PREVALENCE AND FACTORS ASSOCIATED WITH HEPATITIS B AND HUMAN IMMUNODEFICIENCY VIRUS CO-INFECTION AMONG BLOOD DONORS IN KENYAN COASTAL REGION

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Prevalence and Factors Associated With Hepatitis B and Human Immunodeficiency Virus Co-Infection among Blood Donors in Kenyan Coastal Region

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DECLARATION

This thesis my original work and has not been submitted to any other university.

Signature……..Date……

June Alice Akoth

This thesis has been submitted for examination with our approval as University Supervisors.

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DEDICATION

I dedicate this study to my family, friends and Madam Mary Kerich who continue to inspire me and give me the reason to become a better person.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immuno deficiency Syndrome
ART	Anti –Retroviral Therapy
DNA	Deoxyribonucleic acid
ELISA	Enzyme Linked ImmunoAsssay
HAART	Highly active antiretroviral therapy
HbeAg	Hepatitis E antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCC	Hepatocellular carcinoma
HIV	Human immunodeficiency Virus
HTLV	Human T-Cell Leukemia Virus
ISBT	International Society for Blood Transfusion
NASCOP	National Aids Control Program
OR	Odds Ratio
RNA	Ribonucleic acid
SPSS	Statistical Package for the Social Science
TTI	Transfusion Transmissible Infection
UNAIDS	United Nations program on HIV and AIDs
WHO	World health Organization

DEFINITION OF TERMS

Repeat Donors: Someone who has donated more than once in a lifetime.

ABSTRACT

Studies on blood transfusion has shown that transfusion-transmissible infections (TTIs) have heralded a new era in blood transfusion practices worldwide. The blood transfusion practice emphasizes on safety and protection of human life. Infection with Human Immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) can also be acquired through blood transfusion. The infections are global public health problem and remains to be a major cause of morbidity and mortality in Africa and Asia, in which about 2–4 million people infected with HIV have chronic HBV co-infection Worldwide, HBV accounts for about 370 million chronic infections according to the WHO, and there are approximately 50 million chronic carriers of hepatitis B virus (HBV) in Africa, with a 25% mortality risk. HBV/HIV co infection leads to increased morbidity and mortality as compared to HIV or HBV mono-infections. This was a descriptive cross-sectional study whose objective was to determine the prevalence and factors associated with HIV- HBV co-infections among blood donors in the Kenyan Coastal region. The study employed consecutive sampling technique, participants were selected as they presented themselves for blood donation. Data was collected using a structured questionnaire and analyzed for descriptive statistics using SPSS version 22 and Microsoft excel 2013. X^2 and Fischer Exact used to test for associations at 95% confidence. Four hundred and twenty respondents participated in the study, of which 71% (298) were male and 29% (122) female. The respondents were drawn from Mombasa, Kilifi, Kwale, Tana River, Taita Taveta and Lamu counties, age between 16years and 65years. The prevalence for HBV and HIV were 3.1% and 1.43% respectively and prevalence of 0.5% for HIV-HBV co-infection among the blood donors. Prevalence of Co-infection among the HIV infected participants was found to be 33%. Factors associated with HBV- HIV co-infection were marital status and occupation ($p< 0.05$). The study results showed the prevalence of HIV, HBV and HBV- HBV co-infection as 1.4%, 3.1% and 0.5% respectively, however, on the factors observed, age, sex, marital status, occupation and geographical area, the study showed no significant factors associated with Hepatitis B and Human Immunodeficiency Virus co-infection among blood donors in the Kenyan coastal region The results of this study emphasizes the need for extended screening of blood donated for transfusion and also suggests the need for a larger study to address challenges of blood safety.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Hepatitis B virus (HBV) and human immunodeficiency virus (HIV) are blood borne viruses transmitted primarily through sexual contact and illegal injection drug use. Because of these shared modes of transmission, a high proportion of adults at risk for HIV infection are also at risk for HBV infection. HIV-positive persons who become infected with Hepatitis B virus (HBV) are at increased risk for developing chronic HBV infection. In addition, persons who are co-infected with HIV and HBV can have serious medical complications, including an increased risk of liver-related morbidity and mortality (WHO, 2013). According to the Joint United Nations Program on HIV/AIDS (UNAIDS), about 33 million people are infected with HIV worldwide, and the majority of them live in Asia and Africa. Approximately 10% of the HIV-infected population has concurrent chronic hepatitis B, with co-infection more common in areas of high prevalence for both viruses. In countries where the HBV and HIV viruses are highly endemic, the rate of HBV- HIV co-infection can be as high as 25 % (UNAIDS, 2011).

Co-infection with hepatitis B virus (HBV) and HIV is common, with 70-90% of HIV-infected individuals in the United States having evidence of past or active infection with HBV. Factors affecting the prevalence of chronic HBV include age at time of infection and mode of acquisition, which vary geographically. As a result of these factors, cases of hepatic diseases have also been on the rise. Studies show that HIV co infection adversely impacts on the natural history of HBV and HCV by accelerating progression to chronic liver disease due to drug-related hepatotoxicity (Muriuki *et al*., 2013).

In the United States and Western Europe, HBV often is acquired in adolescence or adulthood via sexual contact or injection of illegal drug use (WHO, 2013). Both HBV and HIV are endemic, or even hyper endemic, in the black population of sub-Saharan Africa, with as many as 20% of the population living in the sub-continent being co-infected with the two viruses. In the study conducted in the sub-continent in which occult HBV infection has been evaluated in patients with HBV/HIV-1 co-infection, the number of patients co-infected with HBV and HIV-1 increased from 4.8% without testing to 12.4% with testing (WHO, 2013). Introduction of blood banks and better storage techniques, blood transfusion has become more widely used. Approximately 160,000 units of blood are collected annually in Kenya, of which 95% are from voluntary donors. Blood is one of the major sources of transmission of Hepatitis B, HIV and many other diseases.

Due to discovery of these hazards, the attitude of physicians and patients about transfusion of blood has changed dramatically. Physicians and patients are becoming more concerned about safe blood transfusion. These hazards can be minimized by proper screening and selection of donors. Timely transfusion of blood saves millions of lives, but unsafe transfusion practices puts millions of people at risk of TTIs (Alter *et al.*, 2006).

Data evaluation of sero-prevalence of transfusion transmissible infection among blood donors gives an overview or assessment of the occurrence of infections in the blood donor population and consequently the safety of the collected donations. Co-infection can also result to higher viral load of hepatitis virus and greater liver damage and increase in incidence of HBV reactivation and re-infection. Hence considering the high infectivity, morbidity and mortality due to HBV, routine evaluation of

hepatitis B virus markers may be carried out in all the HIV infected individuals (Suresh *et al*., 2012).

This study determined the prevalence of hepatitis and HIV co- infection among blood donors in Coastal region, Kenya (Regional Blood Transfusion Centre, Mombasa), which can be used a surrogate measure of the prevalence in the entire population as blood donors are assumed to be healthy people in the population (IARC,2010).

1.2 Statement of the Problem

Human immunodeficiency virus (HIV) and hepatitis virus (HBV) are of great concern due to their prolonged viraemia and carrier or latent state. HIV-Hepatitis co-infection is of public health importance because it leads to greater morbidity than either of the two diseases alone, and it affects many people. HBV-HIV coinfection also causes fatal, chronic and life-threatening disorders. In developing countries, liver disease due to chronic HBV has become a growing problem, particularly in those infected with HIV; therefore, it is important to document HIV co-infections in regions with high hepatitis chronicity and HIV infection rates.

The risk of HIV transfusion through infected blood products exceeds that of any other risk exposure. Ninety percent of recipients transfused with HIV antibody-positive blood are found to be HIV infected at follow-up. As of December 2001 to June 2003, an estimated 14,262 persons have been diagnosed with AIDS as a result of transfusion with contaminated blood or blood products (CDC, 2003)

Unsafe blood transfusions have contributed to the enormous burden of HIV infections in sub Saharan Africa and still continue to add to this burden. The risk of HIV infection through unsafe blood is exceptionally high (95–100%) compared to other common routes of HIV exposure: for

example, 11–32% for mother-to-child transmission and 0.1%–10% for sexual contact. Sub-Saharan Africa has a particularly high level of transfusion-associated HIV compared with other regions due to a higher risk of infected blood being transfused. This results from a combination of factors: high rates of transfusion in some groups of patients (particularly women and children), a higher incidence and prevalence of HIV infection, dependence on unsafe blood donors and inadequate testing of blood for HIV in some countries. Women and children account for a disproportionate number of HIV infections through unsafe blood because they are the main groups of patients receiving blood transfusion.

HIV-HBV co-infection are estimated at 10–20% in countries where HBV infection is either endemic or intermediate to high HBV cases. Co-infections with HBV and HIV-1 are common, not only due to shared modes of transmission of the viruses, but also because HIV-1 infection causes multi-dimensional immune suppression, which reduces the probability of spontaneous recovery from HBV infection. Liver disease is now the leading cause of morbidity and mortality in individuals co-infected with the two viruses.

Monitoring of the magnitude of transfusion-transmissible infections in blood donors by determining prevalence and factors associated with HIV-Hepatitis co- infection is important for estimating the risk of infection in blood transfusion. Optimizing donor recruitment strategies to minimize infectious diseases transmission, can be used as a surrogate measure of the population to determine the burden of these condition in the general public and initiate a preventive measure to curb the menace, especially with the advent of ARVs which directly has an impact on the liver.

In Kenya, study done on prevalence of hepatitis B and C viral co-infections among HIV-1 infected individuals in Nairobi, Kenya, revealed a prevalence of 18% HIV-HBV co-infection.

1.3 Justification of the study

Co-infection with HIV and hepatitis B virus (HBV) is said to be common, however, there are limited data to provide an international perspective on this epidemic. Introduction of HAART worldwide including resource-limited settings with high HBV endemicity such as Asia and Africa, as ART directly impacts the liver and is important as since liver disease is a leading cause of non-AIDS death in HIV-infected patients receiving HAART, detecting HBV prior to HAART is important to better understand the scope of the disease and to prioritize treatment needs. Routine screening of blood before transfusion is an opportunity for estimating prevalence of HIV-Hepatitis co infection in the region. The extent of HIV-Hepatitis co-infection in many countries including Kenya has not been determined nationally or regionally except for few studies done in Nairobi settlement areas (Alter *et al.*, 2006).

Up-to-date information on the epidemiology and burden of disease attributable to HBV, HCV and HIV is essential for the development of appropriate national policies in any country. Sero-epidemiological studies on HBV and HIV are an important step in formulating preventive policies and strategies. The prevalence rates of these infections vary according to the risk factors involved such as socioeconomic status (occupation and education level), geographical areas, socio-demographics (age, sex and marital status). This study will determine how these factors are associated with the HIV-HBV co-infection. The initial burden of infectious markers in the community, which vary from one country to another, different regions within the same country are rarely available in African countries (Daw *et al.*, 2014) including Kenya coastal region.

The data and information from this study will contribute significantly to ongoing efforts to improve transfusion-related infections in blood recipients and general blood transfusion practices by targeting safe

communities. This data can help in policy making to include HBV as a mandatory screening for all HIV infected individuals and in targeting potential blood donors to ensure they are properly reached with key messages and education in wider efforts hence blood safety and public health.

1.4 Objectives

1.4.1 General Objective

To determine prevalence and factors associated with Hepatitis B and Human Immunodeficiency Virus co-infection among blood donors in the Kenyan coastal region.

1.4.2 Specific Objectives

1. To determine the prevalence of HIV and HBV among blood donors in the Kenyan coastal region.
2. To determine the prevalence of HBV- HIV co-infection among blood donors in the Kenyan coastal region.
3. To determine factors associated with HBV- HIV co-infection among blood donors in the Kenyan coastal region.

1.5 Research questions

1. What is the prevalence of HIV and HBV among donors in Kenya Coastal region?
2. What is the prevalence of HBV- HIV co-infection among blood donors in the Kenyan coastal region?
3. What are the factors associated with HBV- HIV co-infection among blood donors in the Kenyan coastal region?

1.6 Conceptual Framework

An outcomes research study typically rests on a hypothesis relating an outcome. The variables are categorized as either 1) an outcome or dependent variable which is HIV-HBV co-infection or 2) an independent or predictor variable, upon which the outcome variable is dependent (Age and sex, occupation, geographical area, knowledge and practice). Hence, this framework consists of sets of variables and the relationships between them. The conceptual framework is shown as a graphical model in Figure 1.1.

Independent variables

Dependent Variable

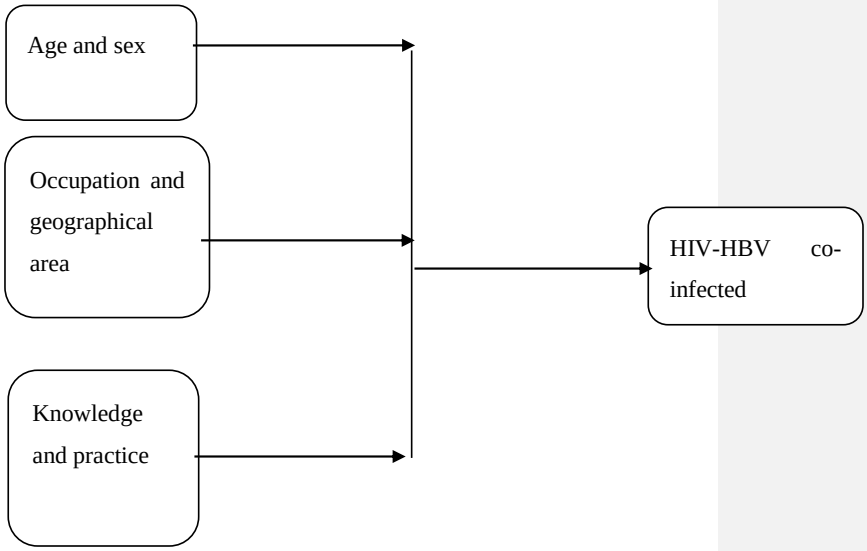


Figure 1.1 Conceptual Framework

CHAPTER TWO

LITERATURE REVIEW

2.1 Hepatitis B Virus

2.1.1 Dynamics of Hepatitis B infection

Hepatitis B is caused by the hepatitis B virus (HBV); an enveloped virus containing a partially double stranded circular DNA genome and classified within the family hepadnaviridae. Hepatitis B virus causes inflammation of the liver called hepatitis, previously serum hepatitis. The infection is preventable by vaccination (Kwon SY *et al*., 2011). Hepatitis has been known for centuries, referred simply to as inflammation of the liver due to protein AA. It was not until the 1940's that doctors began to realize that a virus was possibly responsible for the inflammation of the liver. A conclusion was made in the 1970's, when doctors made a clear link between what was then called protein AA and hepatitis. This protein is now called Hepatitis B Surface Antigen (HBsAg) and scientists have discovered Hepatitis strains ranging from A to G (Gerlich *et al*., 2013).

Viral hepatitis is among the major causes of chronic liver disease. The diseases include chronic hepatitis, liver cirrhosis, and hepatocellular carcinoma (HCC). Main causes of these illnesses are hepatitis B and C viruses. More than 350 million people worldwide are affected with chronic hepatitis B and thus pose a serious threat to public health. It is believed that 2-3% of the world's population are infected with HCV, which is approximately 170 million individuals. All of them are at risk of developing cirrhosis and primary liver cancer (Hwang *et al*., 2011).

The burden of viral hepatitis, though not accurately known, is believed to be one of the highest in the world. Hepatitis A, B, C and E are the types mostly found in the African region. The prevalence of HBV is estimated

at 8% in West Africa and 5-7% in Central, Eastern and Southern Africa. (Zampino *et al*., 2015). The sub-Saharan region is highly endemic with HBsAg carrier rates of 9-20%, whereas 56-98% of the adult population shows evidence of past exposure to HBV infection. Studies in Kenya showed HBsAg carrier rates of 5 - 30% (Muriuki et al., 2013). The first peak of HBV infection in Kenya appears to be during early school age, whereas the second peak occurs at puberty and childbearing age (Muriuki *et al.,* 2013).

2.1.2 Clinical Manifestation of HBV

First infection with HBV results in an acute hepatitis B infection and this is mostly asymptomatic. Acute HBV infection generally presents after an incubation period of six weeks to several months with an onset of nonspecific symptoms that may include fever, malaise, anorexia and nausea, followed by the onset of jaundice, dark urine and pale stools. Approximately 25% to 40% of infected adults will be symptomatic (Agyeman *et al.,* 2016).

Some patients may have nonspecific symptoms such as fatigue (Gerlich *et al*., 2013). In most instances, significant clinical symptoms will develop only if liver disease progresses to decompensated cirrhosis with jaundice, ascites, peripheral oedema, and encephalopathy. Physical examination will be normal in most instances. In advanced liver disease there may be stigmata of chronic liver disease such as splenomegaly, spider angiomata, Caput medusae, palmar erythema, testicular atrophy, gynecomastia (Mutuma *et al*., 2011).

The disease is self-limiting in more than 95% of patients with acute HBV infection, leading to complete recovery and life-long immunity (Gerlich *et al*., 2013). 5% of immune compromised adults, the disease may progress to chronic hepatitis B infection. The age of acquisition of the

infection plays an important role in determining the course of the infection. Up to 90% of those who acquire the infection during the perinatal period progress to chronic infection. Less than 1% of individuals with acute hepatitis B infection may develop fulminant hepatic failure that has high mortality rate reaching approximately 80% (Mutuma *et al*., 2011).

Chronic active infection requires active HBV viral replication in the presence of HBV DNA. HBsAg without detectable HBV DNA or HBeAg defines chronic carrier state. These patients usually have anti-HBeAg and normal liver chemistries. Small amounts of HBV DNA might be detected as long as HBsAg antigens are present. This indicates that presence of HBsAg could diagnose chronic infection without determining the presence or absence of HBV DNA, HBeAg or anti-HBeAg.

2.1.3 Diagnosis and management of HBV

HBV infection sample of choice is blood. Serological tests for viral antigens and antibodies can be performed on either serum or plasma. Both HBV antigens and antibody are stable at room temperature for days, at 4°C for months, and frozen at -20°C to -70°C for many years. A number of nucleic acid-based tests, which have been the subject of recent reviews are available to directly detect HBV-DNA in serum or plasma (Ul Islam *et al.,* 2015). Care must be taken to avoid the degradation of the viral nucleic acid in the specimen (Ul Islam *et al.,* 2015).

Diagnosis of acute or chronic HBV infection requires serologic testing. HBsAg is present in both acute and chronic infection. The presence of IgM antibody to hepatitis B core antigen (IgM anti-HBc) is diagnostic of acute or recently acquired HBV infection. Antibody to HBsAg (anti-

HBs) is produced after a resolved infection and is the only HBV antibody marker present after vaccination. The presence of HBsAg and total anti-HBc, with a negative test for IgM anti-HBc, indicates chronic HBV infection. The presence of anti-HBc alone might indicate acute, resolved, or chronic infection or a false-positive result (Keshvari *et al*., 2015).

Acute hepatitis B infection does not usually require treatment because most adults clear the infection spontaneously (Gerlich *et al*., 2013). Early antiviral treatment may only be required in less than 1% of patients, whose infection takes a very aggressive course (fulminant hepatitis) or who are immuno compromised. On the other hand, treatment of chronic infection may be necessary to reduce the risk of cirrhosis and liver cancer. Chronically infected individuals with persistently elevated serum alanine aminotransferase, a marker of liver damage, and HBV DNA levels are candidates for therapy (WHO, 2015).

2.1.4. Factors associated with HBV Infection

Factors associated with HBV infection include sexual activity, smoking, tattooing, age, gender, marital status, education level, geographical area and occupation. Although, most infections by hepatitis B in developed countries is as a result of sexual activity, injecting drug use, or occupational exposure. While in developing countries, other causes of infections can include household contact, vertical transmission hemodialysis, transmission from a surgeon and the receipt of organs or blood products (Mutuma *et el*., 2011). Other factors associated with HBV infection includes HBV awareness and history of acupuncture.

2.2 Human Immuno Deficiency Virus

2.2.1 Introduction

Human immunodeficiency virus (HIV) is a lentivirus (a member of the retrovirus family) that causes acquired immunodeficiency syndrome (AIDS), a condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. In 2009, AIDS claimed an estimated 1.8 million lives, down from a global peak of 2.1 million in 2004. Approximately 260,000 children died of AIDS in 2009. A disproportionate number of AIDS deaths occur in Sub-Saharan Africa, retarding economic growth and exacerbating the burden of poverty (UN report, 2010). An estimated 22.5 million people (68% of the global total) live with HIV in sub-Saharan Africa. Two types of HIV have been characterized: HIV-1 and HIV-2. HIV-1 is the virus that was initially discovered and termed both LAV and HTLV-III. It is more virulent, more infective and is the cause of the majority of HIV infections globally. The lower infectivity of HIV-2 compared to HIV-1 implies that fewer of those exposed to HIV-2 will be infected per exposure. (Yesufu *et al.*, 2011).

The majority of HIV infections are acquired through unprotected sexual relations, blood transfusion, mother-to-child transmission and sharing needles. HIV infects primarily vital cells in the human immune system such as helper T cells (specifically CD4+ T cells), macrophages and dendritic cells. When CD4+ T cell numbers decline below a critical level, cell-mediated immunity is lost and the body becomes progressively more susceptible to opportunistic infections. A period of rapid viral replication ensues, leading to an abundance of virus in the peripheral blood. During primary infection, the level of HIV may reach several million virus particles per milliliter of blood. HIV is active within lymph nodes, which typically become persistently swollen (Cunningham *et al*., 2010).

2.2.2 Clinical Manifestation of HIV

The WHO system classifies HIV infection into one of four hierarchical clinical stages from stage 1 (asymptomatic) to stage 4 (AIDS). Those infected are classified into a particular stage when they demonstrate at least one clinical condition in that stage's criteria (Weinberg *et al*., 2010)

Stage 1. Patients who are asymptomatic or have persistent generalized lymphadenopathy (lymphadenopathy of at least two sites [not including inguinal] for longer than 6 months) are categorized as being in stage 1, where they may remain for several years.

Stage 2. Even in early HIV infection, patients may demonstrate several clinical manifestations. Clinical findings included in stage 2 (mildly symptomatic stage) are unexplained weight loss of less than 10 percent of total body weight and recurrent respiratory infections (such as sinusitis, bronchitis, otitis media, and pharyngitis), as well as a range of dermatological conditions including herpes zoster flares, angular cheilitis, recurrent oral ulcerations, papular pruritic eruptions, seborrhoeic dermatitis, and fungal nail infections.

Stage 3. As disease progresses, additional clinical manifestations may appear. Those encompassed by the WHO clinical stage 3 (the moderately symptomatic stage) category are weight loss of greater than 10 percent of total body weight, prolonged (more than 1 month) unexplained diarrhea, pulmonary tuberculosis, and severe systemic bacterial infections including pneumonia, pyelonephritis, empyema, pyomyositis, meningitis, bone and joint infections, and bacteremia. Mucocutaneous conditions, including recurrent oral candidiasis, oral hairy leukoplakia, and acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis, may also occur at this stage (Weinberg *et al*., 2010).

Stage 4. The WHO clinical stage 4 (the severely symptomatic stage) designation includes all of the AIDS-defining illnesses. Clinical manifestations for stage 4 disease that allow presumptive diagnosis of AIDS to be made based on clinical findings alone are HIV wasting syndrome, *Pneumocystis pneumonia* (PCP), recurrent severe or radiological bacterial pneumonia, extrapulmonary tuberculosis, HIV encephalopathy, CNS toxoplasmosis, chronic (more than 1 month) or orolabial herpes simplex infection, esophageal candidiasis, and Kaposi's sarcoma. Other conditions that should arouse suspicion that a patient is in clinical stage include cytomegaloviral (CMV) infections (CMV retinitis or infection of organs other than the liver, spleen or lymph nodes), extrapulmonary cryptococcosis, disseminated endemic mycoses (Example coccidiomycosis, penicilliosis, histoplasmosis), cryptosporidiosis, isosporiasis, disseminated non-tuberculous mycobacteria infection, tracheal, bronchial or pulmonary candida infection, visceral herpes simplex infection, acquired HIV-associated rectal fistula, cerebral or B cell non-Hodgkin lymphoma, progressive multifocal leukoencephalopathy (PML), and HIV-associated cardiomyopathy or nephropathy. Presence of these conditions unaccompanied by the AIDS-defining illnesses, however, should prompt confirmatory testing.

These categories apply to adults and adolescents 15 years-of-age and older. A modified version of the WHO Clinical Staging System is available for infants and children under 15 (Weinberg *et al*., 2010).

2.2.3 Diagnosis and Management of HIV

2.2.3.1 Diagnosis of Acute HIV-1 Infection: Acute HIV-1 infection is defined as detectable HIV-1 RNA or p24 antigen (the antigen used in currently available HIV antigen/antibody (Ag/Ab) combination assays) in the setting of a negative or indeterminate HIV-1 antibody test result.

With the evolution of HIV enzyme-linked immunosorbent assays (ELISA) from first to third generation tests, the window period (the time between transmission and production of HIV antibodies when an HIV ELISA test result may be falsely negative) for confirming HIV infection through antibody testing has narrowed from approximately 56 to 21 days. However, because acute HIV infection occurs before the appearance of HIV antibodies, it can be diagnosed only by demonstrating the presence of p24 antigen or HIV viral RNA, which can be detected as early as 14 to 15 days and 11 to 12 days after infection, respectively (Taylor *et al.,* 2015). Reactive HIV antibody test result or Ag/Ab combination test result must be followed by supplemental confirmatory testing. Negative or indeterminate HIV-1 antibody test result in a person with a reactive Ag/Ab test result or in whom acute HIV-1 infection is suspected requires plasma HIV-1 RNA testing to diagnose acute HIV-1 infection (Chu *et a*l.,2010).

2.2.3.2 Management of HIV Infection

The most important clinical considerations for patients with acute HIV infection is psychosocial evaluation and stabilization, including a domestic violence screen and referral to counseling or support services if available. Physicians should educate patients about their potentially heightened infectiousness, and discuss effective transmission risk reduction strategies. These include consistent and effective condom use, limiting drug and alcohol intake (which may impair the ability to negotiate safe sex), and the incorporation of alternative sexual practices that do not involve the exchange of body fluids (Chu *et al*., 2010).

Anti-retroviral therapy (ART) is recommended for all HIV-infected individuals and should be offered to all patients with early HIV infection.

2.3 HIV and Hepatitis B Co- Infections

2.3.1 Epidemiology of HIV and Hepatitis B Co- Infections

Co infection with human immunodeficiency virus (HIV) and hepatitis B virus (HBV) is common due to shared routes of transmission. In areas of low endemicity, such as North America, Australia and Europe, HBV and HIV infection are usually acquired in adulthood through sexual or percutaneous transmission (WHO, 2010). In areas of low endemicity, the prevalence of chronic co infection is around 5-7% among HIV infected individuals. In countries with intermediate and high HBV endemicity, the main routes of transmission of HBV are perinatal or in early childhood; in these countries HBV co infection rates are 10-20% (WHO, 2010).

2.3.2 Mode of Transmission of HIV and HBV

The common modes of transmission for both HIV and HBV in developing countries are prenatal, early childhood, unsafe injections practices, blood transfusions and sexual contact. Having been infected, this infection runs a clinical course of an incubation period lasting between 4 - 12 weeks, acute illness of 2 weeks – 3 months and eventual recovery for individuals who resolve their infection in case of HBV (WHO, 2011). Many infected adults are without classical symptoms and individuals in whom HBsAg is present in their blood for more than six months are considered to be chronically infected with HBV. Such individuals with chronic infection have a high risk of liver cirrhosis and hepatocellular carcinoma but may pass the medical tests required for blood donors and the current serological test of HBsAg may be negative, this has a grave implication on blood safety in countries like Kenya where only HBsAg tests are used as indicators for infection (Mori *et al.*, 2015).

2.3.3 Impact of HBV-HIV Co- Infection

2.3.3.1 Impact on the Natural History of HBV and HIV

The rate of progression and complications from viral hepatitis are accelerated in patients with HIV. After acquiring HBV infection, HIV infected individuals are 6 times more likely to develop chronic hepatitis B than HIV negative individuals. In addition, HIV infected individuals are more likely to lose previously developed protective anti-HBs antibody and develop acute hepatitis B infection; this risk is also associated with lower CD4 counts (Kerubo *et al.*, 2015). HBV-HIV co-infection has more negative effects. The influence of HIV on HBV is characterized by a more frequent evolution towards chronicity, an increased viral replication rate, a viral reactivation leading to fibrosing cholestatic hepatitis, and an increased progression towards fibrosis and liver cirrhosis (Fouelifack *et al.*, 2012).

2.3.3.2 Impact on blood transfusion

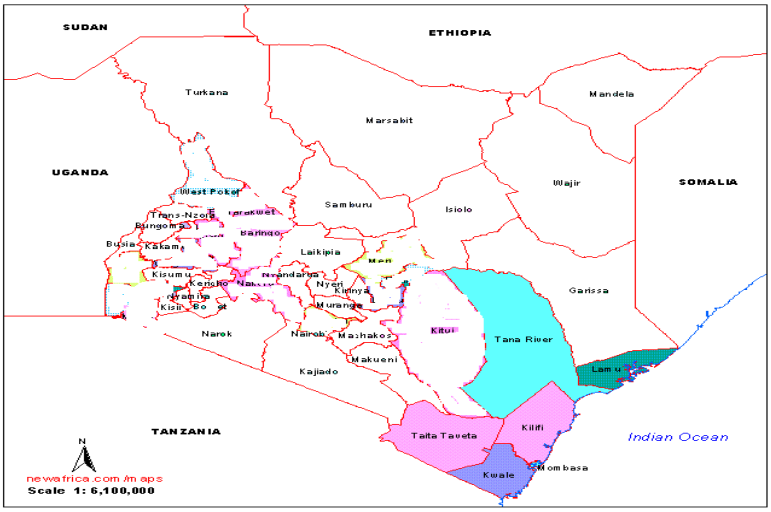
Human immunodeficiency virus and hepatitis B virus infections are two major viral infections worldwide. The presences of infection markers to these two viruses in blood donors obviously present great risk to blood recipient. Most people infected by these viruses have no symptoms and do not know that they carry the virus, but all who are infected can transmit the virus to others. So there should be a creation of enough awareness by those involved in formulating policies on blood donation and everyone interested in building a safe society. HIV and HBV are among the major viruses transmitted by transfusion. 5-10 % of Human Immunodeficiency Virus (HIV) transmission in Africa is as a result of contaminated blood transfusions, while 12.5% of patients who received blood transfusion are at risk past transfusion hepatitis (Mutuma *et al.*, 2011).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Area

The study was carried out at the Regional Blood Transfusion Centre, Mombasa which serves Mombasa, Kilifi, Kwale, Taita-Taveta and Lamu counties. Approximately 1200 units of blood are collected every month across the counties, therefore a good catchment area to give a good representation of the coastal region and the laboratory in the centre was used as testing site for the for HIV and HBV. Figure 3.1 below shows the map of the study catchment area.



Source: https://www.researchgate.net/figure/Administrative-map-of-Kenya-showing-Coastal-region-of-Kenya-the-study-area-shaded

Figure 3.1 Map of Kenya showing study catchment area

3.2 Study Design

This study was cross-sectional.

3.3 Study Population

Blood donors both relative (those donors who volunteered because they had a sick relative) and voluntary donors who visited Regional Blood Transfusing Centre Mombasa and all the county hospitals within the former coast region (Mombasa, Taita Taveta, Lamu, Kwale, Kilifi and Tana River).

3.3.1 Inclusion and Exclusion Criteria

All eligible blood donors aged between 16 -65 years who consented to the study were included in the study. All deferred donors (those who do not meet the set criteria) and donors aged below 16 years and above 65 years, all those who did not consent were excluded from the study.

All school going children aged 16 years consent to donate was given by the guardian or school principal for those in school premises as the policy of Kenya Blood transfusion service (Policy guidelines on blood transfusion in Kenya, 2001)

3.3.2 Sample Size Determination

The prevalence of HBV-HIV co-infection reported as high as 10–20% in countries where HBV infection is either endemic or intermediate to high HBV. In study done in Nairobi, Prevalence of hepatitis B and C viral co-infections among HIV-1 infected individuals, the rate of HBV_HIV was 6% (Mukami *et el*., 2013), this is the rate that was used for sample size estimation for the study, since the study was done in Kenya.

The sample size was calculated using Cochran sample size determination formula,

(Cochran *et al*, 1989) Thus,

$$n=\frac{Z^2 (P) (1-P)}{d^2}$$

Where n=minimum sample size required

Z=Z score corresponding to the level of confidence with which it is desired to be sure that the true population lies within +/-% points of the sample estimate (95%=1.96).

P=expected population proportion (6%)

d= maximum tolerable error=5%

q=100-50=50%

$$n=\frac{(1.96)^2 \text{ X } (0.06 \text{ x} 0.4)}{(0.05)^2}$$

n=369

This means a minimum of 369 samples was sufficient for the study but a total of 420 samples were enrolled into the study. Stratified sampling technique was employed to divide the donors into six counties and then proportional allocation method used. In which we divided the blood donor population into subgroups (Counties) called strata based on the overall proportions of the donor population, and calculated the number of donors to be sampled from each subgroup (County). Using formula;

[sample size/population size} x subgroup size.

3.4 Sampling Technique

This study employed a systematic stratified sample collection method in which all the population were be given equal opportunity. The counties presented stratum in which sample to be drawn were based on the number of donors per the county. The participants were selected as they presented themselves for blood donation. Eligible participants filled the consent form and donor questionnaire voluntarily (Appendix 1) which was witnessed by the health officer who attended to the donor and appended their signature before collection of data. All health officers signed a confidentiality agreement form. The data was collected from 1st July to 30th September 2015.

3.5 Data Collection Procedure

Data was collected using a structured questionnaire (Appendix 2) designed for the study which included personal data, occupation, area of residence, education level, religion and knowledge on hepatitis. The questionnaires were given unique numbers so as to link the data collected and the results after testing. Data collected were entered in excel database and backed up in external disc, access restricted by use of password and hard copies kept in a lockable cabinet.

3.6 Instruments and testing method

Blood samples were collected into 5ml sterile plain vacutainers and transported to the Regional blood center using cooler boxes with ice packs by road for testing using Thermo scientific Eliza Machine (Reader, Washer and Incubator). ELISA assay was used to test for both HIV and HBV infections. HBV was tested using test kit Hepanostika HBsAg Ultra manufactured by bioMérieux, France Lot number A66BA Expiry 28th February, 2016 and HIV was tested using test kit fourth generation Vironostika® HIV Uni-Form II Ag/Ab manufactured by bioMérieux,

France, Lot number A6V50 Expiry 28th February, 2016. Vironostika is one step Micro-elisa test for the immunological detection of HIV-1and 2. All positives were repeated twice, first using the same kit and confirmed using Murex HIV Ag/Ab Combination (Abbott/Murex) and Murex HBsAg to ascertain positivity.

3.7 Data processing and analysis technique

Data was coded and entered in an excel sheet and verified. Descriptive statistics were analyzed using Microsoft Excel 2010, SPSS version 22 and Chi square - Fisher's exact. 95% confidence Intervals (CI) at P value ≤ 0.05 in univariate analysis. Multiple logistic regression was used for multivariate analysis to determine the independent factors (Age, sex, marital status, occupation, education level and geographical area) for exclusively HBV-HIV co-infection.

3.8 Ethical Considerations

This study was approved by Kenya National Blood Transfusion Management and Pwani University Ethical committee (Appendix 3 and 4). All participants voluntarily enrolled to the study and signed an informed consent form (Appendix 1) which was witnessed by the health officer who attended to the donor and appended their signature before collection of data and blood samples. The questionnaire used to collect data was anonymous and only linked to the blood sample tube only by a code generated by the Blood transfusion center and study number. The coding system is approved by International Society for Blood Transfusion (ISBT). The staff working in the study also signed a confidentiality agreement to protect the identity of the participants.

CHAPTER FOUR

RESULTS

4.1 Introduction

This study was carried out from 1st July, 2015 to 30th September, 2015. There were 420 respondents enrolled into the study, of which 71% (298) were male and 29% (122) female. The respondents were drawn from Mombasa, Kilifi, Kwale, Tana River, Taita Taveta and Lamu as indicated in Table 4.1. Out of the 420 respondents, 152 were repeat donors.

Table 4.1 Distribution of respondents by county

County	No. of donors	No. enrolled	%	Male %	Female %
Kilifi	6092	89	21.2	16.9	4.3
Kwale	5469	81	19.3	12.6	6.7
Lamu	1523	22	5.2	4.8	0.5
Mombasa	7823	113	26.9	17.9	9
Taita Taveta	6577	92	21.9	13.8	8.1
Tana River	1592	23	5.5	5	0.5
Total	29076	420	100.0	71	29

4.2 Socio demographic and socio-economic characteristics of respondents

The respondents were divided into six age groups; the age range was from 16 to 64 years (Median age group was 25-34yrs) (Figure 4.1).

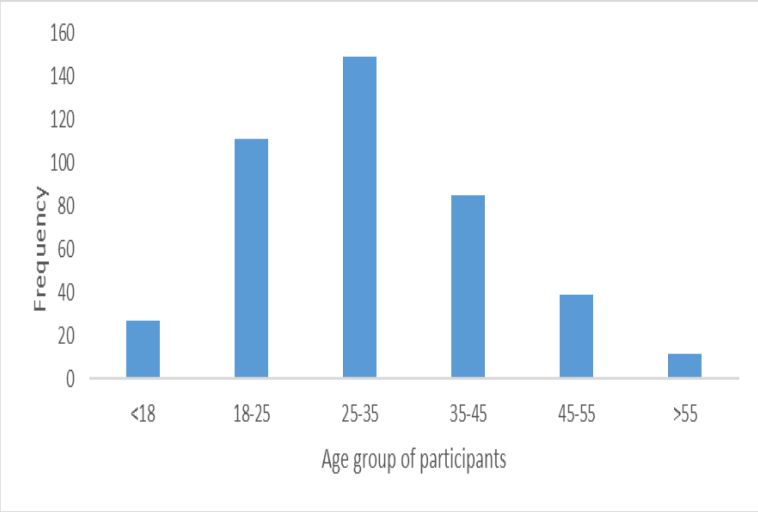


Figure 4.1 Age group of the study respondents

Among the respondents, 52.9% were single with males being more than females (66.7% males and 33.3% females). Married respondents were 44.5% (75.9% males and 24.1% females), Divorced and Widowed were 1.7% and 1% respectively with most of them being males.

Education level, majority of the respondents achieved tertiary education level at 61.9%, followed by secondary education at 28.1%. Those with no formal education were 3.8%. Informal employment that included traders, farmers, hawkers, drivers, casuals and fishermen were 38.3%, students at 27.4%, formal employment that included, teachers, nurses, managers, IT office, security, police and mechanics were 25.2%., 9.1% unemployed (Table 4.2).

Table 4.2 Social demographic characteristics among the study respondents

		Frequency	Males	Female	%
Marital Status	Single	222	148	74	52.9
	Married	187	142	45	44.5
	Divorced/Separated	7	5	2	1.7
	Widowed	4	3	1	1.0
	Total	**420**	**298**	**122**	**100**
	None	16	12	4	3.8
	Primary	26	15	11	6.2
Education					
	Secondary	118	77	41	28.1
	Tertiary	260	194	66	61.9
	Total	**420**	**298**	**122**	**100**
	Formal	106	82	24	25.2
Occupation	Informal	161	119	42	38.3
	Unemployed	38	26	12	9.1
	Student	115	71	44	27.4
	Total	**420**	**298**	**122**	**100**

4.3 Prevalence of HIV among study respondents

Among the respondents, six out of the 420 respondents were infected with HIV representing an overall prevalence of 1.40% (6/420). Among the males and females the HIV prevalence was 1.34% (4/298) and 1.63% (2/122) respectively.

4.3.1 Distribution of HIV infected study respondents by age, sex and marital status

The respondents age were grouped into six strata <18, 18-25, 25-35, 35-45, 45-55 and >55. Respondents in age group 45-55 years had the highest prevalence of HIV at 5.1%, however there was no significant association between age, gender (p-value 0.332 and 0.807 respectively) and HIV infection. Results showed that marital status had significant association with HIV status (p=0.036. The proportion of those who are HIV positive was highest among the divorced population with prevalence of 14.3%. There was no infection among the widows (Table 4.3.1).

Table 4.3. Distribution of HIV infection by age, sex and marital Status among study respondents

		N	No (%)	Yes (%)	X^2 (fisher exact)	df	P value
Age group	<18	26	27 (100)	0	5.745	5	0.332
	18-25	111	109 (98.2)	2 (1.8)			
	25-35	149	147 (98.7)	2 (1.3)			
	35-45	83	83 (100)	0			
	45-55	39	37 (94.9)	2 (5.1)			
	>55	12	12 (100)	0			
Gender	Male	298	294 (98.7)	4 (1.3)	0.06	1	0.807
	Female	122	120 (98.4)	2 (1.6)			
Marital status	Divorced	7	6 (85.7)	1 (14.3)	8.520	3	0.036
	Married	187	185 (98.9)	2 (1.1)			
	Single	222	219 (98.7)	3 (1.3)			
	Widowed	4	4 (100)	0			

4.3.2 Distribution of HIV infected study respondents by county

Mombasa County and Kwale County had the highest prevalence in HIV with 2.7% and 2.5% respectively. Lamu and Tana River had no HIV infection. No significant association between geographical area and HIV infection (Table 4.4).

Table 4.4. Prevalence of HIV per county.

		N	No (%)	Yes (%)	X^2 (fisher exact)	Df	**P value**
County of residence	Kilifi	89	89 (100)	0	3.894	5	**0.565**
	Kwale	81	79 (97.5)	2 (2.5)			
	Lamu	22	22 (100)	0			
	Mombasa	113	110 (97.3)	3 (2.7)			
	Taita Taveta	93	94 (98.9)	1 (1.1)			
	Tana River	23	23 (100)	0			

4.4 Prevalence of HBV among study respondents

Out of the 420 respondents of the study, 13 were infected with hepatitis B representing 3.1% prevalence (13/420). There were 10 males and 3 females who were infected with HBV, Prevalence of HBV was higher among the male respondents than the females with 3.7% and 1.6% respectively. The table 4.4 indicates the frequency distributions.

4.4.1 Distribution of HBV infected study respondents by age, sex and marital status

The results show that among the respondents in age group 45-55years had the highest HBV prevalence of 5.1%, age group 25-35 years and 35-45 years had prevalence 4% and 3.6% respectively. Results from the study showed that marital status had significant association with HBV infection (p=0.006). The proportion of those who are HBV infection was highest among the widowed and divorced respondents. (Table 4.5).

Table 4.5 Distribution of HBV infection as by age, sex and marital status

		N	No (%)	Yes (%)	X^2 (fisher exact)	Df	P value
Ages	<18	26	27 (100)	0	2.906	5	0.714
	18-25	111	109 (98.2)	2 (1.8)			
	25-35	149	143 (96)	6 (4)			
	35-45	83	80 (96.4)	3 (3.6)			
	45-55	39	37 (94.9)	2 (5.1)			
	>55	12	12 (100)	0			
Gender	Male	298	287 (96.3)	11 (3.7)	1.183	1	0.277
	Female	122	120 (98.4)	2 (1.6)			
Marital status	Divorced	7	6 (85.7)	1 (14.3)	12.608	3	0.006
	Married	187	179 (95.7)	8 (4.3)			
	Single	225	222 (98.7)	3 (1.3)			
	Widowed	4	3 (75)	1 (25)			

4.4.2 Prevalence of HBV among study respondents by county

Kwale County had the highest prevalence of hepatitis B (4.9%), followed by Lamu and Tana River at 4.5% and 4.3% respectively, Taita Taveta County had the lowest prevalence of HBV. (Figure 4.2).

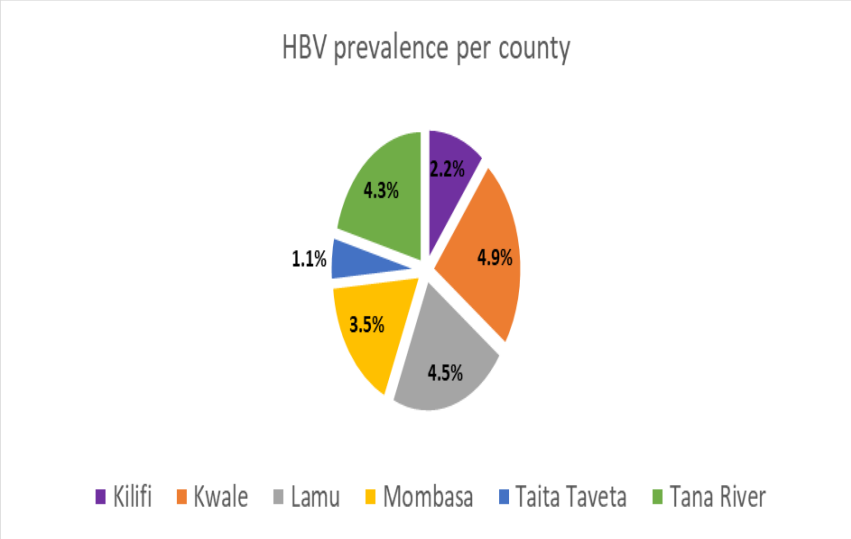


Figure 4.2 Prevalence of HBV per County among study respondents

4.5 Prevalence of HIV- HBV Co-Infection among study respondents

Among the respondents two were infected with both HIV and HBV infections representing a prevalence of 0.5% (2/420). Two males were co-infected with both HBV and HIV and no female was co-infected giving a prevalence of 0.67% among male respondents. Among the HIV infected there was 33.3% (2/6) prevalence of HBV-HIV co-infection.

4.5.1 Distribution of HIV-HBV co-Infection by age, sex and marital status

HIV-HBV co-infection was observed among respondents aged between 18-25 years and 45-55 years, of whom were all males. There was no co-infection among the females. There was no significant association with HBV infection with variables observed ($p>0.05$) (Table 4.6).

Table 4.6 Prevalence of HBV/HIV co-infection among study respondents by socio-demographics

Demographic		N	No (%)	Yes (%)	X^2 (fisher exact)	Df	P value
Ages	<18	26	26 (100)	0	5.354	5	0.378
	18-25	111	110 (99.1)	1 (0.9)			
	25-35	149	149 (100)	0			
	35-45	83	83 (100)	0			
	45-55	39	38 (96.5)	1 (3.5)			
	>55	12	12 (100)	0			
Gender	Male	298	296 (99.7)	2 (0.7)	0.438	1	0.494
	Female	122	122 (100)	0			
Marital status	Divorced	7	7 (100)	0	0.071	3	0.995
	Married	187	186 (99.5)	1 (0.5)			
	Single	225	224 (99.6)	1 (0.4)			
	Widowed	4	4 (100)	0			
Level of education	None	16	16 (100)	0	0.599	3	0.897
	Primary	26	26 (100)	0			
	Secondary	118	117 (99.2)	1 (0.8)			
	Tertiary	260	259 (99.6)	1 (0.4)			
Occupation	Formal	106	106 (100)	0	4.493	1	0.320
	Informal	161	160 (99.6)	1 (0.4)			
	Unemployed	38	37(97.4)	1 (2.6)			
	Student	115	115 (100)	0			

4.6 HIV, HBV and HBV-HIV co-infection prevalence by county

There was no HIV infection among the Kilifi, Tana River and Lamu Counties respondents, Mombasa County had the highest percentage of 0.7% of the total HIV prevalence followed closely by Kwale County with 0.5% prevalence HBV infection was high in Mombasa and Kwale County with 1% each of the overall prevalence followed by Kilifi County with 0.5%. Tana River, Lamu and Taita Taveta had 0.2% prevalence of the overall HBV prevalence each (Table 4.5). HIV-HBV Co-infection was observed in Mombasa and Kwale Counties (Table 4.7). There was no significant association between HBV_HIV prevalence by geographical area, (P p> 0.05).

Table 4.7 Distribution of HIV, HBV, co-infection by counties

County	N	No (%)	Yes (%)	X^2 Fischer Exact	Df	P value
Kilifi	89	89 (100)	0			
Kwale	81	80 (98.8)	1 (1.2)			
Lamu	22	22 (100)	0			
Mombasa	113	112 (99.1)	1 (0.9)	2.495	5	0.767
Taita Taveta	92	92 (100)	0			
Tana River	23	23 (100)	0			

4.7 Awareness and Practice of the Study Respondents on Hepatitis

4.7.1 Respondents Sources of Information on HBV

A total of 243(59%) donors had heard of hepatitis and 177(41%) had not heard of it prior to the donation time, out of the 243 who had heard of

hepatitis B, seven were infected with HBV giving a prevalence of 2.9% among them and 2.5% prevalence among those that had knowledge prior. Table 4.8 shows different sources in which the donors had heard about the disease and distribution of infection among the respondents.

Table 4.8 Sources of information and distribution of HBV infection among respondents who answered yes, Kenya coastal region (2015)

Source	Number (%)	HBV+ (%)
Newspapers and magazine	10 (4.1)	**2 (0.8)**
Radio	0	**0**
Television	0	**0**
Brochure, posters and other printed materials	211 (86.8)	**4 (1.7)**
Family, friends, neighbors and colleagues	22 (9.1%)	**1 (0.4)**
Total	243 (100)	**7 (2.9)**

4.7.2 Awareness of the respondents on HBV

Only those donors who answered of having heard of hepatitis responded to this part of the questionnaire on assessing the knowledge, a total of 243 responded to this section, Out of the 243 respondents, 220 (90.5%) agreed that unscreened blood can transmit hepatitis through blood transfusion. Most of the donors were not sure whether HBV vaccine was available 212 (87.2%). The respondents agreed that HBV can be transmitted through unsafe sexual intercourse and piercing of ears or tattooing representing 216 (88.9%) and 201 (82.7%) respectively. Table 4.9

The overall awareness of the study respondent on HBV was poor, (Table 4.10).

Table 4.9 Respondents knowledge on HBV

Hepatitis may be transmitted by;	**Yes (%)**	**No (%)**	**Neutral (%)**	**Total**
Unscreened blood for transfusion	220 (90.5)	6 (2.5)	17 (7)	243
Sharing plate with infected person	22(9.1)	157 (64.6)	64 (26.3)	243
Hugging infected person	23 (9.5)	120 (49.4)	100 (41.1)	243
Unsafe sexual intercourse	23 (9.5)	4 (1.67%)	216 (88.9)	243
Piercing of ears or tattooing	30 (12.3)	12 (4.9)	201(82.7)	243
Sharing toilet with infected persons	23 (9.5)	79 (32.5)	141(58)	243
Sneezing and coughing	3 (1.2)	142 (58.4)	98(40.3)	243
Has vaccine for hepatitis available	10 (4.1)	21 (8.6)	212(8.7)	243

Table 4.10 Respondents awareness on HBV infection

	Poor	%	Good	%	Very Good	%
Unscreened blood for transfusion	23	9.5	23	9.5	197	81.1
Sharing plate with infected person	86	35.4	21	8.6	136	56.0
Hugging infected person	123	50.6	2	0.8	118	48.6
Unsafe sexual intercourse	220	90.5	19	7.8	4	1.6
Piercing of ears or tattooing	213	87.7	24	9.9	6	2.5
Sharing toilet with infected persons	164	67.5	79	32.5	0	0.0
Sneezing and coughing	101	41.6	110	45.3	32	13.2
Has vaccine for hepatitis available	233	95.9	10	4.1	0	0.0
Average Score		59.8		14.8		25.4

4.7.3 Practice of the respondents

4.7.3.1 Blood donors

Out of the 420 respondents, 152 were repeat donors (have donated more than once in their lifetime), none of the repeat donors were infected with any of the diseases. There were 268 first time donors, out of which 13(4.9%) had HBV infection, six (2.2%) HIV infection and 33.3% (2/6) of those HIV infected respondents were co-infected with hepatitis B. None of the donors had been vaccinated against HBV (Table 4.11).

4.7.3.2 Use of IDU

Donors who answered yes to having used IDU were 58, of which 3.8% were infected with HBV and 2% infected with HIV. Of the HIV infected, one was co-infected (100%).The respondents who had not used IDU (366) had 3% and 1.4% prevalence for HBV and HIV respectively (Table 4.11).

4.7.3.3 Safe sex practice

Respondents who were practicing safe sex and had prevalence of HIV 0.2% (1); HBV 0.5% (2); HBV-HIV were 0%. Similarly, the respondents who did not practice safe sex and HIV were 1.2% (5); HBV 2.6% (11); and HBV-HIV were 0.5% (2). Among the respondent who tested negative for HIV, 50.7% (213) practiced safe sex while 47.9% (201) did not; for HBV 50.5% (212) practiced safe sex and 46.4% (195) did not and HBV-HIV co-infection; for HBV-HIV co-infection 51% (214) practiced safe sex while 48.5% (206) did not. Table 4.7.3 is a summary of practice. (Table 4.11).

Table 4.11 Practice of the study respondents

	Yes(5)	NO (0)						
	NO.	HBV^+	HIV^+	HBV-HIV+	NO.	HBV^+	HIV^+	HBV-HIV+
Are you a regular Blood donor	152	0	0	0	268	13(4.9%)	6(2.2%)	2(33.3%
Have you been vaccinated for Hepatitis	0	-	-	-	402	13(3.2%)	6(1.4%)	2(0.5%)
Have you ever used contraindicated injected drug (IDU)	54	2(3.8%)	1(2%)	1(100%)	366	11(3%)	5(1.4%)	1(20%)
Do you ask your barber to change the blade before shaving	78	2(2.6%)	1(1.3%)	0	342	11(3.2%)	5(1.5%)	0
Do you practice safe sex	211	2(0.5%)	1(0.2%)	0	209	11(2.6%)	5(1.2%)	2(0.5%)

CHAPTER FIVE

DISCUSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 DISCUSSION

The study determined the prevalence of HIV, HBV, HIV-HBV Co-infection and factors associated with HIV- HBV co-infections among blood donors in Coastal region, Kenya. Four hundred and twenty respondents participated in the study. Donors were divided into six age groups ranging from 18 to 64 years. There were 298 (71%) males and 122 (29%) females. This is similar to another study done in Africa in which the female and male donors accounted for 12.1% and 87.9% respectively (Tessema *et al.*, 2010). Low blood donation by women could be attributed to cultural beliefs in coastal Kenya that women should not donate blood because of the monthly blood loss that occurs during menses (Dikosso, 2010). This was a descriptive cross-sectional study, the study showed prevalence of 3.1% and 1.43% for HBV and HIV respectively among the blood donors. The study also determined prevalence by age, sex, county, level of education and occupation. Prevalence and associations were determined through descriptive analysis and significance of relations through X^2 and Fischer exact. We created a summary table that showed the relationships of the variables (occupation, education level, marital status, geographical area, age and sex) and HIV, HBV and HIV-HBV co-infection.

5.1.1 Prevalence of HIV among study Respondents

Among the 420 respondents, six were infected with HIV presenting 1.4% (6/420). The Prevalence of HIV in this study was low compared to WHO Sub Saharan Africa HIV prevalence rate for Kenya (UNAIDS, 2014). Reduction in prevalence among the respondents could be due to the

stringent donor selection criteria, enforced by blood transfusion centre to reduce the rate of sero-positivity by the use of donor questionnaire. The questionnaire is used to determine the donor history, exposure and risk behavior. Study on Sero-prevalence of transfusion-transmissible infectious diseases among blood donors in Kassala, eastern Sudan also showed a prevalence of 3% for HIV among blood donors which indicates a lower prevalence as compared to WHO prevalence 0f 6% ((UNAIDS, 2014).

Another study done in Kenya by (Kerubo *et al.*, 2015) on Hepatitis B, Hepatitis C and HIV Co-infection in two informal urban settlements in Nairobi showed HIV prevalence of 20.4%. This prevalence is higher compared to the prevalence in the current study and prevalence of HIV in Kenya of 6% (UNAIDS, 2014) this big difference can be attributed to the strict donor selection procedure done before blood collection.

5.1.1.1 HIV prevalence among study respondents by on age, sex and marital status

There was no significant association between age, gender and HIV infection with p value > 0.05 However, respondents in age group 45-55 years had the highest prevalence of HIV at 5.1% as compared to other age groups with less 2% prevalence across the groups.

Marital status had significant association with HIV status in this study finding. The proportion of those who are HIV positive was highest among the divorced population with prevalence of 14.3%. This finding is comparable to HIV prevalence of 43.1% recorded among divorcee/separated in a study on prevalence, co-infection and associated risk factors of hepatitis B virus (HBV) and Human immunodeficiency virus (HIV) in Benue State, Nigeria (Adekeya *et al.*, 2013). High prevalence of these viruses among divorcee/separated may be due to

unusual freedom, restrain from multiplicity of sexual partners due to lack of family cover, sex for favour, sexual assaults.

5.1.2 Prevalence of HBV among study respondents

Prevalence of 3.1% for HBV in this study was equally low compared to WHO Sub Saharan Africa prevalence of HBV at 10% (WHO, 2010). This can also be compared to study done on Hepatitis B, Hepatitis C and HIV-1 Co-infection in two informal urban settlements in Nairobi, Kenya (Kerubo *et al*., 2015) which had prevalence13.3% for HBV which is significantly higher than the study finding of 3.1%.

Study on Sero-prevalence of transfusion-transmissible infectious diseases among blood donors in Kassala, eastern Sudan (Tajeldin *et al.*, 2011) also showed prevalence of 4.3% which was almost equal to this study findings but lower than WHO prevalence, which further reveals low prevalence of HBV among blood donors.

5.1.2.1 *Prevalence* of HBV by age, sex and marital status among study respondents

Study respondents in the age group 25-35years, 35-45 years and 45-55 years had the highest prevalence of 4%, 3.5% and 5.1% respectively. This is comparable to study in Nigeria in which age group 36- 45 years had the highest prevalence of HBV (Kanu *et al.*, 2015). This high infection rate could probably be attributed to the fact that this age group contains active young adults in the society so it may be attributed to some negative social behaviour like sexual activity with multiple partners, it could also be due to more social mobility thus greater vulnerability of infection, improved socioeconomic status, and perceived freedom that come with young adulthood.

There were high prevalence of HBV among the male respondents than female respondents with prevalence of 3.7% and 1.6% respectively. This could be attributed to low blood donation by women due to to cultural beliefs in coastal Kenya that women should not donate blood because of the monthly blood loss that occurs during menses (Dikosso, 2010). This study finding is comparable to study done in Kenya on Prevalence of Hepatitis B Virus Infection in Kenya (Ly *et al.*, 2016), which the estimated HBsAg prevalence was highest among males than females with prevalence of 3.5% and 1.2% respectively.

5.1.2.2 Prevalence of HBV by county (Geographical area) among study respondents

The results of the study showed that Kwale County had the highest prevalence of hepatitis B (5.1%), with Lamu and Tana River at 4.5% and 4.4% respectively, Taita Taveta County had the lowest prevalence of HBV. High HBV prevalence in these regions could be attributed to the socio- economic status of the regions, nutritional diets as these areas are pruned to droughts and low literacy rate as observed from the donor questionnaires which could lead to poor sanitation hence horizontal transmission.

Study done on HBV prevalence in Kenya in 2016, found HBV prevalence to be disproportionately distributed in the former eight provinces of Kenya, HBV prevalence was high among residents of the North Eastern Province, the reason for which is not clearly evident from the study but may be due to shared common cultural or traditional practices and/or risk factors (Ly *et al.*, 2016).

5.1.3 Prevalence of HIV-HBV co-infection among study respondent

Prevalence rates of HBV/HIV co-infection has been shown to vary according to the risk factors involved, socioeconomic status and initial

burden of infectious markers in the community. It also varies from one country to another and even between different regions within the same country, sample size, test kit sensitivity and specificity (Balogun, T. M., Emmanuel, & Ojerinde, 2012). In Kenya varied HBV/HIV co-infection rates have been reported; (Chepkurui *et al.,* 2015), reported a prevalence of 5% of HBV/HIV coinfection in Kericho County, similar prevalence of co-infection has been reported in Kenya, (Kerubo *et al.,* 2015) reported prevalence of 4.26% HBV/HIV co-infection in Nairobi, while Harania *et al*. (2008) and Muruiki *et al*. (2013) both reported a 6% co-infection prevalence in Nairobi at different time point.

The HBV/HIV co-infection rates was also consistent with findings from other regions such as 9.9% HBV/HIV co-infection in Lusaka Zambia (Kapembwa *et al*., 2011), 4% among patients attending Royal Victoria Teaching Hospital in Malawi (Mboto *et al*., 2010), 9.2% in Nigeria (Lesi *et al*., 2007), 3.9% in Ethiopia (Shimelis *et al*., 2008) and 6% in South Africa (Lodenyo *et al.,* 2000).

The HBV prevalence rate of 0.48 % was found among the study respondents indicating low endemicity. Variation in prevalences among blood donors observed may be attributed to difference in geographical setting and stringent donor selection.

5.1.3.1 Prevalence of HBV among HIV infected respondents

Among the HIV infected study respondents (6 respondents) two had HBV infection representing prevalence among of 33.3% (2/6), this is comparable to study done by Helen M. Chun *et al* (2010) which found HBV-HIV co-infection prevalence of 24.9%, and study from Ethiopia at 34% (Tessame *et al.,* 2010). Higher rates of HBV (6 -27.6%) have been

reported from studies carried out in Nairobi among HIV infected outpatient population and (Mukami *et al.*, 2013).

The high rate of co-infection 2/6(33.3%), among blood donors found is higher than what was observed in Tanzania (8.6%) (Matee *et al.*, 2006) but similar to neighbouring Ethiopia (34%) (Tessame *et al.*, 2010). This high rate of co-infection might be due the fact that they share the similar route of transmission.

5.1.4 Factors associated with HIV-HBV co-infection among the respondents

This study finding that the mono infected with either HIV or HBV and co-infected blood donors shared similar demographic characteristics with respect to education level, marital status, and occupation has also been reported by other authors (Teltela *et al*., 2007; Sadoh *et al*., 2011). Further, studies have reported positive associations between HIV/HBV co-infection and such factors as sex, age, education level, intravenous drug use and homosexual activity (Mohammadi *et al*., 2009; Freitas *et al*., 2014).

5.1.4.1 Age and sex

Regarding the factors associated with HBV-HIV co- infection, the results of this study are consistent with the national and international literature, in which higher prevalence of HBV- HIV co-infection were described in older male, as noted in age group of 45-55years at 3.5 % prevalence. The association between older age groups and HBV-HIV co-infection is a well-known and widely observed fact resulting from the increased risk of exposure with time and the greater vaccination coverage in younger populations (Oliveira *et al.*, 2014). However this study showed that there was no significance association with age, sex and HBV-HIV co-infection.

In this study females were less likely to be HBV/HIV co-infected. In Brazil Freitas *et al*., (2014) showed that HBV infection was significantly associated with male gender. A predominance of the male gender has also been reported previously in other studies possibly due to high-risk behaviors for HBV infection increasing sexual and percutaneous exposure (Brag *et al.*, 2006; Cortés *et al*., 2009).

The HBV/HIV infection occurred most frequently among the patients aged beyond 31 years of age. Freitas *et al*., (2014) also showed that of HBV infection was significantly associated with age over 35 years. Further, this finding was in line with previous studies, which reported that older age was associated with a higher risk of HBV exposure (Braga *et al*., 2006; Cortés *et al*., 2009). Family history of hepatitis, use of illicit drug and homosexual HBV infection within this age group is attributed to being male, a history of operations, a family member who is HBsAg positive, and not being immunized (CDC, 2006).

In this study all the HBV/HIV co-infection occurred among blood donors who recorded not having received HBV immunization. This is in line with other studies performed in southern Brazil between 2009 and 2010 showed that the vaccination coverage of children and adolescents who were born after the hepatitis B vaccination was introduced was over 92% and that the HBsAg and anti-HBc prevalence were less than 1% and 10%, respectively (Tonial *et al*., 2011). Hepatitis B virus vaccination began in 1992 for children younger than five years of age and subsequently expanded to health professionals, students, firefighters, police and the military in 1994 and to adults under 20 years old in 2011; (Livramento *et a*l., 2011) Considering that the marked reduction in the prevalence of HBV infection markers among the general population is primarily a result of immunization against hepatitis B, vaccination may

have also contributed to the decreased prevalence of HBsAg and anti-HBc (Scaraveli *et al*., 2011).

5.1.4.2 Marital status

In terms of marital status, the majority of respondents were married however no corelarion existed with HBV_HIV co-infection, however in Anambra state in Nigeria (Ezegbudu *et al*., 2004) established 0.4% co-infection among married women which was not statistically significant, in this study divorced/widowed had the highest co-infection of 11.1% followed by the singles

The study finding revealed an association between marital status and HBV however no association with HBV-HIV co-infection (P value is more than 0.05). Co-infection was however seen in married and single study respondents. This is similar to study done Kisumu, Kenya which found age, marital status, level of education, religion and occupation not to be statistically significant with HBV/HIV co-infection with p>0.05

5.1.4.3 Education level

HIV-HBV co-infection distribution as by education level in this study revealed that respondents with secondary and tertiary education had prevalence of 0.9% (1/118) and 0.4% (1/260) respectively. A cross sectional study of prevalence and immune status of HIV/HBV co-infected pregnant women in two hospitals in Nigeria (Lar *et al.,* 2013) found occupation and educational level significantly associated with HBV -HIV positive pregnant women. In this study the highest HIV/HBV co-infection was reported among housewives and business ladies with at least secondary education, this finding is similar to the study results which agrees that education level is significantly associated to HIV-HBV co-infection where infection was reported in respondents with educational level of secondary and above. Study on Prevalence, Co-Infection and Associated Risk Factors of Hepatitis B Virus (HBV) and

Human Immunodeficiency Virus (HIV) in Benue State, Nigeria (2014) also revealed that the no significant relationship was observed between HBV- HIV co-infection and literacy in their study (P=0.186)..

5.1.4.4 Geographical area

The observed diverse prevalence rates of HBV/HIV co-infection vary according to the risk factors involved, socioeconomic status, initial burden of infectious markers in the community, which vary from one country to another and even between different regions within the same country, sample size, (Balogun, et al., 2012).

In this study geographical area or area of residence could probably be associated with HIV- HBV co-infection. Co-infection was seen in two counties Mombasa and Kwale with 1.2% (1/81) and 1.09% (1/92) respectively, there was no co-infection in the other counties. This can be attributed to the type lifestyle of the two counties which are more cosmopolitan with a lot of urban rural migration experienced in these counties. This study finding was that there was no significant association of geographical area and HBV-HIV co-infection.

5.1.4.5 Occupation

Distribution in relation to the occupations of the donors showed that the unemployed had the highest prevalence rates of both HBV and HIV with 12.5% and 6.3% respectively with100% Co-infection of those that were HIV infected; this was also seen among the casual laborers. This may be attributed to the group probably being idle and are involved in high risk behavior activities like illegal drug use including injectable illegal drug use, sex work, poor living condition, poor sanitation etc. thus exposing them more.

Hawkers and fishermen came second and third with 9.1% and 8.3% respectively for HBV this could also be attributed to the above reasons as

the unemployed. Mechanics had prevalence rate of HIV at 3.6% while there was a tie of 3.1% for casual laborers and security officers

5.1.5 Awareness of the respondents

Awareness of the donors about HBV revealed that 42% of the donors had not heard of it prior to donation during this study, 86.8% (211/243) heard through brochures, posters and other printed materials of which 72% (152/211) were repeat donors meaning they heard of HBV through Blood transfusion fliers and brochures. None of the donors had heard about HBV through Television or Radio. This was proof enough that this disease is not well understood in the public domain, most donors were not aware of existence of HBV vaccine (87.2%), mode of infection was understood to be similar to HIV but not through contact like sharing of toilets with infected persons was not well understood (58%)

5.1.6 Practice of the respondents

On donor's lifestyle and practice, the study finding was that repeat donors are safe blood donors as none of them tested positive for any of the markers hence WHO recommendation of having a pool of regular voluntary non-remunerated blood donors to ensure provision of safe blood (WHO, 2011). The donors, who answered yes to having used IDU, had high infection rate of HBV and HIV was observed at 3.8% and 2% respectively, with high HBV-HIV co-infection (100%).This could be attributed to the risk behavior associated with illegal use injectable drugs and also not knowing the transmission routes of HBV as they all answered no to not having heard of HBV.

5.2 Conclusions

1. The prevalence of HIV and HBV among blood donors in the Kenyan coastal region is 1.4% and 3.1% respectively.

2. The prevalence of HBV- HIV co-infection among blood donors in the Kenyan coastal region 0.48%.
3. The prevalence of HBV- HIV co-infection among HIV infected blood donors in the Kenyan coastal region 33.3%
4. Marital status and occupation are factors associated with HIV and HBV infection

5.3 Recommendations

This and similar studies brings to point an important aspect to consider when designing management of blood donors and HIV infected persons.

1. Standard HBV vaccination schedule is an important strategy for lowering the incidence of HBV infection among HIV-infected individuals. Also detecting and immunizing susceptible individuals.

2. Epidemiological studies would be instrumental to better understand the risk factors, mechanism of infection, and Hepatitis B and HIV co-infection This would also provide avenues for preventive efforts

3. Hepatitis B screening should be included as a baseline test among HIV infected individuals.

4. A targeted awareness and education on HBV prevention should be protracted to increase blood safety. The occurrence of these infections among the blood donors should still be monitored carefully to further reduce the rates to ensure safer and more reliable blood for transfusion

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APPEDICES

Commented [GK1]: Appendices should be listed sequentially as they appear in the text.

Appendix I: Consent Form for Study Participants

PREVALENCE AND FACTORS ASSOCIATED WITH HEPATITIS-HUMAN IMMUNODEFICIENCY VIRUS CO-INFECTION AMONG BLOOD DONORS IN KENYAN COASTAL REGION

Thank you for participating in this study, I'm student from Jomo Kenyatta University College of Agriculture and Technology (JKUAT), pursuing a Master's Degree in Public Health in Mombasa CBD Campus. This study seeks to study more on co-infection of HIV and Hepatitis. Some questions about yourself will be asked, please answer to the best of your ability and your blood sample tested and results will be used in this study. Whatever information you provide will be kept strictly confidential

Risks and discomforts

There are no known risks associated with this research. However strict measures will be put in place to ensure that the information you give will private and confidential.

Potential benefits

There are no known benefits to you that would result from your participation in this research. This research will help us understand the burden of these infections in our community.

Protection of confidentiality

We will do everything we can to protect your privacy. Your identity will not be revealed in any publication resulting from this study only codes assigned during the study shall be used

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study

If you have any questions or concerns about this study or if any problems arise, please contact me on 0722872146

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature_____

Date:_____

Appendix II: Participants Questionnaire

PREVALENCE AND FACTORS ASSOCIATED WITH HEPATITIS- HUMAN IMMUNODEFICIENCY VIRUS CO-INFECTION AMONG BLOOD DONORS IN KENYAN COASTAL REGION

Thank you for participating in this study; I'm student from Jomo Kenyatta University College of Agriculture and Technology (JKUAT), pursuing a Master's Degree in Public Health in Mombasa CBD Campus. This study seeks to study more on co-infection of HIV and Hepatitis. I will ask you some questions about yourself please answer to the best of your ability. Whatever information you provide will be kept strictly confidential.

SOCIO-DEMOGRAPHIC AND ECONOMIC INFORMATION

Name _____ Age_____ Sex Male ☐ Female ☐

Occupation_____

County of Residence_____ County of Birth_____

Please tick appropriately

Marital status	Single	Married	Divorced/Separated	Widowed

Level of education	None	Primary	Secondary	Tertiary

KNOWLEDGE

Have you had of hepatitis YES ☐ NO ☐

Where did you first learn of hepatitis?

Newspapers and magazine ☐

Radio ☐

TV ☐

Brochures, posters and other printed materials ☐

Health workers ☐

Family, friends, neighbors and colleagues ☐

Other (please explain)

_____

Please tick

Hepatitis may be transmitted by;	Strongly disagree (1)	Disagree (2)	Neither agree or disagree (3)	Agree (4)	Strongly Agree (5)
Unscreened blood for transfusion					
Sharing plate with infected person					
Hugging infected person					
Unsafe sexual intercourse					
Piercing of ears or tattooing					
Sharing toilet with infected persons					
Sneezing and coughing					
Has vaccine for hepatitis					

available					

PRACTISE

	YES(5)	NO (0)
Are you a regular Blood donor		
Have you been vaccinated for Hepatitis		
Have you ever used contraindicated injected drug (IDU)		
Do you ask your barber to change the blade before shaving		
Do you practice safe sex		

Participants Signature_____

Date_____

Appendix III: KNBTS Approval

Appendix IV: Ethical Approval

APPENDIX 1 PUBLICATION