knowledge levels amongst the pregnant women just like how nutrition and HIV are integrated in the antenatal care visits.

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APPENDIX

Appendix I: Consent form

I am **Benjamin Atwine** a student at Mount Kenya University Reg. No. MPH/2017/63226 and a member of the research team that is conducting a study that will assess knowledge and risk factors associated with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital.

Purpose of the study: This study is to assess the knowledge and risk factors associated with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital.

Study Procedures: The study requires you to allow me to ask you questions about hepatitis B disease and about risk factors associated to hepatitis B disease. You will also be required to provide 3mls of blood which will be used in the test for Hepatitis B Surface Antigen (HBsAg). Results for this test will be shared with you once they are back after 5 minutes and Proper counselling given.

Benefits: There are no direct benefits for participating in the study. However, you and others may benefit in future as findings will be shared with hospital management and Ministry of Health and this will contribute to improvement of awareness of hepatitis B disease if knowledge gaps are found.

Risk: There is no risk that shall be posed to you because of participating in the study.

Participant right to refuse to participate in the study: You have the right to refuse to participate in this study or to withdraw at any time. Your refusal to participate or withdraw shall not affect the health care you receive now or in the future. This study's participation is entirely voluntary.

Confidentiality: This study's findings will be kept strictly confidential and will only be used for this research.

Your identity will be safeguarded by using name initials and codes rather than your full name.

Queries and Problems: In case of any questions regarding the study, you may ask now or contact.

Benjamin Atwine (Principal Investigator)

MPH/2017/63226

0773877849

benatwiine@gmail.com

Statement of Consent

I have clearly read and understood all that has been explained to me; that the study to assess knowledge and the risk factors associated with HBsAg positivity among women attending antenatal care at Arua Regional Referral Hospital shall help in improvement of policies in health education and promotion about hepatitis B disease. No risk shall be posed to me. Therefore, I accept to with my own free will to participate in the study on.

Participant signature

……

Date

……

Signature of the Researcher

……

Date

……

Or

Thumbprint incase the participant cannot read or write.

Appendix II: Research questionnaire

Code of respondent: ……

HBsAg Test result: …….

INSTRUCTIONS: Circle the correct response

Questions on social demographic data

1. Indicate the age of the respondent.

   a. <15 years
   b. 16-24 years
   c. 25-34 years
   d. 35-44 years
   e. > 45 years

2. Indicate the latest education level completed by the respondent.

   a. Not attended school
   b. Primary
   c. Secondary
   d. University/Tertiary Institution

3. Employment status of the respondent

   a. Unemployed
   b. Employed
   c. Student

4. Marital status of the respondent

   a. Unmarried
   b. Monogamy
   c. Polygamy

5. Gestational stage of respondent

   a. 1-13 weeks

b. 14-27 weeks

c. >28 weeks

6. Number of live births by the respondent

a. Primipara (1st Child)

b. Multipara (2-4 Children)

c. Grand multipara (>4 Children)

Questions on Knowledge of Hepatitis B Disease

1. Is hepatitis B a virus?

a. Yes
b. No
c. I Don't Know

2. Does hepatitis B affect the liver?

a. Yes
b. No
c. I Don't Know

3. Can hepatitis B be transmitted through use of unsterilized needles and surgical material?

a. Yes
b. No
c. I Don't Know

4. Can hepatitis B be transmitted by contaminated blood and blood products?

a. Yes
b. No
c. I Don't Know

5. Is hepatitis B transmitted through unsafe sex?

a. Yes
b. No
c. I Don't Know

6. Can hepatitis B be transmitted from mother to baby?

a. Yes
b. No
c. I Don't Know

7. Can an infected person remain without symptoms?

a. Yes
b. No
c. I Don’t Know

8. Can hepatitis B affect any person?

a. Yes
b. No
c. I Don’t Know

9. Will an infected person remain infected for life?

a. Yes
b. No
c. I Don’t Know

10. Are babies that are infected at or around the time of delivery at high risk for eventual complications of liver cirrhosis or liver cancer?

a. Yes
b. No
c. I Don’t Know

11. Can hepatitis B infection cause liver cancer?

a. Yes
b. No
c. I Don’t Know

12. Can hepatitis B be prevented by vaccination?

a. Yes
b. No
c. I Don’t Know

Questions on Risk Factors of hepatitis B disease

1. Have you had any past surgeries?

a. Yes
b. No

2. Have you had any past blood transfusion?

a. Yes
b. No

3. Have you had any abortions in the past?

a. Yes
b. No

4. Do you have any piercings on your body?

   a. Yes
   b. No

5. Do you have any tattoos?

   a. Yes
   b. No

6. Have you suffered from a Sexually Transmitted Infection (STI) in the past?

   a. Yes
   b. No

7. How many sexual partners have you had in the past?

   a. <5
   b. >5

8. How often do you use condoms during sexual intercourse?

   a. Consistently
   b. Inconsistently

Appendix III: MKU Ethics and Research Committee clearance letter- Original Letter

Mount Kenya University

REF: **MKU/ERC/1351**
TO: **BENJAMINE ATWINE**

REG: **MPH/2017/63226**

Date: 20 September 2019

Dear Sir/Madam,

RE: KNOWLEDGE OF RISK FACTORS OF HEPATITIS B DISEASE AMONG WOMEN ATTENDING ANTENATAL CARE AT ARUA REGIONAL REFERRAL HOSPITAL, UGANDA

This is to inform you that **Mount Kenya University** has reviewed and approved your above research proposal. Your application approval number is **755.** The approval period is **19/09/2019 – 18/09/2020.**

This approval is subject to compliance with the following requirements;

i. Only approved documents including informed consents, study instruments, MTA will be used
ii. All changes including amendments, deviations and violations are submitted for review and approval by **Mount Kenya University**
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **Mount Kenya University** within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affect the safety or welfare of study participants and others or affect the integrity of the research must be reported to **Mount Kenya University** within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions
vi. 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
vii. Submission of an executive summary report within 90 days upon completion of the study to **Mount Kenya University**

Prior to commencing your study, you will be expected to obtain a research license and other clearances needed from relevant government authorities in the country where the study will be undertaken and data collected.

Yours sincerely,

The Chairman
Mount Kenya University
Ethics Review Committee
P. O. Box 342 - 0100, Thika

Prof. Francis W. Muregi
Chairman, Mount Kenya University IERC

Appendix IV: MKU Ethics and Research Committee clearance letter- Corrected version

Mount Kenya University

REF: **MKU/ERC/1351** Date: 16 January 2020
TO: **BENJAMIN ATWINE** REG: **MPH/2017/63226**

Dear Sir/Madam,

RE: KNOWLEDGE AND RISK FACTORS OF HEPATITIS B DISEASE AMONG WOMEN ATTENDING ANTENATAL CARE AT ARUA REGIONAL REFFERAL HOSPITAL, UGANDA.

This is to inform you that **Mount Kenya University** has reviewed and approved your above research proposal. Your application approval number is . The approval period is **16/01/2020 – 15/01/2021.**

This approval is subject to compliance with the following requirements;

i. Only approved documents including informed consents, study instruments, MTA will be used
ii. All changes including amendments, deviations and violations are submitted for review and approval by **Mount Kenya University**
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **Mount Kenya University** within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affect the safety or welfare of study participants and others or affect the integrity of the research must be reported to **Mount Kenya University** within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions
vi. 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
vii. Submission of an executive summary report within 90 days upon completion of the study to **Mount Kenya University**

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

The Chairman
Mount Kenya University
Ethics Review Committee
P.O Box 342 - 0100, Thika

Prof. Francis W. Muregi
Chairman, Mount Kenya University IERC

Main Campus, General Kago Road, P.O. Box 342-01000 Thika. Tel: +254 67 2820 000,
Cell: +254 720 790 796, 0709 153 000

Appendix V: The AIDS Support Organization (TASO) Uganda Research and Ethics Committee clearance letter

The AIDS Support Organisation (TASO) Uganda Ltd.

TASO Headquarters
Mulago Hospital Complex
P.O. Box 10443, Kampala-Uganda
Tel: +256 414 532 580/1
Fax: +256 414 541 288
Email: mail@tasouganda.org
Website: www.tasouganda.org

TASO COLLEGE OF HEALTH SCIENCES (TACHS)
Kanyanya Off Gayaza-Road,
After Mpererwe
P.O. Box 10443, Kampala
Tel: +256 414 567 637
Fax: +256 414 566 704
Email: training@tasouganda.org

SERVICE CENTRES

TASO ENTEBBE
Plot 15-17 Lugard Avenue
P.O. Box 235, Entebbe
Tel: 0414 320 030/0752 774 135
Email: entebbe@tasouganda.org

TASO GULU
Plot 4 Mathew Lukwiya Road
P.O. Box 347, Gulu
Tel: 0471 432743/ 0752 774142
Email: gulu@tasouganda.org

TASO JINJA
Jinja Referral Hospital
P.O. Box 577, Jinja
Tel: 0393260 117/0752 774 145
Fax: 0434 120382
Email: jinja@tasouganda.org

TASO MASAKA
Masaka Hospital
P.O. Box 1679, Masaka
Tel: 0392 749 998/0752 774 145
Email: masaka@tasouganda.org

TASO MASINDI
Masindi Hospital
P.O. Box 117, Masindi
Tel: 0465 420 636/ 0752 774 144
Fax: 0465 420 636
Email: masindi@tasouganda.org

TASO MBALE
Mbale Hospital
P.O. Box 2250, Mbale
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Fax: 0454 435 851
Email: entebbe@tasouganda.org

TASO MBARARA
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Fax: 0485 421 323
Email: mbarara@tasouganda.org

TASO MULAGO
Mulago Hospital
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Fax: 0414 541 288
Email: mulago@tasouganda.org

TASO RUKUNGIRI
Ishasha Road
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Fax: 0486 442 613
Email: rukungiri@tasouganda.org

TASO SOROTI
Soroti Hospital
P.O. Box 422, Soroti
Tel: 0454 461 380/0752 774 143
Fax: 0454 461 042
Email: soroti@tasouganda.org

TASO TORORO
Plot 30, Cox Road
P.O. Box 777, Tororo
Tel: 0454 442 009/0752 774 140
Fax: 0454 445 334
Email: tororo@tasouganda.org

DISCRETE PROJECTS

GRANTS MANAGEMENT UNIT / GLOBAL FUND
House of Hope, Plot 10
Windor Loop
P.O. Box 10443, Kampala
Tel: 0414 259 555/ 0752 774 109
Email: mail@tasouganda.org

TASO-KARAMOJA PROJECT
Plot 10, Independence Avenue
P.O. Box 131, Moroto
Tel: 0752 744 792
Fax: 0454 445 334
Email: mail@tasouganda.org

TORORO LABORATORY HUB
P.O. Box 777, Tororo
Tel: 0454 442 009/ 0752 774 723
Fax: 0454 445 334
Email: hub@tasouganda.org

16th October, 2019

Our Ref: TASOREC/074/19-UG-REC-009

Benjamin Atwine,
Mount Kenya University
benatwiine@gmail.com

Dear Benjamin,

RE: RESEARCH APPROVAL, "KNOWLEDGE AND RISK FACTORS OF HEPATITIS B DISEASE AMONG WOMEN ATTENDING ANTENATAL CARE AT ARUA RRH, UGANDA"

Thank you for submitting an initial ethics review of the above-referenced academic proposal.

I am pleased to inform you that your correspondence dated **14th October, 2019** with responses to initial review comments **10th October 2019,** met the requirements for approval.

TASO REC, at its secretariat meeting gave annual approval of the study, effective **16th October 2019,** valid until **15th October 2020.**

Documents reviewed and approved:

Document Type	Date	Version
1. The Study Proposal.	14/10/2019	2.0
2. Informed Consent Form.	14/10/2019	2.0
3. Data Collection Tool.	20/09/2019	1.0
4. TASO REC Research Review Application and DOC of Interest.	25/09/2019	1.0
5. Mount Kenya University Ethics Review Committee approval.	20/09/2019	

Amendments: All proposed amendments to the study (including personnel, procedures, or documents) must be approved by the REC in advance before implementation.
Adverse Events/Unanticipated Problems: it is your responsibility to inform the REC of any adverse consequences to participants that occur in the course of the study.
Site Monitoring Visits: shall be undertaken to verify that only approved procedures are being implemented, to ensure that the rights and welfare of participants are being protected.
Study Reports: It is a requirement by the REC that you submit timely progress reports.
Renewal of the study approval. This should be through submission of the Annual Report and a Continuing Review Application, at least 60 days prior to expiration date.
Protocol documents which contain the REC-stamp (if applicable), must be utilized during recruitment of participants, obtaining informed consent and data collection processes.
Proceed with the registration and final clearance of your study by the Uganda National Council of Science and Technology (UNCST) before commencement.

15 OCT 2020

Yours sincerely,

Dr. Kagimu David, Until:.....
Vice Chairperson, TASO RESEARCH ETHICS COMMITTEE (REC)
CC: Executive Director, TASO (U) Limited
CC: Uganda National Council for Science & Technology (UNCST)

Appendix VI: Arua Regional Referral Hospital Ethics and Research Committee clearance letter

TEL: 047 6420018/0476420246
IN ANY CORRESPONDENCE ON
THIS SUBJECT PLEASE QUOTE:
ARRH /355/1
Email:aruarefhosp@gmail.com

THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH
Arua Regional Referral Hospital
Office of the Hospital Director
P. O. Box 3,
ARUA, Uganda.

22nd January, 2020

Mr. Benjamin Atwine,
Mount Kenya University,
Thika.

Dear Mr. Benjamin Atwine

APPROVAL TO PROCEED WITH DATA COLLECTION FOR YOUR STUDY TITLED "KNOWLEDGE AND RISK FACTORS OF HEPATITIS B DISEASE AMONG WOMEN ATTENDING ANTENATAL CARE AT ARUA REGIONAL REFERRAL HOSPITAL, UGANDA".

I have received your amended proposal on the queries raised in the first proposal. The committee is satisfied with the corrections made and grant you permission to proceed with data collection adhering to the research ethics and principles stated in your proposal.

Make sure that you share with the hospital your findings.

Good luck with the study.

Yours sincerely,

For. HOSPITAL DIRECTOR
22 JAN 2020
ARUA REGIONAL REFERRAL HOSPITAL
P. O. BOX 3, ARUA

Dr. Aniku Gilbert
For: HOSPITAL DIRECTOR

Copy: File

Appendix VII: Approval from Uganda National Council of Science and Technology

Uganda National Council for Science and Technology

(Established by Act of Parliament of the Republic of Uganda)

Our Ref: HS785ES **24 November 2020**

Benjamin Atwine
Management Sciences for Health
Kampala

Re: Research Approval: **Knowledge and risk factors of Hepatitis B disease among women attending Antenatal Care ate Arua Regional Referral Hospital, Uganda.**

I am pleased to inform you that on **24/11/2020**, the Uganda National Council for Science and Technology (UNCST) approved the above referenced research project. The Approval of the research project is for the period of **24/11/2020** to **24/11/2021**.

Your research registration number with the UNCST is **HS785ES**. Please, cite this number in all your future correspondences with UNCST in respect of the above research project. As the Principal Investigator of the research project, you are responsible for fulfilling the following requirements of approval:

1. Keeping all co-investigators informed of the status of the research.
2. Submitting all changes, amendments, and addenda to the research protocol or the consent form (where applicable) to the designated Research Ethics Committee (REC) or Lead Agency for re-review and approval **prior** to the activation of the changes. UNCST must be notified of the approved changes within five working days.
3. For clinical trials, all serious adverse events must be reported promptly to the designated local REC for review with copies to the National Drug Authority and a notification to the UNCST.
4. Unanticipated problems involving risks to research participants or other must be reported promptly to the UNCST. New information that becomes available which could change the risk/benefit ratio must be submitted promptly for UNCST notification after review by the REC.
5. Only approved study procedures are to be implemented. The UNCST may conduct impromptu audits of all study records.
6. An annual progress report and approval letter of continuation from the REC must be submitted electronically to UNCST. Failure to do so may result in termination of the research project.

Please note that this approval includes all study related tools submitted as part of the application as shown below:

No.	Document Title	Language	Version Number	Version Date
1	Research Consent form	English	2.0	14 October 2019
2	Reaserch Questionnaire	English	1.0	20 September 2019
3	Project Proposal	English	2.0	
4	Approval Letter	English	2.0	2019-10-14
5	Administrative Clearance	English	2.0	2019-10-14
5	Risk Mitigation Plan	English	02	26 October 2020
6	Revised Informed Consent Form	English	2.0	16 September 2020
7	Progress Report	English	1.0	30 September 2020
8	Approved Renewed Research Protocol	English	2.0	30 September 2020

Yours Sincerely

Hellen Opolot
For: Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

LOCATION/CORRESPONDENCE

Plot 6 Kimera Road, Ntinda
P.O. Box 6884
KAMPALA, UGANDA

COMMUNICATION

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