SERO-PREVALENCE AND RISK FACTORS OF HEPATITIS B VIRUS INFECTION IN YOUNG ADULT BLOOD DONORS IN KISUMU, HOMABAY AND SIAYA COUNTIES, WESTERN KENYA.

A thesis submitted in partial fulfillment of requirements for the award of the degree of Master of Science in Applied Microbiology (Virology Option) of the University of Nairobi,

By

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2020.

DECLARATION

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

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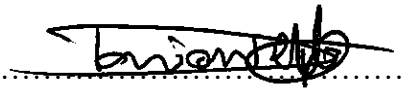
Signed……  ……**Date**……**22 April 2020**……

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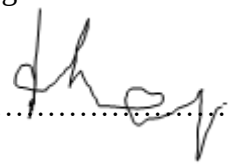
Signed………  ……**Date**…….**22 April 2020**……

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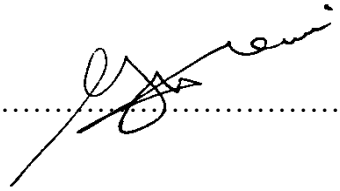
Signed………  ……**Date**……..…**22 April 2020**……..…

DEDICATIONS

To my wife Janet, children Adrian, Angela, Alvina and the unborn for your emotional, moral support and the sacrifices you made while enduring my absence in pursuing this work.

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LIST OF ABBREVIATIONS

CHB	Chronic Hepatitis B
CI	Confidence Interval
CLIA	Chemiluminescence Immunoassay
DNA	Deoxyribonucleic Acid
ELISA	Enzyme Linked Immunosorbent Assay
FRD	Family Replacement Donor
HBcAg	Hepatitis B Core Antigen
HBeAg	Hepatitis B e Antigen
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HBx	Hepatitis B x Antigen
HCC	Hepatocellular Carcinoma
HIV	Human Immunodeficiency Virus
IgG	Immunoglobulin G
IgM	Immunoglobulin M
KAIS	Kenya Aids Indicator Survey
NACC	National Aids Control Council
NACOSTI	National Commission for Scientific, Technology and Innovation
NASCOP	National Aids &STI Control Programme
NBTS	National Blood Transfusion Services
OR	Odds Ratio
PMTCT	Prevention of Mother to Child Transmission

RBTC	Regional Blood Transfusion Center
SPSS	Statistical Package for Social Sciences
TMB	Tetramethylbenzidine
TTI	Transfusion Transmissible Infections
VNRD	Voluntary Non-Remunerated Donors
WHO	World Health Organization.

ABSTRACT.

Hepatitis B virus is a widespread public health menace approximated to have infected 257 million people chronically by 2015.Data on the prevalence of HBV is important in formulating public health policies on HBV control like safe blood transfusion. Young adults aged 15 to 24 years, known to engage in risky activities associated with HBV spread, constitute major blood donors in Kenya. Notwithstanding current blood donation safety measures, HBV still remain hazardous transfusion-transmissible infections in donated blood. This study therefore was to determine the prevalence of HBsAg and related risk factors among this donor group. A cross-sectional study was conducted from April 2019 to August 2019 in Siaya, Kisumu, and Homa Bay counties. One thousand (1000) voluntary blood donors 18 to 25 years old were recruited. A pre-donation questionnaire was used to record their sociodemographic features and prior risk exposures. Blood samples were initially tested for HBsAg using Murex HBsAg Version 3 (DiaSorin, UK) and positives confirmed using ARCHITECT HBsAg Qualitative Confirmatory assay (Abbott Ireland) as per the manufacturer' s instructions. A result was considered positive if the first and confirmatory tests were all reactive. Generally, the prevalence of HBV was 3.4%, with no significant association between various sociodemographic variables and HBsAg positivity. Nevertheless, scarification and risky sexual behavior were significantly linked to HBV infections (odds ratio (OR) = 8.533, 95%confidenceinterval (CI) = 3.128-23.275, *p* value of 0.001 and OR = 5.471, 95%CI = 1.925-15.547, *p* value of 0.002, respectively). This study revealed a prevalence of 3.4% HBsAg among young adult blood donors, with perilous sexual behaviors being the most significant risk factor, evidence that sexual contact still plays a major role in transmission of HBV among this donor group despite blood transfusion safety measures put in place. These study findings should therefore be put into consideration while framing health policies to mitigate effects of HBV infection on safe blood transfusion.

CHAPTER ONE: INTRODUCTION.

1.1 Background Information.

Hepatitis B viral infection is a universal public health problem (WHO Hepatitis B, 2016). Global approximations propose that some minimum of two billion people are diseased with HBV, with 257 million of this number chronically infected (Described as HBsAg positive) (Schweitzer*et al,* 2015).

Developing African region bears the second major global problem of HBV chronic carriers rates after Asia, with about 100 million people suffering HBV infections chronically (Hwang *et al,*.2011). Countries in this region, including Kenya, have an intermediary infection rates of 2%-7% or greater (≥8%) populace infection rates of chronic HBV (WHO Hepatitis fact sheet, 2016).

Even though a gradual general decline in HBsAg infection rates in most countries have been reported, there is remarkable increase in some African and Western countries (Schweitzer *et al.*, 2015). However, true rate of HBV infection in these countries cannot be ascertained because of intermittent health reports as well as poor recording of incidence especially in the countryside where most people reside. Besides, very few studies have been done to elucidate the occurrence of HBV disease in the Sub-Saharan African region, despite the importance of knowledge of HBsAg prevalence in the organization as well as making public health choices regarding hepatitis B control measures such as safe blood transfusion and vaccination. The need for countries like Kenya to have a sustained data on prevalence of HBV infection cannot be overemphasized.

This study consequently sought to document occurrence of HBsAg as well as related risk factors in youths aged 18 to 25 years in three counties within Western Kenya, with a view to encourage and strengthen preventive activities against HBV transmission and infection such as vaccination and safe blood transfusion.

1.2 Problem Statement.

Approximately 257 million people were chronically infected with Hepatitis B by 2015, making this viral infection a universal communal health problem (WHO Global Hepatitis Report, 2017).

Young adulthood is a period of high risk of exposure to HBV infection because it is marked with an onset of very active and risky sexual behaviors such as having multiple sex partners and having sex in exchange for money and other favors (Karl Peltzer, 2010). According to the Kenya Demographic Health Survey (Ministry of health, 2014), the average age at first sexual encounter for males of 20 to 49 years is 17.4 years while that for women under the same age bracket is 18 years. Young adults are also known to experiment with intravenous drug use, use tattoos and other body piercing tools. These are factors associated with high rates of transmission of hepatitis B making the young adult stage a period of high vulnerability to the disease.

In Kenya, donor blood is majorly sourced by the National Blood Transfusion services (NBTS) from young people falling in the age brackets of 15 to 24 years, mostly found in learning institutions such as schools and colleges (Kimani *et al,*.2011). Based on World Health Organization's recommendation of collecting and screening 10 units of blood per 1000 citizens (WHO, 2006), the Kenya National blood transfusion Services have

developed a policy that requires that all blood for transfusion must pass the infectious disease screening tests agreed upon by the Ministry of health, before being made available to the recipient (NBTS Policy Guidelines on Blood Transfusion in Kenya, 2001). This involves screening by a nationally approved and appropriate technique for Transfusion transmissible infection, identified and agreed on by the Ministry of health. Only blood that is non-reactive to these approved infections will be issued for transfusion.

Notwithstanding the current blood donation safety developments put in place, transfusion transmissible infections mainly HIV and hepatitis viruses such as HBV still remain a continuous hazard to blood safety for the recipients (WHO Global Hepatitis Report, 2017). This situation is more endemic in African countries, including Kenya, thus rendering recipients in this areas at danger of contracting the disease (Muriuki *et al.*, 2013). There is need for sustained research and documentation of prevalence rates of infections especially among major donor groups like the youth to ensure blood safety.

While majority of studies conducted on the prevalence of HBV have focused on HIV patients, blood donors in general and the general population, very few have focused on young adult blood donors in Kenya.

1.3 Study Justification.

HBV infection is highly communicable with severe or maybe fatal complications. Young adults are known to be involved in high risk sexual behavior and to experiment with intravenous drug use, factors known to be concomitant in the spread of hepatitis B. To date there are very few studies on prevalence of Hepatitis B among this high risk group in Kenya. This study sort to determine the seroprevalence and associated risk factors of HBV

infection among young adult blood donors, with a view to make possible recommendations on ways to improve donor blood safety, particularly among this key donor population.

1.4 Study Objectives.

The overall objective of the study was to determine the Seroprevalence and risk factors of Hepatitis B virus infection in young adult blood donors within Kisumu, Siaya and Homabay Counties in Western Kenya.

Specific Objectives were:

1. To determine the Seroprevalence of Hepatitis B in young adult blood donors within Kisumu, Homabay and Siaya Counties in Western Kenya

2. To analyze the risk factors associated with Hepatitis B infection in young adult blood donors within Kisumu, Siaya and Homabay Counties in Western Kenya.

CHAPTER TWO: LITRATURE REVIEW.

2.1 Biology of Hepatitis B Virus.

Hepatitis B virus (HBV), a member of the *Hepadnavirus* family, is found in both mammals (*Orthohepadnaviruses*) and birds (*Avihepadnaviruses*) (Schaefer ,2007).

The genetic diversity of HBV is very high, with eight genotypes of HBV and three clades of HBV isolates from apes that appear to be additional genotypes of HBV (Schaefer ,2007). Most genotypes are presently divided into sub genotypes with distinct virological and epidemiological properties. In addition, recombination among HBV genotypes increases the variability of HBV.

Hepatitis B virion is enveloped with a diameter of 42nm and is partly two strand Deoxyribonucleic Acid (DNA), consisting of a 27 nm nucleocapsid core called Hepatitis B Core Antigen (HBcAg) (Figure 1). The core is surrounded by an outer lipoprotein coat that encompasses the surface antigen(HBsAg), as well as a proteolytic self-cleavage derivative of HBcAg and a nonstructural antigen named HBV e antigen (HBeAg) (Maclachlan *et al.*, 2011). The viral DNA and a DNA polymerase with reverse transcriptase activity is encircled by the nucleocapsid.

Hepatitis B virus can also be described morphologically into three distinct groups (Ganem *et al.,* 2001). The small, spherical and noninfectious particles are the most abundant ones. They contain HBsAg measuring 17 to 25nm in diameter and composed of lipid particles. The second group comprises the tubular and filamentous forms of various lengths with a diameter comparable to the first group, as well as HBsAg polypeptides. The third morphological group is those with 42nm diameter virion, is spherical in form and a double

shelled particle. The group also has a structure consisting of an outer envelope containing host-derived lipids and all S-gene polypeptides, the larger (L), middle(M) and small (S) surface proteins also known as pre-S1, pre-S2 and HBsAg. This group has a nucleopeptide that contains a core protein (HBcAg), a 3.2 kb circular, partially double stranded DNA genome and an endogenous DNA polymerase enzyme. (Figure 1)

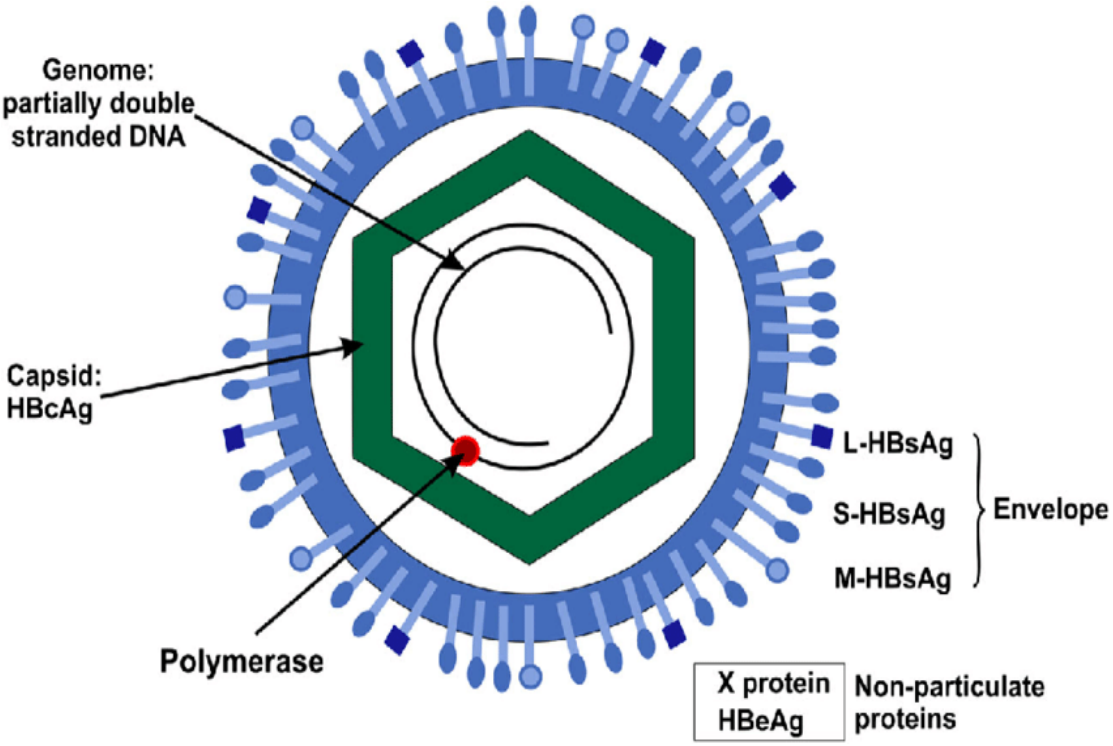

Figure 1 Showing Hepatitis B and the S, L and M surface proteins (MacLachlan and Dubovi,. 2011).

The HBsAg, HBcAg, the viral polymerase and the HBx protein are encrypted by the viral genome (Do and Ghany, 2010). The external envelope comprises embedded proteins useful in viral binding and entry into vulnerable cells. At least nine (A to I) genotypes of HBV are known worldwide, based on more than 8% differences in their genome sequence (Kim *et al.*, 2011, Do and Ghany 2010, McMahon, 2009). Depending on the antigenic epitopes

existing on its envelope protein, the HBV can as well be categorized into four major serotypes namely adr, adw, ayr and ayw (Kramvis *et al.,* 2005).

Classification can also be done according to overall nucleotide sequence variation of the genome into A to H. These genotypes are distinctly distributed geographically and are thus used in tracing the evaluation and transmission of the virus. The differences in genotypes also have an effect on disease gravity, sequence and probability of difficulties, besides reaction to medication and immunization.

2.2 Epidemiology and Burden of HBV Disease.

2.2.1 Epidemiology and Burden of HBV in Kenya.

Epidemiological studies of Hepatitis B virus in Kenya have taken different approaches, putting the current estimates of prevalence of the virus across the populations at between 2% to as high as 13 %. While some studies have focused on the geographical prevalence of the virus, some have focused on key populations such as people living with HIV, Intravenous drug users, healthcare workers among other groups considered at high risk of HBV viral infection (Kangethe *et al.,* 2017, Maina *et al.,* 2017, Ngaira *et al.,* 2016, and Kathleen *et al.,* 2016) Some studies have also focused on the genetic diversity and prevalence of the various strains of the virus (Ochwoto *et al.*, 2016)

Studies have shown that there is a disparity in the HBV infection and prevalence by geographic area in Kenya. While some recent studies in Kenya reported prevalence of 13.3% high in inhabitants of informal town settlement and a 6% infection rate among a HIV infected populace (Kerubo *et al.*, 2015, Ochwoto *et al.*, 2013 and Muriuki *et al.*, 2013), another study on the prevalence of hepatitis B virus surface antigen and HBV associated

hepatocellular carcinoma in Kenyans of various ages (Mutuma *et al.,* 2011) recorded a HBsAg prevalence of 11.2% in Eastern Kenya (Hyams *et al.,* 1989), another study found the prevalence to be 8.8% in Turkana county, the largest and most Northwestern county in Kenya. Yet in another study done among HIV negative adults aged 15 to 64 years based on samples collected from a National survey in 2007 (Kathleen *et al.,* 2016), the HBsAg prevalence rate was reported to be 2.1%, with the highest prevalence being among persons who resided in the North Eastern province (7.4%) followed by persons who ever received blood transfusion (3.62%), males (3.53%), persons who were currently polygamous (3.48%), persons who had no primary education (3.45%), and persons who had ever used condoms (3.29%).

Research carried out on the HBV prevalence in healthcare settings have however seem to produce higher estimates, perhaps owing to selection bias. For example, in a study to determine the proportion, geographic distribution and molecular characteristics of hepatitis viruses among patients seeking medical services at hospitals throughout Kenya, out of the 332 samples collected from patients in four different major hospitals across the country, 168 were HBsAg positive, giving a positivity rate of 50.6% (Ochwoto *et al.*, 2016).

Spread of HBV in Kenya primarily happens in newborns through vertical transmission, while in school attending children and adults, transmission take place horizontally (Waceke, 2010). Heterosexual spread makes up a rising number of HBV contagions with the highest of infections reported during initial years in school, followed by occurrence during adolescence as well as reproductive periods. (Mutuma *et al.*, 2011).

2.2.2 Epidemiology and Burden of HBV in the rest of the World.

The Hepatitis B viral infection is rife and is believed to be having a global presence (Figure 2), estimated to have infected 3.5% of the world's population chronically as at 2015 (WHO Global Hepatitis Report, 2017).

Between 15% to 25% of people with chronic HBV infections die of cirrhosis or liver cancer (Schweitzer *et al.,* 2015). Most infections are reported to occur during infancy or childhood (WHO Hepatitis fact sheet, 2016). With majority of pediatric infections being asymptomatic, cases of acute infection seldom occur in children. However, occurrence of chronic liver infection and cancer in adults is higher (WHO Hepatitis fact sheet, 2016).

The prevalence of the HBsAg in a population can be used to epidemiologically categorize HBV infection in a population into high, intermediate or low prevalence (> 8%, 2%-7%) and <2% HBsAg prevalence respectively) (Franco *et al.,* 2012). These extensive categories are significant in appreciating the major patterns of spread and significances of infections, besides the comparative population burden of the results of chronic hepatitis B, together with liver cancer (Figure 2).

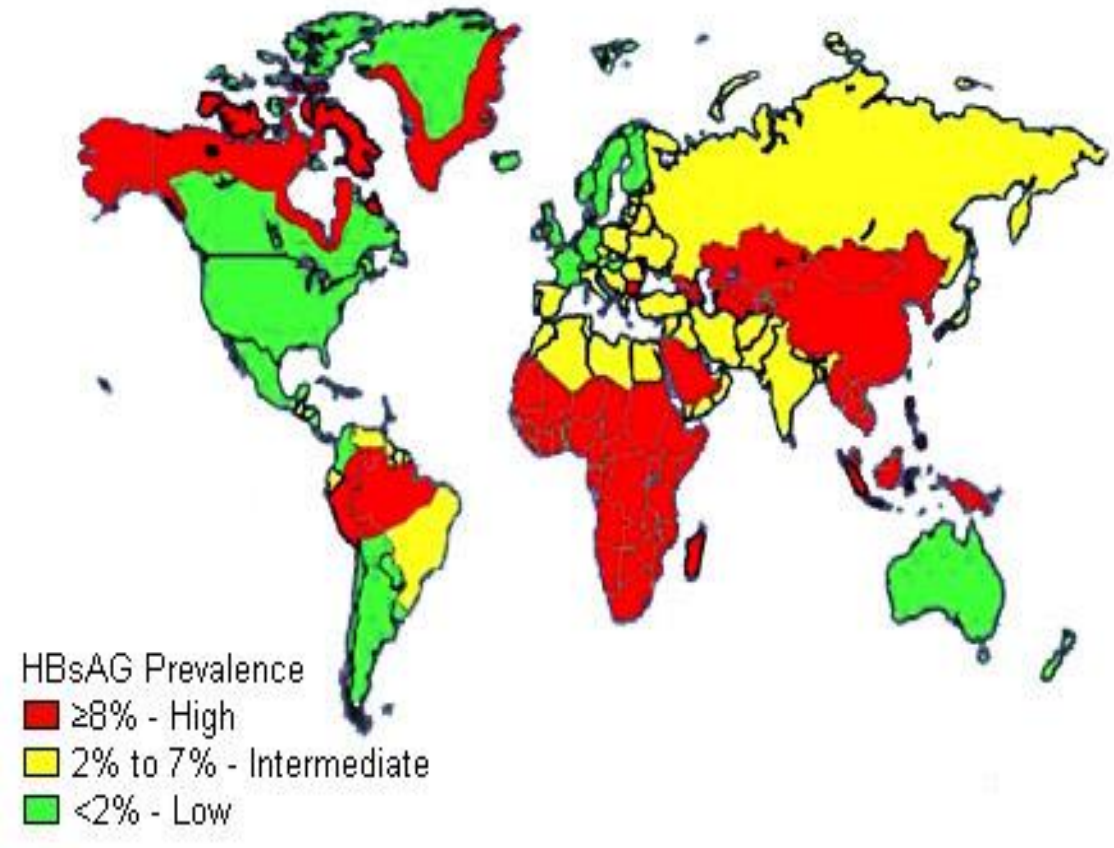

Figure 2 Global Geographic distribution of HBV endemicity (Courtesy of Center for Disease Control, 2012).

2.2.2.1 High Incidence Populaces.

These are countries in which chronic hepatitis B virus disease has infected not less than 8% of the people, with most of these persons having been diseased during delivery or as infants, during which time chances of development to chronicity is elevated (MacLachlan and Cowie, 2015). These high prevalence areas of the world include regions of Sub-Saharan Africa and the Asian Pacific (Figure 2). Generally, 45% of the world's populace is estimated to be living in this areas of elevated incidence (MacLachlan and Cowie, 2015). Vertical transmission has been evidently suggested to be mostly recorded in Asia than

Africa and a bigger number of females in this region are highly infectious during reproductive ages, partially linked to the leading HBV genotype that influences the possibility of HBeAg positivity and elevated levels HBV DNA during peak reproductive ages (Kramvis and Clements, 2010).

In high incidence populations, the effect of newborn vaccination is greatest particularly places in which widespread infant immunization was instigated early. These areas have seen a significant drop in HBV infection in addition to a reduction in liver cancer incidences among groups qualified for vaccines (Chiang *et al.,* 2009).

Some studies (Liang *et al.,* 2009) have reported a drop in prevalence from 9.7% to 1% in China, preventing approximately sixteen to twenty million incidents of chronic hepatitis B from developing. Furthermore, countries like Gambia have reported approximately 95% protective efficacy of infant vaccination in Hepatitis B intervention studies (Plymouth *et al.,* 2009).

Nevertheless, HBV occurrence (HBsAg) still peaks in Sub-Saharan African and Western Pacific regions, viewed as intermediate to high endemicity areas (15% to ≥ 8% prevalence), and prevalence approximations surpass 15% in numerous nations (Franco *et al.,* 2012).

The high endemicity in Sub Saharan Africa differs with geographic locality. However, rates are high in the countryside as paralleled to metropolitan areas (Schweitzer *et al.,* 2015).

2.2.2.2 Intermediate Incidence Populations.

These regions have a prevalence of between 2% to 7% (MacLachlan and Cowie, 2015) and include Northern parts of Africa, Middle Eastern parts of the continent, Eastern and Southern parts of Europe, South Asia as well as parts of Latin America.

Transmission occur in these areas peri-natally or horizontally (MacLachlan and Cowie, 2015).

Due to a reduced incidence of high infectivity among women of childbearing age, perinatal acquisition is less common in intermediate prevalence areas than high prevalence areas. However, the predominant mode of transmission still varies according to country.

It is also worth noting that the categorization of areas as either high, intermediate of low incidence can be changed because of the effect of measures taken, for example vaccination and other deterrence plans, therefore areas that were hitherto considered to be high incidence areas now have prevalence lower than 8% (Chang *et al.,* 2009, Liang *et al.,* 2009).

2.2.2.3 Low Incidence Populations.

Persons residing in lower hepatitis B virus prevalence countries constitute a small number of the world's population, approximated at nearly 12% (MacLachlan and Cowie, 2015). This includes some countries in Northern and Southern America, Western Europe and countries like Japan and Australia. Vertical and horizontal transmission in childhood is minimal, with most infections taking place during adolescence and later in life via sexual contact, injectable drug use as well as other blood related exposures as frequently occurs in healthcare setups.

2.3 Risk Factors of Hepatitis B Infection.

HBV is a highly infectious disease and several risk factors are recorded in several studies as independently related to HBV infection. These include vertical transmission from mother to newborn during delivery, intravenous drug use (IDU), blood and blood products, sexual contacts, particularly risky sexual relations, scarification or tattooing, use of poorly sterilized sharps such as needles and syringes and those who come into contact with carriers, as well as socioeconomic status (Christopher *et al.*, 2015).

Circumcision, Scarification, Tattooing and past surgical procedures have been reported as independent putative risk factors associated with HBV transmission in some studies (Ugwuja *et al.,* 2008). These practices risk causing hemorrhage or ulceration and eventually intensify possibility of percutaneous spread of HBV (Anigilaje *et al.,* 2013, Sadoh *et al.,* 2011, Nwokedinko *et al.,* 2010).

Injections from unprofessional health workers, communal use of sharps and other body penetrating instruments, shared toothbrush as well as uvulectomy (traditional medical practice involving cutting of the uvula) are also considered as possible risk factors in the horizontal transmission of HBV in some locations (Nwokediuko *et al.,* 2011, Nwokedinko *et l.,* 2010).

In Nigeria, a study of the risk factors of hepatitis B viral disease in primary healthcare (Gabriel *et al.,* 2013) demonstrated transfusion of infected blood to be a risk factor in the spread of hepatitis B virus disease amongst a study populace. Additionally, cross-sectional studies carried out in hospitals in Nigeria (Iroezindu *et al.,* 2012 and Adekanle *et al.,* 2010)

as well as in other parts of the world such as Kolkata, India (Das *et al.*, 2011) have also established that hepatitis B viral disease is transmissible via transfused blood.

Intravenous drug use(IDU) has also been independently associated as a risk factor of hepatitis B virus spread, for example, a research to estimate the Global burden of infection attributed to use of injectable drugs as a potential risk in the spread of HIV, HBV and HCV (Louisa *et al.,* 2016) between 1990 and 2013 reports IDU to be increasingly becoming an independent risk factor of hepatitis B virus spread across the globe. In another study of the infectivity status and risk factors of HIV, HBV, HCV as well as Syphilis (Wu *et al.,* 2010) in a Chinese province, 19.3 % of study participants tested positive for HBV, establishing injectable drug use as an independent risk factor of HBV spread in that population. Nevertheless, few studies have been done to establish the role of IDU as a risk factor in HBV transmission in many Sub-Saharan African countries including Kenya.

Unprotected sexual activities, exchange of sex for money and having multiple sex partners are some of the risky sexual behaviors that are recorded as possible risk factors for hepatitis B virus transmission (CDC Morbidity and Mortality weekly report, 2012). In a study to determine the incidences, associations and patterns of hepatitis B surface antigen in a poor income setup (Eke *et al.,* 2011), besides injectable drug use being reported as one of the risk factors, the most important risk factor for Hepatitis B infection reported among young adults in this study was risky sexual behaviors. Studies in the United States (Low endemicity area) have shown low transmission rates in those below 12 years of age and a rise in people older than 12 years (Waceke, 2010). The heightened occurrence in people who are more than 12 years old is linked to the early commencement of sexual contacts (the main means of spread the disease) and the total number of sexual partners.

Young adult's transmission may be important in developing countries such as Kenya since the youth in this countries have been reported to be increasingly engaging in risky sexual behaviors (Ministry of Health, 2014).

In Kenya, several risk factors have been reported to be independently associated with HBV infection. However, very few studies have focused on the risk factors in the general population or young adults, with most studies done focusing on high risk groups. One such study sort to define the burden of HBV infection among high risk group including Men having Sex with Men (MSM), Known HIV positive persons, Female Commercial Sex Workers and Chronic Liver disease patients (Karoney *et al.*, 2020). This study reported high risk factors including sexual activity (> 90%), tattoos and traditional marks (>30%) and traditional circumcision (>40%) among all the study groups, with risk factors such as intravenous drug use (<12%) and history of liver disease (<6%) being less reported among study participants.

In yet another study on the prevalence and associated risk factors of HBV infection among HIV-infected mothers on antiviral therapy and their exposed infants in Nairobi Kenya (Kangethe *et al.*, 2017), risk factors reported to be associated with HBV infection included history of dental surgery, blood transfusion, substance use, body piercing and HBV vaccination. History of dental surgery and history of blood transfusion were independently associated with HBV transmission.

2.4 Transmission of the Virus.

HBV is a very resilient virus and is able to survive for a prolonged period outside the body, with some studies suggesting it can stay as long as seven days on a dry surface (Lok and McMahon, 2009).

Body fluids like vaginal secretions, semen and saliva contains the virus, though it is majorly present in blood (Kidd-Ljunggren *et al.,* 2006). Even though the virus has been detected in saliva, tears, breast milk, urine and sweat, minimal evidence exists of transmission through exposure to this fluid without the involvement of blood. Moreover, breast milk has not ever been demonstrated to escalate the risk of transmission (Zheng *et al.,* 2011).

There are two main modes of spread of HBV worldwide, namely perinatal and horizontal modes (Nelson *et al.,* 2016, WHO HBV treatment guidelines, 2015).

Perinatal spread, also called vertical spread, occurs during delivery from a diseased mother to newborns and makes up most of the HBV infections globally. Devoid of suitable intervention, a female who is positive for the hepatitis B surface antigen converses a 20% risk of transmitting the infection to the young one during delivery (Waceke, 2010). The risk increases to a high of 90% if the mother is equally positive for hepatitis B e antigen.

Horizontal spread takes place via open wounds as well as grazes, transfused infected blood and its components, through unprotected sexual intercourse, use of unhygienic sharps especially needles and syringes among intravenous drug users, use of unsterilized equipment during traditional practices such as circumcision, scarification and tattooing among other means. Hepatitis B virus is also transmissible between members of the same

household, probably via open wound or mucosa coming into contact with virus infected blood.

Spread of the virus through means such as infected blood and blood products as well as hazardous medical practices have decreased significantly with the putting into place control strategies and safe blood transfusion procedures (Jennifer and Benjamin, 2015). Nevertheless, healthcare related infections remain a considerable concern in both poor (Arankalle *et al.,* 2011) and rich settings (Thompson *et al.,* 2009).

Chances for contagion and transmission in adolescent and adults comprises injection of abused drugs, tattooing, use of cocaine, unprotected sex, and being born in a country with high prevalence (WHO Global Hepatitis Report, 2017).

It is important to note that the mode of spread of hepatitis B virus reflects the incidence of chronic hepatitis B in a specified region (Waceke, 2010). In low incidence zones, injectable drug use and unprotected sexual intercourses are the key methods of transmission. However, other risk factors may also be important. The virus is mostly spread between young ones in areas with moderate incidences while regions with high occurrences such as China and South East Asia, the disease is predominantly spread during childbirth.

2.5 Clinical Presentations of HBV infection.

HBV infection can occur acutely or chronically in man with lengthy varying incubation periods of eight weeks to six months (Sandhu *et al.,* 2017).

The existence in serum of HBsAg, secreted viral proteins (HBeAg), alanine and aspartate aminotransferases is considered acute infection (Sandhu *et al.,* 2017). Consequently, there is presence of antibodies to core HBcAg then those against HBeAg and finally HBsAg in

serum, aiding in patient recovery and removal of HBV. Acute infection presents with no symptoms for many yet others experience symptoms like overall ill-health, poor appetite, nausea, vomiting, body pains, minor fever, passing black urine, and then advancements to jaundice (Liang *et al,* 2009).

Chronically, HBV manifests in a similar way to acute infection. However, the patient does not recuperate from the disease as elevation of level of HBV DNA and HBsAg in serum continues extensively post exposure to HBV (McMahon,2008). HBV infection progress to chronicity in 90% of babies born to HBeAg- positive mothers, in 80% up to 90% of newborns diseased in the course of the first year of life, in 20% to 50% of kids below six years and in 6% of those in the age ranges of five to fifteen years and 1% to 5% in the aged populace (Zampino *et al.,* 2016).

2.6 Diagnosis of Hepatitis B Virus Infection.

Generally, the biochemical analysis of the liver functions will give a diagnosis of hepatitis. Confirmation of diagnosis is through evidence in sera of specific antigens or antibodies (Hollinger *et al.,* 2010).

Methods used to characterize HBV infection include serological markers (Table 1), virological (Hepatitis B virus DNA and genotyping), biochemical (Alanine aminotransferase, ALT) makers as well as histological markers such as the extent of hepatofibrosis and inflammation (Danta, 2014).

Table 1. Interpretation of HBV Immunological markers (Adapted from Mast *et al,* 2006)

HBsAg	Total anti-HBc	IgM Anti-HBc	Anti-HBs	Interpretations
-	-	-	-	Never Infected
+	-	-	-	Early acute infection; transient (up to 18 days) after vaccination.
+	+	+	-	Acute infection
-	+	+	-	Acute resolving infection
-	+	-	+	Recovered from past infection and Immune
+	+	-	-	Chronic infection
-	+	-	-	False Positive (i.e Susceptible);Past infection; Low level chronic infection; Passive transfer to infant born to HBsAg positive mother
-	-	-	+	Immune if concentration is ≥ 10mIU/mL, passive transfer after Hepatitis B immunoglobulin administration.

2.6.1 Serological Assays.

For HBV, serological indicators of illness include HBsAg, anti-HBs, HBeAg, anti-HBe and anti-HBc IgM and IgG (Song and Kim, 2016).

Documentation of this serological indicators allows identification of patients with HBV disease, clarify the normal sequence of persistent Hepatitis B, asses the medical phase of the disease and to make a follow up of antiviral therapy.

2.6.1.1 HBsAg Serological Marker

HBsAg serological marker is the main characteristic indicator of Hepatitis B viral disease. Following an acute exposure to HBV, HBsAg is detectable in serum within 1 to 10 weeks. Continued appearance of this marker for a period beyond 6 months implies chronic HBV infection (Kao, 2008).

Numerous studies have described the link between transcription activity of covalently closed circular DNA (cccDNA) in the liver and serum HBsAg levels (Thompson *et al.,* 2010, Nguyen *et al.,* 2010 and Chan *et al.,* 2007). Alterations in the serum HBsAg levels for the duration of the various phases of infection indicate the distribution of cccDNA during the respective phases of the disease. The serum HBsAg titers are greater in patients with HBeAg-positive chronic Hepatitis B (CHB) than in HBeAg-negative CHB (Jaroszewicz *et al.,* 2010, Thompson *et al.,* 2010 and Nguyen *et al.,* 2010).

Observation of the quantitative HBsAg levels forecasts treatment reactions to interferon and disease progression in HBeAg-negative CHB patients with normal serum alanine aminotransferase levels (Martinot-Peignoux 2013 *et al.,* 2013, Chan *et al.,* 2011).

2.6.1.2 Anti-HBs Antibody Serological Marker

Anti-HBs is known as a neutralizing antibody that confers longstanding immunity (Weber, 2005). It is the only serological marker detectable in serum of patients who have acquired immunity through vaccination.

The Anti-HBs occurs concurrently with anti-HBc IgG in patients with a past HBV infection. Sporadically, the concurrent appearance of HBsAg and anti-HBs has been described in patients who are HBsAg positive. In many circumstances, anti-HBs antibodies are unable to neutralize the circulating viruses, therefore these patients are considered as carriers of HBV.

2.6.1.3 HBeAg Antigen and Anti-HBe Antibody Serological Markers.

Previously, HBeAg and anti-HBe had been used to know infectivity and viral replication. However, their use for this purpose has typically been substituted by HBV DNA assay. HBeAg to anti-HBe seroconversion is linked to the remission of hepatic disease (Deny and Zoulim, 2010). Nevertheless, active viral replication is persistent in some patients with HBe seroconversion because of mutations in the pre-core and core region that hinder or reduce the production of HBeAg (Kao, 2008).

2.6.1.4 IgM and IgG anti-HBc Antibodies Serological Markers.

HBcAg is an intracellular occurrence in infected hepatocyte, and therefore not identified in the serum. For the duration of acute infection, anti-HBc IgM and IgG appears 1 to 2 weeks after the presence of HBsAg alongside elevated serum aminotransferase and symptoms.

Following 6 months of acute infection, anti-HBc IgM wanes off. Anti-HBc IgG remains detectable in both patients with resolved HBV infection and chronic hepatitis B (CHB).

Some HBsAg-negative individuals are positive for anti-HBc IgG with no anti-HBs, and in such cases, should be considered as isolated anti-HBc positive. It can be seen in three conditions. First, it can be mainly seen as IgM class during the window period of acute phase. Secondly, after acute infection had ended, anti-HBs has reduced below the cutoff level of detection. Thirdly, after several years of chronic HBV infection, HBsAg has reduced to undetectable levels. In case the outcome of serological markers shows isolated anti-HBc positive, anti-HBc IgM should thus be checked in order to evaluate the likelihood of recent HBV exposure.

2.6.2 Virological Assays.

2.6.2.1 HBV DNA

The level of HBV replication can be directly quantified using polymerase chain reaction (PCR) and other molecular amplification techniques.

Detection of HBV DNA is currently an essential part of hepatitis B virus diagnosis and treatment, with continuously low levels of intrahepatic HBV DNA without detectable HBsAg indicating occult HBV disease (Hollinger *et al.,* 2010, Raimondo *et al.,* 2009). HBV DNA assays should be tested in chronic liver disease patients to find out occult HBV infection characterized by existence of detectable HBV DNA without serum HBsAg (Raimondo *et al,*.2007).

The existence and use of real-time PCR has additionally enhanced the performance and quantification of HBV DNA during diagnosis.

2.6.2.2 HBV genotyping

This involves sequencing of the HBV genome. Presently, nearly nine genotypes (A-I) that vary geographically have been identified (Hollinger *et al.,* 2010), the main genotypes being A-D.

Currently, genotyping is mostly used in research laboratories, but occasionally, it is used in patient diagnosis especially in emergency cases such as disease outbreaks where concise and faster diagnosis may be required. The method is also increasingly becoming a method of choice in identifying patients at great risk of disease progression (WHO, 2018).

2.6.3 Biochemical assays.

The biochemical markers used in the measurement of the gravity of liver disease comprises of alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphate, gamma-glutamyl transpeptidase (GGT), bilirubin, serum albumin and globulin, blood counts and prothrombin time and hepatic ultrasound (Raimondo *et al,*. 2009). The major biochemical marker indicative of viral hepatitis is ALT (Danta, 2014).

Typically, ALT levels are greater than AST levels. Nevertheless, as the infection advances to cirrhosis, the ratio may be inverted. A gradual drop in serum albumin levels and/or rise of gamma-globulin and the protraction of prothrombin time, frequently complemented by decreasing platelets counts are typically observed following development of cirrhosis. Studies have recorded that approximately 12% to 43% of patients suffering chronic HBV

with normal ALT levels have considerable hepatic cirrhosis, probably stage 2 fibrosis (Raimondo *et al*,. 2009).

2.7 Interventions for HBV Infection.

An all-inclusive response to hepatitis B necessitates the carrying out of effective, high-impact measures (WHO Hepatitis Report, 2017). This encompasses five core synergistic interventions including Hepatitis vaccination, HBV Prevention of maternal transmission (HBV PMTCT), Transfusion Blood safety, Injection Safety, Harm reduction and Testing and Treatment of HBV (Nayagam *et al.,* 2016).

2.7.1 Treatment.

The aim of treatment of viral hepatitis is a reduction in viral replication, to reduce symptoms, to enhance liver histology with decline in infection and fibrosis, and therefore reduced chances of development to cirrhosis and Hepatocellular Carcinoma (HCC) and eventually improvement and long-term survival (Chimika, 2015).

Treatment of HBV began in 1985 and with time improved from the use of interferons to more recently discovered nucleotides analogues such as Tenofovir and Entecavir (WHO Guidelines to care and treatment of HBV,2016). Nonetheless, below 8% of the population diagnosed with hepatitis B virus disease received WHO-recommended antiviral treatment (WHO, World health Statistics, 2016) as at 2015, majority of whom were found in developed countries. The situation in developing countries like Kenya is worse, with challenges of availability and affordability of antivirals very rampant. Even when this drugs are available, they rarely in effect result to a cure.

Currently, extensive therapy is necessary for most patients and prevention (Immunization) remains the safest way of combating hepatitis B. This can only be enhanced with availability of data on the prevalence rates of HBV infections, including for different age sets for a more effective and targeted interventions.

2.7.1.1 HBV Treatment Guidelines in Kenya

The aim of HBV treatment as contained in the HBV treatment guidelines in Kenya (2014) is to reduce the risk of progression to chronic liver disease, prevent transmission to others and prevent long term complications such as cirrhosis and hepatocellular carcinoma (HCC) and death. Various studies have assessed the impact of treatment for chronic HBV in the risk of HCC, with systemic assessment of available data indicating relative reduction by about 50 to 60 % after antivirals treatments. Nevertheless, these treatments do not entirely eliminate the risk, especially in patients who develop nucleoside resistance (Okoth *et al,.*1986).

The treatment guidelines demand a determination of patients' eligibility for treatment based on indicators such as Alanine aminotransferase (ALT) levels, HBeAg status, HBV DNA levels, Liver biopsy when indicated and HBsAg serum levels quantification. Clinical categories that the guideline recommends for consideration for treatment include chronic Hepatitis B, Liver cirrhosis (both compensated and decompensated), patients with HBV and are to undergo immunosuppressive therapy and pregnant women who are HBsAg positive and have a high viral load ($>10^7$ Iu/ml).

Unfortunately, complete eradication of HBV from host hepatocytes cannot be achieved with the currently available agents because of the persistence of HBV covalently closed circular DNA (cccDNA).

Globally, there are seven agents that are recognized for management of CHB (Guidelines for the treatment of chronic HBV and HCV viral infections in Kenya, 2014). This are nucleoside analogue and immune-modulating drugs, with Peg Interferon and Tenofovir recommended as first line drugs in Kenya. The treatment duration varies from 48 weeks to a daily lifetime dose, depending on the drug of choice.

2.7.2 Vaccination.

2.7.2.1 HBV Vaccination Policy

A vaccine developed against the hepatitis B virus remains the backbone of hepatitis B control (Chimika, 2015).

WHO advocates for all newborns to be immunized against hepatitis B virus, with the vaccine being administered in three or four separate doses, as a segment of current routine immunization schedules.

Protective immunity is induced in at least 95% of immunized children and adolescents, with protection going for twenty years or more (WHO Hepatitis B Fact Sheet, 2012). Despite successful vaccination programs that have seen changing epidemiology of HBV disease (Meireles *et al.*, 2015), WHO Africa region still has coverage gaps.

Worldwide administration of the three doses of HBV vaccine reached 84% in 2015 (WHO Hepatitis report, 2017). However, countries like Kenya have recorded a decline in coverage from a peak of 96% in 2011 to a low of 82% in 2017 (WHO, 2018 Global summary).

In order to reach adequate exposure levels for purging HBV as envisaged by the World Health Assembly (2016), there is need for covering those not already immunized, predominantly in the African continent (WHO Hepatitis report, 2017).

The availability and documentation of the prevalence rates of HBV infection not only in the overall population but even among special groups at high risk of disease transmission such as young adults can greatly aid such intervention processes. Groups with potentially high prevalence such as adolescents and young adults require improved testing and treatment services. Elucidating prevalence among this risk group, as this study portends, is therefore very essential.

2.7.2.2 HBV Vaccination Policy in Kenya.

Universal child immunization is now accepted as the ideal approach for the early long term control of chronic HBV infection and its sequelae (cirrhosis and liver cancer).

The Hepatitis B Vaccination Policies in Kenya is contained in the Guidelines for the Treatment of Chronic Hepatitis B and C viral infections in Kenya (2014) and the Kenya National Policy Guidelines on Immunization (2013), with HBV vaccine being part of the Kenya Extend Programme on Immunization (KEPI).

Since the main route of spread of Hepatitis B in Kenya is child to child (horizontal transmission) rather than perinatal transmission, Hepatitis B vaccination at birth has no

significant benefit over Hepatitis B vaccination started at 6 weeks of age, in the reduction of HBV infections of young children. Consequently, infants in Kenya are vaccinated with 3 doses of Hepatitis B vaccine in combination vaccines containing diphtheria and tetanus toxoids, and haemophyllus influenza type b given at 6, 10 and 14 weeks after birth (Kenya National Guidelines on Immunization, 2013).

It is recommended that healthcare workers and other risk groups be given three doses of a monovalent Hepatitis B vaccine administered at 0, 4 and 6 months for the prevention of hepatitis B infections.

Adults in need of quick preventions, for example within 48 hours after exposure, can have a scheduled of 0, 7 and 21 days (Guidelines for the Treatment of Chronic Hepatitis B and C viral infections in Kenya, 2014). After an accelerated dose, a booster at one year is recommended. Duration of protection provided by HBV vaccine remains unknown. It is recommended that individuals at continuing risk of infection be provided a single booster dose once only, around 5 years after primary immunization.

CHAPTER THREE:MATERIALS AND METHODS.

3.1 The Study Design.

This was a cross-sectional study involving consenting voluntary blood donors who are between the ages of 18 to 25 years.

3.2 Study Area.

The counties of Kisumu, Siaya and Homa Bay (Figure 3) serve as the major blood source for most hospitals in Western region. These regions also have some of the highest HIV infections rates besides recording perilous sexual behavior among young adults, intravenous drug practices and other activities that have been related to high levels of transmission and infection with HBV (Ministry of Health, 2014, Kimani *et al.*, 2011). It is on this basis that these areas were selected for the study. Laboratory processes were performed at the Virology laboratory at the Kisumu Regional Blood Transfusion Center (RBTC) and The National Blood Transfusion Center Virology Laboratory in Nairobi.

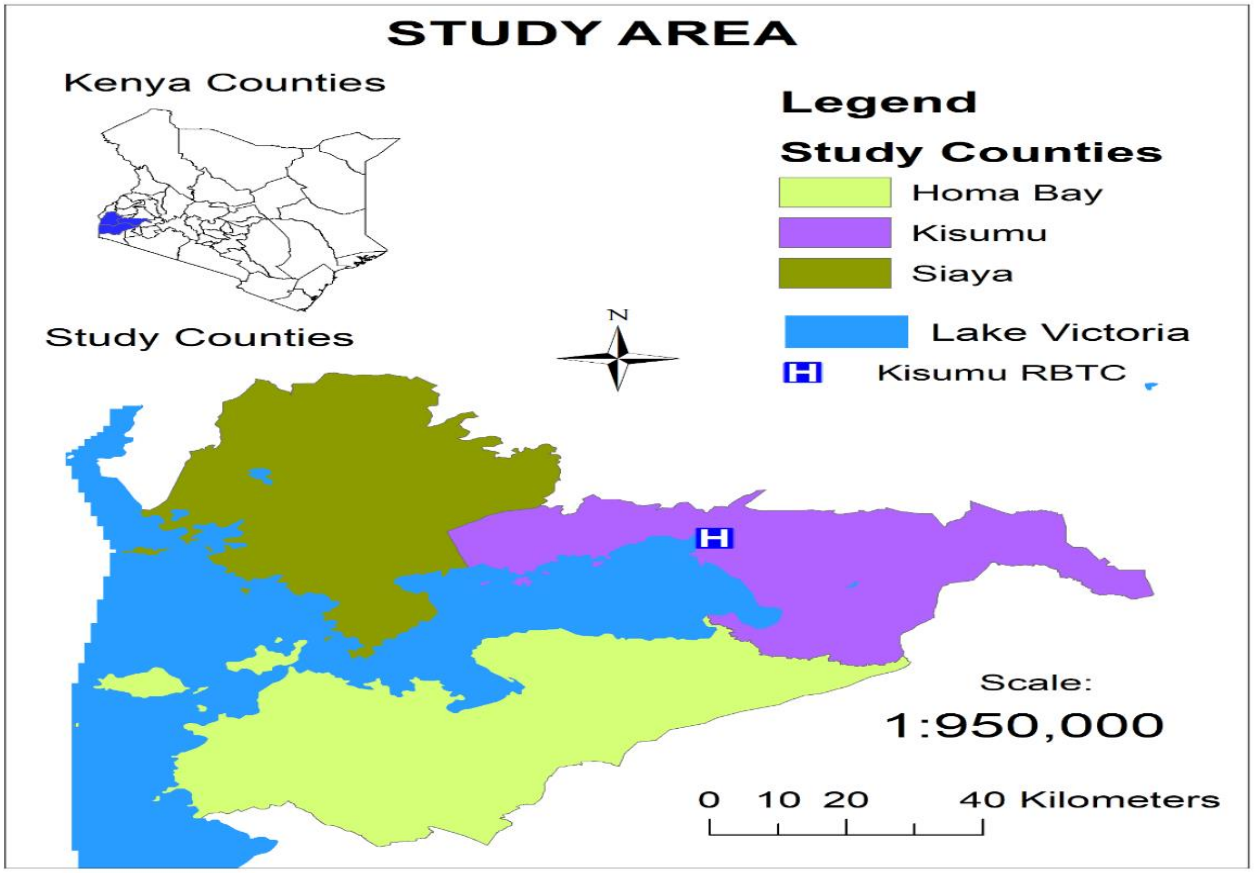

Figure 3 Map showing the study areas of Kisumu, Homabay and Siaya counties and the location of the Regional blood transfusion center where laboratory processes were performed (RBTC).

3.3 Target Population.

The target population were voluntary blood donors found in the age range of 18 to 25 years from Homabay, Kisumu and Siaya counties.

3.4 Calculation of Sample Size.

Desired sample was determined by the formula of Fisher (1998):

$N = \frac{Z^2PQ}{D^2}$ Where-:

N is the sample size whereas *Z* the standard normal deviation (at 1.96) corresponding to 95% confidence level. *P* represents a percentage in the target population approximated as having a particular trait. In this study, an estimated prevalence of 3.46% was used based on a study on the determinants of Seroprevalence of transfusion communicable diseases in volunteer blood donors in Homabay, Kisumu and Siaya counties in western Kenya (Onyango *et al.*, 2018) that found the prevalence of HBV infection to be 3.46. *D* is the level of exactness preferred, here fixed at 0.02 corresponding to the 1.96. *Q* is calculated as 1.0 – *P* (Table 2.).

Table 2. Calculation of the Sample size.

Z^2	P	Q	D	$N = \frac{Z^2PQ}{D^2}$	N
$(1.96)^2$	0.0346	1-0.0346	$(0.02)^2$	$\frac{3.84\text{x}0.0346(1-0.0346)}{0.0004}$	320

3.5 Sampling Technique.

A total of 1000 young adult blood donors from 33 different public high schools, middle level colleges and Universities in Kisumu, Siaya and Homabay (Appendix 3) targeted for blood donor recruitment activities were recruited into the study. Purposive random sampling was applied in selection of schools, colleges and study participants. The schools and colleges were selected using Microsoft Excel from a list of schools and colleges where the Kisumu regional blood transfusion center planned to source donor blood. Public high schools and colleges are the major voluntary blood donor sources for KNBTS. Donor aged between 18 years to 25 years, and consenting to the study were enrolled, while those aged below 18 years, and those aged above 25 years were excluded. All donors who did not consent were also disqualified.

3.6 Data Collection tools.

3.6.1 Questionnaire.

The standard National Blood Transfusion Service questionnaire (Appendix 1and 2) was administered in English or Kiswahili to the study participants, with each study subject questioned on sociodemographic characteristics and exposure to various risk factors including involvement in perilous sexual behaviors, scarification of the body, intravenous drug use and past injuries such as needle sticks. Practices that constituted perilous sexual behaviour that the questionnaire sort to know from the participants included a history of receiving money, goods or favors in exchange for sexual activities, having sexual activity with a person of unknown background, having been raped or sodomised and having sex with multiple partners. Past injuries included having had a stab wound, accidental needle

sticks injury or injection. For ethical reasons and integrity of the test process, a bar coded donor identity was then used to link each donor questionnaire to the blood samples.

3.7. Laboratory Processes.

3.7.1 Blood collection and Serological Analysis.

After donor blood collection, whole blood sample from donor bags was dispensed into red top vacutainer tubes and left to clot at room temperature (Fig 5). Thereafter, 75ul of serum was then pipetted from the vacutainer tube for analysis using Murex HBsAg Version 3 (Manufactured by DiaSorin S.p.A UK Branch) as per manufacturers' instructions. Samples that turned positive for HBsAg using this initial test were shipped to Regional Blood Transfusion Laboratory in Nairobi, where confirmatory test was done by Chemiluminescence Immunoassay (CLIA) using the ARCHITECT HBsAg Qualitative Confirmatory assay (Abbott Ireland, Diagnostics Division, Sligo, Ireland) (1P98) as per the manufacturers' instructions. A result was considered positive if the first test and the confirmatory test were all reactive.

Figure 4. a, b, c and d showing the investigator processing samples at the RBTC virology Laboratory in Kisumu.

Figure 5 .Blood samples from Kisumu County being processed for loading into the ETI-Max 3000 Microtitter Plate analyzer at Kisumu RBTC Virology Laboratory.

3.7.2 The Assay Principles.

3.7.2.1 Enzyme Linked Immunosorbent Assay (ELISA) Principle.

In this study, initially, HBsAg was assayed by use of Murex HBsAg Version 3. This kit uses Antigen Capture ELISA principle (Figure 6).

Test samples were pre-incubated in a monoclonal antibody specific for different epitopes of 'a' determinants of HBsAg coated microwells (WHO Diagnostic Public Report. 2016, Murex HBsAg Version 3 user manual, 2009).

Horseradish peroxidase conjugated to affinity purified goat antibody to HBsAg was then added to the wells with specimen followed by a first wash and then a second incubation process.

After the second incubation process, any HBsAg existing in the sample was attached to the well to form an antibody-antigen-antibody-enzyme composite. If there was no HBsAg, no conjugate would be attached.

Following a second wash to take out excess specimen and unattached conjugate, a liquid mixture with 3,3',5,5'-tetramethylbenzidine (TMB) plus hydrogen peroxide was put into the wells, at which instance wells having HBsAg and thus bound to conjugate changed to a purple colour which then converted to orange color on the conclusion of the reaction to sulphuric acid.

Depending on test results, samples that produced an absorbance equivalent to or more than the cut-off value were treated as primarily reactive in the assay and therefore tested again in duplicate. Samples reactive in not less than one of the re-tests were presumed to have HBsAg and thus established positive.

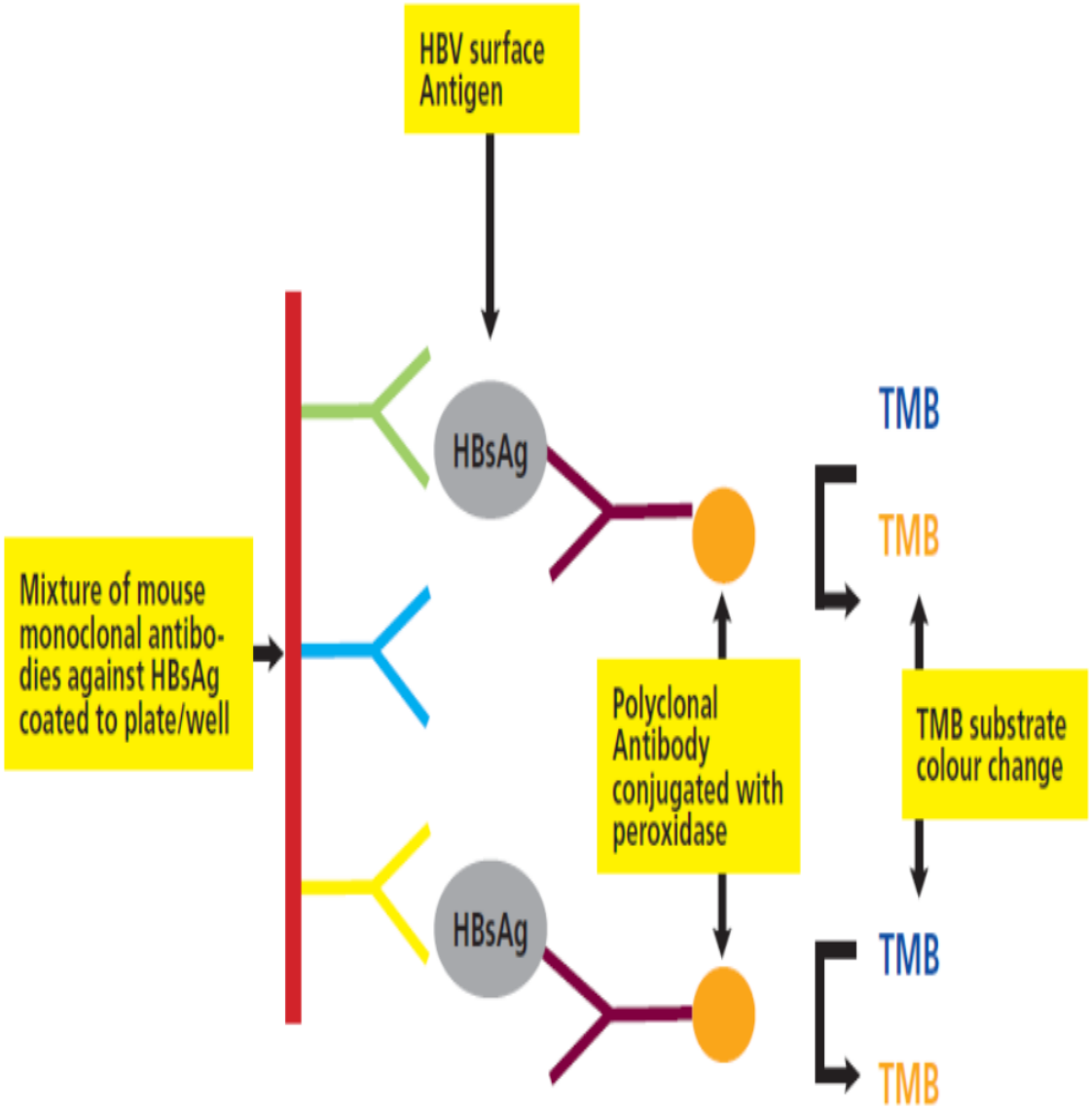

Figure 6. An illustration of the Antigen capture ELISA principle (MacLachlan and Dubovi, 2011).

3.7.2.2 Chemiluminescence Immunoassay (CLIA)Principle

All samples that tested positive for HBsAg using the ELISA test were shipped to Nairobi, where a confirmatory test was done using the ARCHITECT HBsAg Qualitative Confirmatory assay (Abbott Ireland, Diagnostics Division, Sligo, Ireland).

This test kit uses the Chemiluminescence Immunoassay (CLIA) principle and is used for confirming the presence of HBsAg in human serum and plasma by means of specific antibody neutralization. The assay consists of 2 single tests that are both modified 1-step pretreatment immunoassays.

To carry out the test, the sample and pretreatment-1 were combined in a reaction vessel (RV) and incubated. This was to allow HBsAg present in the sample be neutralized by the antibody in the pretreatment-1.

An aliquot of the pretreated sample was then added to the reaction mixture. Nonnutralized HBsAg present in the sample were bound to the anti-HBs coated microparticles and to the anti-HBs acridinium-labelled conjugate.

After washing, ancillary wash buffer was added to the reaction vessel and processed. This sequence was repeated for the sample combined with pretreatment-2, which was not containing neutralizing antibodies.

Sample was considered HBsAg positive if the signal for the Nonnutralized sample (Incubated with pretreatment-2) was greater than or equal to the cut-off ($S/CO \geq 0.70$) and the relative light unit (RLU) of the sample was reduced by at least 50% compared to the Nonnutralized sample.

3.8 Data Management and Analysis.

The data generated was entered into MsEcxel, cleaned and analyzed by use of statistical Package for Social Science (SPSS), version 24 (IBM Corp, Armonk, NY, USA). Presentation of descriptive statistics was done in frequencies and percentages by use of tables and charts. Chi-square test was used to test the statistical significance between the risk factors and the outcome variable (HBsAg test result) with a P-value of less than or equal 0.05 ($P \leq 0.05$) considered statistically significant. The association between HBsAg seroprevalence and various risk factors was established using logistic regression where Odds ratios(OR) with their 95% confidence intervals (CI) aided to examine the effect of the various risk factors on the occurrence of HBsAg Seropositivity. A P-value less than 0.05 ($P< 0.05$) was regarded as significant.

3.9 Ethical Considerations.

This study obtained approvals from the Kenya National Blood Transfusion Management (Appendix 4), and The University of Nairobi board of Postgraduate studies. Confidentiality of the study participants was safeguarded through use of codes and ignoring materials that pinpointed at the study subjects. Participants who were found positive for HBsAg were confidentially informed of their status and referred to local hospitals for treatment.

CHAPTER FOUR: RESULTS.

4.1 Sociodemographic Characteristics of Study Participants.

Young adult voluntary blood donors totaling 1000 and aged between 18 years to 25 years spread across the counties of Kisumu, Siaya and Homa Bay were enlisted into the study. Specimen from all the study subjects were tested for HBsAg. In general, there was no substantial variances in proportions distribution among demographic variables tested. There was no statistically significant association between the soci-odemographics such as age, age group, gender, place of origin and number of donations and HBsAg test result. This is summarized in Table 3. below.

The average age of the study participants was 19.54 (SD= 1.642, Range=18-25) years with most of the study subjects categorized as 18 to 21 years (n=882) while only 118 fall between the ages of 22 to 25 years. Of the donors positive for HBsAg (n=34), 3.1% (n=31) were within the age range of 18 to 21 years, while only 0.3% (n=3) of those within the age range of 22 to 25 years tested positive for HBsAg (Figure 7). Neither age nor age groups had a statistically significant association with HBsAg test result at P-values of 0.584 (Table 3.).

In this study, 618 (68.1%) participants were males while 382 (38.2%) were females. Of the total 34 participants positive for HBsAg, 55.9% (n=19) were males while 44.1%(n=15) were female (Figure 8). Gender had no statistically significant association with HBsAg test results at a p value of 0.470 (Table 3.).

Study participants aged between 18 to 21 years constituted majority of the first time donors at 90.3%(n=866) out of the total 959 first time donors, while those in the age brackets of

22 to 25 formed a major portion of repeat donors at 61% (n=25) of the total 41 repeat donors. Of the total HBV positive cases, 31 were first time donors, while only 3 were repeat donors (Figure 9). There was no statistically considerable association between the number of times a donor had donated blood with HBsAg test outcome as shown in Table 3. (p value of 0.158).

Kisumu County had the highest number of participants at 38.1%(n=381) followed by Homa Bay county with 32.2%(n=322) and finally Siaya County with 29.7%(n=297) participants. The county of origin had no statistically significance association with HBsAg test result at a p value of 0.458 (Table 3.)

Table 3. Table below shows HBsAg positivity in relation to Sociodemography in young adult blood donors in Kisumu, Homa bay and Siaya Counties. The data shows figures (n) and percentages (%) of HBsAg seronegative (966) and seropositive (34) as spread among Sociodemographics and p-values (0.05 significance level)

Characteristic	Non-reactive, n (%)	Reactive, n (%)	p-value
Age brackets			0.584
18-21	851(85.1%)	31(3.1%)	
22-25	115(11.5%)	3(0.3%)	
Gender			0.470
Male	599(59.9%)	19(1.9%)	
Female	367(36.7%)	15(1.5%)	
Number of donations			0.158
First	928(92.8%)	31(3.1%)	
Repeats	38(3.8%)	3(0.3%)	
Counties of Origin			0.458
Kisumu	371(37.1%)	10(2.62%)	
Homa Bay	311(31.1%)	11(3.42%)	
Siaya	284(28.4%)	13(4.38%)	

4.2 Seroprevalence of HBsAg in Young Adult blood donors.

Young adult blood donors totaling one thousand (N=1000) were recruited as participants across the three counties. Of the Thirty-Seven (N=37) that initially tested positive for HBsAg, thirty-four (n=34) were confirmed to have the HBsAg in their blood. This gave an overall HBsAg Seroprevalence of 3.4%. The two test methodologies used as initial and confirmatory tests in this study were notably applied because of the good analytical agreement between the methods, and could therefore reliably detect and confirm HBV infection in the study population. Comparatively across the three counties (Figure 10), seroprevalence was highest in Siaya county at 4.38%(n=13), followed by Homa Bay with 3.42%(n=11) while Kisumu county had 2.62%(n=10).

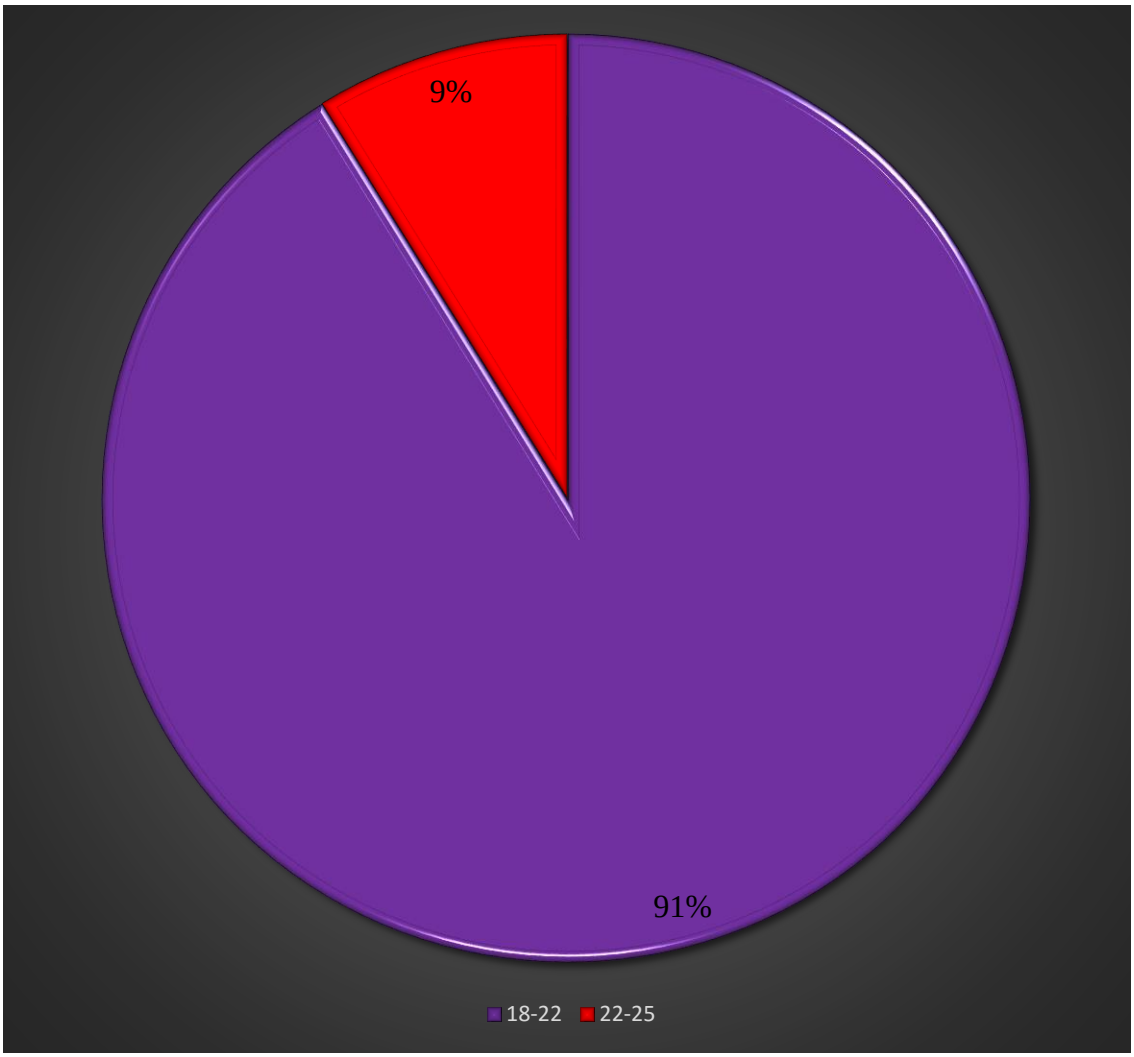

Figure 7. Distribution of HBsAg Positivity based on Age brackets.

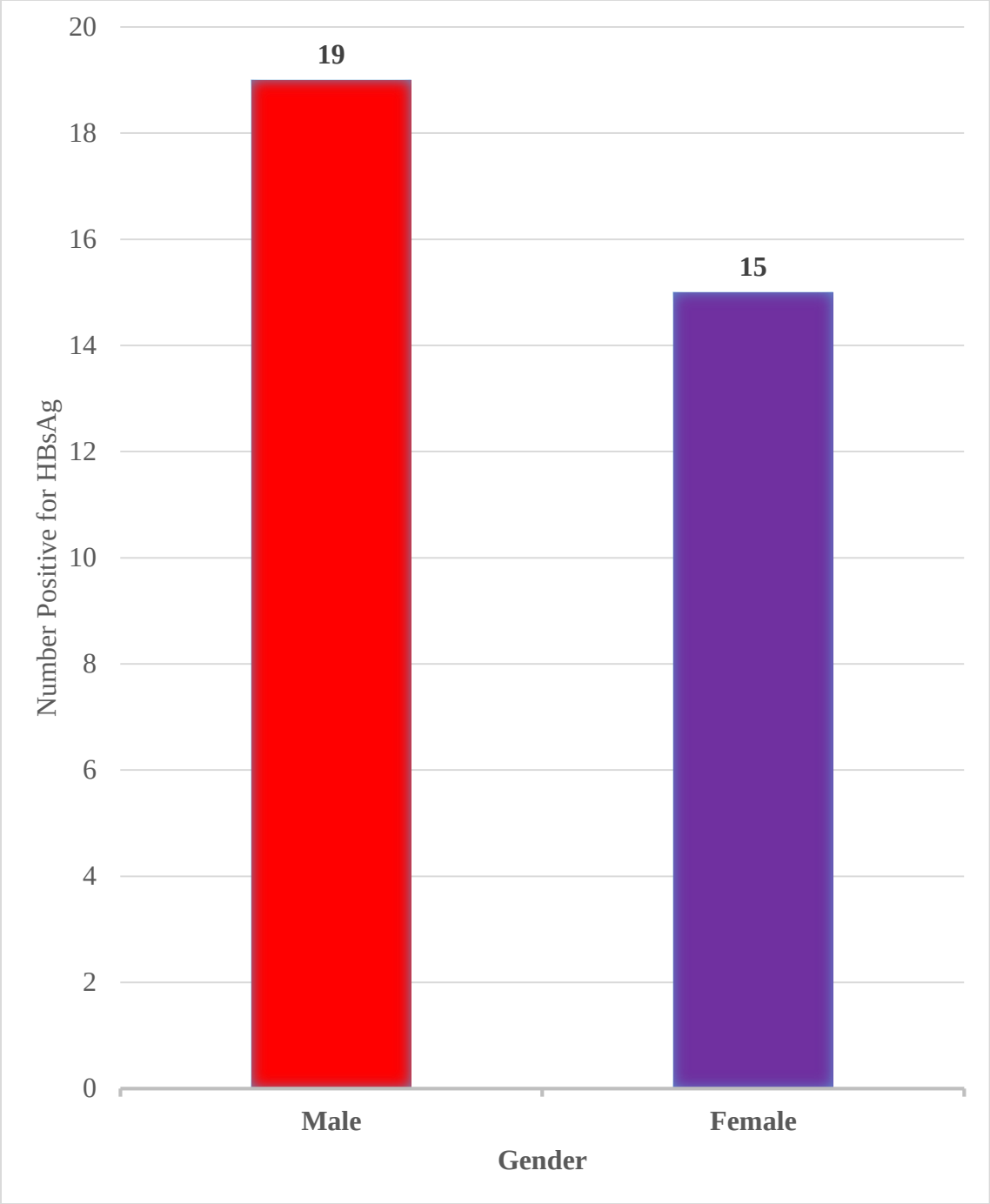

Figure 8. Distribution of HBsAg Positivity per Gender.

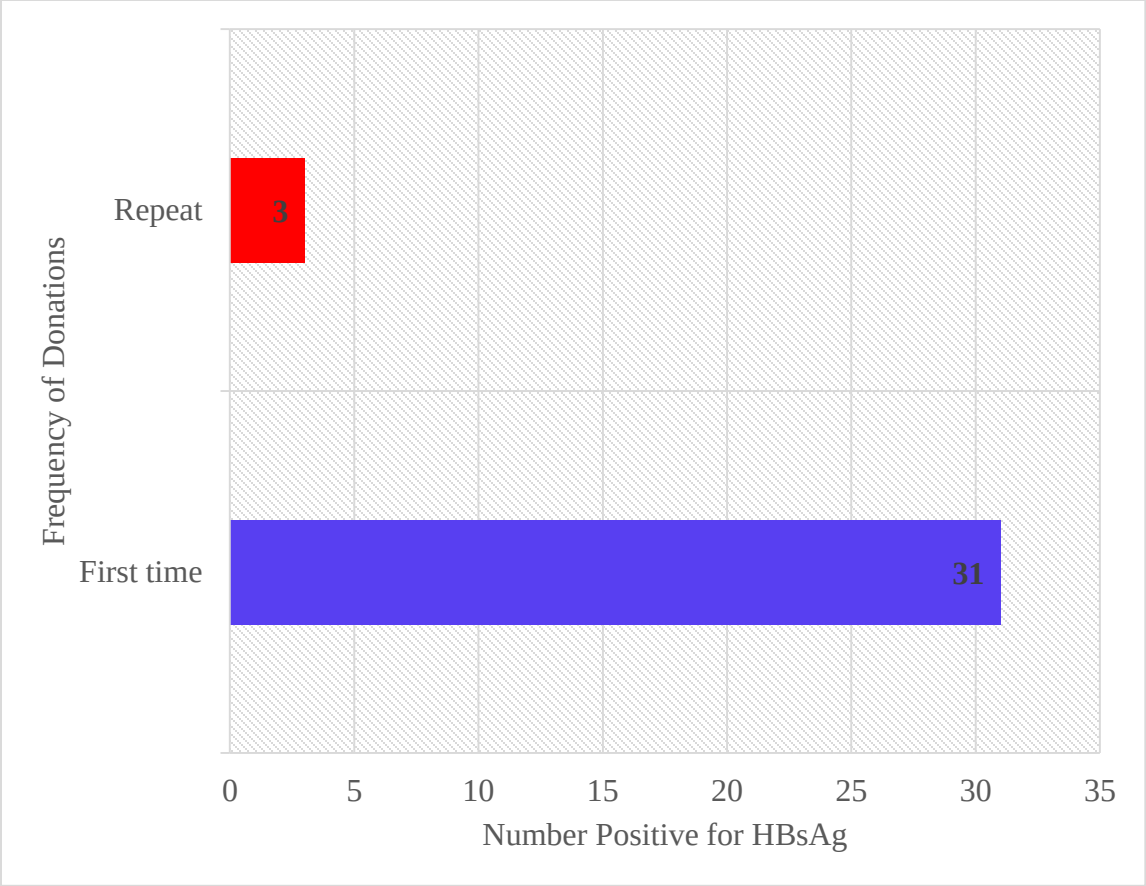

Figure 9. Distribution of HBsAg Positivity per frequency of donations.

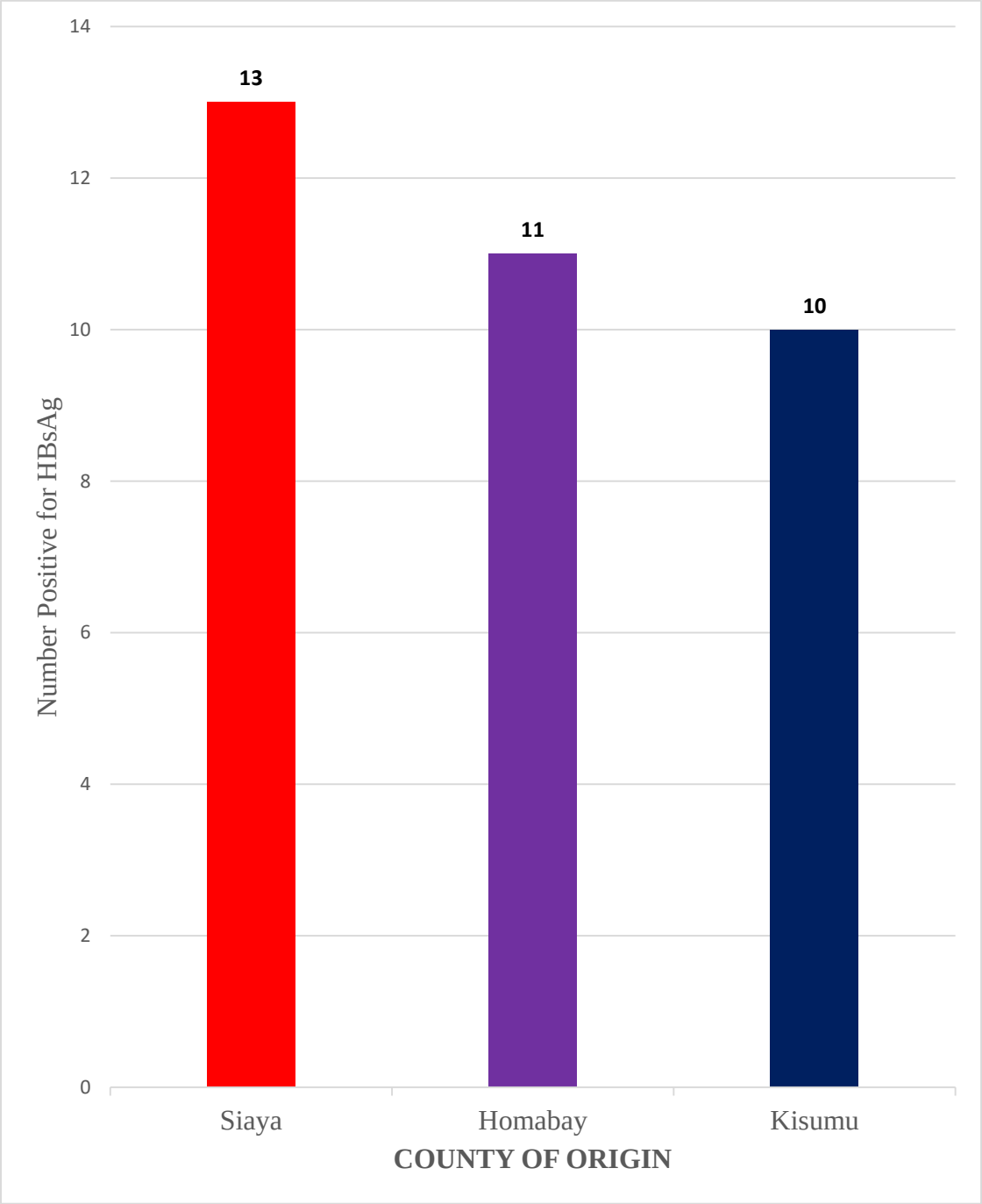

Figure 10. Distribution of HBsAg Positivity per County.

4.3 Risk factors associated with HBsAg seroprevalence in Young Adult blood donors.

The risk factors associated with HBsAg seroprevalence in young adult blood donors in this study are summarized in Table 4. below. Among 31 (3.1%) young adult donors who had a history of high risk sex behavior, 8 reported having received or given money, goods or favor in exchange for sexual activity, 6 reported having had sex with persons whose background they did not know, 2 reported having been raped, 5 had sexually transmitted diseases, 7 had sexual activity with persons besides their regular partner, while 3 had engaged in more than one of the risky behaviors. Of all the participants who reported the above perilous sexual activities, 6 (19.4%) were positive for HBsAg (Figure 11). On bivariate logistic regression analysis, hepatitis B virus infection and high risk sex behaviour showed a statistically significant association at a p value of 0.001. Donors who reported having engaged in high risk sex behaviors had greater odds of HBsAg positivity (OR=8.066, 95% CI=3.067-21.214) than those with no history of high risk sex behavior.

Scarification was reported among 38 (3.8%) young adult blood donors, some with visible scarification marks on their bodies (Figures 12 and 13), out of which 5 (13.2%) were confirmed HBsAg positive cases (Figure 11). Statistically significant relationship was found between HBV disease and scarification (p=0.002). Donors with scarification on the skin had higher odds of HBsAg positivity (OR=4.875, 95% CI=1.774-13.392) than those with no scarification.

Table 4. Risk Factors associated with HBsAg among young adult blood donors in Kisumu, Siaya and Homa bay Counties.

Risk Factor	Total Donors (N=1000)	HBsAg(N=34) *Positive (%)	Bivariate OR (95% CI)	Multivariate OR (95% CI)	P Value
High Risk Sex Behavior	31(3.1%)	6(19.4%)	8.066(3.067-21.214)	8.533(3.128-23.275)	0.001
Scarification	38(3.8%)	5(13.2%)	4.875(1.774-13.392)	5.471(1.925-15.547)	0.002
History of Injury	21(2.1%)	3(14.3%)	5.097(1.46-18.213)	2.912(0.736-11.523)	0.128
Intravenous Drug Use	15(1.5%)	1(6.7%)	2.061(0.263-16.139)	1.256(0.147-10.750)	0.835

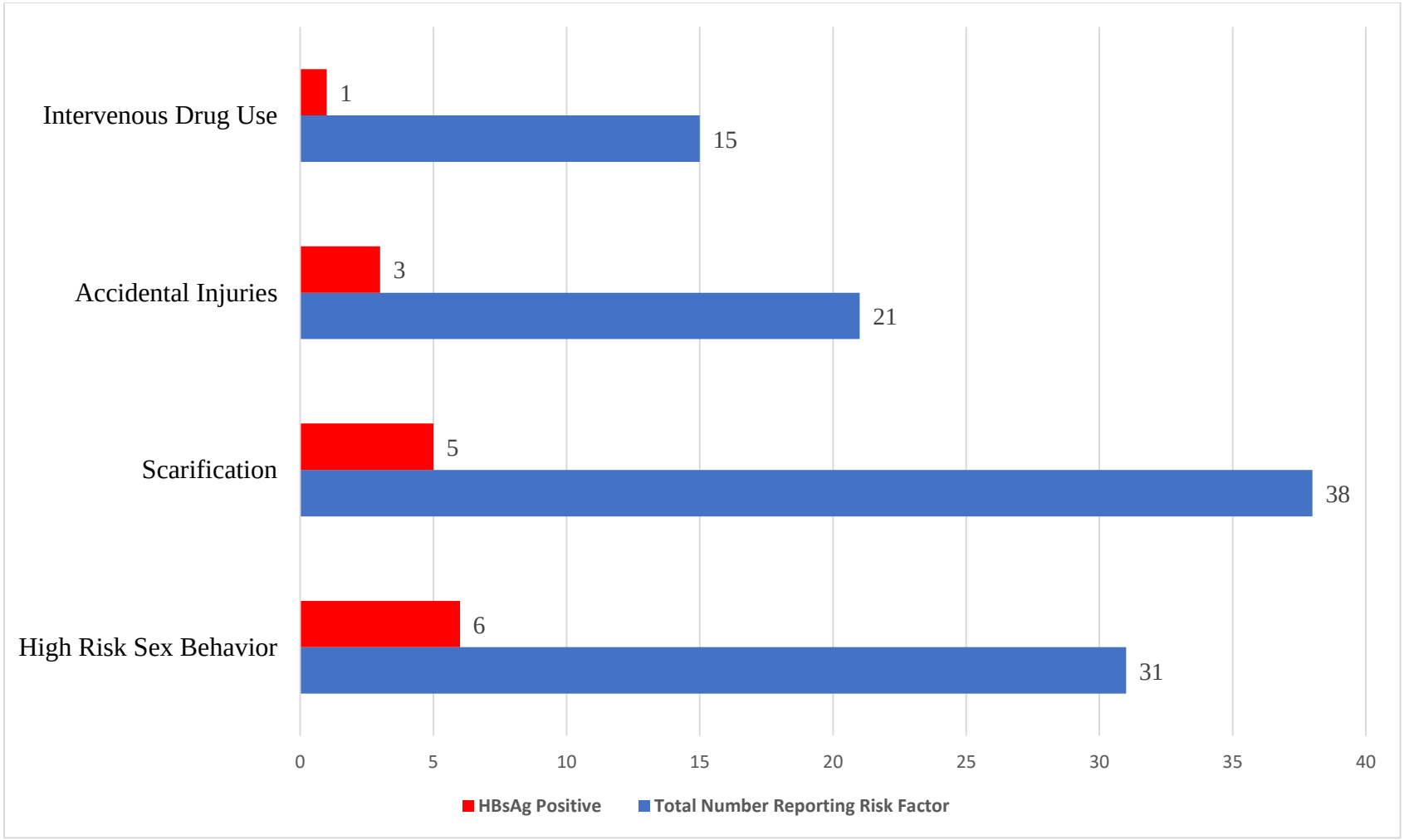

Figure 11.Distribution of reported Risk Factors among Young Adult blood donors and associated HBsAg Positivity.

Figure 12. Tattooing marks as shown by one of the young adult blood donors in Homabay County.

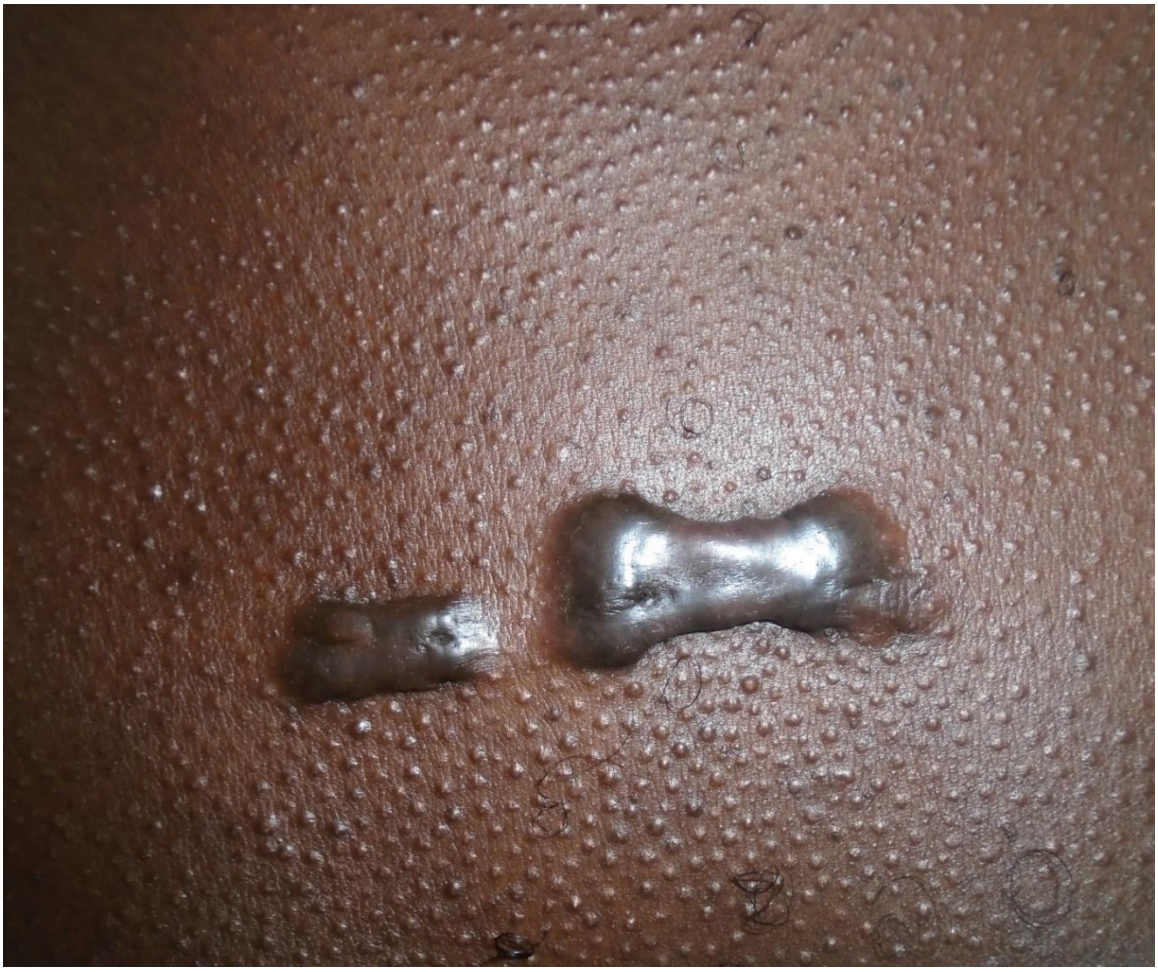

Figure 13. Scarification marks resulting from an incision of the skin made by a traditional healer as shown by one young adult donor in Siaya County.

History of injuries such as accidental needle sticks or stab wounds was reported by 21 (2.1%) young adult donors, out of which only 3 (14.3%) tested positive for HBsAg (Figure 8). Bivariate logistic regression analysis found a statistically significant link between HBV disease state and past injury (p=0.012). Those who had a history of injury had higher odds of HBsAg positivity than those with no history of injuries (OR=5.097, 95% CI=1.426-18.213).

Intravenous drug use was reported in 15(1.5%) young adult blood donors among who only one (6.7%) was a confirmed HBsAg positive case (Figure 8). There was no statistically important association linking intravenous drug use to HBV infection (p value of 0.491). Bivariate logistic regression showed that donors with a history of intravenous drug use were 2.061 times (OR=2.061, 95% CI=0.263-16.139) more probable to be HBsAg positive as compared to those who have not used intravenous drugs.

In multivariate analysis of a selection of variables for independent determinants of HBsAg positivity in young adult blood donors, past risky sexual activities (OR=8.533, 95% CI=3.128 to 23.275) and scarification (OR=5.471, 95% CI=1.925 to 15.547) remained statistically significant predictors of HBs Ag positivity (Table 4) with p values of 0.001 and 0.002 respectively. However, there was no statistically significant association between HBs Ag positivity and history of injury as well as intravenous drug use among young adult donors (p values=0.126, 0.835 respectively).

CHAPTER FIVE: DISCUSSIONS.

5. 1 Sociodemographic Characteristics of Study Participants.

Although the HBV infection rates is well documented in developed countries, the socio-demographics and impacts of this infection is not well documented in limited resources countries like Kenya.

Transfusion of blood and blood products is very critical and is a lifesaving measure that an immeasurable number of people worldwide depend on. Nonetheless, blood transfusion is equally important as a mode of spread of infectious viruses such as Hepatitis B virus.

Studying socio-demographic patterns of HBV infections among key donor populations such as the young adult blood donors is important particularly in the context of safety of blood donated for transfusion purposes.

In the analysis of sociodemographic and risk factors linked to HBs Ag Sero-prevalence in this research work, none of the sociodemographic factors namely age, gender, number of donations and place of donor origin had any significant association with HBs Ag seropositivity at p values of 0.584, 0.470, 0.158 and 0.458 in that order at 5% significance level.

This study targeted young adult blood donors between the age groups of 18 to 25 years. Majority of the donors in this study totaling 882 were in the lower age category of 18 to 21 years, making 88.2% of the total donors compared to only 118 (11.8%) in the upper age category of 22 to 25. The Kenya national blood transfusion services routinely target donors of younger age, generally below 25 years and usually school going or in colleges, as this group is understood to be more prepared to donate blood besides being low risk individuals.

This study reports majority of the donors to be younger falling in the age category of 18 to 22 years (n=882). Findings reported in this research somewhat agrees with a study in Ethiopia (Tessema *et al.,* 2010) which found 52.8% of the donors to be of between 17 to 25 years. Almost similar findings have also been made is Kenya (Kimani *et al.,* 2011) in a study that reported 59% of volunteer donors to be less than 25 years of age.

The average age of young adult donors reported in this research was 19.5 years, indicating a relatively younger category of donors. Comparably, a review of blood donors in Africa (Tagny *et al.,* 2010) reported the average age of donors in Kenya to be 28.9 ± 8.5 years, 28 ± 7.9 years in Bukina Faso while other countries of Eastern and Southern Africa reported mean ages of less than 28 years.

This study also reports a greater number of male young adult donors as compared to female ones. Male donors comprised 61.8% (618) of the total number of donors, whereas female donors were only 38.2% (382) in total in this research. This finding could be accredited to the point that most exclusions from donations were females, probably due to medical deferrals, especially low hemoglobin level. This finding is corroborated by findings in other studies that have also reported a dominance of males in blood donations, such as the Kenya Aids Indicator Survey (KAIS) report (2007) that reported 81.4% males donating blood against 18.6% female donors among voluntary and family replacement donors. Besides, a review of blood donors across African countries (Tagny *et al.,* 2010) also reported male dominance in blood donor programs, with 61% of donors being males in Togo and 71.2% being males in Bukina Faso.

In general, none of the sociodemographics (Age, gender, number of study and county of origin) had any significant association with HBsAg seropositivity in this study.

5.2 Sero-prevalence of HBs Ag among young adult blood donors.

Epidemiological studies of HBV are critical in the preparation of preventive policies and approaches of healthcare programs.

Africa has the second highest HBV infection rate after Asia (Barth *et al.*, 2010). The rates of incidence of this infection varies from one country to another, between different regions within the same country as well as according to the risk factors involved, sociodemographic status and primary burden of infection markers in the community.

Such data are however seldom obtainable in African countries (Daw *et al.*, 2014). This research sort to determine the seroprevalence and risk factors associated with HBsAg infection among young adult blood donors who are between 18 to 25 years old in Kisumu, Siaya and Homa Bay counties in Western Kenya and reports an overall seroprevalence of 3.4% in the three counties.

A total of 1000 voluntary young adult blood donors were recruited into the study. Out this, 381 (38.1%) of the total donor population recruited into the study were from Kisumu, 322 (32.2%) were from Homabay while 297(29.7%) were from Siaya county.

The outcome of the study established that 10 (2.62%) of the participants from Kisumu tested positive for HBsAg, with Homabay and Siaya recording 11(3.42%) and 13(4.38%) positivity respectively, with county of origin having no significant association with HBsAg positivity ($p=0.458$). The findings here are comparable to a study done to determine the incidences and determinants of HBV virus disease amongst teenagers in Enugu, Nigeria (Eke *et al.*, 2015) where HBsAg seroprevalence was found to be 3.1%.

The 3.4% seroprevalence determined among young adult blood donors in this study is suggestive of intermediary endemicity and increased predisposition to HBV infections. Even though the findings from this study were slightly lower than a 3.9% seroprevalence across the general population earlier reported in the same study area (NASCOP 2005), it falls within the range of Hepatitis B prevalence in Sub-Saharan Africa which is viewed as intermediate to high endemicity areas with 15% to ≥ 8% (Franco *et al.,* 2012).

This study finding is also within the ranges in various studies in Kenya which have reported prevalence of as low as 1.97-2.77% national estimates for the period 2006 to 2010 (KNBTS 2011) to a national peak of 5.2% seroprevalence recorded in the period 2011-2012(KNBTS 2012). Studies in Ethiopia (Tessema *et al.,* 2010) and Egypt (El-Gilany *et al.,* 2006) have also reported comparable results of 4.7% and 4.3% seroprevalence respectively.

While the high incidences of HBsAg reported in the studies involving a cross section of the general donor population could be attributed to the highly contagious nature of HBV virus and widespread presence of the virus in most body fluids including blood, vaginal and menstrual fluids as well as semen (Mutuma *et al.,* 2011), the comparatively lower prevalence of 3.4% among this group of blood donors as illustrated in this research could be justified by the three major consecutive stages of the biological history of Hepatitis B virus illness, namely the immune tolerance, immune clearance and the low replication phases (WHO, 2002) that makes the young adult period a stage of low prevalence. Furthermore, this is supported by a comparable earlier cohort investigation in Sub Saharan Africa where approximately a third of young adult HBV carriers cleared their HBsAg and consequently proceeded to immune clearance phase in 10 years of HBV disease, as two

thirds of the remaining children tested positive for HBsAg and persistently remained tolerant to the virus (Mendy *et al.,* 2009).

The 3.4% seroprevalence of HBsAg reported among young adult blood donors in the current study should be worrying for two major reasons.

First, a section of the study subjects, who were 18 to 25 years old, may have benefited from childhood HBV immunization which was introduced in Kenya in the year 2002 (Lucy *et al,.*2017). Consequently, it is expected that this group who might have benefited from the vaccination could have benefited from the long term protection offered by the vaccine. Even though it is quite possible that a course of hepatitis B vaccine may give lifelong immunity, the duration of protection still remains unknown (Lucy *et al,.*2017). Some of the beneficiaries of the childhood vaccination against Hepatitis B covered in this study might have lost protection and thus acquired infection. Therefore, it is recommended that persons at continuing risks of infection such as young adults should be offered a single booster dose vaccine at least five years after primary immunization (Guidelines for the treatment of chronic Hepatitis B and C in Kenya, 2014). The Hepatitis B vaccine is safe and effective, but it should not be viewed as an alternative to strategy of preventing transmission.

The second cause of worry of a prevalence of 3.4% among this study subject is the fact that considerable safety measures to ensure safety of blood during transfusion has been put in place. This is buttressed by a previous study that reported a HBsAg seroprevalence of 3.46% among the general population of blood donors in the three counties of Kisumu, Homa bay and Siaya (Onyango *et al.,* 2018) despite the blood donation safety enhancements laid out across the regional blood transfusion centers in the country.

The 3.4% seroprevalence reported in the current study is an indicator that the efforts so far put to improve donated blood safety, particularly among the preferred donors such as the young adult donors has not yielded much in ensuring that donated blood is safe for transfusion.

5.3 Risk factors Associated with HBsAg seroprevalence in Young Adult donors.

High risk sex behaviors, Intravenous drug use, Scarification and History of injuries such as needle sticks have all been reported as independent risk factors of HBV infection in various studies.

In this research work, bivariate analysis of various determinants including high risk sex behavior, Scarification and History of Injury indicated a significant association with HBsAg seropositivity except intravenous drug use.

In multivariate analysis, high risk sex behavior and scarification were the only risk factors putatively established to be significantly associated with HBsAg positivity at p values of 0.001 and 0.002 respectively. In the current study, donors who stated having been involved in high risk sex behaviors had greater odds of testing positive for HBsAg (OR=8.066, 95% CI=3.067-21.214) than those with no history of high risk sex behavior.

Thirty-one (31) donors in this study reported having engaged in high risk sex, out of which 6 (19.4%) turned positive for HBsAg, making high risk sex behavior the most significant predictor of HBsAg positivity in the study (p value of 0.001). This trend has been previously reported in a study on the seroprevalence and determinants of TTIs among voluntary blood donors in Kisumu, Siaya and Homabay counties (Onyango *et al.*, 2018) which reported a significant association between high risk sex behavior and HBV infection.

The findings in this current study also corroborates that done earlier in a local study which reported that practice of sex in exchange for cash payments was linked to HIV infection and other co-infections such as HBV (National Aids Control Council, NACC, Kenya, 2016). Studies in other regions have also associated history of risky sexual behaviors such sexual intercourses with no condom use in the dynamics of spread of HBV.

In a research work on the sexual spread of hepatitis B virus infection amid blood donors in a tertiary hospital in Nigeria (Adekanle *et al.,* 2010), 20% of respondents who tested positive for HBV had also reported having engaged in unprotected sexual intercourses. Similarly, numerous incidences of HBV transmissions related to high risk sexual behaviors are previously recorded in various parts of the world such as Egypt where a research on communal spread of Hepatitis B virus (Jimenez *et al.,* 2009) reported a 50% prevalence among people who engaged in high risk sex behavior. In addition, a study of prevalence, determinants and means of transmission of acute viral Hepatitis B and C (Ion-Nedelcu *et al.*, 2009) reported 51% of participants having involved in high risk sex behaviors.

There can be several explanations to the association between high risk sex behavior and HBsAg positivity, with sexual intercourse majorly linked to the spread of HBV in several parts of the world, free of HBV endemicity (Meheus *et al.*, 2000).

One such possible explanation to the association between high risk sexual behaviors and HBsAg seropositivity is that the low income status of most the young adults in low income areas could be leading them to be initiated into high risk sexual behaviors such as multiple sexual relationships and exchange of money for sexual favors, thus rendering them susceptible to hepatitis B virus infection among other sexually transmitted diseases.

There are reports of upsurge in sero-prevalence in all countries within Latin America during or after adolescence (Tanaka *et al.,* 2000), suggesting that sexual activity, which mostly involve high risk behavior, is a major route of transmission. The findings in this study of high risk sex behavior as an independent risk factor among young adult blood donors could possibly be used to formulate and give instructions on a targeted health related training, psychotherapy and health promotion when dealing with these group of donors who make a majority of the donor source for the Kenya National Blood Transfusion Services.

However, in contrast to this study findings, a study in Egypt (Awadalla *et al.,* 2011) reported that TTIs including HBV was not linked to risky sexual behaviour. Similarly, a study on viral Hepatitis in voluntary blood donors (Olokoba *et al.,* 2009), observed that none of the risk factors examined such as high risk sex behavior had any significant association with HBV infection.

Scarification is another putative risk factor that had a meaningful link to HBsAg positivity in this current study at a p value of 0.002 on multivariate analysis.

Although indisputable studies absolutely attributing the acquisition of HBV through scarification is hardly available, this study reports a significant association between HBsAg positivity and scarification, with 5 (13.2%) of the 38 study subjects with scarification marks testing positive for HBsAg.

Some of the donors who had visible scarification marks on their bodies on further probing reported that the marks were a result of traditional practices involving making a cut on the skin to deliver herbal medicines for relief from distinct medical conditions, while some had

modern body tattoos for aesthetic appeal. This traditional scarification mainly done at the community level by traditional doctors as part of healing care where they use poorly sterilized or totally unsterilized instruments have very high chances of causing transmission of diseases such as hepatitis B virus. This finding is not surprising since some epidemiological studies have demonstrated that sociocultural practices involving scarification are an important route of spread of the Hepatitis B viral infection (Christopher *et al.,* 2015).

Tattooing as well as other skin penetrating practices have also remained characteristically associated with HBV disease (Yang *et al.,* 2015, Jafari *et al.,* 2012 and Pereira *et al.,* 2009). Furthermore, several studies have reported a close association between HBsAg positivity and scarification whereby repeated use of unsterile instruments for scarification have been claimed to be a reason for HBV transmission (Olokoba *et al.,* 2011, Emechebe *et al.,* 2010, Adewole *et al.,* 2009 and Nyirenda *et al.,* 2008).

The findings in the current study is also supported by a previous study to define the occurrence of HBsAg and HBV related HCC in Kenyans of different ages (Mutuma *et al.,* 2011) where high prevalence of HBV was associated with poor hygiene practices such as traditional body scarification as a type of traditional treatment, pointing at horizontal transmission of HBV among the study population. In modern society, tattooing is done as form of body modification for beauty and aesthetic appeal. This practice is very common among young adults and is achieved through processes that involves cut through the skin, removal of skin parts, chemical imprinting and other techniques that may cause skin lacerations. This processes involves the use of various equipment that require standard sterilization procedures to prevent horizontal transmission of viral infections such as HBV.

This is seldom followed. It is therefore plausible to suggest that the involvement of young adults in such practices as reported in this study could have exposed them to the horizontal transmission of HBV.

Also corroborating the results in the current study is a report in another research finding stating that Hepatitis B is one of the viral pathogens transmissible through use of infected tools during traditional practices such as skin scarification as a form of treatment as well as tattooing in modern society (Roland *et al.,* 2017).

Results in this study is also in agreement with studies elsewhere (Nwokedinko *et al.,* 2010, Telatela *et al.,* 2007) that have implicated body scarification among other practices such as sharing of sharps, body piercing instruments as possible routes of transmission of HBV in many settings. Furthermore, cultural practices involving scarification and body tattooing which have the potential of triggering hemorrhage and skin ulceration have been reported to intensify the possibility of percutaneous spread of HBV (Anegilaje *et al.,* 2013, Sadoh *et al.,* 2011).

Even though scarification has been linked to Hepatitis B seropositivity in this study, some preceding studies (Omeje *et al.,* 2017, Emechebe *et al.,* 2009 and Ugwuja *et al.,* 2009) have reported non-significant association between scarification and hepatitis B infection.

In the current study, Intravenous drug use and history of injuries such as needle stick injury did not show any significant association with Hepatitis B seropositivity among young adult blood donors. Out of the 15 respondents who admitted having used intravenous drugs, only one (6.7%) was confirmed positive HBsAg case, with no significant link between HBsAg positivity and Intravenous drug use (p value equals 0.835). This compares positively to a

prior research work in the same areas (Onyango *et al.,* 2018) that reported no significant association between TTIs including HBV and previous exposure to illicit drug use. Similarly, studies in other parts of Africa have reported no significant link between HBV disease and intravenous drug use. In another research work to establish the risk factors linked to the seroprevalence of Hepatitis B virus diseases amongst adolescents in Enugu, Nigeria, Christopher *et al.,* (2015) recorded no significant association between intravenous drug use and Hepatitis B virus disease.

In this current research, the lower number of respondents admitted having used intravenous drugs and therefore the insignificant association could be attributed to the fact that not many participants were willing to divulge information about past use of injectable drugs, possibly because of the stigma associated with intravenous drugs abuse and the criminalization of the use of this drugs.

Another risk factor that recorded no significant association with Hepatitis B infection in this study is history of injuries such as needle sticks. Out of the 1000 young adult blood donors recruited into this study, only 21 (2.1%) reported history of injuries, out of which only 3(14.3%) were confirmed HBsAg positive cases, with no significant association at a p-value of 0.128. Some studies have demonstrated that people who are HBeAg positive generally have high HBV viral loads, and therefore transmission rates of HBV involving such people through injuries such as needle stick injuries, other percutaneous exposure such as knife cuts or small cuts acquired from barber shops is very high, between 30%-62% (EMI Guidelines, 2016).

However, the risk of transmission of HBV in the general community through such means have been very difficult to estimate, and the exact incidences of such injuries and rates of

transmission remain unknown in most areas (EMI Guidelines, 2016), with the very limited published cases (Res *et al.,* 2011) indicating there is very low risk of transmission of HBV through such community acquired injuries.

Nonetheless, history of injuries, especially needle sticks injuries, have been reported as having a significant link with HBV disease particularly amid healthcare workers in several studies (Ziraba *et al.,* 2010, Pereira *et al.,* 2009, and Hasan *et al.,* 2005).

5.4 Limitations of the Study.

1. There was insufficient data on the use of intravenous drugs, as it is possible that some of the study participants purposely declined to provide information about their past or current use of injectable drugs due to stigmatization associated with the use of drugs and criminalization of use of injectable drugs in Kenya.

2. It was not possible to collect data on the vaccination status of the study participants, as most people do not keep this records after childhood.

3. The data available for this study for this study to evaluate the infectious risks posed by occult HBV infections in this study population was limited by the unavailability of some test methods. The study was dependent on two test methods (ELISA and CLIA) to test and confirm the presence of disease but could not employ molecular amplification techniques to detect HBV DNA to identify occult HBV infections within the study population.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS.

6.1 Conclusion.

1. This study revealed a prevalence rate of 3.4% HBsAg positivity among young adult blood donors within the counties of Kisumu, Siaya and Homabay.

2. The risk factors that were identified to be independently associated with HBsAg positivity are high risk sex behavior and scarification. The most reported risk factor among study participants was high risk sex behavior. This is evidence that sexual contact plays a major role in transmission of HBV among this group of blood donors.

3. Other known risk factors included in the study but had no association with HBsAg positivity in this study were history of injuries and intravenous drug use.

6. 2 Recommendations.

1. This study reports a significant HBsAg infection rate of 3.4% among a key donor population despite recent blood donation safety improvements put in place to ensure safe blood transfusion. This study finding should be taken into consideration by health officials particularly the Kenya National Blood Transfusion Services while framing policies geared towards mitigating the effect HBV infection on safe blood transfusion as the reported infection rate presents a significant risk to donor blood safety. The aim should be to reduce prevalence levels among this key donor population.

2. The study reveals a significant burden of HBV infection among young adult blood donors, who are a key donor population. Policy guidelines for the treatment of chronic Hepatitis B and C viral infection in Kenya recommends that a booster vaccine be provided at least once after the primary immunization to persons who are at continuing risk of

infection. In view of this study findings, this policy should be made mandatory by health ministry in Kenya to ensure provision of booster vaccination doses among young adults in schools and colleges, and enforcement ensured just like the policy on childhood vaccination against HBV.

3. This study reports high risk sex behavior among young adult blood donors as a significant risk factor associated with HBsAg transmission. Focus should therefore be put on fostering safe sex education in learning institutions to minimize risky sexual behaviors among young adults who are a major blood donor source.

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APPENDICES

Appendix 1. National Blood Transfusion Questionnaire (English Version)

NATIONAL BLOOD TRANSFUSION SERVICE

Clinic Venue ---------- Clinic Code: ----------Donor Number---------

DONOR REGISTRATION FORM (Donors please complete this section below)

Surname……..Other Name……

Student Number/ National ID Number……Date of Birth: --------- /--Sex: F/M

Marital Status……. Single/Married/Divorced/Separated/Widowed

Contact Details: Postal Address (where you would like to receive your correspondence)

Home phone number: ---------- Cell phone number: ----------

Email: ----------

Level of education: None/ Primary/ Secondary/ Tertiary Occupation:

...…….....

When did you last donate Blood? …….. Blood Group: …….

HEALTH QUESTIONNAIRE

Circle the appropriate answer

1. Are you feeling well and in good health today?	Yes/No
2. Have you eaten in the last 6 hours?	Yes/No
3. Have you ever fainted?	Yes/No
In the past 6 months have you:	
4. Been ill, received any treatment or any medication?	Yes/No
5. Had any injections or vaccinations (immunizations)?	Yes/No
6. Female Donors: Have you been pregnant or breast feeding?	Yes/No
In the past 12 months have you:	
7. Received a blood transfusion or any blood products?	Yes/No
Do you have or have you ever had:	
8. Any problems with your heart or lungs e.g. asthma?	Yes/No
9. A bleeding condition or a blood disease?	Yes/No
10. Any type of cancer?	Yes/No
11. Diabetes, epilepsy or TB?	Yes/No
12. Any other long term illness Please Specify	Yes/No

RISK ASSESSMENT QUESTIONNAIRE

Circle the appropriate answer

In the past 12 months have you:	
1. Received or given money, goods or favors in exchange for sexual activities?	Yes/No
2. Had sexual activity with a person whose background you do not know?	Yes/No
3. Been raped or sodomized?	Yes/No
4.Had a stab wound or had an accidental needle stick injury e.g. injection needle?	Yes/No
5. Had any tattooing or body piercing e.g. ear piercing?	Yes/No
6. Had a sexually transmitted disease (STD)?	Yes/No
7.Live with/ had sexual contact with someone with yellow eyes or yellow skin?	Yes/No
8.Had sexual activity with anyone besides your regular sex partner?	Yes/No
Have you ever:	
9. Had yellow eyes or yellow skin?	Yes/No
10. Injected your-self or been injected, besides in a health facility?	Yes/No
11. Used non-medical drugs such as Marijuana, Cocaine etc.?	Yes/No
12. Have you or your partner been tested for HIV?	Yes/No
13. Do you consider your blood safe to transfuse to a patient?	Yes/No

Appendix 2. National Blood Transfusion Questionnaire (Kiswahili Version).

NATIONAL BLOOD TRANSFUSION SERVICES.

Mahali pa kliniki---------- Nambari ya mahali pa Kliniki: ----------

Nambari ya wafadhili----------

FOMU YA WAFADHILI (Wafadhili tafadhali jibu maswali yaliyofuata)

Jina---------- Majina nyingine: ---------- ----------

Nambari ya shule ya Mwanafunzi / Nambari ya kitambulisho: ----------

Tarehe ya kuzaliwa: ----------Jinsia..... Mwanamke/Mwanaume

Hali ya Ndoa: Hujaolewa/umeoa au olewa/umetengana au mjane/umetaliki au talikiwa.

Kuwasiliana maelezo: Anwani ya posta (ambapo ungependa kupokea mawasiliano yako--------

----

Nambari ya simu ya nyumbani: ---------- Simu ya mkono: ----------

Barua pepe: ----------

Kiwango cha elimu: Hakuna Msingi/Eneo la Msingi----------

Kazi----------

Lini mara ya mwisho kuchangia damu.....Aina ya damu.....

MASWALI YA AFYA

Mduara jibu sahihi

1. Je, wewe kujisikia vizuri na afya njema leo?	Ndiyo / La
2. Wewe umekula katika masaa 6 ya mwisho?	Ndiyo / La
3. Na wewe milele umepata kizuizi?	Ndiyo / La
Katika kipindi cha miezi 6 na wewe umekuwa;	
4. Mgonjwa, kupokea matibabu yoyote au dawa?	Ndiyo / La
5. Umekuwa na sindano yoyote au chanjo (kinga)?	Ndiyo / La
6. Wanawake Wafadhili: Je, umekuwa na mimba au kunyonyesha?	Ndiyo / La
Katika kipindi cha miezi 12 na wewe;	
7. Umepokea damu au bidhaa yoyote ya damu?	Ndiyo / La
Je, una au na wewe milele na:	
8. Matatizo ya moyo wako au mapafu mfano pumu?	Ndiyo / La
9. Hali ya kutokwa na damu au ugonjwa wa damu?	Ndiyo / La
10. Aina yoyote ya Kansa?	Ndiyo / La
11. Kisukari, kifafa au kifua kikuu?	Ndiyo / La
12. Ugonjwa nyingine yoyote yamuda mrefu? Tafadhali taja	Ndiyo/ La

TATHMINI MASWALI HATARI

Mduara jibu sahihi

Katika kipindi cha miezi 12 na wewe;
1.Umepokea au kupewa fedha, mali au neema badala ya shughuli za ngono? Ndyio /La
2. Ulikuwa na shughuli za ngono na mtu ambaye historia hamjui? Ndyio / La
3. Umebakwa? Ndyio / La
4.Ulikuwa na jeraha ya kuchomwa au ajali wa sindano, mfano kuumia sindano wenye? Ndiyo / La
5. Umetoboa mwili kwa mfano kutoboa sikio? Ndiyo / La
6. Ulikuwa na ugonjwa wa zinaa (STD)? Ndiyo / La
7. Umeishi au ulikuwa na ngono na mtu wa macho wa njano au ngozi ya manjano? Ndiyo/La
8. Ulikuwa na shughuli za ngono na mtu yeyote zaidi ya mpenzi wako mara kwa mara ?Ndiyo /La
Na wewe milele;
9. Ulikuwa na macho ya njano au ngozi ya manjano? Ndiyo / La
10. Umejichanja mwenyewe au umechanjwa katika kituo cha afya? Ndiyo / La
11. Umetumia madawa zisizo matibabu, madawa ya kulevya kama vile bangi, Cocaine nk? Ndiyo / La
12. Je, wewe au mpenzi wako mumewahi kupima VVU? Ndiyo / La
13. Je, unaona kama damu yako uko salama kumwongezea mgonjwa? Ndiyo / La

Appendix 3. DISTRIBUTION OF STUDY PARTICIPANTS BY COUNTY AND INSTITUTIONS. SEROPREVALENCE AND RISK FACTORS OF HBV INFECTION IN ADOLECENT BLOOD DONORS WITHIN SELECTED COUNTIES OF WESTERN KENYA, BY HILARY AWILI (BSc, UoN)

COUNTIES	INSTITUTIONS	INSTITUTION POPULATION	TOTAL NUMBER OF REGISTERED DONORS	TOTAL NUMBER OF DONORS PARTICIPANTING IN STUDY	% OF DONORS PARTTICIPATING IN STUDY	FEMALE	MALE
KISUMU	JOEL OMINO SEC	459	25	15	60%	06	09
	OBWOLO MIXED SEC	364	34	20	53%	08	12
	OUR LADY MUHORONI	567	57	43	75%	23	20
	MIWANI SEC	606	63	34	54%	00	34
	RAE GIRLS SEC	704	75	35	40%	35	00
	KASAGAM SEC	809	24	25	83%	13	11
	ST AUGUSTINE KANDIEGE	789	86	65	74%	08	57
	ACHEGO GIRLS	800	100	25	24%	25	00
	MASENO UNIVERSITY	NA	24	21	88%	09	12
	KASAGAM YOURTH GRP	200	20	12	55%	05	07
	CATHOLIC UNIVERSITY	NA	26	22	85%	11	11
	KORU GIRLS SEC SCHOOL	1025	85	35	44%	35	00
	UZIMA UNIVERSITY	NA	34	12	32%	12	00
	KISUMU POLY	NA	27	10	37%	10	00
TOTAL	**15**	**6323**	**700**	**381**	**54.4%**	**199**	**182**
HOMABAY	KENDU MTC	240	104	52	51%	16	38
	MAWEGO GIRLS SEC	400	84	35	42%	32	00
	AGORO SARE HIGH	1117	89	33	37%	00	33
	OTHORO MIXED	526	87	34	39%	03	31
	NYANGIELA MIXED	476	57	34	60%	05	30
	MAWEGO SDA CAMP	200	120	50	51%	10	34
	ORERO BOYS	1200	78	34	44%	00	34
	ORIWO BOYS	2004	112	50	53%	00	50
TOTAL	**8**	**6,163**	**732**	**322**	**44%**	**66**	**256**

COUNTIES	INSTITUTIONS	INSTITUTION POPULATION	NO. OF REGISTERED DONORS	NO. OF STUDY PARTICIPANTS	%PARTTICIPANT	FEMALE	MALE
SIAYA	NYAMIRA GIRLS	1340	120	50	43%	50	00
	MAJANGO MIXED	400	34	15	47%	06	09
	SAWAGONGO HIGH	1100	43	19	44%	00	19
	MITIRO MIXED	420	65	13	20%	05	08
	RARIEDA MIXED	350	43	21	51%	03	18
	GOT ABIERO MIXED	330	51	26	53%	07	19
	NDIGWA MIXED	540	30	19	63%	05	14
	MAKASEMBO MIXED	650	100	50	51%	20	30
	NYAMBARE MIXED	254	47	34	76%	16	18
	BAR KOWINO MIXED	600	123	50	41%	15	35
TOTAL	**10**	**5984**	**655**	**297**	**45.3%**	**127**	**170**
G.TOTAL	**33**	**18,470**	**2087**	**1000**	**47.9%**	**382**	**618**

Appendix 4. Approval letter, Kenya National Blood Transfusion Center.

Telephone: 020-2012867
Hotline: +254 716775245
Email: info@nbtskenya.or.ke
Website: www.nbtskenya.or.ke

NATIONAL BLOOD
TRANSFUSION SDERVICES-HQS
LOCATION:KENYATTA NATIONAL
HOSPITAL, NPHLS GROUNDS
P.O BOX 29804-00202
NAIROBI

MINISTRY OF HEALTH

When replying please quote

Ref: MOH/KNBTS/RES & DEV/VOL.1/10 14th February 2019

Hilary Awili

University of Nairobi,

P.O BOX 29053-00625

RE: PERMISSION TO CONDUCT A RESEARCH STUDY

Make reference to your letter dated February 11, 2019 received on February 13, 2019. Thank you for your response to the issues raised by the research committee. This is to inform you that the issues raised have been adequately addressed.

Due consideration has been given to the issues raised and the study is hereby granted approval for commencement effective 15th day of February 2019, for a period of four months.

Please note that the authorization to conduct this study will automatically expire on 15th June 2019. If you plan to continue with data collection beyond this date, please submit an application for continuing approval to the research committee at least one month prior to the expiry date of study indicated herein.

You are requested to submit any amendments to your study protocols and other information pertinent to the study to the research committee prior to initiation.

You may embark on the study.

Yours sincerely,

Dr. Josephine Githaiga,

HEAD-KNBTS

Kenya National Blood Transfusion Service

It's safe and it saves.

ISO 9001 2008 Certified