PREVALENCE AND RISK FACTORS ASSOCIATED WITH HEPATITIS B AND C AMONG PATIENTS WITH LIVER DISEASE AT JUBA MEDICAL COMPLEX, SOUTH SUDAN

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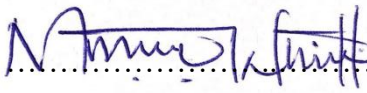
AN UNDERGRADUATE RESEARCH REPORT SUBMITTED TO THE INSTITUTE OF ALLIED HEALTH SCIENCE IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF A BACHELOR'S DEGREE IN MEDICAL LABORATORY SCIENCE OF CLARKE INTERNATIONAL UNIVERSITY

NOVEMBER, 2021

DECLARATION

I, Moses Midu Wilson, pronounce that this research report is original and I compiled it basing on previous literature which was duly acknowledged with references and citations. This work has not been submitted to any university or institution of learning for an award of the Bachelor's degree or any other academic purpose.

Signature:  ……..

Date: January 4, 2022

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2017-BMLS-FT-AUG-003

APPROVAL

This is to certify that this research report has been developed under my supervision and ready for submission.

Signature: ……

Date: 7 / Jan / 2022

MS. MARTHA NAKAYE

DEDICATION

To my mum, Mary Sungufue Yoere. You are the center of my world, “the wind beneath my wings”. You are my all in all.

To my brothers George Ginimaida, Batrus Miwai, Justin Tambua, and my sisters Beatrice Nuna, Loice Nabie. I am where I am today because of your support.

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Much thanks to God Almighty for bringing me this far. I am what I am today because of your love and your Grace.

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OPERATIONAL DEFINITIONS

Acute liver failure; this is loss of the functions of the liver that happens rapidly, probably in days or weeks, and usually in an individual who has no history of pre-existing liver disease [Mayo clinic].

Chronic liver disease; This is a progressive deterioration of the functions of the liver that happens over a long period of time, probably months or years [Sharma, 2021].

Dependent variable; it is the variable that depends on other factors that are measured. This variable(s) is expected to change as a result the research's manipulation of the independent variable(s).

Independent variable; this is a stable variable; it is unaffected by the other variable(s) that is being measured. Furthermore, it refers to the condition of an experiment that is manipulated systematically by the researcher [Dr. Camille, 2021].

Risk factor; medically, it is defined as something which increases someone's chance of developing a disease or condition. For example, cigarette smoking is a risk factor for lung cancer, and having unprotected sex with different sexual partners is a risk factor for HIV/AIDS.

Co-infections; Prof. Pascale Allotey defines co-infection as the simultaneous infection of a host by multiple pathogen species. Furthermore, it can also occur as simultaneous infection of single cell by two or more virus particles, which can take place simultaneously by initial infection followed by superinfection.

Prevalence; In epidemiology, Wikipedia defines prevalence as the proportion of a particular population detected to be affected by a medical condition at a specific time.

LIST OF ABBREVIATIONS AND ACRONYMS

ALF - Acute liver failure

CLD - Chronic liver disease

DNA - Deoxyribonucleic acid

EIA - Enzyme Immunoassay

HBV - Hepatitis B Virus

HBVsAg - Hepatitis B Virus surface antigen

HCC - Hepatocellular carcinoma

HCV - Hepatitis C Virus

HIV - Human Immunodeficiency Virus

IgG - Immunoglobulin G

NA - Not applicable

NGOs - Non-Governmental Organizations

PWID - People who inject drugs

RNA - Ribonucleic acid

WHO - World Health Organization

ABSTRACT

Background: Hepatitis B and C viruses are a major public health problem worldwide affecting billions of individuals. Limited information exists on this matter in South Sudan. This study was undertaken with the aim of determining the prevalence and risk factors of hepatitis B and C virus infections in patients with liver disease at Juba Medical Complex, South Sudan.

Methodology: The study was conducted on 69 clinically diagnosed liver disease patients. Possible associated factors with infections by the viruses were collected from the subjects using questionnaire. Serum was screened for the presence of hepatitis B surface antigen and anti-hepatitis C virus antibodies using Enzyme immunoassay.

Results: Hepatitis B surface antigen was detected in 26 (37.9%) and anti-HCV antibody 11 (15.9%) patients clinically diagnosed to have liver diseases. Hepatitis B virus infection was higher in males 16/38 (42.1%) compared to 10/31 (32.2%) in females, while anti-hepatitis C virus antibody was higher in females 6/31 (19.4%) compared to 5/38 (13.2%) in males. Of the study participants, 4 (5.8%) had dual hepatitis B and C virus co-infection. The prevalence increased with age; the highest prevalence of hepatitis B was in the age group of 20 – 29 years 25 (36.2%), and that of hepatitis C virus was in age group of 30 – 39 year. None of the 69 subjects younger than 5 years and none above the age of 80 years had HBsAg or anti-HCV. Various risk factors for acquiring both hepatitis infections were identified; gender, age, injury with sharp object, family history of hepatitis, and surgical history.

Conclusion: This study provided much important information concerning hepatitis B and C prevalence and risk factors among patients with liver disease; it showed the intermediate endemicity for HCV infection and pointed to an increasing trend of HBV incidence, which might reclassify South Sudan in high HBV endemicity area, among liver disease patients. This could be attributed to the lack of enough control measures by the government. In this study, HBV and HCV infections were associated with history of injury with sharp object and history of blood transfusion. Therefore, prevention and control measures are needed to reduce the spread of these infections among liver disease patients.

CHAPTER ONE: INTRODUCTION

1.0 Introduction

This chapter presents the background of study, problem statement, objectives of the study, research questions, significance of the study and conceptual framework on the study of the prevalence of hepatitis B and C and the risk factors among patients with liver disease attending Juba Medical Complex (JMC), South Sudan.

1.1 Background

Viral hepatitis is an unsmiling public health worry affecting several hundred million individuals worldwide and a higher percentage of this number is accounted for by the developing countries [Michael Owusu1, 2018]. The main types of viral hepatitis that have been discovered in humans are typically five. They include hepatitis A (caused by hepatitis A virus), hepatitis B (caused by hepatitis B virus), hepatitis C (caused by hepatitis C virus), hepatitis D (caused by hepatitis D virus) and hepatitis E (caused by hepatitis E virus) [Owusu M, 2018]. Hepatitis A and E viruses are usually asymptomatic however, they can also result in acute illnesses that are usually characterized by jaundice [Ochwoto et al, 2016]. Unlike hepatitis A and E whose mode of transmission is the fecal-oral route, hepatitis B and C are transmitted through blood and semen of an infected individual.

HBV was discovered in 1965 when Blumberg and co-workers found the hepatitis B surface antigen which was at first called the Australia antigen because it was seen in serum of a patient from Australia [Blumberg BS, 1977]. Dr. Baruch Samuel Blumberg was then awarded the 1976 Noble Prize in Physiology or Medicine for this tremendous and amazing discovery [Berinyuy & Alawode, 2019, p.4].

However, in the modern days the rapid and continuous discoveries of the viral disease around the globe have helped us to deepen our understanding and how complex this unusual invisible enemy is. Batholomew goes ahead to explain that even though there has not been any significant decrease in the overall prevalence of the virus, there is hope that our grand sons and daughters will see a decrease in both the worldwide carrier rate and the incidence of new HBV infections if current HBV vaccinations are handled well [Batholomew C, 2011].

Choo isolated HCV initially from the serum of a person who had non-A, non-B hepatitis in 1989 by [Choo Q.L. et a, 1989]. About 14 - 16 years later, after the identification of HCV as the cause for non-A, non-B (NANB) hepatitis, chronic hepatitis occurred more frequently as indicated by persistent viral infection in more than 80% of adults who were infected but in only about 50% of infected children or younger women who were infected [Leonard B. Seeff, 2015].

Leonard states that follow-up over 2 to 4 decades indicated that many infected persons developed progressive hepatic fibrosis, sometimes culminating in liver cirrhosis and/or cancer of the liver. Furthermore, long-term natural history studies are somewhat a challenge because the disease onset is often silent and the progression extremely slow [Leonard B. Seeff, 2015].

The acute phase is the initial stage of the infection which patients with HBV go through. However, not all patients transit the disease beyond this stage. The early phase of this stage of the disease is characterized serologically by the presence of hepatitis B surface antigen (HBsAg), high serum HBV-DNA, HBeAg, and normal level of serum aminotransferase level (ALT), and minimal or non-significant inflammation on liver biopsy [Altiparmak E and Koklu S, 2005]. Furthermore, a later phase of the acute phase, also known as immunity phase, is identified by elevated serum titres of anti-HBsAg IgG (HBsAb), anti-HBcAg IgG, reduced or completely no HBsAg and HBV-DNA, and a normal liver histology [Berinyuy & Alawode, 2019, p. 4]. This is true for the individuals who recover fully from the infection after gaining full and permanent immunity from the exposure.

Acute hepatitis C infection is not always diagnosed because most of the individuals who have acute hepatitis C infection are asymptomatic. To support this argument, in the transfusion setting, where acute onset of HCV infection has been best documented, 70% to 80% of the cases were asymptomatic [McCaughan G.W. et al, 1992]. HCV-RNA can be detected in the serum of the infected individual within 1 to 2 weeks after infection [Thimme R. et al, 2001]. The level of HCV-RNA increases rapidly during the first few weeks, and then peaks between 10^5 to 10^7 IU/ml shortly before the peak of serum aminotransferase levels and onset of symptoms [Farci P, 1991].

At this stage those unfortunate patients who fail to produce adequate immune response factors to deal with the infections end up living with the disease their entire lifetime. In this case, it is said the diseases have become chronic [AASLD, 2007].

Chronic phase of HBV takes place as a progression of the early phase of the acute infection when the patient fails to produce the necessary immune response to combat the disease and ensure total viral clearance and resolution of the disease [Berinyuy B, 2019]. It is serologically identified by relative rise in serum anti- HBcAg IgG, absence or decreased titres of anti-HBsAg IgG, and either normal or non-significant liver damage as shown by ultrasonography [WHO, 2008]. Furthermore, this phase of the disease may be characterized by normal or elevated serum aminotransferase levels (AST, ALT) and other markers of hepatic integrity [AASL, 2007]. The physical signs and symptoms at this stage include; jaundice, fever, dark-urine formation, nausea, among others. These symptoms can occur even though they will last shortly after which they get resolved following recovery.

Chronic phase of HCV is identified by persistence of HCV-RNA in the blood for at least 6 months after onset of acute infection [Stephen L. 2016]. HCV is self-limiting in only 15%-25% of patients in whom HCV-RNA in the serum becomes undetectable and ALT levels goes back to normal levels. Stephen and Timothy cite that 75%-85% of the individuals who are infected with hepatitis do not clear the virus in their system by 6 months, and this causes the disease to become chronic. Furthermore, the rate of chronic HCV infection is affected by many factors, including the age of the individual, gender, ethnicity, and the development of jaundice during the acute infection [Stephen L. and Timothy R., 2016].

Hepatitis B virus can cause a number of clinical syndromes ranging from acute hepatitis with recovery and total clearance of the virus, fulminant hepatitis with massive liver necrosis, non-progressive chronic hepatitis, as well as progressive chronic disease sometimes ending with liver cirrhosis. HBV-induced chronic liver disease is a big cause of the development of hepatocellular carcinoma (HCC) [Robbins, 2013].

Evidently HCV infection has a much higher rate of progression to chronic disease and unfortunately cirrhosis than HBV. In fact, hepatitis C is the disease that requires liver transplant in many of the developing countries [Robbins Basic Pathology, 2013]. In the developed world, hepatitis C is highly associated with HIV due to the commonly shared risk factors and modes of transmission [W. Hladik, P. Kataaha, 2006].

1.2 Problem statement

Although the prevalence of HBV and HCV in South Sudan is unclear, a significant number of the hospital admissions and mortality in medical wards in South Sudan are due to CLD. The country has been placed by the WHO into the intermediate zone of prevalence for both hepatitis B and C. The exact number of persons infected is unknown for the reason that no large-scale epidemic data exist to assess the true HCV and HBV infection burden in South Sudan despite its increasing threat to the country's public health [Belbacha I, 2011]. Challenges such as barriers to screening, cost-related factors, and inadequate knowledge and awareness of hepatitis B and C has made it difficult combat this invisible enemy [F.M.Averhoff, 2012].

It is important for the government to establish every possible means to see that the general population is aware of the burden that the infections possess, and device a means to reduce the spread. This can be achieved by public sensitization through education about the risk factors contributing to the spread, free testing and treatment programs, and carrying out research on the diseases.

Furthermore, a significant number of the hospital admissions and mortality in medical wards in South Sudan are due to CLD. Therefore, to ensure the optimal clinical managements of CLD patients, it is important to know the HBV and HCV status of these patients. The epidemiology comparison of hepatitis B and C has been reported that HCV infection is not highly endemic in the population and that the epidemiology of HCV differs from that of HBV [M C McCarthy et al 1994] however, this data is based on the general population.

Therefore, this study was set out to determine the prevalence and associated risk factors with hepatitis B and C among patients with liver disease at Juba Medical Complex, South Sudan.

1.3 Objectives of the study

1.3.1 General objective

To determine the prevalence of Hepatitis B and C and associated risk factors among patients with liver disease visiting Juba Medical Complex, South Sudan.

1.3.2 Specific objectives

i. To determine the prevalence of Hepatitis B and C among patients with symptoms of liver disease at Juba Medical Complex.
ii. To determine if injury with sharp object, history of blood transfusion, intravenous drug use, alcohol consumption, family history of hepatitis, and history of surgery contribute to hepatitis B and C infections in patients with symptoms of liver disease at Juba Medical Complex.
iii. To establish the rate of co-infection of HBV and HCV among chronic liver disease patients at Juba Medical Complex.

1.4 Research questions

i. What is the prevalence of Hepatitis B and C infections among patients with symptoms of liver disease at Juba Medical Complex?
ii. Is injury with sharp object, history of blood transfusion, intravenous drug use, alcohol consumption, family history of hepatitis, and history of surgery associated with hepatitis B and C infections in patients with liver disease at Juba Medical Complex?
iii. What is the rate of co-infection of HBV and HCV among chronic liver disease patients at Juba Medical Complex?

1.5 Significance of the study

This study therefore seeks to enrich the existing body of knowledge with focus and the general public on the prevalence of hepatitis B and C and the associated risk factors among patients with liver disease which will be of great importance in the creation of suitable programs to address this public health concern.

The findings of this research will be used to plan appropriate training, create awareness through public awareness campaigns that support the prevention of hepatitis B and C hence the reduction of mortality and morbidity rate especially at Juba Medical Complex.

This study will add to the body of knowledge in academic research on the prevalence of hepatitis B and C and the associated risk factors in liver disease patients. In addition to that, it will form useful material for reference for other researchers and learners in general.

1.6 The scope of the study

The study on the prevalence of hepatitis B and C and the risk factors among patients with liver disease attending Juba Medical Complex, South Sudan was conducted between October and November through a quantitative cross-sectional study design. The study was conducted among all the patients with clinical signs of liver disease at Juba Medical Complex, South Sudan. The samples were collected from the patients after consent and analyzed in the laboratory. The study specifically determined the prevalence of hepatitis B and C and the risk factors among liver disease patients attending Juba Medical Complex in South Sudan.

1.7 A conceptual framework

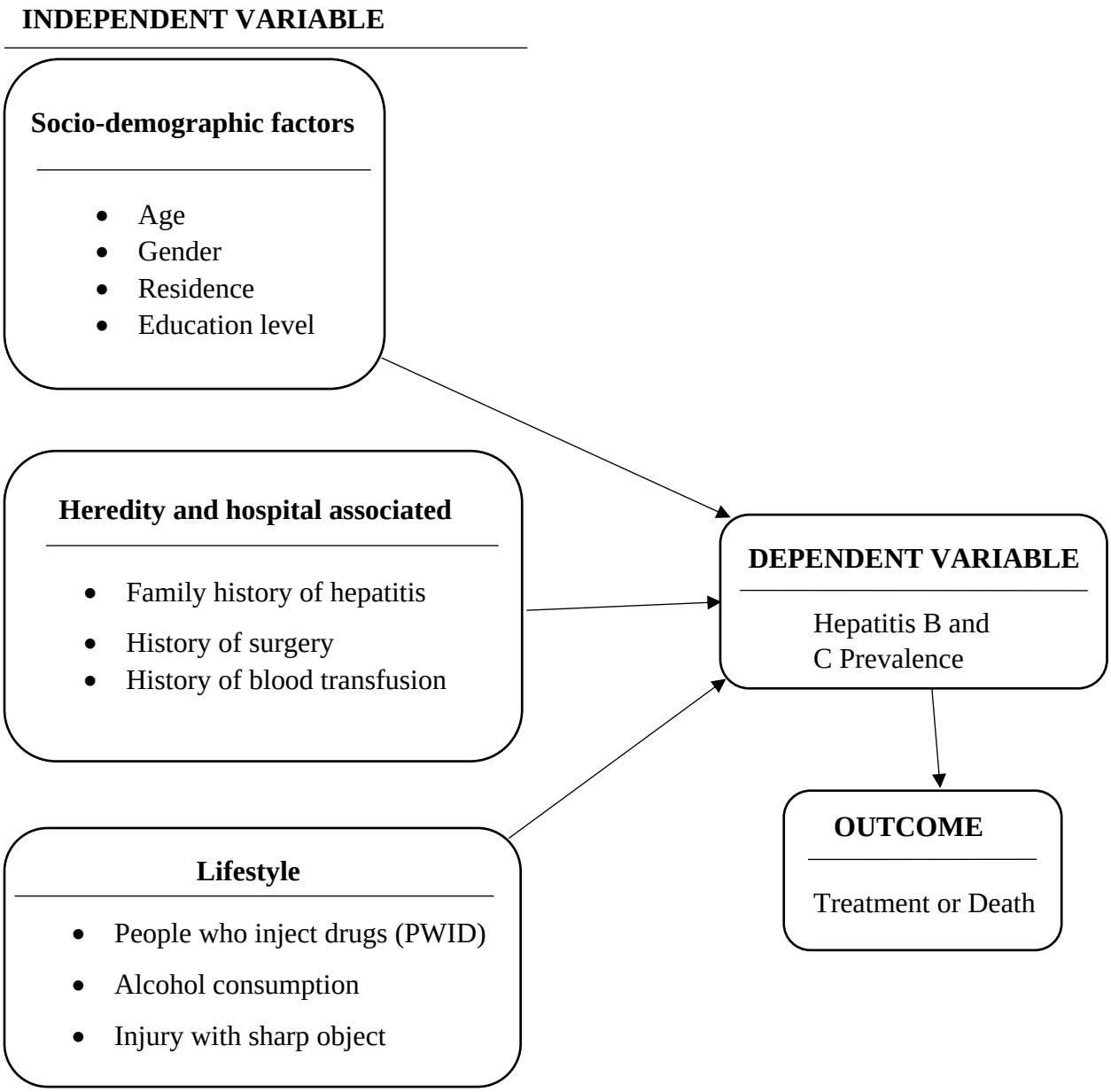


Figure 1: A conceptual frame work showing the relationship between the dependent variable and the independent variable.

The conceptual frame work above shows the relationship between the independent and dependant variables. The dependent variable is the prevalence of hepatitis B and C, and the independent variable is the factors associated with HBV and HCV. The outcome of interest was either treatment of the patients or death.

CHAPTER TWO: REVIEW OF LITERATURE

2.0 Introduction

This chapter will discuss the published literature on the prevalence of hepatitis B and C among patients with liver disease, Risk factors contributing to the prevalence of Hepatitis B and C among patients with liver disease, and epidemiology comparison of hepatitis B and C among patients with symptoms of liver disease at Juba Medical Complex.

2.1 The prevalence of Hepatitis B and C among patients with symptoms of liver disease

Globally HBV is the most common hepatitis causing virus accounting for almost 2 billion infections around the world [Goldstein ST, Zhou F, 2005], [WHO, 2015] and about 3% of the world's population (170 million) has chronic hepatitis C infection. Furthermore, around 5–10% of chronic hepatitis B infections among adult populations are in sub-Saharan Africa and East Asia [T. A. Shaw-Stiffel, 2000].

About 1.4 million people die yearly from hepatitis-related acute and chronic liver diseases globally [Abel G, 2013]. Of these deaths HBV takes the highest percentage with 48%, HCV 47%, and the remaining percentage is shared among the other hepatitis viruses.

HCV also is a major cause of liver disease. The worldwide carrier rate is estimated at 175 million persons (a 3% prevalence rate, ranging widely from 0.1% to 12%, depending on the country) [Robbins, 2013]. In a study done by Abel GirmaAyele and Solomon Gebre-Selassie (2013) showed that the prevalence of HBV and HCV infections among CLD patients was high.

A systematic literature review on hepatitis B and C prevalence in the EU/EEU countries looked at fifty estimates for the prevalence of HBV in the general population from eligible studies, and 45 estimates for HCV.

Of the 50 prevalence estimates for HBV, representative estimates for the general population (risk of bias score ≥ 4) were available for 13 countries: Belgium, Croatia, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Romania, Slovakia and Spain [European CDC, 2016]. The number of estimates available per country ranged from one estimate for Hungary and the United Kingdom to 10 estimates for Italy and random sampling method was used in most of the cases for data collection.

For HBV, the prevalence in the general population ranged from 0.1% [Talento (2010)] in Ireland to 4.4% in Romania [Gheorghe (2013)] Greece and Romania account for the highest HBV prevalence, 3.3% and 4.4% respectively [Drositis (2013)], well as most of the countries have an HBV prevalence around or less than 1%. But the most recent estimate for the country Greece is much higher than the prevalence range of 0.0%–2.1% reported in the previous review [ECDC, 2010]. However, this most recent estimate is entirely based on population data from Crete simply because no nation-wide estimate for Greek was available to accurately support this review. A number of higher quality prevalence estimates were in stock for Italy which, when all pooled, showed a HBV prevalence of 0.7%. However though, studies which were carried out individually portrayed a prevalence estimates ranged from 0.5% in the region of Apulia located in Southern Italy, to 5.8% in the province of Bergamo found in Northern Italy [De Paschale (2012)], therefore, showing a high heterogeneity in the available estimates of HBV prevalence.

HCV prevalence estimates that were considered to represent the general population (risk of bias score ≥ 4) were available for only 13 countries: Belgium, Croatia, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Latvia, Romania, Slovakia and Spain. The number of study estimates that were between one estimate (included; Belgium, Greece, Hungary, Ireland, Latvia, Romania and Slovakia) and 14 the estimates for Italy.

The prevalence of HCV in the whole population that were reported ranged from 0.1% in Belgium, Ireland and then the Netherlands to 5.9% in Italy [Quoilin (2007)], [Talento (2010)], [Vriend (2013)]. Among those studied, countries that had a relatively high HCV prevalence were Romania (3.2%) [Gheorghe (2010)], Greece (2.2%) [Drositis (2013)], Latvia (2.4%) and Slovakia (2.0%) [Tolmane (2011)], [Schreter (2007)]. It was also estimated that Italy and Spain had the largest number of HCV prevalence estimates available.

It is important to note that the above studies were done on all individuals regardless of whether they had liver disease or not since. I therefore included this because limited data is available on the prevalence of hepatitis B and C among patients with liver disease.

In the African region, HBV is very endemic and perhaps affects an estimate of 5-8% of the population, most especially West and Central Africa, and an estimated 19 million people in Africa have been infected with the HCV [WHO, 2017]. In Sub-Saharan Africa the prevalence of HBV

remains at 6.1% and 3.0% for HCV [Valsa M, 2002], although no current data statistics is available.

A study was done on 65,671 samples of all ages to determine the prevalence of hepatitis B and C virus infections and their related risk factors in Libya. All subjects gave a blood sample and completed a questionnaire on demographic and risk behavior data. The prevalence of HBV surface antigen (HBsAg) and that of anti-HCV were 2.2% and 1.3% respectively. The prevalence of anti-HCV increased with age, rising gradually after age 30 years, in contrast to a stable prevalence of HBsAg in all age groups 10 years and above [A.-N. Elzouki, 2012].

A similar study carried out in Addis Ababa, Ethiopia to determine Prevalence and Risk Factors of Hepatitis B and Hepatitis C Virus Infections among Patients with Chronic Liver Diseases in Public Hospitals. Out of the 120 liver disease patients who were diagnosed clinically, Hepatitis B surface antigen was detected in 43 (35.8%) and that of anti-HCV antibody 27 (22.5%) patients clinically diagnosed to have chronic liver diseases. Hepatitis B virus infection was higher in males 29/76 (38.2%) compared to 14/44 (31.8%) females, while anti-hepatitis C virus antibody was higher in females 13/44 (29.5%) compared to 14/76 (18.4%) males. Of the study participants, 3 (2.5%) participants had the two hepatitis, hepatitis B and C virus coinfection. In this study, the researchers concluded that the prevalence of hepatitis B surface antigen and anti-HCV antibody was greater in patients below 50 years of age [Abel G. and Solomon G., 2013].

And lastly but not the least, Hatim MY Mudawi, in his study of the epidemiology of viral hepatitis in Sudan (2008), he showed that Sudan is classified among the countries with high hepatitis B virus sero-prevalence. The study revealed that exposure to the virus varied from 47%–78%, with a hepatitis B surface antigen prevalence ranging from 6.8% in Central Sudan to 26% in Southern Sudan. Studies pointed towards infection in early childhood in Southern Sudan while there was some degree of increasing infection rate with increasing age in Northern Sudan. The study also showed that hepatitis B virus was the commonest cause of chronic liver disease and hepatocellular carcinoma and was the second commonest cause of acute liver failure in Sudan. In the same study, hepatitis C virus showed a low seroprevalence of 2.2%–4.8% [Hatim MY Mudawi, 2008].

Therefore, with these studies it is proven that the prevalence of HBV and HCV is high worldwide, and since no adequate data is available on the prevalence in South Sudan, this research is aimed at answering that question.

2.2 Risk factors contributing to the prevalence of Hepatitis B and C among patients with liver disease.

Age;

A number of studies have put forward their findings that if you are old you have a higher risk of exposure to viral hepatitis B and C than the younger people. Taking us to British Columbia, a study was done to analyze the risk factors associated with hepatitis B and C infection. Out of the 415 participants who took part in this study, the highest rates for HBV and HCV were in 25 to 44-year-old residents. The analysis of risk factors and infection predictors in 354 residents showed that intravenous drug use and history of hepatitis were associated with infection HBV and HCV. The study goes on to stress the point that the relative risk was 4.4 times that in nonusers. It also points out that in the group of residents with history of hepatitis, the relative risk was 6.2 and 4.5 times for HBV and HCV respectively. Tattooing or history of transfusion was not associated with increased risk for HCV, but these two were a significant for HBV [Prefontaine RG, 1994].

Smoking;

Shun-Chun Chuang and colleagues conducted a meta-analysis to look at the interaction between hepatitis B and C and cigarette smoking on the risk of HCC where they searched systematically PUBMED and the China National Knowledge Infrastructure databases and collected a total of 16 eligible publications which were identified. These individuals dichotomized cigarette smoking and chronic HBV and HCV into present or absent, Additive (S) and multiplicative interaction indexes (V) between smoking and the two viruses and their 95% CI were then calculated for each of the two studies. They found a much more than additive interaction between HBV and cigarette smoking and more than multiplicative interaction between HCV and cigarette smoking [Shu-Chun, 2010].

People Who Inject Drugs;

[Ray S, 2015] sampled 3,748 male PWIDs primarily for longitudinal HIV incidence study. These male participants were also screened for HBV at their first follow-up visit using HBVsAg, and HCV antibody tests which was then followed by the most accurate HCV-RNA PCR test. All those participants who were tested HIV negative at first testing were again tested for the same virus at first follow-up visit. The study results showed a prevalence of HIV, HBV, and HCV among the 2,292 participants that were tested at first follow-up visit was 25.9%, 9.7% and 53% respectively. Furthermore, 6.4% of the participants had HIV mono-infection, 34.1% had HCV mono-infection, and 19.6% had HIV-HCV co-infection. And lastly 26% of HIV-positive participants who didn't have HCV were positive for HBV.

History of surgical procedure;

Furthermore, Taye [Taye, 2019] spearheaded a study to assess the magnitude of HBV and HCV and the associated the associated factors among surgical patients at Hawassa University comprehensive specialized Hospital in Hawassa City, Southern Ethiopia. The result of this study showed that the prevalence of HBsAg and that of Anti-HCV among these patients were 9% and 5.5% in that respective order. Furthermore, to assess the risk factors among these patients questionares were administered to them which collected information about the associated risk factors. It was found the patients who practiced multiple sexual partner (AOR = 2.58, CI 1.18 - 5.61), dental procedure (AOR = 4.20, CI 1.87 - 9.55) and blood transfusion (AOR = 3.84, CI 1.27 - 11.65) had an increased odds of HBV infection and the ones who had history of surgical procedure (AOR = 6.05: 95% CI 1.59 - 23.04) and dental procedure (AOR = 3.70: 95% CI 1.40 - 9.77) had a higher odds of hepatitis C infection.

Other associated factors;

A relatively larger study was conducted in Colombia to assess the prevalence of HBV and HCV and associated factors in key groups attending a health services institution [Jaiberth, 2019]. This study was a multiple-group ecological study that covered 2,624 participants from the general population out of which 1,100 were men who had sex with men (MSM), 1,061homeless persons, 380 professional sex workers, 260 young people who are vulnerable, 202 individuals who use drugs, 41 prisoners, and 103 individuals from the lesbian, gay, bisexual and transgender

community. The prevalence of both viruses with a 95% CI and its associated risk factors was then determined for each of the groups.

The final results showed that the prevalence of HBV and HCV in the general population was at 0.15% and 0.2%, respectively; 0.27% and 2.09% among MSM; 0.37% and 2.17% in homeless persons; 0.26% and 0.0% in sex workers; 0.39% and 0.0% in vulnerable youths; and then 5.94% and 45.54 among PWID. It was evidently concluded that HBV and HCV infections are highly prevalent within these key groups, with the main associated factor being PWID [Cardona-Arias, 2019]

In a study carried out in Burera, a rural district in Rwanda to determine the seroprevalence of hepatitis B and C and their associated factors in people aged 45 or older, the prevalence of HBV and HCV were 6.4% and 9.4% respectively with 0.3% co-infections. Age, social economic level, history of blood transfusion, as well as history of injury with a sharp object were significantly associated with HCV infection [Patrick G, 2018].

Age-adjusted risk factors for HCV infection were previous hospitalization, surgical operations, previous blood transfusions and intravenous drug use; for HBV infection only family exposure or contact with HBV case were identified as risk factors in the prevalence of hepatitis B and C. Abel GirmaAyele and Solomon Gebre-Selassie goes ahead to explain that dental extraction procedure at health facility was associated with hepatitis C virus infection [Abel G. and Solomon G., 2013].

2.3 The co-infection of HBV and HCV among chronic liver disease patients.

The HBV and HCV share the same transmission pathways and therefore, co-infection is highly anticipated. It has been estimated that the worldwide prevalence of co-infection is 1-15% [Marianna G, 2018]. Many clinical studies have shown that progression of disease is a lot quicker in HBV-HCV dual-infections as compared to patients with mono-infection. In addition to chronic liver disease, co infection of HBV and HCV is frequently found in injection drug users with a prevalence of up to 42.5% [Pallas JR, 1999], patients on hemodialysis 3.7% [Reddy GA, 2005], patients undergoing organ transplantation 8% [Aroldi, 2005], HIV-positive patients 66% [Kalinowska-Nowak A, 2000], and beta-thalassemia individuals [Irshad, 2002], suggesting that these are the high-risk population for HBV and HCV co infections.

A study was done on 666 patients attending six public clinics in Juba city to compare the epidemiology of hepatitis B virus with hepatitis C. It was found that HCV infection is not highly endemic in the studied population and the epidemiology of hepatitis C differs from that of hepatitis B [McCarthy, 1994].

Yet another study on 100 chronic liver disease patients to study the co-infection and correlations of hepatitis B and C showed that Hepatitis B and C are the major causes chronic liver disease at the place of study. It concluded that patients with dual HBV and HCV infection do have greater risk of developing cirrhosis or progressing to HCC than mono-infected patients [Udhayvir S, 2018]

Considering the above literature on the prevalence and risk factors associated with hepatitis B and C, it is quite evident that hepatitis B has the highest prevalence around the world as compared to the prevalence of hepatitis C. Therefore, serious public health measures have to be put in place to combat the alarming prevalence of hepatitis B such that the disease can be brought under control.

CHAPTER THREE: METHODOLOGY

3.0 Introduction

This chapter explains the research methodology that will be used to attain the objectives of this study. It consists of the site study area, study design, study population, target population, study population with inclusion and exclusion criteria, study variables, source of data, sample size determination, sampling procedure, data collection techniques, data collection tools, quality control issues, plan for data analysis and ethical consideration.

3.1 Study area

The study area was Juba Medical Complex (JMC) a private hospital which is located in Juba City, Central Equatoria State – South Sudan. The country has an estimated population of 12 million based on annual population growth of 3% from a population census conducted in 2008 and lack of proper functioning primary health care facilities upcountry, many South Sudanese have nowhere to go to but this private hospital since it offers a range of first-class medical services. Military and police hospitals, if any, are non-functional country wide, forcing soldiers and officers to share the limited facilities with civilians in this private institution.

This hospital offers a wide range of laboratory tests including biochemical tests, using the latest chemistry machines, which are rarely done in a number of advanced hospitals in South Sudan. At JMC, a multidisciplinary team of doctors work hand-in-hand to evaluate and treat each individual diagnosed with liver disease. The doctors and surgeons use state-of-the-art technology to manage most of the viral hepatitis and other complications of the liver. Record has it that each year JMC doctors treat around 500 patients with liver disorders. The JMC teams often collaborate with other colleagues throughout South Sudan and beyond who are who see a great deal in improving outcomes and care for people with liver disease. Therefore, I did not find any facility in the country that could suit my study better than Juba Medical Complex.

Juba Medical Complex is directly funded by NGOs and the government through the ministry of health, South Sudan

Departments and services include: Pediatrics, ENT, Internal Medicine, Surgery, Obstetrics/Gynecology, Ophthalmology, Mental Health, Physiotherapy, Diagnostic Services: Laboratory, Ultrasonography, Radiology; Finance/Administration/Statistical Unit.

3.2 Study design

This study was a quantitative descriptive and cross-sectional study design.

3.3 Study population

The study population included patients with clinically diagnosed liver disease.

3.4 Selection criteria

3.4.1 Inclusion criteria

All patients at Juba Medical Complex with signs and symptoms of liver disease regardless of time of onset and duration, within the given study period and have consented to participate.

3.4.2 Exclusion criteria

All eligible candidates who declined to consent to participate in the study, mentally unstable individuals who could neither speak nor write.

3.5 Sample size determination

In this research, the sample size was determined using Kish-Leslie formula at 95% level of confidence and the proportion of attribute available in the study population will be taken to be (5%). The formula is written as;

$$n = \frac{Z^2 PQ}{e^2}$$

Z = standard score at 95% confidence level corresponding to 1.96

P = proportion of patients with hepatitis B and C

$\boldsymbol{n}$ = the study population that will be required for study

Q = (1- P) = the probability of not having hepatitis B and C

e = the margin of error between the estimated and true population prevalence of patients with hepatitis B and C of 5%.

The prevalence used was 21%, which was the prevalence of both hepatitis B and C in patients clinically diagnosed to have chronic liver diseases in public hospitals in Adis Ababa, Ethiopia [Abel GirmaAyele, 2013].

Therefore; $\boldsymbol{n} = \frac{(1.96)2 \times 0.21(0.41)}{(0.05)2}$

n = 126

Therefore; 126 participants will be enrolled in the study.

3.6 Sampling procedure

The sampling procedure that was employed was the purposive non-probability sampling method where the subjects were selected basing on the criteria of having liver disease. On daily basis, the clinical note on the laboratory request form of every patient coming to the laboratory was looked at and those that had history of liver disease were singled out and asked verbally for their consent to enroll them into the study. Similarly, those results that showed abnormal LFT parameters were also asked for consent to be enrolled into the study.

All those who agreed to take part in the study were given the consent form to sign, and regarding the minus, the caretakers signed on their behalf. Individuals who signed on the informed consent form were recruited into the study and those who failed to sign were not recruited.

3.7 Study variables

The dependent and independent variables used to direct this study as stated below.

3.7.1 Dependent variable

The dependent variable was the prevalence of hepatitis B and C among patients visiting Juba Medical Complex.

3.7.2 Independent variables

Independent variables included the risk factors associated with HBV and HCV among patients at Juba Medical Complex.

3.8 Data collection methods

With the consent of the attending physician and the patient, the participants were asked to fill the questionnaires by individual assistance of the researcher, and specimen sample was taken for testing for HBV and HCV using EIA. Patients testing positive for HBV and HCV infection by EIA were informed of their status and its ramifications by the attending doctor.

3.8.1 Questionnaire

A self-administered questionnaire was used to gather data related to socio-demographic and associated risk factors. The socio-demographic factors include; age, gender, residence, and education level. The associated risk factors include; history of blood transfusion, injury with sharp object, intravenous drug use, alcohol consumption, family history of hepatitis, and history of surgery.

3.8.2 Laboratory methods

Four milliliters of blood were collected from study participants together with age and gender data and serum separated and divided in two aliquots. One aliquot was for HBsAg screening using The HBsAg One Step Hepatitis B Surface Antigen Test Strip (Serum/Plsma), and the other for anti-HCV-antibody screening using HCV One Step Hepatitis C Virus Test Strip (serum/plasma), as per manufacturer instruction. Serological tests were employed during this study since the more advanced molecular testing was expensive to perform. (see appendix III).

3.9 Quality control.

Manufacturer's instructions were followed when performing HBV and HCV tests and the strips were quality controlled whenever a new box was opened to eliminated false positive or false negative results.

Quality control of the test strips was done by using known positive and negative samples. The results were read by two lab technologists to come to an agreed result.

The questionnaire was pretested on 5 participants who were selected from Juba Medical Complex to ensure that the questionnaires were clearly understood by the target participants before data collection. The aim of pretesting was to help identify gaps on the questionnaire designed in order to make adjustments that ensured their ability to collect the required information.

Training of the 2 research assistants that were going to help the respondents answer the questionnaire. This ensured that these research assistants understood and also helped the respondents to understand and fill in the questionnaire correctly.

3.10 Ethical considerations and consent.

Ethical approval was obtained from the Institute of Allied Health Sciences and REC at Clarke International University and the administration of Juba Medical Complex before commencing with the study. Further approval was sought from each participant or guardian through a signed consent form prior to drawing a blood sample and obtaining age and gender information.

Confidentiality was ensured by the use of unique identification numbers on each questionnaire instead of personal names. During data collection, each participant's information was kept confidential and was strictly used for the study undertaken.

Every liver disease patient who voluntarily accepted to participate in the study had to sign an informed consent form to ensure respect and autonomy. Answered questionnaires were only accessed by the researcher and those concerned with the study. The respondents were informed that their participation caused no harm and there was no direct gain or benefit from participation however their participation was to be useful for the future planning.

3.11 Statistics and data management

After collecting data, the raw data was checked for uniformity, accuracy, and consistency. Then entered, processed, and analysis of quantitative data into the computer was done manually using Microsoft excel 2016 and Statistical Package for Social Sciences (SPSS V20) program.

Quantitative data was presented in form of tables, percentages, and frequency distribution descriptively.

Pearson chi-square tests were used to show the association between the socio-demographic and associated variables and prevalence of HBV and HCV among liver disease patients, at JMC, South Sudan which implied that only variables with P-values of less than 0.05 were considered to be statistically significant.

3.12 Limitation of the study

Because of the relatively fewer number of cases, all patients with signs and symptoms of liver disease visiting the hospital were included in the study. Due to resource constraints, this study was not able to conduct confirmatory tests for those results that were positive and viral load was not performed. The study was not able to measure the prevalence of these viruses in the different subgroups of liver disease classifications

3.13 Dissemination of results

After finalizing with the research, dissertation will be compiled and presented to the Institute of Allied Health Sciences at Clarke International University. A copy of the dissertation will be given to the Clarke International University library such that it can be referred by other students. And finally, a manuscript will be submitted for review and publication.

CHAPTER FOUR: RESULTS

3.0 Introduction

This chapter presents the study population, the prevalence of HBV and HCV infections, the distribution of risk factors associated with the infections, and the rate of co-infection of HBV and HCV infection.

3.1 Socio-demographic factors

A total of 74 patients diagnosed with liver disease both clinically and based on laboratory results were recruited. Of these, 69 (93.2%) subjects completed the study. Of these, 38 (55.0%) were males and 31 (44.9%) were females [male to female ratio of 1.2 : 1]. The mean age of 29.8 years, standard deviation (SD) ±13.3 years (range = 6 – 70). Majority, 91.3% were below the age of 50 years, 28 (40.6%) were had attended secondary school, 25 (36.2%) had attended university, 7 (10.1%) had attended tertiary institution, 5 (7.2%) had attended primary school, 4 (5.8%) had unknown level of education, while 0 (0%) subjects were in nursery. In relation to residence area, 13 (18.8%) subjects out of the 26 residential areas were from Gudele residential area. The prevalence of HBsAg and anti-HCV ab in relation to sociodemographic characteristics is shown in Table 1.

All subjects that were enrolled into the study had at least one or more of the Liver functions tests parameters (Total protein (TP), Albumin, AST, ALT, ALP, TB, DB) abnormal.

Table 1: The prevalence of HBsAg and anti-HCV-Ab in relation to sociodemographic characteristics in patients with liver disease.

Sociodemographic characteristics		Serostatus for HBV		Serostatus for HCV	
Gender		Positive No. (%)	Negative No.(%)	Positive No. (%)	Negative No. (%)
	Male (38)	16 (23.2)	22 (31.9)	5 (7.2)	33 (47.8)
	Female (31)	10 (14.5)	21 (30.4)	6 (8.7)	25 (36.2)
Residence	Thongping	1 (1.4)	3 (4.3)	1 (1.4)	3 (4.3)
	Hai Referendum	2 (2.9)	0 (0.0)	1 (1.4)	1 (1.4)
	Gudele	5 (7.2)	8 (11.6)	1 (1.4)	12 (17.4)
	Jebel	2 (2.9)	1 (1.4)	0 (0.0)	3 (4.3)
	New site	2 (2.9)	2 (2.9)	0 (0.0)	4 (5.8)
	Hai Neem	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)
	Suk Site	1 (1.4)	0 (0.0%)	0 (0.0)	1 (1.4)
	Rock City	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
	Sirikat	0 (0.0)	5 (7.2)	2 (2.9)	3 (4.3)
	Amarat	2 (2.9)	0 (0.0)	1 (1.4)	1 (1.4)
	Mia Saba	0 (0.0)	1 (1.4)	1 (1.4)	0 (0.0)
	Lologo	2 (2.9)	1 (1.4)	0 (0.0)	3 (4.3)
	Check point	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)
	Konyokonyo	1 (1.4)	1 (1.4)	0 (0.0)	2 (2.9)
	Munuki	2 (2.9)	4 (5.8)	1 (1.4)	5 (7.2)
	Juba	1 (1.4)	1 (1.4)	0 (0.0)	2 (2.9)
	Gureyi	1 (1.4)	1 (1.4)	0 (0.0)	2 (2.9)
	Nimra talata	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)
	Kator	0 (0.0)	2 (2.9)	1 (1.4)	1 (1.4)
	Khor William	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)
	Mauna	2 (2.9)	0 (0.0)	0 (0.0)	2 (2.9)
	Atlabara	0 (0.0)	3 (4.3)	0 (0.0)	3 (4.3)
	Jebel Dinka	1 (1.4)	1 (1.4)	0 (0.0)	2 (2.9)
	Lemon Gaba	0 (0.0)	1 (1.4)	1 (1.4)	0 (0.0)
	Hai Cinema	0 (0.0)	2 (2.9)	0 (0.0)	2 (2.9)
	Bongroki	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)
Education level	Nursery	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Primary	2 (2.9)	3 (4.3)	0 (0.0)	5 (7.2)
	Secondary	10 (14.5)	18 (26.1)	3 (4.3)	25 (36.2)
	University	8 (11.6)	17 (24.6)	4 (5.8)	21 (30.4)
	Tertiary institution	5 (7.2)	2 (2.9)	2 (2.9)	5 (7.2)
	Unknown	1 (1.4)	3 (4.3)	2 (2.9)	2 (2.9)

3.2 Prevalence of HBV and HCV infections

The prevalence of HBsAg in patients with liver disease was 26 (37.9%). The prevalence was higher in males 16/38 (42.1%) than in females 10/31 (32.2%) but the different was not statistically significant (95% CI: 26.62 – 33.03; *P* = 1.608). The prevalence of HBV was highest in age group of 20 – 29 years, 25 (36.2%) but none in the age group above 80 years (0%) [figure 1]. More subjects from Gudele residential area, 5 (7.2%) had HBsAg positive than any of the 26 residential areas.

Among patients with liver disease, 11 (15.9%) subjects were positive for anti-HCV-Ab. The prevalence was higher among females, 6/31 (19.4%) than males 5/38 (13.2%). The prevalence of HCV by age group is that it was highest in the group of 30 – 39 with 4 (10.3%) and lowest in age groups of 0 – 9, 10 – 19, 50 – 59, and those above 80 (0%) years of age [figure 2]. Seropositivity of anti-HCV-Ab was high is subjects from Sirikat residential area, 2 (2.9%) more than any other area.

Figure 2: The distribution of hepatitis B surface antigen by age among patients with liver disease.

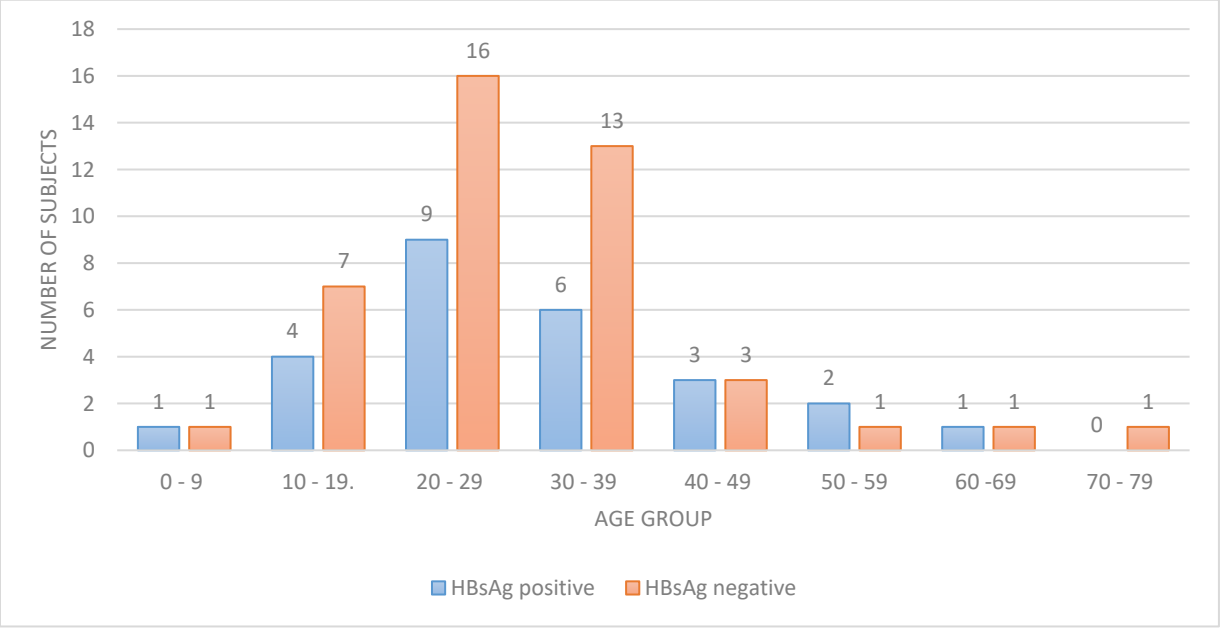
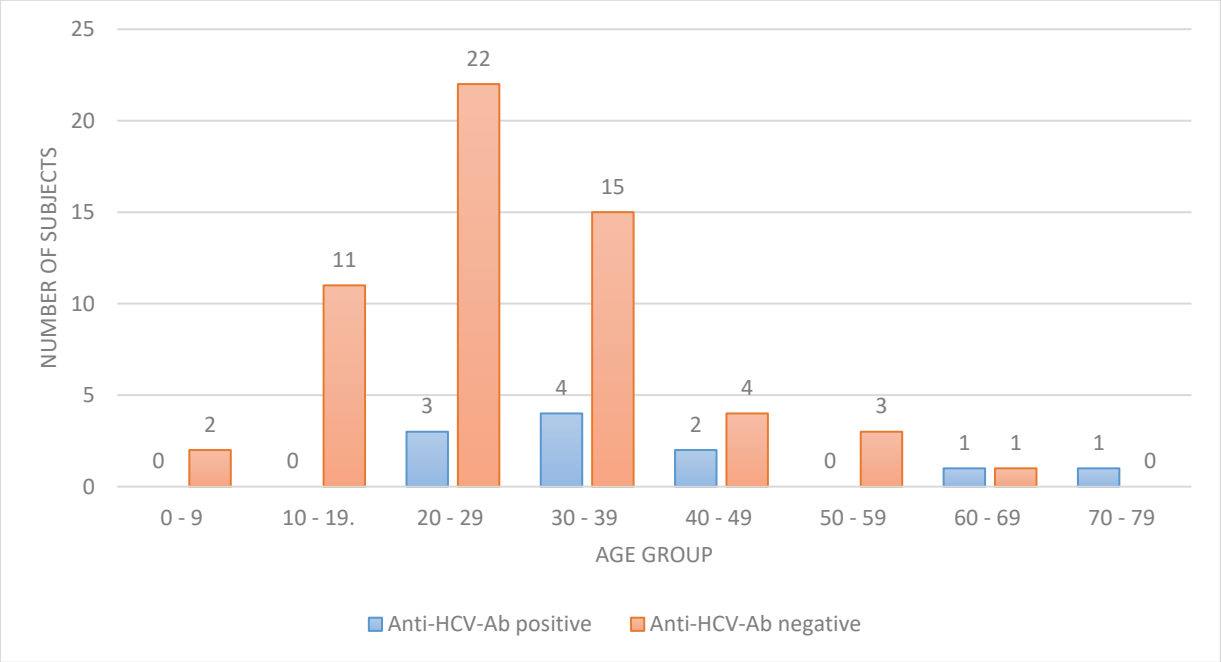


Figure 3: The distribution of anti-hepatitis C antibody by age among patients with liver disease



3.3 The rate of co-infection of HBV and HCV

Four subjects (5.8%) were positive for both HBsAg and anti-HCV-Ab sero-markers. Two of the subjects were males and two were females. The two males were in the age group of 40 – 49 and 60 – 69 years of age while the females were in the age group of 20 – 29 and 40 – 49 years of age. The subjects resided from Hai Referendum, Munuki, Gudele, and Hai Amarat with 2 subjects attending tertiary institution, 1 from secondary, and 1 whose education background is unknown. All the subjects had history of injury with sharp object, consumed alcohol, 2 had history of surgery, and 1 had history of blood transfusion. Furthermore, their ALP levels were all raised up to three times the upper limit ($P > 0.05$).

3.4 Distribution and factors associated with HBV and HCV

Of the 69 patients diagnosed with liver disease, 39 (56.5%) had history of injury with sharp object. Of these, 13/39 (33.3%) and 8/39 (20.5%) were positive for HBsAg and anti-HCV-Ab respectively. 5 (7.2%) of the subjects had history of blood transfusion ($P > 0.05$), and of these 2/5 (40%) and 2/5 (40%) were tested positive for HBsAg and anti-HCV-Ab respectively. Of the liver

disease patients, only 1(1.4%) subject injected drugs and was tested positive for HBsAg but negative for anti-HCV-Ab. 26 (37.7%) of the patients with liver disease had history of alcohol consumption. Of these, 10/26 (38.5%) of the subjects had positive tests for HBsAg and 7/26 (26.9%) subjects were positive for anti-HCV-Ab. It was further found out that those who had history of hepatitis in their family were 6 (8.7%) and all the six were history of HBV. Of these, 4 (66.7%) were tested positive for HBsAg and 0% was tested positive for anti-HCV-Ab. Moving forward, 20/69 (29.0%) of the patients who had liver disease had history of either a minor or major surgery. Of these, 6 (30.0%) were positive for HBsAg and 5 (25%) were positive for anti-HCV-Ab (OR = 0.621; 95% CI: 0.204 – 1.892, $P = 0.400$) and (OR = 2.389; 95% CI: 0.635 – 8.984, P = 0.189), respectively (Table 2). Other associated risk factors tested did not show any association with the infections ($P > 0.05$) (Table 3).

Table 2: Distribution of associated factors among liver disease patients with respect to serostatus of hepatitis B virus in Juba Medical Complex, South Sudan.

Associated factors	**Hepatitis B surface antigen No.(%)**			**OR (95%, CI)**	***P* value**
	Positive	Negative	Total		
Heredity and hospital					
History of blood transfusion	2 (40.0)	3 (60.0)	5	1.111 (0.173 – 7.133)	0.912
History of surgery	6 (30.0)	14 (70.0)	20	0.621 (0.204 – 1.892)	0.400
Family history of hepatitis	0 (0.0)	0 (0.0)	0	NA	NA
A					
B	4 (66.7)	2 (33.3)	6	3.727 (0.632 – 21.984)	0.125
C	0 (0.0)	0 (0.0)	0	NA	NA
D	0 (0.0)	0 (0.0)	0	NA	NA
E	0 (0.0)	0 (0.0)	0	NA	NA
Lifestyle					
Alcohol consumption	10 (38.5)	16 (61.5)	26	1.055 (0.387 – 2.876)	0.917
People Who Inject Drugs	1 (100.0)	0 (0.0)	1	2.720 (1.992 – 3.715)	0.195
Injury with sharp object	13 (33.0)	26 (66.7)	39	0.654 (0.245 – 1.746)	0.395

Table 3: Distribution of associated factors among liver disease patients with respect to serostatus of hepatitis C virus in Juba Medical Complex, South Sudan.

Associated factors	**Hepatitis C surface antigen No. (%)**			**OR (95%, CI)**	***P* value**
	Positive	Negative	Total		
Heredity and hospital					
History of blood transfusion	2 (40.0)	3 (60.0)	5	4.074 (0.596 – 27.872)	0.127
Family history of hepatitis	0 (0.0)	0 (0.0)	0	NA	NA
A					
B	0 (0.0)	6	6	1.212 (1.081 – 1.357)	0.264
C	0 (0.0)	0 (0.0)	0	NA	NA
D	0 (0.0)	0 (0.0)	0	NA	NA
E	0 (0.0)	0 (0.0)	0	NA	NA
History of surgery	5 (25.0)	15 (75.0)	20	2.389 (0.635 – 8.982)	0.189
Lifestyle					
Alcohol consumption	7 (26.9)	19 (73.1)	26	3.592 (0.936 – 13.791)	0.053
People Who Inject Drugs	0 (0.0)	1 (100)	1	1.193 (1.075 – 1.324)	0.661
Injury with sharp object	8 (20.5)	31 (79.5)	39	2.323 (0.559 – 9.644)	0.237

CHAPTER FIVE: DISCUSSION OF RESULTS

5.0 Introduction

This chapter discusses the results of the research study, under the title the prevalence of hepatitis B and C among patients with liver disease, the associated risk factors contributing to the prevalence of HBV and HCV, and the rate of co-infection of HBV and HCV among chronic liver disease patients at Juba Medical Complex.

5.1 The prevalence of hepatitis B and C among patients with liver disease among patients with liver disease.

In this study, data analysis revealed high frequency of hepatitis B and C among patients with liver disease. The prevalence of HBsAg and anti-HCV-Ab in patients with liver disease was 37.9% and 15.9% respectively. This study showed a high prevalence of HBV compared to the prevalence of 26% in the general population [Hatim, 2008]. A somewhat similar research conducted in India has reported high prevalence of HBV of 55% and HCV of 25.8% in patients with Chronic liver disease [Anagaw B, 2012]. A study conducted in 97 recruited CLD patients in Pakistan showed that one-fourth (24.7%) were positive for HBsAg and 61.1% for anti-HCV-Ab [Kakumu S, 1998]. Furthermore, a study in Vietnam showed that the prevalence of CLD due to HBV and HCV was 47% and 23%, respectively [S. Kakumu, 1998]. A recent study in Ethiopia indicated a prevalence of 1% and 0% for HBV and HCV respectively, in the general population without looking at any risk infection [Kakumu S, 1998]. On the contrary to the above reports, higher prevalence of HCV to HBV in Pakistan, 64.9% HCV versus 24.7% HBV higher HCV prevalence of 73.5% was reported among patients with CLD in Egypt [I. A. Waked, 1995]. The higher prevalence in these studies could be due to geographical variation and the higher propensity of HCV in causing liver disease than HBV.

Regarding HCV alone, a study showed a prevalence of 26% in India [Issar, 1995], 30.4% from Pakistan in patients with chronic liver disease [Khan, 2003], 75.5% in Egypt among patients with chronic liver disease [I. A. Waked, 1995], and 22% in Sudan among patients with HCC [Madawi, 2008].

Age distribution of liver disease patients showed 91.3% of the patients were 50 years of age and below. A comparable high age distribution of 75.8% of CLD cases age below 50 years was observed by Abel et al [Ayele, 2013]. The chronic infection with hepatitis viruses results into slow progressive of liver disease. It may even end up in cirrhosis, chronic liver failure, and HCC [Shimotohno, 2000].

Furthermore, my study showed that HBV had higher prevalence in males while HCV was found more in females ($P > 0.05$). My result was in line with a study done in Madagascar on prevalence of HCV which reported higher prevalence of anti-HCV in females their male counterparts [E. R. Charles, 2008]. Although no known risk exposure by gender accounting for the differences was obtained from this data.

5.2 The risk factors contributing to hepatitis B and C infections in patients with symptoms of liver disease

The prevalence of HBV and HCV among subjects who had history of injury with sharp object was 33.3% and 20.5% respectively. Therefore, with such a high prevalence it can be concluded that injury with sharp objects are a major source of both hepatitis B and C infections among liver disease patients [OR = 2.323, 95% CI: 0.559 – 9.644, $P = 0.237$] (Table 3). In comparison, a similar study done by Annette Pruss-Ustun (2003) showed that sharp injuries are a major source of HCV infection among health-care workers, causing approximately 39% of the HCV infections globally. To a greater extent, HBV infections among health-care workers are also driven by occupational exposures to contaminated sharps with a percentage of 37% [Pruss-Ustun, 2003]. Infections with HCV occupationally takes place during adulthood, the age at which the risk of severe long-term damage to the liver, which may include liver cirrhosis, HCC, is at its highest [G. Dore, unpublished data, 2001]. For the case of adults, the long-term consequence of HBV infections is less severe than that for HCV.

The combined prevalence of both HBV and HCV infections in the subjects who had history of blood transfusion was 40% and 40%, respectively. With reference to a similar study done, the overall prevalence of HBV and HCV infection in those study subjects who had history of blood transfusion was 22.2% and 29.6%, respectively [Abel Girma, 2013]. Therefore, with regards to

blood transfusion, there was association detected in acquisition of HBV and HCV. This might be explained by the neglect to screen for potential blood borne pathogens in the blood bank.

The prevalence of HBV and HCV among liver disease patients who had history of surgical procedure was 30.0% and 25.0%, respectively. However, history of any surgical procedure surgery could not be inferred from this study as a cause of infection either by HBV or HCV. To compare the results, a study that was aimed at determining the seroprevalence of HBV and HCV in subjects undergoing elective eye surgery, only yielded 1.8% and 1.2% positive results for HBV and HCV, respectively [P. Pasquini, 1988]. A similar study on the frequency of HBV and HCV among subjects gave a report of a low prevalence, even much lower when compared to my finding in patients with history of surgery.

Family history of hepatitis was not associated with the prevalence of hepatitis B among the study population in this study [OR = 3.727; 95% CI: 0.632 – 21.984; P = 0.125) (Table 2). There was no association of history of hepatitis B with prevalence of hepatitis C in the study. To compare my findings, Makuza et al. (2019) in contrary showed that having a person in the family with viral hepatitis [OR = 1.367, 95% CI: 1.21 - 1.53] were significantly associated with HBV infection. According to him, he mentioned that this can be attributed to a genetic characteristic of the virus where the virus can be transmitted genetically from one generation to the other.

Furthermore, my study showed that Gudele residential area, which is found in the urban region of Central Equatoria State, had a relatively high prevalence of HBV (7.2%) as compared to the other residential areas. However, a study by Ahmad et al. showed that the frequency of HBV and HCV among rural and urban dwellers was 45% and 55% respectively, which contradicts with this study. My findings showed that there was a higher prevalence of HBV in the urban population. This higher prevalence of infection in Gudele residential area may be due to the nature of living in which the areas is so populated as compared to other residential regions and this might expose the residents for different risk factors. The sociodemographic characteristics have not been significantly associated with the prevalence of HBV and HCV infections.

5.3 The rate of co-infection of HBV and HCV among chronic liver disease patients

The prevalence of HBV and HCV co-infection among patients with liver disease in this study was relatively low (5.8%). The rate was high in subjects who were in the age group of 40 – 49 (60%)

and unfortunately all the subjects who had co-infections where alcohol consumers and had history of injury with sharp object. Higher findings were shown by other studies in patients on hemodialysis (3.5%), patients undergoing organ transplantation (8%), and injection drug users (42.5%) [G. A. Reddy, 2005]. However, these results may underestimate the true number of people with HBV/HCV co-infection as there is an entity of occult HBV infection in patients with chronic hepatitis C infection [I. Cacciola, 1999]. The difference in the magnitude of co-infection among these studies and our study could be attributable to difference in the study population, geographical variation, and difference in methodology. In this study, cases of HCV-associated liver disease were lower than HBV-associated cases.

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.0 Introduction

This chapter projects the conclusion and recommendation according to the results of the study.

6.1 Conclusion

This study concludes that the prevalence of HBV and HCV among patients with liver disease attending Juba Medical Complex is high. History of injury with sharp objects and history of blood transfusion were the most commonly associated risk factors for both HBV and HCV at the health facility.

6.2 Recommendation

I would recommend that all clinically diagnosed liver disease patients should be tested for HBV and HCV serostatus. Care must be taken by all individuals to prevent injury with sharp objects, blood banks should make sure that before blood transfusion is carried out the blood is thoroughly tested for blood borne pathogens.

To prevent the spread of HBV and HCV, people must be well educated about the diseases and their mode of transmission. Furthermore, immunization activity against HBV in South Sudan should be looked at as a measure to combat the killer disease. Mass vaccination campaigns should be carried out by the government through ministry of health, this is because, according to the findings of this study the prevalence of both hepatitis B and C are is relatively high.

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APPENDICES

APPENDIX I; INFORMED CONSENT TO PARTICIPATE IN RESEARCH

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

Prevalence and the risk factors associated with hepatitis B and C among patients with liver disease at Juba Medical Complex, South Sudan.

The person who is in charge of this research study is Moses Midu Wilson. The research will be conducted in Juba city, South Sudan.

Purpose of the study

The purpose of this study is to:

I. Assess the prevalence of Hepatitis B and C among patients with symptoms of liver disease at Juba Medical Complex.

II. Find out the risk factors contributing to hepatitis B and C infections in patients with symptoms of liver disease at Juba Medical Complex.

III. Study the co-infection of HBV and HCV among chronic liver disease patients at Juba Medical Complex.

Study Procedures

You are being asked to participate in this study, as you are a liver diseased patient who can help us better understand the prevalence of hepatitis B and C and the associated risk factors among patients with liver disease. If you take part in this study, you will be asked to:

- Provide a blood sample of approximately 4mls;
- Take part in a one-time, one-on-one, semi-structured interview;
- The interview will take approximately 5 minutes;
- The interview will take place at a location most convenient to you as the participant;
- The interview will be transcribed, in the form of a questionnaire, to ensure accuracy in reporting your statements;

Benefits

There may be no direct benefits associated with your participation in the study, but the information you will provide will be useful in planning and organizing health awareness campaigns on hepatitis B and C in South Sudan and worldwide.

Risks or Discomfort

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

Compensation

No research participants will be compensated

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are: The research team, including the Principal Investigator and those involved with the study.

I may publish what I have learnt from this study. If l do, l will not include your name. l will not publish anything that would let people know who you are.

Voluntary Participation / Withdrawal

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

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

If you have any questions, concerns or complaints about this study, or experience an adverse event or unanticipated problem, contact the researcher on +211 920 498 473, +211 918 611 973, or +256 783 908 473.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the CIUREC Chairperson Dr. Samuel Kabwigu on (0312307400) and the executive secretary of UNCST on (0414 -705500) respectively.

Assessment of understanding

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

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

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

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

_____

Thumb print of Person Taking Part in Study

Note: Leave this space for the CIUREC stamp

_____ _____

Signature of Person Obtaining Informed Date

Consent / Research Authorization

_____

Printed Name of Person Obtaining Informed Consent / Research Authorization

APPENDIX II; RESEARCH METHODS/TOOLS

1) **QUESTIONNAIRE TO OBTAIN DATA ON RISK FACTORS**

Name: …… (Optional)

Gender: 1. Male ☐ 2. Female ☐

Age……

Nationality: ……

Residence: ……..

Education level	Nursery ☐
	Primary ☐
	Secondary ☐
	University ☐
	Tertiary institution ☐
History of blood transfusion	Yes ☐ No ☐
Injury with sharp object	Yes ☐ No ☐
Intravenous drug use	Yes ☐ No ☐
Alcohol consumption	Yes ☐ No ☐
Family history of hepatitis	Yes ☐ No ☐
If (Yes); family history of	Hepatitis A ☐ Hepatitis B ☐ Hepatitis C ☐ Hepatitis D ☐ Hepatitis E ☐

History of surgery	Yes ☐ No ☐

AISTIBYAN I YAHSUL EALAA ALBAYANAT TASHGHIL EAMIL ALKHATAR (ARABIC)

Asm: …… (Akhtiari)

Jins tadhkir ‘aw tanith: 1. Aldhikr ☐ 2. unthaa ☐

Eumar……

Jinsia: ……

‘iiqama: ……..

Mustawaa altaelim	Madrasat hadana ☐
	Madrasat abtidayiya ☐
	Madrasat aedadia ☐
	Jamiea ☐
	Altaelim aleali ☐
Yarikh naql aldam	Naeam ☐ Raqm ☐
‘iisabatan bijism hadin	Naeam ☐ Raqm ☐
Mutaeati mukhadirat	Naeam ☐ Raqm ☐
Aistihlak alkuhul	Naeam ☐ Raqm ☐
Tarikh altihab alkabid	Naeam ☐ Raqm ☐
‘iidhan (Naeam); tarikh aleayila	‘iiltihab alkabid A ☐ ‘iiltihab alkabid B ☐ ‘iiltihab alkabid C ☐

	‘iiltihab alkabid D ☐ ‘iiltihab alkabid E ☐
Tarikh aljiraha	Naeam ☐ Raqm ☐

2) LABORATORY METHODS

Four milliliters of blood were collected from study participants together with age and gender data and serum separated and divided in two aliquots. One aliquot was used for HBsAg screening and the other for anti-HCV antibody screening as per manufacturer instruction. Serological tests were employed during this study since the more advanced molecular testing was expensive to perform.

Procedure for venous blood collection

Materials required

Latex gloves
Tourniquet
70% isopropyl alcohol pads
Safety engineered sterile needles
Vacutainer holder
5-ml syringes
Appropriate Vacutainer tubes: Red top (plane tube)
HBsAg Rapid Test Strip
HCV Rapid Test Strip
Timer
Centrifuge
Sharps container

Procedure for venous blood collection

I Selected a sterile, dry, preferably plastic syringe of the capacity 5ml and attached to it a 19 or 20 SWG needle.

Applied a soft tubing tourniquet to the upper arm of the patient to enable the veins to be seen and felt. Then asked the patient to make a tight fist which made the veins more prominent.

Using the index finger, I felt the arm for a suitable vein, selected a sufficiently large straight vein that did not roll and with a direction that can be felt.

Cleaned the puncture site with 70% ethanol and allowed to dry.

With the thumb of the left hand holding down the skin below the puncture site, I made the venipuncture with the bevel of the needle directed upwards in the line of the vein. Steadily withdrew the plunger of the syringe at the speed it was taking the vein to fill.

When sufficient blood was collected, the tourniquet was released and instructed the patient to open his or her fist. Removed the needle and immediately pressed on the puncture site with a piece of dry cotton wool. Removed the tourniquet completely. Instructed the patient to continue pressing on the puncture site until the bleeding stopped.

Removed the needle from the syringe and carefully filled the container(s) with the required volume of blood. And then discarded the needle safely.

Mixed immediately the blood in a plain red top container. Immediately labeled carefully all the blood samples.

Checked that bleeding from the venipuncture site had stopped. Covered the area with a small dressing.

The blood samples were then centrifuged to obtain serum which were used for the test.

HBV and HCV screening procedure

We removed the test from its sealed pouch and placed it on a clean, level surface. Then labeled the test with the patient number. We then transfer 2 drops of the serum obtained after centrifuging, to the sample pad of the strip with a disposable pipette which is provided in the kit, then added 1 drop of the buffer and start the timer.

Color started to move across the membrane as the test began to work. We then waited for the colored band(s) to appear for 10 minutes.

Interpretation of the results

For positive result; two bands appeared on the membrane. One band appeared in the control region (C) and another band appeared in the test (T) region.

For negative result; only one band appeared in the control region (C). No apparent colored band appeared in the test (T) region.

For invalid result; if control band failed to appear. Results from any test which did not produce a control band at the specified reading time was discarded, procedure reviewed and repeated with a new test. If this problem persisted, we were to stop using the kit immediately.

APPENDIX III; LABORATORY PROCEDURES

HBsAg Rapid Test for HBV

(HBsAg Rapid Test Strip) has been designed to detect the HBsAg through interpretation of a visible color development in the strip. The strip can detect HBsAg in whole blood, serum, and plasma. The membrane was immobilized with anti-HBsAg antibodies colloidal gold conjugates, the specimen is allowed to react with colored anti-HBsAg antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough HBsAg in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred [Blumberg, 1971].

Rapid Anti-HCV Test.

The HCV Rapid Test Strip has been designed to detect anti-HCV antibodies through interpretation of visible color development in the internal strip. The strip can detect anti-HCV antibodies in whole blood, serum, and plasma. The membrane was immobilized with protein A on the test region. During the test, the specimen is allowed to react with colored recombinant HCV antigens colloidal gold conjugates, which were pre-coated on the sample pad of the test. The mixture the moves on the membrane by a capillary action, and interacts with reagents on the membrane. If there were enough HCV antibodies in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred [Lancet, 1991].

APPENDIX IV; RISK MANAGEMENT PLAN

NAME OF THE RESEARCHER/STUDENT:

MOSES MIDU WILSON

TITLE OF THE PROPOSAL/PROTOCOL:

PREVALENCE AND THE RISK FACTORS ASSOCIATED WITH HEPATITIS B AND C AMONG PATIENTS WITH LIVER DISEASE AT JUBA MEDICAL COMPLEX, SOUTH SUDAN

Introduction

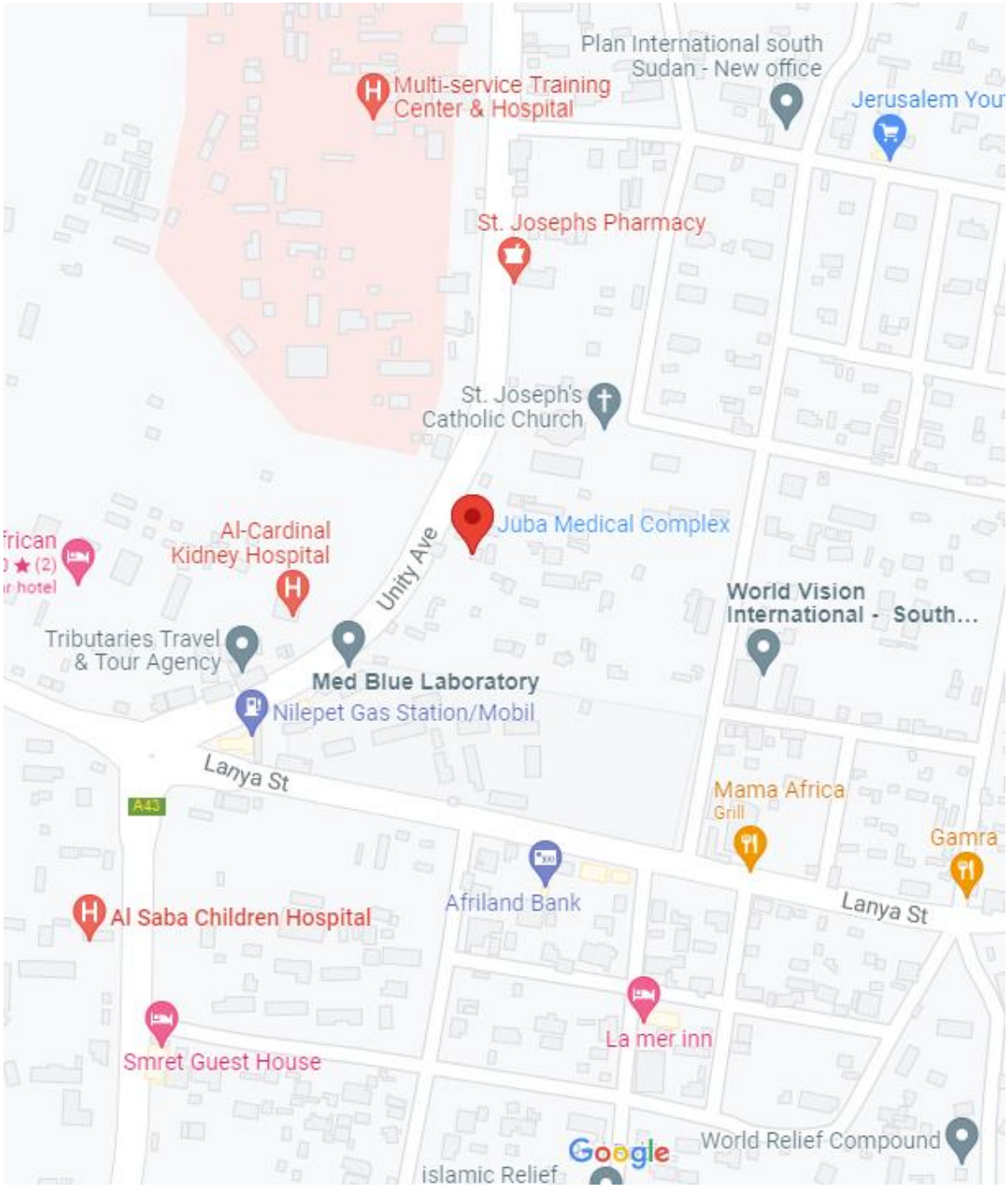
The COVID-19 is a disease that is transmitted by people carrying the virus. The disease can be spread by person to person through respiratory droplets expelled from the nose and mouth when a person coughs or sneezes. It can also be transmitted when humans have contact with hands or surfaces that contain the virus and touch their face, mouth or nose with the contaminated hands. There is currently no vaccine or treatment for COVID-19. Due to the rapidly increasing number of cases in the country, there is a great danger posed among communities to have cross infection from either symptomatic or asymptomatic individuals if mitigation or prevention measures are not well observed.

The research team engaging study participants using face to face approach to collect data may be at high risk of infection which may potentially increase the risk of transmitting COVID-19 between study participants, their household members, participant to study staff and vice versa. This Plan is designed to ensure the health and safety of research teams, support staff, participants and community members against COVID-19. To ensure the protection of study participants and the research team, the following protocol will be observed;

1. All persons involved in the study (principal investigator and research assistants) will put on masks and covering the mouth and the nose properly and consistently.
2. All research assistant/s will be given alcohol-based sanitizer to be used during training and collection of data.

3. Social distance of two meters will be maintained at all times during training of research assistants and during data collection.
4. All research assistant must undergo screening for COVID-19 through temperature check at all check points at the study sites.
5. Study participants without masks will not be recruited in the study.
6. No exchanging hands/sharing of pens, books and other items during data collection with the study participants
7. The research team will be trained on risk prevention and identification of COVID-19 disease symptoms prior to data collection.
8. The study team will on a daily basis conduct reviews of risk prevention and management procedures based on need of risk awareness, identification, documentation and communication.

APPENDIX V: MAP SHOWING LOCATION OF JUBA MEDICAL COMPLEX



APPENDIX VII: ACCEPTANCE LETTER

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

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

Kampala, Monday 18th October 2021

To;
Managing director,
Juba Medical Complex - Juba, South Sudan.

Dear Sir/Madam,

RE: ASSISTANCE FOR RESEARCH

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

This is to introduce to you **Moses Midu Wilson,** Reg. No. **2017-BMLS-FT-AUG-003** who is a student of our University. As part of the requirements for the award of a Bachelors Degree of Medical Laboratory Sciences of our University, the student is required to carry out research in partial fulfillment of his award.

His topic of research is: **Prevalence and the Risk Factors Associated with Hepatitis B And C among Patients With Liver Disease At Juba Medical Complex, South Sudan.**

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

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

Yours sincerely,

for

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

Approved
02/11/21

JUBA MEDICAL COMPLEX
02 NOV 2021
SOUTH SUDAN JUBA

#Make a Difference

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

APPENDIX VIII; WORK TIMELINE

Activity	June	July	August	September	October	November	December	January
Proposal development	■	■	■					
Corrections and approval				■	■			
Data collection					■	■		
Data analysis						■		
Report writing and corrections						■	■	■
Report submission								■

APPENDIX IX; BUDGET FOR THE RESEARCH

Item	Quantity	Unit cost (USD)	Total cost (USD)
Printing and binding	3 books	4	12
Hard cover binding	2 books	8	16
Transport	Lump sum	Lump sum	150
HBVsAg strips	150 strips	0.15	22.5
HCV strips	150 strips	0.15	22.5
Printing questionnaires	69 papers	0.02	1.38
Consent forms	69 papers	0.02	1.38
Syringes (5ml)	150 pcs	0.04	6
Vacutainer (red top)	150 tubes	0.26	39
Total			270.78