PREVALENCE AND RISK FACTORS OF PREVIOUS OR ACTIVE HEPATITIS B INFECTION AMONG HIV-1 DISCORDANT HETEROSEXUAL COUPLES

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Declaration

This dissertation is my original work and has not been presented for a degree or other awards in any other University

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Dedication

This book is dedicated to all the brave people living with HIV and AIDS and their partners, especially those who are HIV negative.

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List of Abbreviations

ARVs	Antiretroviral
CCC	Couple Counseling Center
HAART	Highly Active Anti Retroviral Therapy
HBV	Hepatitis B Virus
HBsAg	Hepatitis B surface Antigen
HBsAg	Hepatitis B surface Antibody
HCC	Hepatocellular Carcinoma
HIV-1	Human Immune deficiency Virus
KAIS	Kenya AIDS Indicator Survey.
KNH	Kenyatta National Hospital
NASCOP	National AIDS and STI Control Program
PrEP	Pre-Exposure Prophylaxis
STIs	Sexually Transmitted Infections
WHO	World Health Organization
TB	Tuberculosis
VCT	Voluntary Counseling and Testing Centers

Operational Definitions in the Study

Co-Infection: In this study, co-infection defines HIV-1 infection and presence of a HBV marker in a single participant.

Discordant couples: A pair of heterosexual sexual partners in which one has a sexually transmitted infection and the other does not. In this study a couple was defined as per the parent study i.e. That they should have been sexually active for at least 3 months with at least 6 sexual acts.

HBsAg: Presence of active Hepatitis Infection evidenced by Hepatitis B surface antigen

HBsAb: Indication of previous Hepatitis B infection evidenced by presence of Hepatitis B antibody

Index participants: HIV-1 positive partner diagnosed by two HIV-1 rapid tests and confirmed by double well ELISA test

Partner participants: HIV-1 negative partner with negative HIV-1 rapid tests

Active HBV Prevalence: Detection of HBsAg

Prevalence of Previous HBV: Detection of HBsAb with negative HBsAg.

Abstract

Background Hepatitis B Virus (HBV) and HIV are two diseases which spread in the same manner, but HBV is more infectious than HIV-1 during the infectious period. Active HBV requires modification of HIV-1 therapy and is associated with increased risk for transmission of HBV. We aimed to determine the prevalence of HBV and knowledge of HBV among HIV-1 discordant couples with no history of HBV vaccination.

Methods We conducted a cross-sectional study within the University of Washington Partners Pre-Exposure Prophylaxis (PrEP) study in Nairobi and Thika. 81 discordant couples per site in Nairobi and Thika were enrolled by use of structured questionnaires to determine the prevalence, knowledge and awareness of HBV infection in discordant HIV-1 couples. Previous HBV status was determined by HBsAb positive test and active HBV status was determined by HBsAg test positive.

Results A total of 161 couples (322 participants) were enrolled; couples in which the HIV infected partner was female (index partner) accounted for 37% while couples in which the index partner was male was 13%. Overall, 31% participants had at least one positive serologic marker for HBV. The prevalence for active HBV (HBsAg) was 1%, with previous HBV prevalence (HBsAb) at 30%. The mean age was 33 years (SD 8.4).

Prevalence: HBV prevalence was higher among HIV positive women compared to HIV negative women (10.2% vs. 5.9% p=0.05, OR 0.5, CI 0.2-1.0). However, among the men, there was a higher prevalence of HBV among the HIV negative than the HIV positive participants (8.4 vs. 6.2% p=0.04, OR 3.0, CI 1.3-6.5). Among the HIV negative participants, there was a higher prevalence of HBV among the men (16.8%) than the women (11.8%) (p<0.01, OR 2.6, CI 1.2-5.9), while among the HIV positive participants there was a higher prevalence of HBV among the women (20.5%) than the men (12.4%) (p=0.03, OR 0.4, CI 0.2-9.8). We found increasing prevalence of HBV with increasing age (p=0.001, OR 1.6, CI 1.2-2.1). HBV and HIV infection were not associated (p=0.4). Overall, 61(38%) couples were discordant for HBV, 81(50%) couples were concordant negative for HBV and 19 (12%) couples were concordant positive for HBV

Knowledge of HBV: A total of 62.11% had heard of HBV with 8% of them having adequate knowledge of HBV. HIV positive participants with adequate knowledge were 13% of compared to 3.7% of HIV negative participants (p=0.05 OR 2.7, CI 0.95-7.9).Those who had one positive serological marker for HBV were not more likely to have adequate knowledge of HBV than those without a marker.

Conclusions and recommendations: A discordant couple with a HIV positive woman had a significantly higher HBV prevalence rate than a discordant couple with a HIV negative woman. HBV knowledge is inadequate among the HIV negative participants; this is a target group for health education regarding risk factors of HBV infection and HBV vaccination to prevent HBV infection.

CHAPTER 1 : INTRODUCTION

1.1 Background information

The WHO estimates that about 2 billion people worldwide have been infected with the HBV and about 400 million live with chronic infection, of which an estimated 1 million persons die each year due to the acute or chronic consequences of Hepatitis B (WHO, 2008). Twenty five percent of adults who become chronically infected during childhood later die from liver cancer or cirrhosis (scarring of the liver) caused by the chronic infection (WHO, August 2008). The Hepatitis B virus is 50 to 100 times more infectious than HIV-1. There are currently 39.5 million people infected with HIV-1, with over 4 million people newly infected and 3 million HIV-1 related deaths in 2006 (AIDS, UNAIDS/WHO, 2006)

People living with HIV-1 and AIDS commonly have other infections. This is as a result of the shared transmission mode of these infections with HIV-1 for diseases such as HBV. Additionally, individuals who are immunosuppressed due to HIV-1 are more susceptible to acquiring other infections. These co-infections not only complicate management of patients with HIV-1 but may also contribute to increased HIV-1 transmission rates (WHO HIV-1 antiretroviral newsletter, 2007). Liver disease due to chronic HBV infection is becoming a leading cause of death among persons with HIV-1 infection worldwide (Weber R, 2006).

It is well known that HIV-1 patients who are co-infected with other infections have higher morbidity and mortality. HBV co-infection requires modification of antiretroviral regimens and may contribute morbidity to HIV-1 infected individuals.

HIV-1 sero-negative partners in a discordant HIV-1 partnership are at high risk of HIV-1 and HBV acquisition. Most HIV-1 analysis is done at an individual level. However, the latest Kenya AIDS Indicator Survey 2008 analyzed couples who were engaged in a sexual relationship and were either married or co-habiting. It was found that at least two thirds of all HIV-1 infected couples were discordant couples whereby one partner was HIV-1 infected and the other partner was negative with the female partner being the infected partner in 30-40% of the cases (KAIS, 2007). This of great public health significance as it gives those

involved in HIV-1 programs a chance for targeted preventive measures to reduce the chances of HIV-1 and HBV acquisition, particularly with vaccination to prevent HBV.

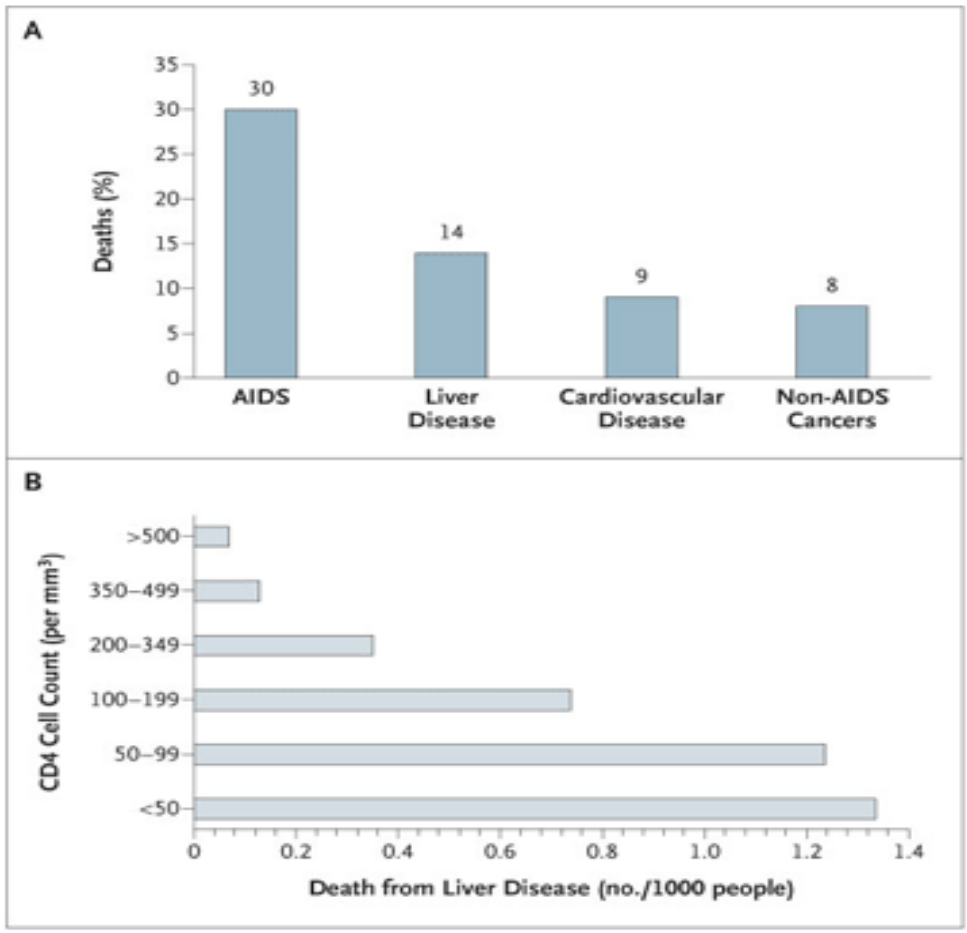
The convergence of HIV-1 and HBV co-infection was first discovered during the 1980s. The two diseases are spread in the same manner, which comprises of sexual contact, mother-to-child transmission during delivery, blood transfusion and needle pricks. Hepatitis is a general term meaning inflammation of the liver and can be caused by many different viruses such as Hepatitis A, B, C, D and E. Of all these viruses causing Hepatitis, few are of greater global importance than Hepatitis B virus, due to the severe and chronic effects on the liver.

Subsequent sections of this book particularly, Chapter one and two will describe the epidemiology of HBV while exhaustively reviewing previous literature. Chapter three will outline the objectives of the study and its methodology, with the results being depicted in Chapter four. An in-depth discussion of the results of this study and other similar studies will be undertaken in Chapter five.

1.2 Epidemiology

Co-infection with HIV-1 and HBV is common due to their shared transmission pathways. (Margaret James Koziel M. G., 2007) Liver disease due to chronic HBV infection is becoming a leading worldwide cause of death among persons with HIV-1 infection. (Weber R, 2006).

Similarly, an increase in the incidence of liver cancer and ARV-related hepatotoxicity in patients with HIV-1 and HBV co-infection is well documented. Figure 1.1 shows the results of a study done in a cohort of HIV-1 positive patients on HAART, showing that liver disease is becoming a leading cause of death among HIV-1 infected people worldwide. A lower CD4 cell count also predisposes the HIV-1 infected patients to more mortality and morbidity from the effects of chronic liver disease. (Margaret James Koziel M. a., 2007)



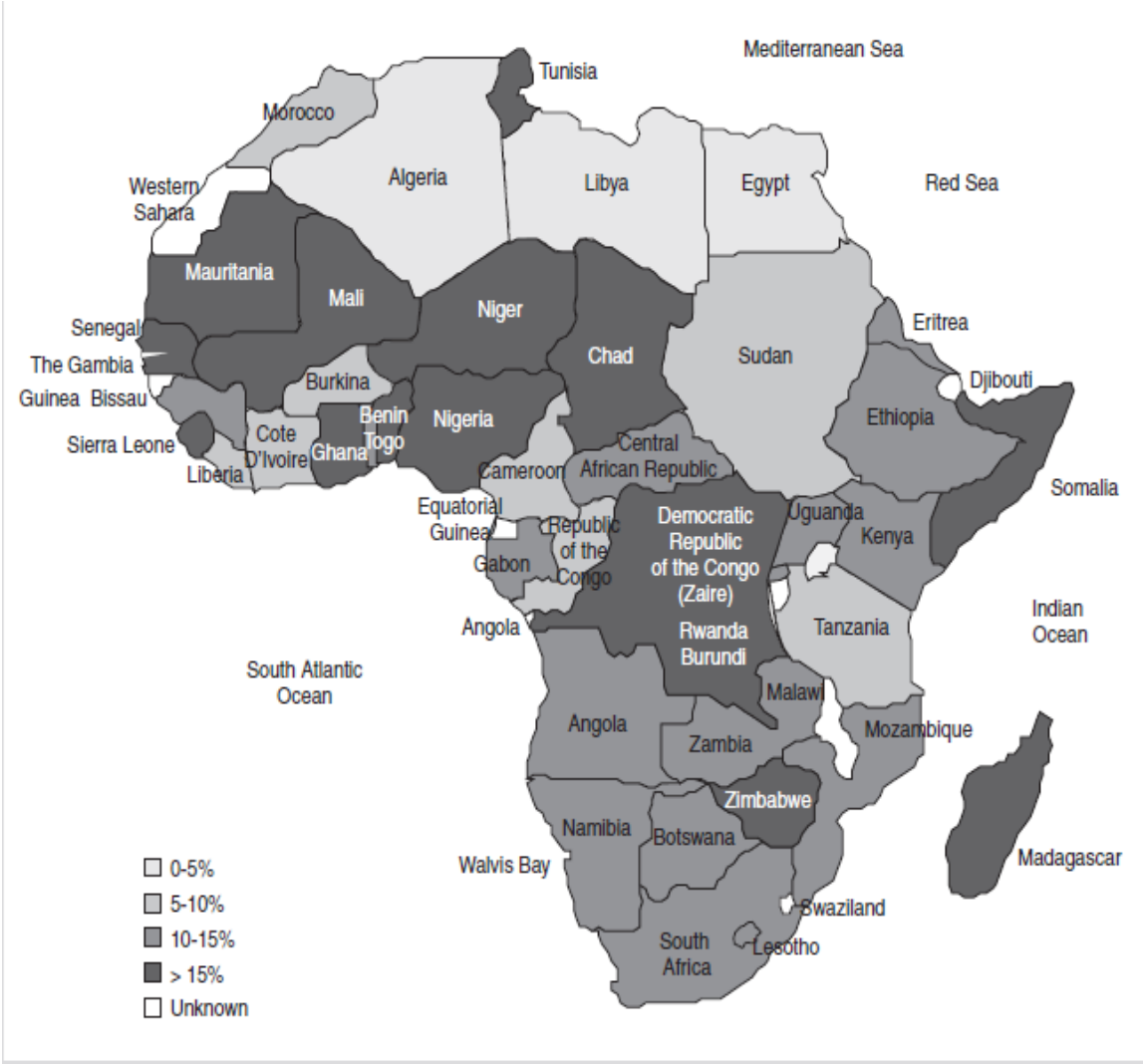
(Peters, 2007)

Figure 1.1: Deaths in a cohort of 23,441 patients treated with anti-HIV-1 drugs.

1.2.1 Prevalence of Hepatitis B

Worldwide HBV prevalence ranges from 0.1% to 20%. This wide range is largely due to differences in age at the time of infection. Following acute HBV infection, the risk of developing chronic infection varies inversely with age: 90% for perinatal infection, 25–50% for infection at age 1–5 years and 1–5% for all others (WHO, Hepatitis B. Geneva, 2002).

Africa carries the major burden of HIV infection and, along with Asia, is the largest reservoir of chronic HBV. HBV is the most common cause of chronic liver disease worldwide with 400 million chronic carriers, of whom 50 million are estimated to reside in sub-Saharan Africa (Lok A, 2001). Figure 1.2 indicates the infection levels of HBV in Africa. Kenya has an active HBV prevalence of 10-15%, sharing the prevalence with countries such as Uganda, Ethiopia, Mozambique and Malawi among others (Feld J O. P., 2005).



(Nancy J. Nordenson, 2011)
Figure 1.2: Active HBV prevalence in Africa.

1.2.2 Prevalence of HBV infection among HIV-1-infected people

HBV and HIV-1 have common routes of transmission and endemic areas, but HBV is about 100 times more infectious. Consequently, more than 70% of HIV-1-infected people have a blood marker of past or present HBV infection. (WHO, Hepatitis B. Geneva, 2002)

A study done in Nigeria showed a prevalence rate of 20.6% of active HBV/HIV-1 co-infection (Mem Inst Oswaldo Cruz, 2007). In Kenya a study done at the Aga Khan

University Hospital showed a prevalence of 6% of active HBV co-infection in HIV-1 infected individuals (Harania, 2008). With Hepatitis B being 100 times more infectious than HIV-1, preventive measures will assist in reducing the long-term liver complications seen in chronic Hepatitis B infection among HIV-1/HBV discordant couples.

Because of the serious impact of liver disease in co-infection of HIV-1 and HBV, developed countries routinely test for viral Hepatitis in HIV-1 positive patients. However, this is not commonly done in Kenya. In most cases, ARVs are started without testing for HBV, yet finding the HBV-HIV-1 co-infection early will give the patient better treatment options. Starting a HIV-1/HBV co-infected patient on ARV treatment alone later results in liver toxicity due to use of inappropriate medication. This becomes a double tragedy because HIV disease also results in liver disease.

1.3 Why discordant couples?

Interestingly, as noted earlier, in a Kenya AIDS Indicator Survey performed in 2008, the largest populations at high risk for HIV-1 acquisition are HIV-1 negative partners in discordant relationships. It was estimated that 84% of all the people surveyed did not know their HIV-1 status, and of those who did not know their status, 60% did not know their partner's status. Seventy-seven percent of respondents with a stable partner did not know their own or partners HIV-1 status. Similarly, of those who knew their HIV-1 positive status, 36% had no idea on their partner's status. It is therefore likely that very few discordant couples are using condoms. This is summarized in figure 1.3.

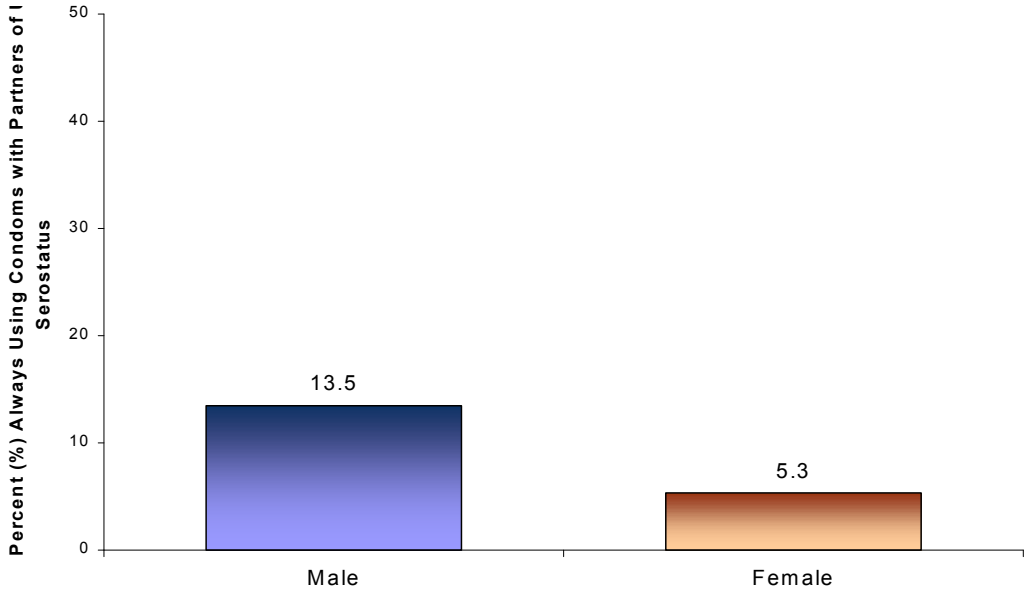


Figure 1.3: Percentage of people always using a condom with partners of unknown sero-status. (KAIS, 2007)

In summary, most Kenyans who are HIV-1 positive do not know their status, neither do they know their partner's HIV-1 status, and the use of condoms for protection against HIV-1 transmission is very low (KAIS, 2007). In addition, 6% -10% of all married couples are in a discordant relationship and nearly 50% of all HIV-1 positive men and women have a partner who is HIV-1 negative. This translates to nearly 400,000 discordant couples in Kenya. Hepatitis B infection was not investigated in this survey, but given that the same mode of transmission applies for the two diseases, HBV may pose a health threat to both the HIV-1 infected and uninfected partner in the future.

CHAPTER 2 : LITERATURE REVIEW

2.1 HBV and HIV-1 co-infection

HBV infection and HIV-1 are devastating disease agents that share common modes of transmission, therefore, HIV-1 infected individuals are at risk of HBV infection (Santiago Munoz et al, 2006). For HIV-1 negative partners of HIV-1 positive partners, transmission of HBV could occur without HIV-1 transmission given that the HBV is 100 times more infectious than HIV-1, mainly because of the high HBV viral load in the bodily fluids, which include saliva, sweat and blood (Kukka, 2004).

HIV-1 infected individuals have a 3-6 times chance of developing chronic Hepatitis B due to their lowered immunity, than those who are not HIV-1 infected, and consequently are 14 to 17 times higher risk of mother to child transmission of HBV during pregnancy and delivery as well as during sexual contact with an infected partner.

The world's predominant mode of HBV transmission is perinatal. If a pregnant woman is a HBV carrier, her newborn baby has a 90% likelihood of being infected and becoming an HBV carrier. Of these children, 25% will die later from chronic liver disease or liver cancer (WHO, Hepatitis B. Geneva, 2002). Studies have shown that females are more likely to have both markers for HBV as well as HIV. The reasons for this are outlined below.

Physiological reasons

- The viral load in semen is higher than in vaginal mucus.
- The vaginal membrane is thinner than penile tissue
- Semen remains longer in the vagina.
- Young women are more prone to micro lesions.

Socio-economic reasons

- Women accept pain and discomfort.
- Social pressure to bear children.
- Vulnerability of younger women/adolescents.

- Women lack knowledge in sexual issues and are unable to express their opinions on such.
- Inability to negotiate for safe sex.

(Dr.Mamy, 2009)

Notably, research shows that in unprotected sexual intercourse, women's risk of HIV infection is 2 to 4 times that of men**.** Women are also more vulnerable to other STIs thus multiplying the risk of contracting HIV tenfold (Gray GE, 2004) (UNAIDS, 1997)**.**

After an acute HBV infection acquired in adulthood, 90–95% of adults develop an immune response that eliminates the virus. This results in the development of protective antibodies for Hepatitis B surface antigen (HBsAg). Fortunately, less than 1% of these adults develop an acute Hepatitis infection and the remaining 5–10% become chronically infected (WHO, 2007). Co-infection with HBV increases the risk for hepatotoxicity of HAART and likelihood of onset of an AIDS-defining illness, compared with infection with HIV-1 alone (Feld J O. P., 2005).

There is higher risk of fulminant liver infection in those with HBV/HIV-1 co-infection than those with HIV-1 or HBV alone (Weber R, 2006). This is mainly because of the following reasons:

- Complications of HBV- after an average of 30 years, 30% of those with chronic Hepatitis end up developing liver cirrhosis, and without treatment 5-15% die within 5 years. Up to 80% of liver cancers in the world are due to HBV (WHO, Hepatitis B. Geneva, 2002).
- Reciprocal Impact of HIV-1 and HBV may be analyzed by determining the impact of HIV-1 on HBV progression and the impact of HBV on HIV-1 progression as shown below.

2.2 Impact of HIV-1 on HBV progression

1. HBV infection is more severe in the HIV-1 infected patient.
2. In HBV/HIV-1 patients with liver cirrhosis, progression to HCC appears much faster and earlier than those with mono infection with HBV. The HCC also develops multi focal lesions more than those with mono infection (Pouti M et al, 2004).
3. HIV-1 is a risk factor for reactivation of the HBV in patients who have already developed antibodies (Whereby 70% cases of HIV-1 patients have HBsAb) especially in severe

immunocompromised patients (Levine OS et al, 1995). HIV-1 positive individuals with present HBsAb and negative HBsAg can have a reactivation of Hepatitis with reduced CD4 cell count (Feld J O. P., 2005).

4. Patients co-infected with both HIV-1 and HBV have more liver related mortality especially after starting HAART.

2.3 Impact of HBV on HIV-1 Disease Progression

1. Most studies done to determine any influence of HBV on HIV-1 progression have not shown any role in HIV-1 progression (Konopnicki D et al. , 2005).
2. There is an increased risk of liver disease during treatment or interruption of HAART in HIV-1/HBV co–infection.

Tests were performed on 378 HIV-1-positive individuals in Kenya's Aga Khan Hospital. A total of 23 (6%) were found to be co- infected with active Hepatitis B, four patients (1%) were co infected with Hepatitis C, and one patient was infected with HIV-1 and both Hepatitis B and Hepatitis C. Older age was significantly associated with co-infection ($p < 0.05$). Unsurprisingly, a lack of Hepatitis B vaccination was also a risk factor for HBV infection ($p = 0.0001$). Neither drug use nor sexual behavior appeared to be risk factors for either Hepatitis infections (Nelson, 2008). In comparison with other countries, Africans were more likely to have the HBV than Europeans or Latin Americans. However, mode of spread in Africans and especially Kenyans seem to be more on sexual behavior rather than intravenous drug use and sharing of needles.

In another study (Ferez et al, 1992) whose main objective was to determine the prevalence of Hepatitis B infection in discordant couples for HIV-1 and analyze the distinct rates of transmission as well as the role of previous Hepatitis B infection on HIV-1 transmission, data from 136 couples showed eighty eight (65%) of the couples showed at least one partner with evidence of Hepatitis B infection. Eighty one (60%) HIV-1 positive and twenty eight (21%) HIV-1 negative partners showed evidence of infection. Sixty-seven couples showed discordant Hepatitis B serology with 60 HIV-1 positive partners and 7 HIV-1 negative partners showing infection. Twenty-one couples (15%) showed concordant evidence of Hepatitis B infection. No couples showed HIV-1 sero-conversions during follow up while

two of 17 couples (12%) developed concordant Hepatitis serology at one year of follow up. The study concluded that recent trends in both HIV-1 and Hepatitis B infection suggest that heterosexual transmission is an increasingly important risk factor. Little data is available on differential risk of transmission of both viruses heterosexually. These preliminary prevalence data would suggest a comparative increased risk of Hepatitis B transmission in HIV-1 discordant couples.

A different study (Poblete R, 1992) was undertaken to assess the prevalence of Hepatitis B infection in discordant couples for HIV-1 in comparison with a cohort of concordant couples, whereby follow up of Hepatitis B serology in the discordant cohort group was done. The couples recruited for a prospective HIV-1 transmission study were tested for HBsAg, and HBsAb. The negative partners had other risk factors for HIV-1 excluded by an entry questionnaire and drug testing. The concordant couples were tested similarly and HIV-1 transmission was assessed to be by heterosexual contact with the present partner. Data are available on 197 HIV-1 discordant and 16 HIV-1 concordant couples. 132 (67%) discordant couples showed at least one partner with Hepatitis infection. 28 (14.2%) couples both showed Hepatitis B while 65 (33%) were negative. Among the concordant couples 11 (68.7%) showed one partner with Hepatitis B. 4 (25%) couples both showed Hepatitis while 5 (31%) were negative. Follow up studies on HIV-1 discordant couples showed 9 of 38 (24%), initially discordant Hepatitis couples, with evidence of infection. There was no evidence of HIV-1 transmission. The study concluded that there was no difference in Hepatitis B in the two cohorts ($p > 0.1$). Hepatitis B was transmitted in the discordant couples with no evidence of HIV-1 transmission. Correlation with sexual behavior may indicate reasons for differential transmission of Hepatitis B.

The risk of chronic Hepatitis B is greater in cases of HBV/HIV-1 co infection and congenital or acquired immune suppression. HBV-related liver diseases (including cirrhosis and its complications) are more progressive in cases of HIV-1 co-infection than in mono-infection.
On knowledge of HBV, a study in China found that of the 250 participants who completed the survey, 34% did not know that chronic HBV infection is often asymptomatic and 29% did not know the complications of chronic HBV infection. Furthermore, 34% failed to

recognize all the modes of HBV transmission and 30% did not know the importance of the Hepatitis B vaccine in preventing liver disease (Chao, 2010).

2.4 Public Health Significance HBV/HIV Co-Infection

2.4.1 HBV related morbidity and mortality

HBV infection is a major global public health problem. Of the approximately 2 billion people who have been infected worldwide, about 350 million are chronic carriers of HBV (WHO , 2008) . Approximately 15–40% of infected patients will develop cirrhosis, liver failure, or hepatocellular carcinoma (HCC). HBV infection accounts for 500 000 to 1.2 million deaths each year (Mahoney FJ, 1999), and is the 10th leading cause of death worldwide. Hepatocellular carcinoma incidence has increased worldwide, and the disease is now the 5th most frequent cancer, killing 300 000– 500 000 people each year (Parkin DM, 2000). Infection with HIV and HBV compounds the burden of disease as it increases morbidity and mortality.

Once established, cirrhosis cannot be cured; however, its progress may be stopped if the HBV infection which is the trigger factor in this case is removed. Without treatment, the typical progression is from compensated cirrhosis to decompensated cirrhosis. The latter is characterized by cessation of enzymatic processes in the liver and subsequent severe clinical complications such as fluid retention in the abdomen, jaundice, internal bleeding, and hepatic encephalopathy. Patients with decompensated cirrhosis are candidates for liver transplantation, without which death results from end-stage liver disease (Lavanchy, D., 2004). Cirrhosis, liver failure, or HCC will develop in approximately 15–40% of individuals with HBV (Lok A, 2001).

2.4.2 The economic burden of HBV

Little data is available on cost analysis of complications of HBV in developing countries where most of the burden of disease lies. However, the economic burden is high due to the direct cost of medication and treatment of hepatocellular carcinoma and end stage liver disease. The indirect cost of lost productivity and lost work days escalates with increasing severity of disease (Lavanchy D. , 2004)

In Korea where cost analysis has been performed for the economic burden of HBV, of the direct and indirect disease-related costs, 45.3% were related to cirrhosis. The direct costs (prevention- and disease related) of HBV disease, amounting to $696.2 million, were equivalent to 3.2% of the South Korean national health care expenditure for 1997. Of the total annual cost for HBV 13.2% of this sum was attributable to prevention costs (vaccine), 20.9% to indirect costs of HBV-related diseases, and the remaining 65.9% went to direct disease-related medical costs (Yang BM, Paik SW, Hahn OS et al, 2004)

2.4.3 The role of prevention of HBV among HIV infected people

Hepatitis B viral infection is a preventable disease by way of a safe and effective vaccine which is 95% effective in preventing the development of chronic infection. The vaccine has been available for more than 20 years, though in Kenya it was integrated in the Kenya National Expanded Programme of Immunization (KEPI) for infants in November 2001. The delay in integration of the vaccine into KEPI was mainly due to the very high cost of HBV vaccine, poor cold chain systems, reluctance due to questions of vaccine safety and the lack of urgency by the government probably because HBV was not considered a priority disease: a situation shared by many developing countries (Muraskin, 2003).
A health policy recommended that all health care workers be immunized against HBV as they are considered high risk for the acquisition of the disease. However, HIV infected people have not yet been accorded that privilege. HBV prevention by vaccination would be the most effective way of reducing the burden of disease of HBV on HIV infected people.

Most Antiretroviral therapy programs in Kenya are none recommended treatment for HBV-hence increasing susceptibility for the development of resistance to HBV for the HIV/HBV co-infected person (Adrian M Di Bisceglie, 2010). The consequence will be a group of HIV positive people with no treatment for their HBV infection. This is of great public health significance as the systems necessary to carry out testing and provide information on HBV are well developed within the national HIV programs country wide.

2.5 Statement of Research Question

2.5.1 Research Problem

HIV-1 positive patients are prone to co-infections with various illnesses, which mostly result in higher morbidity and mortality. Co-infection with HBV in particular may result in liver failure especially when Highly Active Anti-Retroviral Therapy (HAART) is administered due to liver toxicity. While initiation of HAART should result in improved health status of HIV-1 positive patients, in the case of co-infection of HIV with HBV, the drug regimen should be inclusive of a drug, which has antiviral activity against both HIV-1 and HBV.

The prevalence of HBV infection in Kenya among HIV-1 discordant couples has not been well researched and neither has the relationship between socio demographic factors and possible HBV infection, as well as the difference in prevalence between HIV positive and negative people. A number of constraints may have contributed to this gap in information, such as:

1. A lack of awareness on the major public health significance of HBV.
2. A lack of awareness on the potential impact of adequate preventive services – especially vaccination against HBV which may not only prevent hepatocellular carcinoma, but also have an impact on the prevalence of other diseases such as HIV, their mortality and morbidity.
3. Competing priorities in the public health sector with other HIV co-infectious diseases such as TB.
4. Insufficient technical knowledge of integration of preventive measures of HBV with other infectious diseases

In developed countries, testing for HBV co-infection in HIV-1 is well integrated into the health protocol and policies. This is not the case in most developing countries, Kenya included.

Hepatitis kits are readily available in blood donation centers whereby Hepatitis is screened as routine tests. This service has not extended to other HIV-1 testing centers such as the VCTs. This study sought to find out how the prevalence of HBV is associated with factors such as HIV status, socio demographic factors, gender and sexual and risk behavior and knowledge

of HBV infection among HIV-1 discordant couples. Discordant couples are considered a high risk population and particularly the HIV negative partner in the relationship mainly because transmission occurs in a discordant couple relationship.

The research question is therefore;

"WHAT IS THE PREVALENCE AND RISK FACTORS OF ACTIVE OR PREVIOUS HEPATITIS B INFECTION AMONG HIV-1 DISCORDANT COUPLES?"

2.5.2 Justification

This study will have a major impact in the management of HIV-1/HBV co-infected patients from the point of the primary provider. This is because both HIV-1 and HBV tests may be done concurrently by rapid tests hence affecting the course of treatment in a patient with co-infection.

In addition, knowledge of Hepatitis status to an individual whether HIV-1 positive or negative is beneficial as carriers and active infections can be detected much earlier hence reduces the devastating sequel of Hepatitis disease.

A vaccine against HBV has been available since 1982. Hepatitis B vaccine is 95% effective in preventing HBV infection and its chronic consequences, and is the first vaccine against a major human cancer, the Hepatocellular Carcinoma. Since 1982, over one billion doses of Hepatitis B vaccine have been used worldwide. In many countries where 8% to 15% of children used to become chronically infected with HBV, vaccination has reduced the rate of chronic infection to less than 1% among immunized children (WHO , 2008).

Kenya introduced a pentavalent vaccine including the DTP (Diphtheria Tetanus Pertussis), Haemophilus influenzae type b and Hepatitis B virus antigens in Nov 2001. It is commendable that HBV vaccination has been included in the Kenyan Expanded Immunization Program for infants, but this is not enough. Most adults currently acquiring Hepatitis were never vaccinated against HBV, and with the increase in HIV-1 infection a preventive measure in way of vaccination may very well be the best protection against chronic consequences of HBV.

This study will therefore provide much-needed data, which will be useful in changing health policy in Kenya, and encourage HIV-1 with concurrent HBV testing. In addition, health care workers in the field of HIV-1/HBV co-infection will use the information obtained from this study to help in the provision of better medical care in terms of prevention and treatment of those with co-infection, or those at higher risk of co-infection.

The Couple Counseling Center in KNH Nairobi and Thika clinics for follow-up of discordant HIV-1 couples have been suitably chosen as they contain a cohort of HIV-1 discordant couples who visit the site monthly and represent Nairobi and its metropolitan surroundings.

It is therefore important to determine the prevalence of HIV-1/HBV co- infection in the Kenyan setting as well as the patterns of risk behavior among them. Discordant couples have been chosen as the study population as the HIV-1 negative partner is at risk of HIV-1 and HBV acquisition and are therefore in dire need for preventive measures such as vaccination against HBV and consistent use of the condom.

The HIV-1 positive partner also needs to be tested for HBV as a routine initial test to provide the adequate care and reduce mortality and morbidity related to liver disease, which is radically increased in the case of HIV-1/HBV co-morbidity.

2.6 Objectives

2.6.1 Broad Objective

The study primarily aims to determine the prevalence of HBV and association between HBV infection and selection of possible predictors among HIV-1 discordant couples.

2.6.2 Specific Objectives

1. Determine the socio-demographic characteristics of discordant couples
2. Determine the prevalence of HBV among discordant couples
3. Determine the association between HBV and HIV-1 status
4. Determine the association between HBV and socio-demographic characteristics

5. Determine the knowledge of HBV by HIV-1 discordant couples

6. Determine the association between HBV and selected predictors- Knowledge of HBV, sexual and risk behavior.

CHAPTER 3 : RESEARCH METHODOLOGY

3.1 Study Area

The study took place in two health clinics namely: the Couple Counseling Center in KNH-Nairobi and Thika clinics where HIV-1 discordant couples are followed up. Participants from all over Nairobi and Thika environs visit the clinic on a quarterly basis for the index participant and monthly for the partner participant.

3.2 Design of the Study

The study is a cross-sectional study to estimate the prevalence and possible risk factors of HBV in HIV-1 discordant couples attending the Nairobi and Thika clinics.

3.3 Variables

The study included active or previous HBV status as the outcome variable and HIV-1 status, knowledge of HBV infection, socio-demographic factors, gender, sexual behavior and risk factors as potential predictors of HBV status.

3.4 Study Population

The study population consisted of HIV-1 discordant couples where one partner was HIV-1 positive by two rapid tests and confirmed by double well Elisa test, and a negative HIV-1 partner whose two rapid tests are negative.

3.4.1 Inclusion criteria

The inclusion criteria into the study were guided by the parent clinical trial study. They included:

- Age above 18 years and below 65 years.
- In a heterosexual HIV-1 discordant relationship.
- Give written informed consent for procedures, which included blood draws for testing and HIV-1 testing during initial screening to the parent study.
- CD4 cell count of more than 250 cells/ul.

3.4.2 Exclusion criteria

The exclusion criteria for the study were:

- Age less than 18 years or above 65 years.
- Unable to give written consent because of mental status.
- Not in a heterosexual HIV-1 discordant relationship.

3.5 Sampling Technique

The study was nested within the PrEP study which consisted of discordant couples who were enrolled in a Phase III clinical trial, aimed at determining if administration of ARVs to the negative partner will prevent HIV-1 acquisition – better known as Pre-exposure prophylaxis (PrEP). HBV and HIV tests were done by the parent study at screening prior to enrollment into the parent study. Participants found to have HBsAb were classified as being immune to Hepatitis B, those with HBsAg were classified under Hepatitis B infected while those without a serological marker for HBV were classified under HBV susceptible. Participants found to be HBV susceptible were immunized by the PrEP study.

Participants for this study were picked as they came for the clinic appointments. They were introduced to the study by the research assistant and the consent forms given to those who were willing to participate in the study.

The Sampling took place between 30/08/2010 and 15/10/2010. A table showing participant number and date of sampling may be found in Appendix H.

3.6 Sample Size Determination

The error of estimation in the study had been set at 0.05 with the prevalence of HBV among HIV-1 patients at 70% as per the prevalence of the presence of HBsAb (WHO, Hepatitis B. Geneva, 2002)

$$n = \frac{(Z\alpha_{1/2})^2 (p\,(1-p))}{E^2}$$

Where $Z\alpha_{1/2}$ is the relative coefficient 1.96

p is 0.7

E is the error of estimation, 0.05. – Level of significance

Therefore $n = \frac{(1.96)^2\,(0.70)\,(0.30)}{}$

0.05^2

n= 322 participants.

The estimated sample was therefore 322 participants- 161 index (HIV-1 positive participants) and 161 partner participants (HIV-1 negative)

3.7 Data Collection Techniques

This was achieved by

- Review of laboratory results obtained from the PrEP study file determining presence or absence of HBsAb and HBsAg which is determined by an ELISA (Enzyme Linked Immune Assay) based test for the detection of HBsAg in human plasma or serum. The test is known as the Murex HBsAg Version 3.
- Use of questionnaires that were interviewer administered to the participants to determine knowledge and awareness of HBV infection in discordant HIV-1 couples. A Qualified and experienced research assistant and the principle researcher administered these questionnaires.

The study employed principally primary data. Data collection method was primarily use of questionnaires as well as data from the clinic records to identify discordant couples and Hepatitis B status. The type of data that was acquired from this study was quantitative data for the determination of prevalence rates of HBV, risk factors and knowledge of HBV infection in participants. Knowledge of Hepatitis B encompasses the following;

- Infection transmission,
- Type of infection,
- Prevention,
- Organs primarily affected,
- Complications of HBV.

Risk factors predisposing the participants to possible infection include;

- Sharing of needles
- History of blood transfusion

- Sexual behavior by sexual contacts per month, sexual partners since knowledge of discordance and use of condoms.

3.8 Minimization of Data Errors

Minimization of data errors was by reviewing the questionnaires and daily cleaning of data. All data was copied in compact discs to ensure against any loss of data. Correct data entry was ensured by use of unique identifiers in this case being the participant enrollment number, hence minimizing duplication and omission of data.

Pretest of instruments prior to the actual study took place in a clinic similar to the Nairobi and Thika clinics. The clinic is situated in KNH Couple Counseling Center where discordant HIV-1 participants are regularly followed up. The aim of pretesting was to determine if the questions in the questionnaire are answerable. This provided a good opportunity to familiarize with the likely environment. Training of one research assistant on correctly filling the questionnaires was conducted before commencement of the study.

Data cleaning and quality assurance was in three different levels. The first level involved the interview session with the discordant partners, the second level during data entry and the third level after all the data had been entered into the computer program. This involved the following processes,

- Consistency checks of all entries
- Duplicate entries in the questionnaires
- Range checks
- Missing data checks

3.9 Data Analysis

A do file in STATA was created and specific software installed to enable the above processes to be carried out. Consistency checks were done by running the "data check" command at all levels of data entry. Similarly this eradicated duplicate entries which was reinforced by presence of unique identifiers for each participant and their related data.

Missing data checks was done by running "missing" for the data set to determine if there were any missing entries. If any missing entries were found the hard copy of the questionnaire was re-examined and the entry re-entered.

Data were entered manually onto the Windows XP Access data base computer program directly from the questionnaire and once all 322 entries were complete the data was transferred using STATA transfer computer program onto the STATA version 11.1 data analysis program.

Presentation of data findings was by use of tables, pie charts and frequency histograms. Analysis was by chi square analysis to determine the association between HIV infection, socio-demographic factors and risk factors with HBV prevalence. For statistically significant associations, logistic regression by determination of odds ratio was performed. The Mantel-Haenszel (MH) adjusted odds ratio was calculated on stratified data to control for confounders and for the determination of the strength of association of HBV prevalence by HIV status and gender.

3.10 Ethical Considerations

Ethical clearance was sought from the Ethical Research Committee in Nairobi. The protocol was strictly adhered to and no patient was coerced into doing anything against his or her will. Written consent was mandatory from all the participants of the study. Consenting was done on reading and understanding the written informed consent form. Those who still wanted to be in the study signed their name and date on the participants' part of the form, and the consenter signed their name and date on the consenter part of the form. For participants who did not know how to read or write, the consenter read the consent form to them and a witness signed for them on their behalf.

The participant then put a thumb mark on a designated space on the consent form. Absolute confidentiality was accorded to the participants. No document contains both the name and enrollment numbers of the participants to avoid identification. Following the consenting process, the questionnaires were administered with the first section being asked to the couple together and the section on risk factors being asked to each participant individually.

Participants who were included in the study had already signed and consented for HIV-1, HBsAg and HBsAb testing and blood draw procedures as per the protocol for the Pre-Exposure prophylaxis study. Blood results for HIV and HBV were retrieved from the participants' records with permission from the Principal Investigators of both Nairobi and Thika sites.

The information was handled with utmost care and confidentiality, and kept under lock and key. The questionnaires will be kept available for further analysis or scrutiny for a period of 2 years.

3.11 Limitations of the study

This study may not be generalized to the wider discordant population in Kenya as certain precincts of time and money dictated sampling from only two sites rather than all provinces. The population in this study did not cut across different settings and cultures especially in determining by a great extent the association of socio demographic factors, knowledge and sexual behavior with HBV infection.

In addition, the design of the parent study, of which this is an ancillary required that no HIV negative participant with active HBV infection was enrolled because the HIV negative partners in the PrEP study were required to take study drug. This therefore limited the analysis of active HBV among HIV negative participants, which may have affected the prevalence level.

The parent study did not differentiate if HBsAb was acquired due to a previous infection or vaccination. The current study therefore did not distinguish between the two and may have enrolled participants with HBsAb due to previous vaccination.

The study omitted analysis of HBV prevalence due to mother to child transmission, which is the commonest mode of HBV transmission in developing countries. The omission was mainly because there was no way of determining mother to child transmission. HBV antibodies which would have been acquired due to mother to child transmission of HBV persist for life and may have been included in the prevalence of previous infection of HBV in this study.

The study only used HBsAg and HBsAb as markers for active or previous infection respectively, mainly because the parent study only used these parameters during screening for their participants. Acute infection is characterized initially by the presence of hepatitis B e antigen (HBeAg), hepatitis B surface antigen (HBsAg) and HBV DNA beginning in the preclinical phase. Ideally, the combination of Immunoglobulin M (IgM), HBsAg, elevated liver enzymes Alanine Transaminase (ALT) and hepatitis B core antigen (anti-HBc) which appears early in the clinical phase, constitute a diagnosis of acute infection.

CHAPTER 4 : RESULTS

4.1 Introduction

The study participants in this study were HIV discordant couples currently enrolled in a clinical trial study in Nairobi and Thika sites. A total of 322 participants (161 couples) were enrolled in this study. The male to female ratio was 1:1. There were 118 HIV positive females coupled with 118 HIV negative males and 43 HIV negative females coupled with 43 HIV positive males.

4.2 Socio-Demographic Characteristics

(a) Age:

The mean age among the HIV discordant couples was 35.8 years (SD 8.4) for males and 30.8 years (SD 7.4) for females. The overall average age was 33.3 years (SD 8.4). The youngest participant was 20 years while the oldest was 61 years, whereas 28 years and 38 years were the 25th and 75th percentiles respectively. The lower limit range was 20 years and the upper limit range was 54 years with a few outliers as shown in Figure 4.1

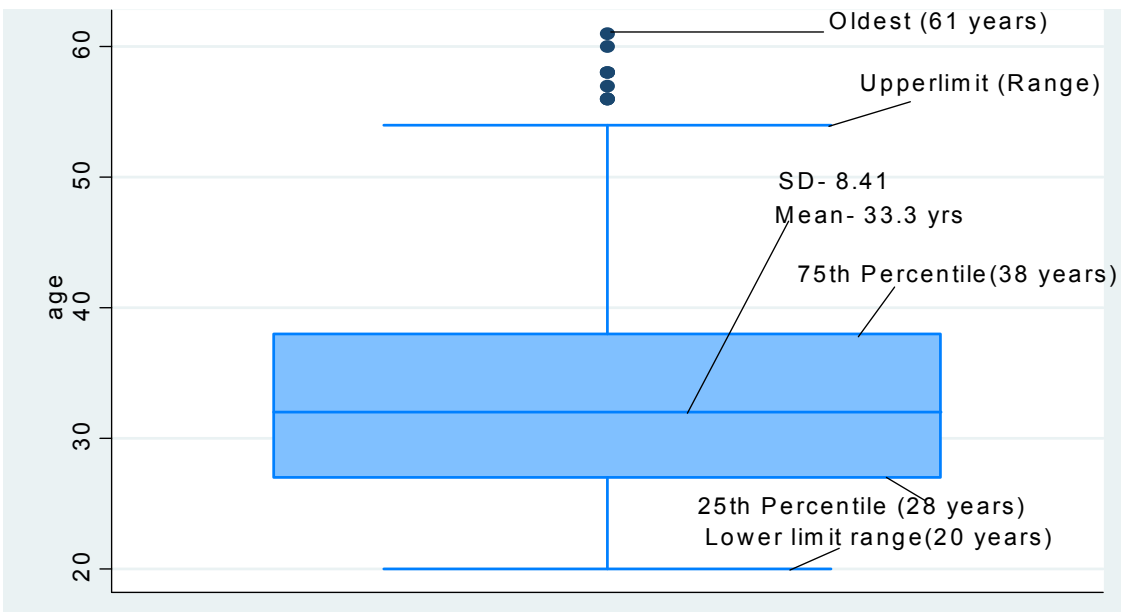


Figure 4.1: Box plot showing age distribution of HIV discordant couples

Among the male participants, the oldest participant was 61 years and the youngest 21 years old. The 75th percentile was 41 years and the 25th percentile was 31 years. Among the female participants the oldest was 58 years old and the youngest 20 years old. The difference in ages was statistically significant ($p<0.05$, OR 0.54, CI 0.41-0.71). The 75th percentile was 36 years while the 25 percentile was 26 years. (Figure 4.2)

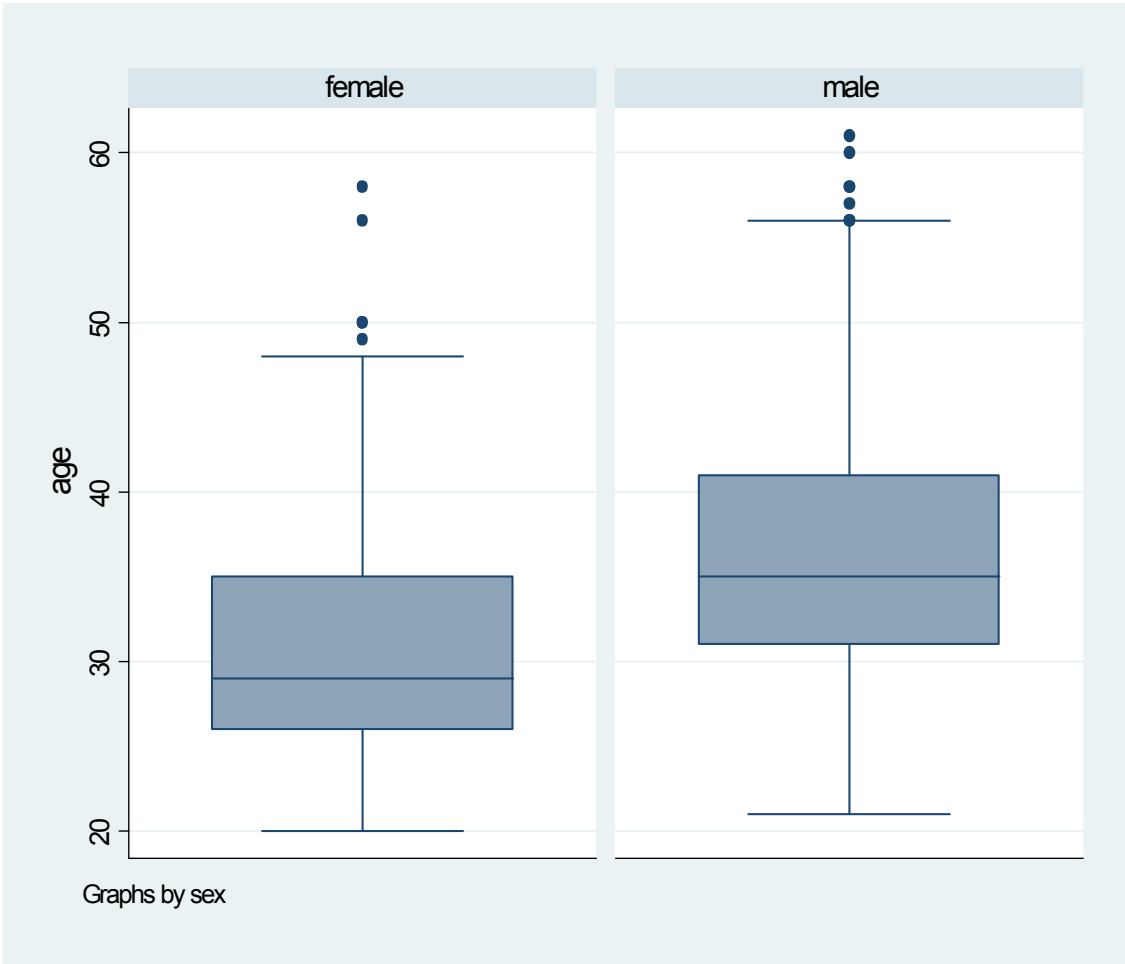


Figure 4.2: Box plot showing age distribution stratified by sex

(b) Education level:

In the total population, only 7 (2%) participants had never been to school, 168 participants (52%) had attained primary level education and 147(46%) participants had attained secondary and tertiary education.

Equal numbers of males and females reported that they had never attended school, while 61.5% and 43% of females and males, respectively, had attained primary education.

Only 36% of all females had attained secondary or tertiary education compared to 55% of males. (p<0.05,OR 2.2, CI 1.40-3.4) (Figure 4.3)

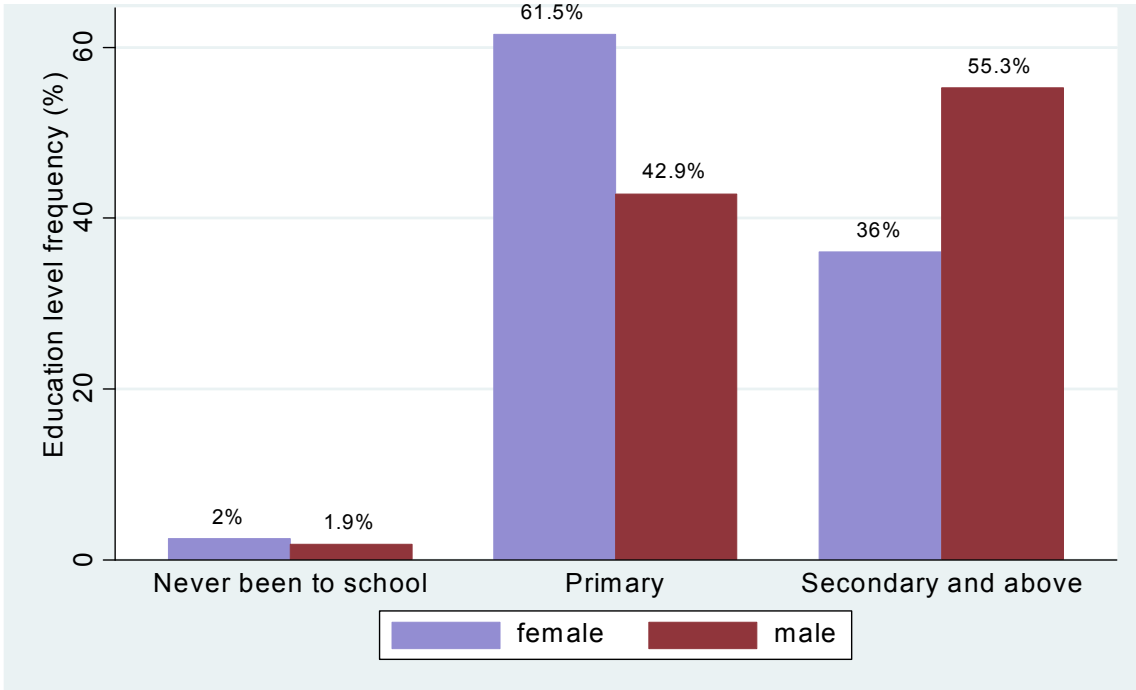


Figure 4.3: Education level among HIV discordant couples, stratified by sex.

(c) Employment state:

In the total population, 30 (9%) participants were employed, 227(71%) were self-employed, 64(19%) had no employment and 1 (0.3%) participant was a student and was categorized under 'other'.

More women (37.9%) compared to men (1.9%) were unemployed (p<0.05). Only 13% of males were employed compared to 5.6% of females. Most participants were self-employed - 55.9% females and 85% males (p<0.05, OR 1.3, CI 1.0-1.6) (Figure 4.4).

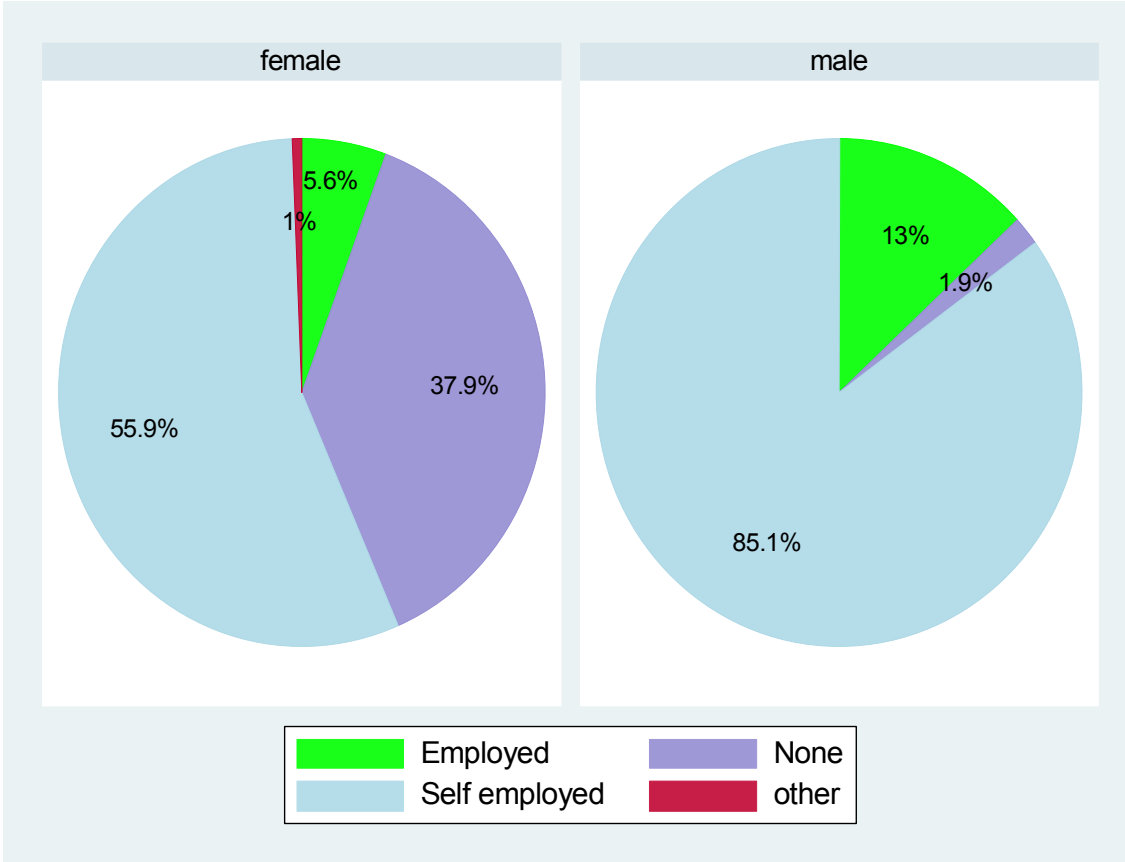


Figure 4.4: Employment pattern among HIV discordant couples

(d) Marital Status:

A total of 136 (42%) participants were married with only one partner. In this study marriage included church and civil ceremonies. Those co-habiting were 179 (55.6%) participants and those married with more than one partner were 7(2.2%) participants.

58% of all females reported that they were cohabiting compared to 53% of males. 1% of females had more than one marital partner compared to 3% of males, while 40% of all females and 44% of males reported that they were married to one partner. (Figure 4.5)

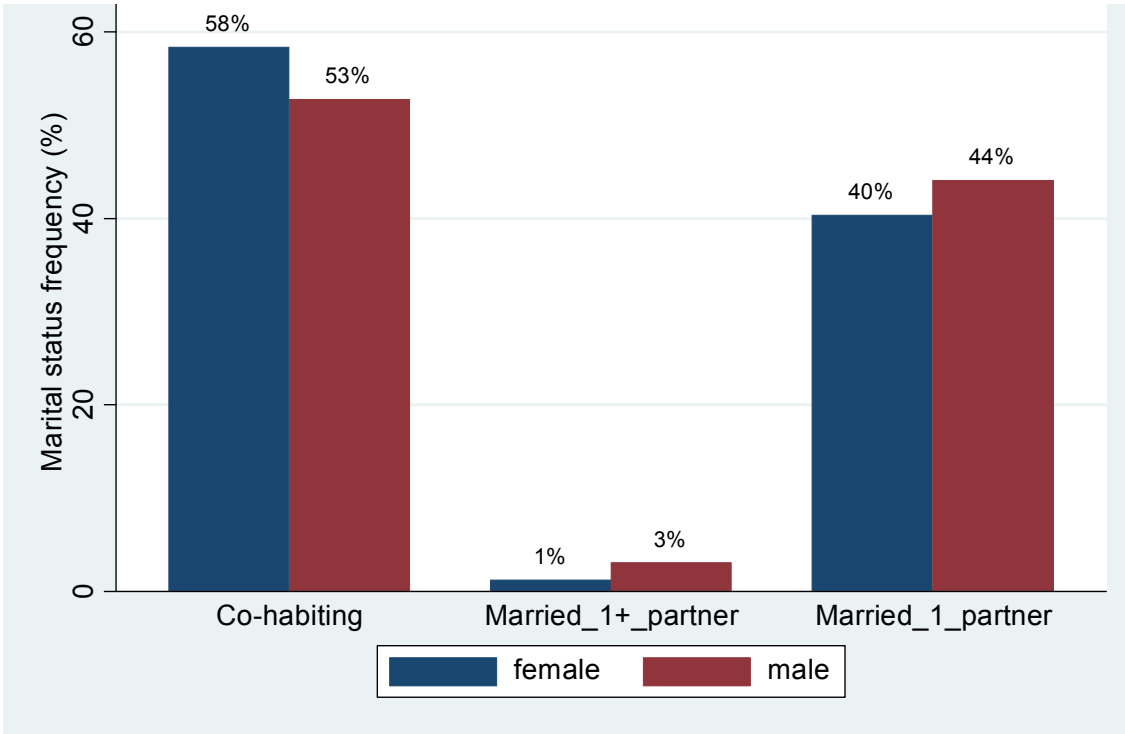


Figure 4.5: Marital status of HIV discordant couples stratified by sex.

4.3 Prevalence of HBV among HIV Discordant Couples

The prevalence of HBV in this study was taken to be the total number of participants with a positive marker for Hepatitis B. This included the Hepatitis B surface antigen, which is a marker for active or chronic infection and the Hepatitis B surface antibody which is a marker for either recent or previous infection. Overall, 99 participants (31% prevalence) had a positive marker for Hepatitis B. 223 participants (69%) were negative for Hepatitis B.

There was no statistically significant difference in HBV prevalence between the HIV positive participants (33%) and HIV negative participants (29%) (p=0.4).

Of all the 161 couples, there were 61(38%) couples who were discordant for HBV meaning either one tested positive for the virus while the other tested negative. Half of all the couples were concordant negative, while 19 (12%) couples were concordant positive (Figure 4.6).

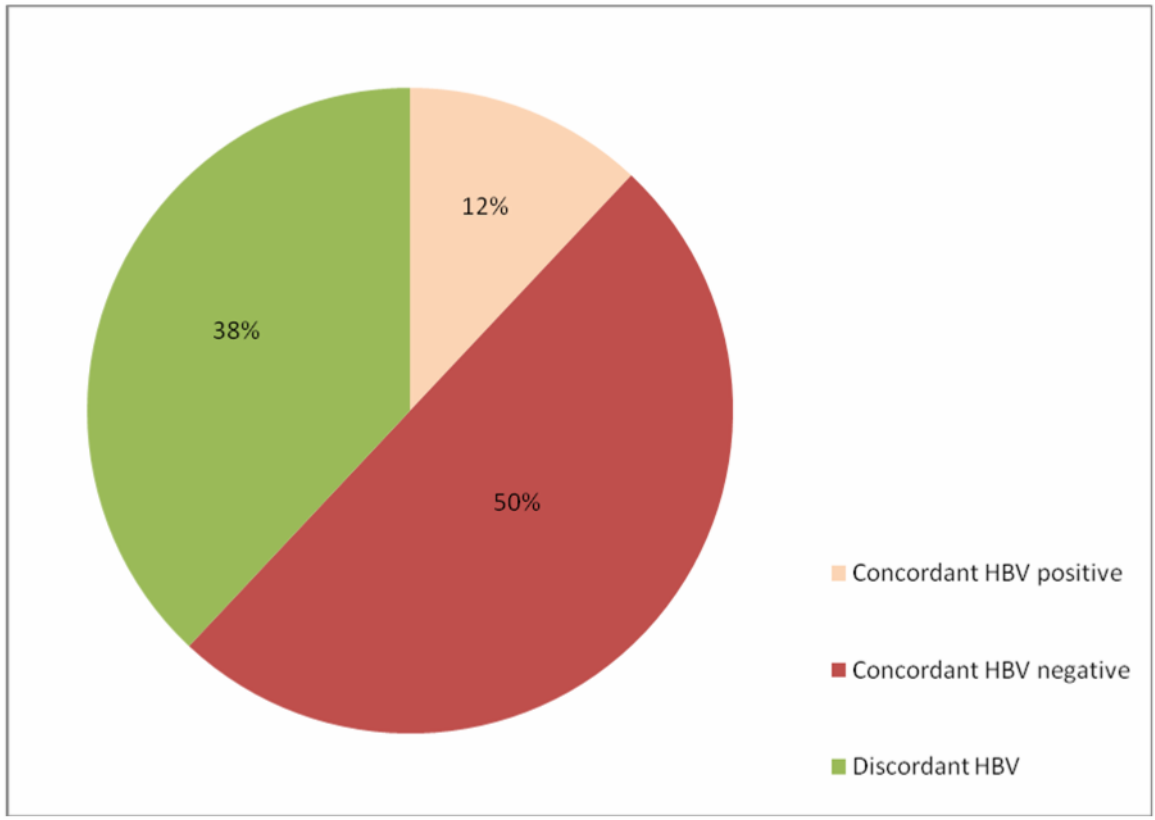


Figure 4.6: HBV status among HIV discordant couples.

(a) HBV prevalence by sex

The prevalence of HBV was higher among HIV positive females (10.2%) compared to their HIV negative counterparts (5.9%) (p=0.05, OR 0.5, CI 0.2-1.0), in sharp contrast to the male population where HBV prevalence was higher among the HIV negative males (8.4%) compared to the HIV positive males (6.2%). This difference in HBV prevalence was statistically significant at (p<0.05, OR 3.0, CI 1.3-6.5) (Figure 4.7).

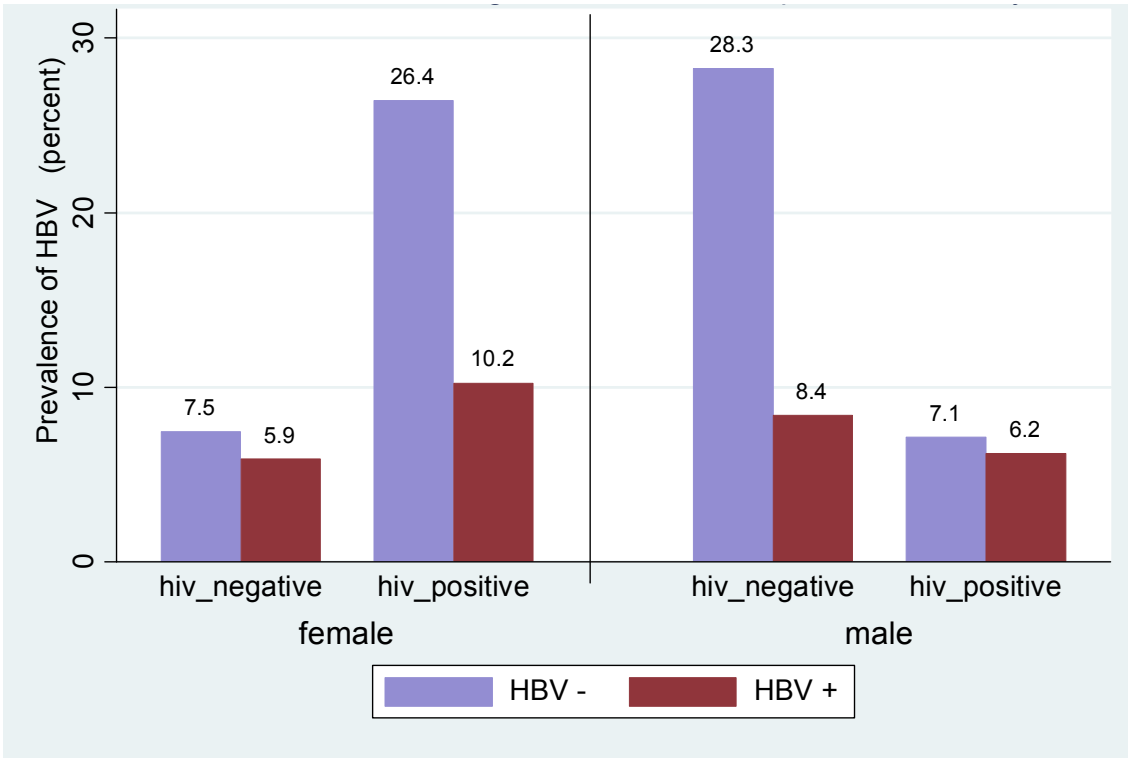


Figure 4.7: Prevalence of HBV stratified by sex among HIV discordant couples.

Among HIV negative participants (n=161), there were more HBV positive males (16.8%) compared to females (11.8%). This difference in HBV prevalence was highly significant ($p<0.01$, OR 2.6, CI 1.2-5.9). But among the HIV positive participants (n=161), there were significantly more HBV positive females (20.5%) compared to males (12.4%) ($p<0.05$, OR 0.4, CI 0.2-9.8)

(b) HBV prevalence by education level

The highest prevalence of HBV is among those who have attained secondary education and above for males with a HBV prevalence of 9% and for females those who have attained primary education at 10.9% prevalence. The lowest prevalence is among those who have never been to school 0.3% for males and 0.6% for females. (Fig. 4.8) The difference in HBV prevalence by education was not statistically significant ($p>0.05$).

For purposes of cross tabulation with HBV prevalence and determination of chi square test of siginificance , the number of participants who have never been to school was collapsed into

those who have attained primary education, creating a category primary education and below. Despite this correction there was no statistically significant difference in HBV prevalence ($p>0.05$).

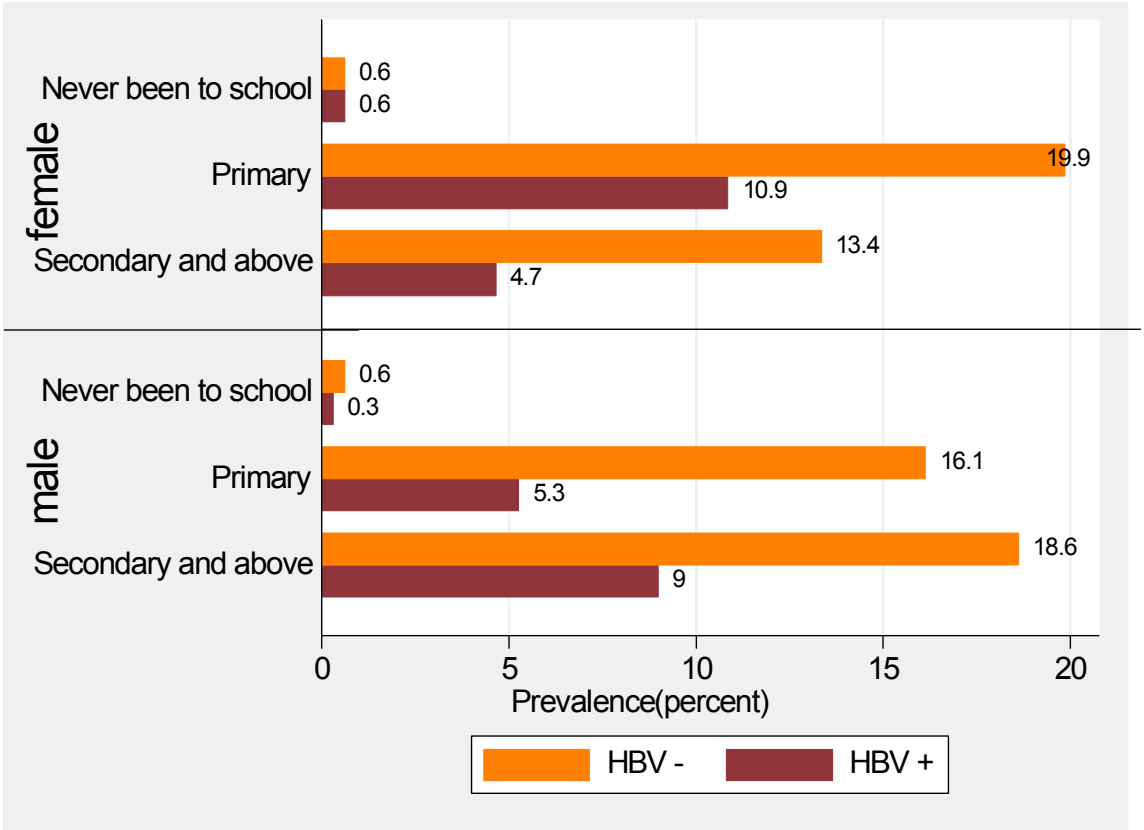


Figure 4.8: HBV prevalence by education level among HIV discordant couples.

(c) HBV prevalence by employment status

The highest prevalence for HBV was among the self- employed category for both male (13.4%) and female (10%) On stratification by HIV status, the highest prevalence in both HIV negative (11.8) and HIV positive (11.8) was among the self-employed category There was no significant difference between the state of employment and HBV prevalence ($p>0.05$).

(d) HBV prevalence by type of marriage

The highest prevalence of HBV was in co-habiting females with a rate of 10.2%. There was no statistically significant difference in HBV prevalence among the different marital status

groups (p>0.05). On collapsing the category Married with more than one partner, the difference in HBV prevalence was still not significant (p>0.05) (Figure 4.11).

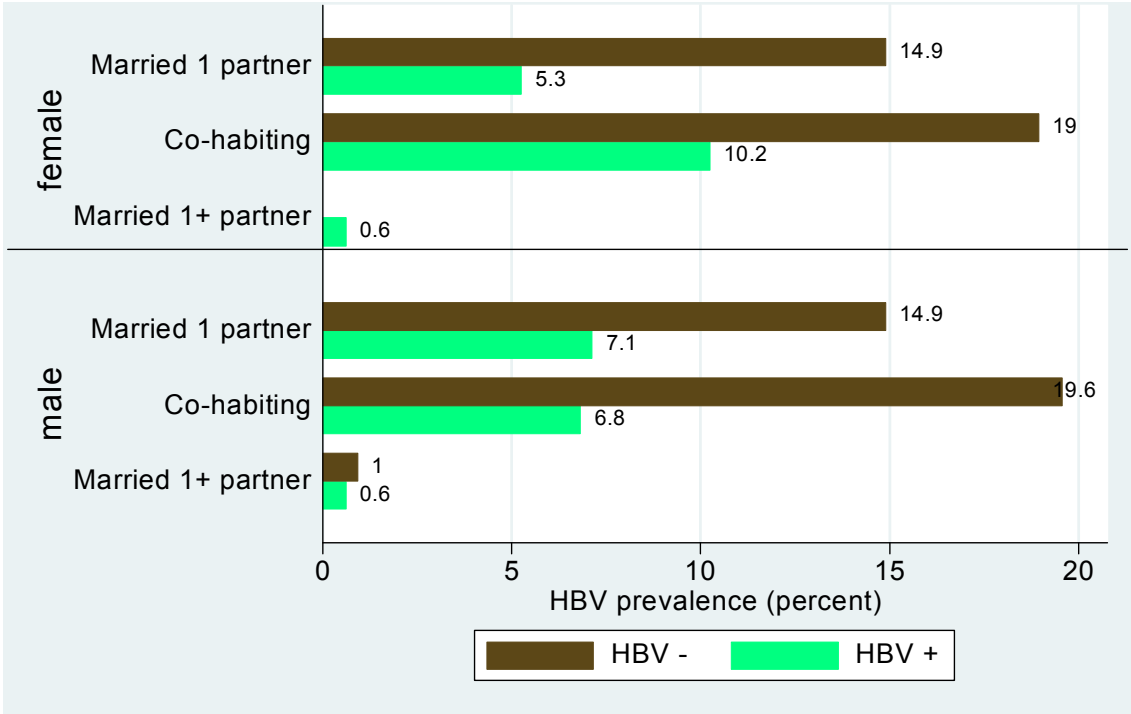


Figure 4.9: Marital status by HBV status among HIV discordant couples

Table 1 summarizes the association between the socio-demographic characteristics in particular age, occupation, educational level, marital status and HBV prevalence based on the p value after conducting a chi^2 test. No association was found with all the socio-demographic characteristics except for age where a significant association was found (p<0.001, OR 1.6, CI 1.2-2.1)

Table 4.1: Bivariate analysis between HBV status and socio-demographic characteristics.

	Socio-demographic variable	Pearson Chi^2 test- of variable and HBV status	P value/OR	Association
1.	Age-group	19.5	0.001, OR 1.6	Yes
2.	Sex	0.4	0.5	No
3.	Employment state	4.4	0.09	No
4.	Education Level	0.7	0.9	No
5.	Marital Status	2.4	0.3	No

4.4 Association between HBV and HIV-1 Status

The association between HBV and HIV is calculated using a two by two table and Pearson chi square test performed (Table 4.2). It was found out that there was no association between HIV status and HBV status (p=0.39).

Table 4.2: Association between HBV status by HIV status

		HIV status		
		HIV+	HIV-	Total
HBV status	HBV +	46 (28.6%)	53 (33%)	99 (30.8%)
	HBV –	115 (71.4%)	108 (67%)	223 (69.2%)
	Total	161 (100%)	161 (100%)	322 (100%)

Person chi^2= 0.7 p=0.39

4.5 Knowledge of HBV by HIV-1 Discordant Couples

Knowledge on HBV was determined by asking questions on the following categories.

1. If the participant had ever heard of HBV.
2. Causes of HBV.

3. How HBV is acquired.
4. How HBV infection can be prevented.
5. The organ in the body commonly affected by HBV.
6. Complications of HBV.

200(62.11%) participants answered that they had heard of HBV while 122 (38%) participants answered that they have never heard of HBV. Among those with a positive marker for HBV, 61% had ever heard of HBV infection, while 39% responded that they had never heard of the infection.

Knowledge of HBV is summarized to include the answers to all the questions asked in Table 4.3. The worst answered question was on the acquisition of HBV with only 3% of the respondents giving the correct answer. 11% of the respondents to the question on prevention of HBV got the correct answer which was the best answered question as well as the question on causes of HBV. Majority (75%) of the respondents did not know that a virus causes Hepatitis B infection, while 55% and 53% had no knowledge on how HBV is acquired and its complications respectively.

Table 4.3: Table summarizing knowledge of HBV among HIV discordant couples.

Category	Correct	Wrong	Did not know
Causes of HBV	11%	14%	75%
Acquisition of HBV	3%	42%	55%
Prevention of HBV	11%	48%	41%
Organ affected by HBV	9%	47%	45%
Complications of HBV	4%	43%	53%

A knowledge adequacy variable was created for the total performance of the study participants who have ever heard of HBV. The variable included percentage performance based on the number of questions asked whereby 0% knowledge was the score of participants

who did not get any correct answer, 20% knowledge scored 1 correctly answered questions, 40% knowledge scored 2 correctly answered questions, 60% and 80% scored 3 and 4 correctly answered questions respectively.

No participant achieved 100% knowledge level.

This variable was further categorized in to two to give adequate knowledge of HBV and inadequate knowledge of HBV, where inadequate knowledge included a knowledge level of 40% or less (2 or less correctly answered questions). Adequate knowledge included a knowledge level 60% or more (3 or 4 correctly answered questions).

Overall, females had more accurate data on the cause of HBV than males, though this difference was not statistically significant. It is also noted that more HBV negative participants did not have correct knowledge of HBV than those who were HBV positive.

Of the 200 participants who answered that they have heard of HBV, 16 (8%) participants had adequate knowledge of HBV while 184 (92%) had inadequate knowledge. More females (8.5%) had adequate knowledge of HBV on all the questions asked compared to males (7.5%) (Figure 4.10). However the difference was not statistically significant ($p>0.05$)

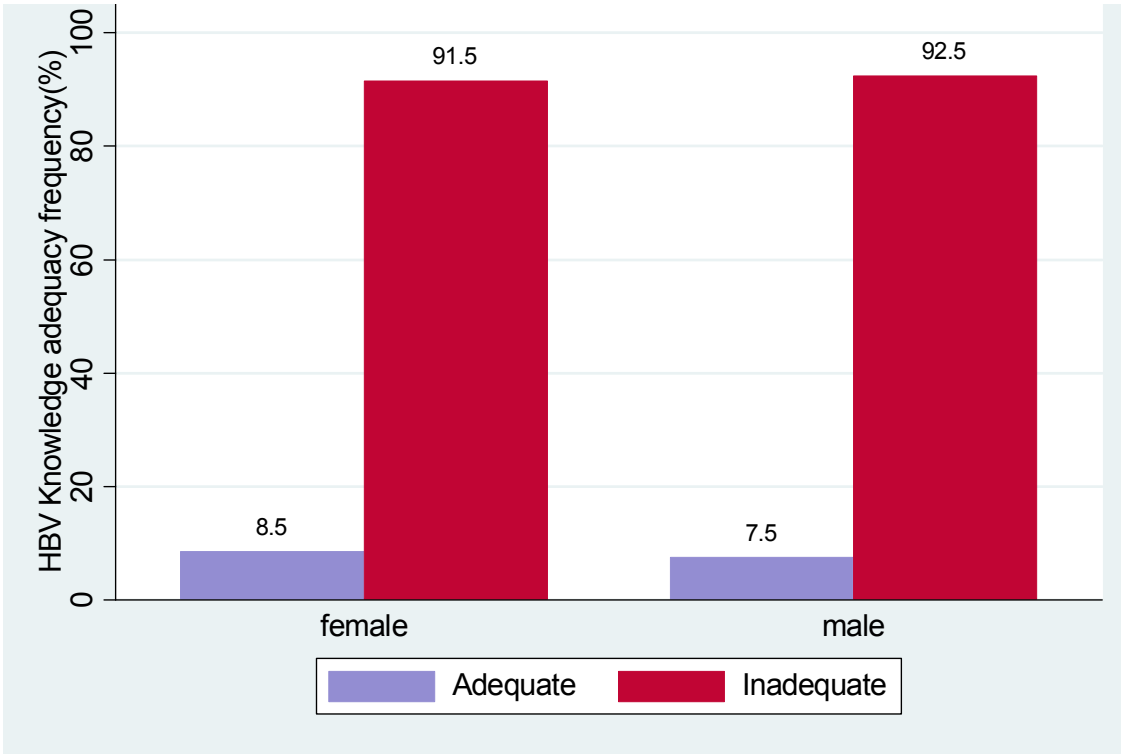


Figure 4.10: Knowledge adequacy by sex among HIV discordant couples who have ever heard of HBV.

Of all HIV negative participants who reported that they had heard of HBV 3.7% had adequate knowledge of the disease compared to 13% of all HIV positive participants. The difference in knowledge adequacy was statistically significant ($p < 0.05$, OR 2.7, CI 0.95-7.9) (Fig 4.11).

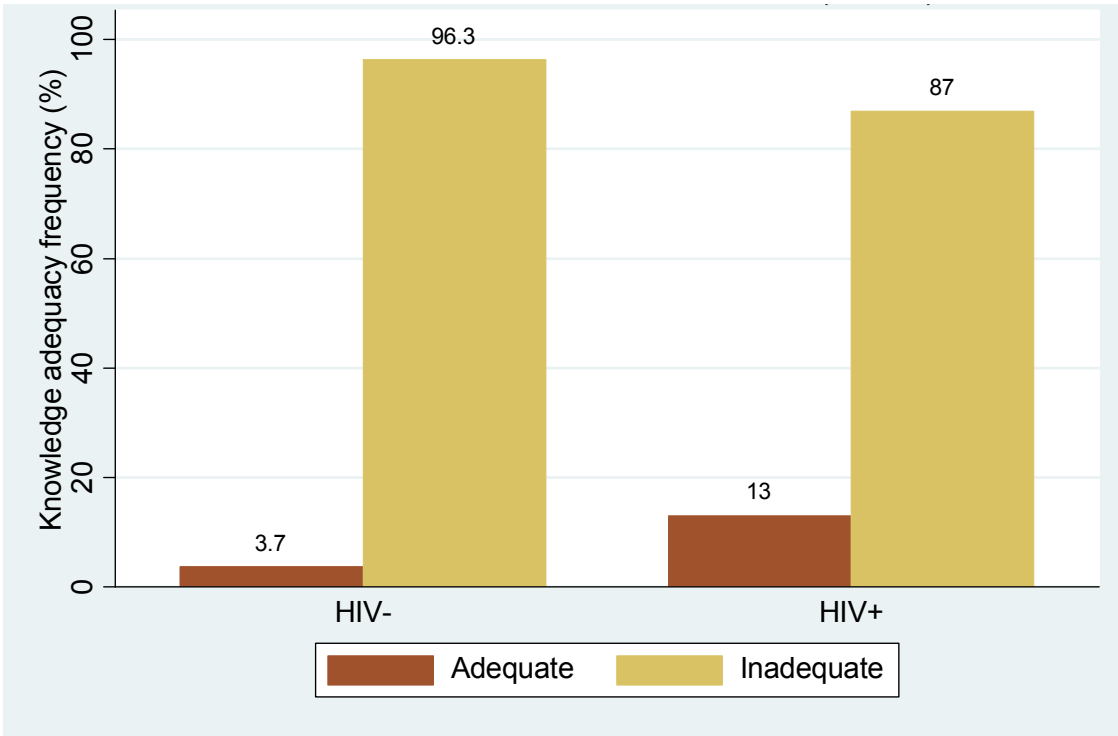


Figure 4.11: Knowledge adequacy by HIV status among those who have ever heard of HBV.

The study further found that 5% of HBV positive participants had adequate knowledge of HBV compared to 9.3% of HBV negative participants who had adequate knowledge (Figure 4.12). This difference was not statistically significant ($p>0.05$).

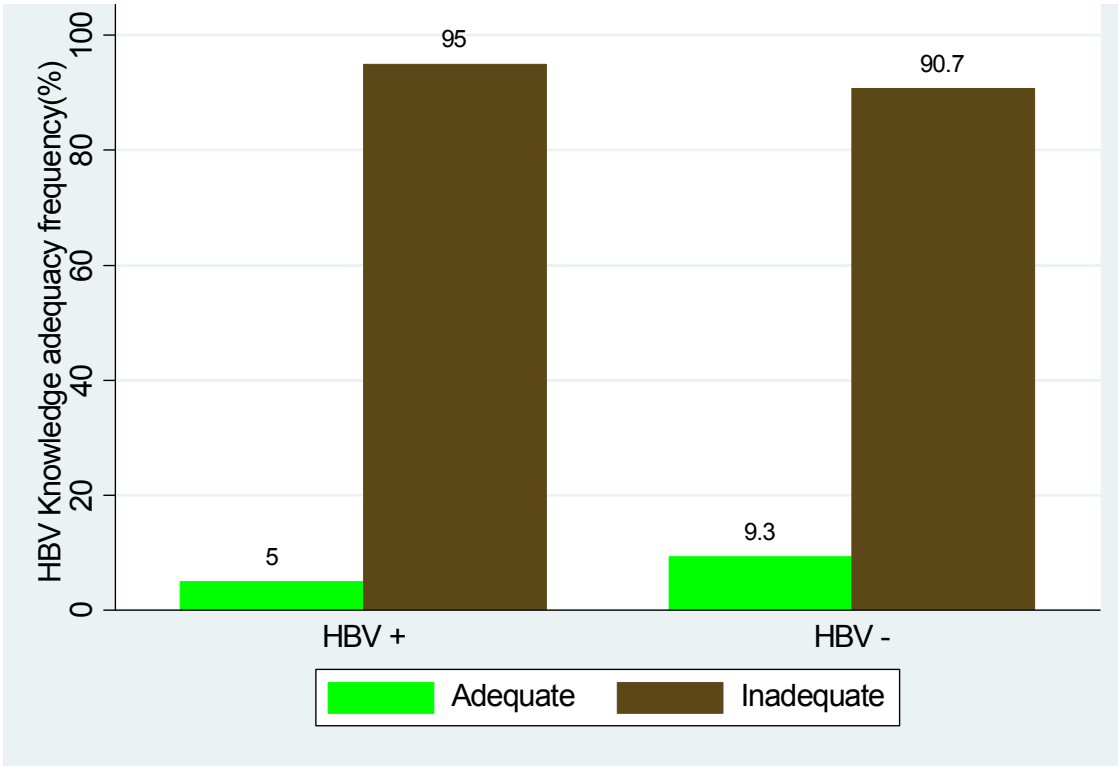


Figure 4.12: HBV knowledge by HBV status among those who have ever heard of HBV

In determining the HBV prevalence rate among those who have ever heard of HBV, the highest rate was 9% prevalence in HIV negative males with inadequate knowledge followed closely by HIV positive females who had a prevalence of 8% also with inadequate knowledge of HBV. Interestingly, there was no HIV negative female with adequate knowledge of HBV (Figure 4.13).

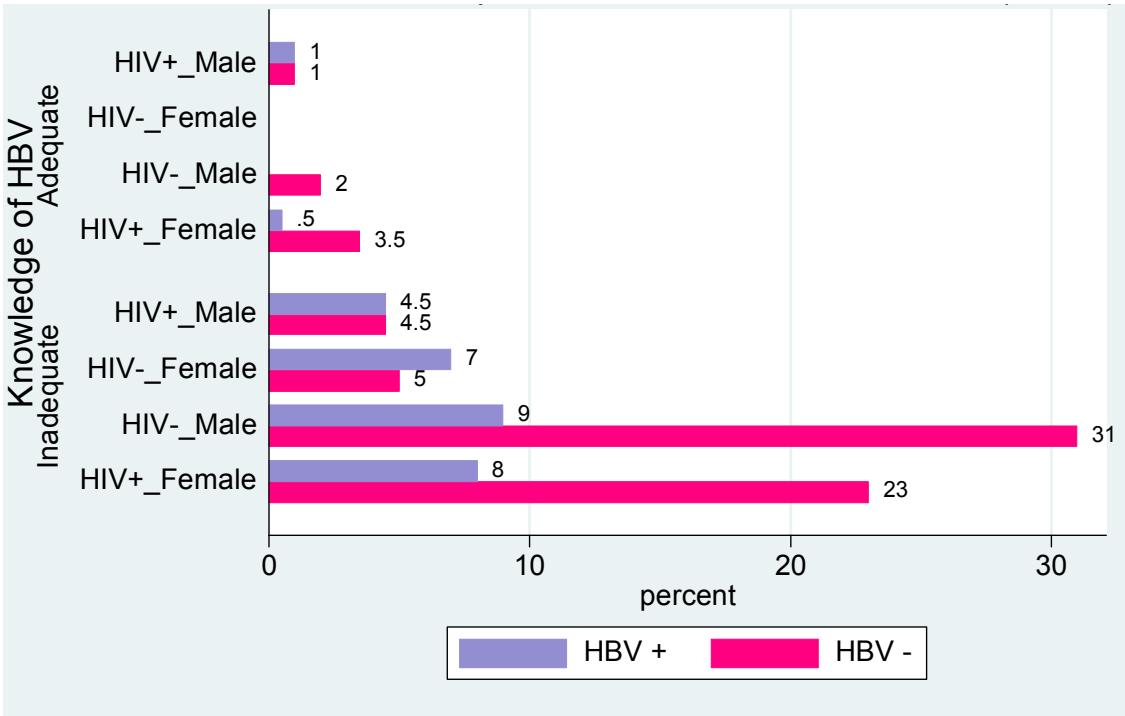


Figure 4.13: HBV prevalence by Knowledge adequacy among those who have heard of HBV.

4.6 Association between HBV, Sexual Behavior and Risk Factors

(a) Sexual behavior.

The participants were asked how many sexual partners they have had since one partner was diagnosed with HIV, use of condoms since diagnosis (Index participant n=161) or since knowledge of discordance (Partner participant n=161).

For index participants, 14(9%) participants had other partners, 146(90.6%) participants had their study partner as the only sexual partner since they were diagnosed with HIV. A negligible 1(0.6%) refused to respond to the question. For partner participants, 13(8%) participants had other sexual partners other than their study partner, 146(91%) participants had their study partner as the only sexual partner since knowledge of discordance, while 2(1%) participants refused to respond to the question.

Among the index participants, the highest prevalence of HBV was among the females at 19.6% who had reported to having only one sexual partner compared to 11.7% for HIV

positive males who had reported to having only one sexual partner. The difference in HBV prevalence between the HIV positive male and female was statistically significant ($p<0.05$).

Among partner participants, the highest prevalence was among the males at 14.5% compared to females 10%. The difference in HBV prevalence between the HIV negative male and female was not statistically significant. ($p=0.8$). Figure 19 illustrates the HBV prevalence by the number of partners since diagnosis with HIV, stratified by sex.

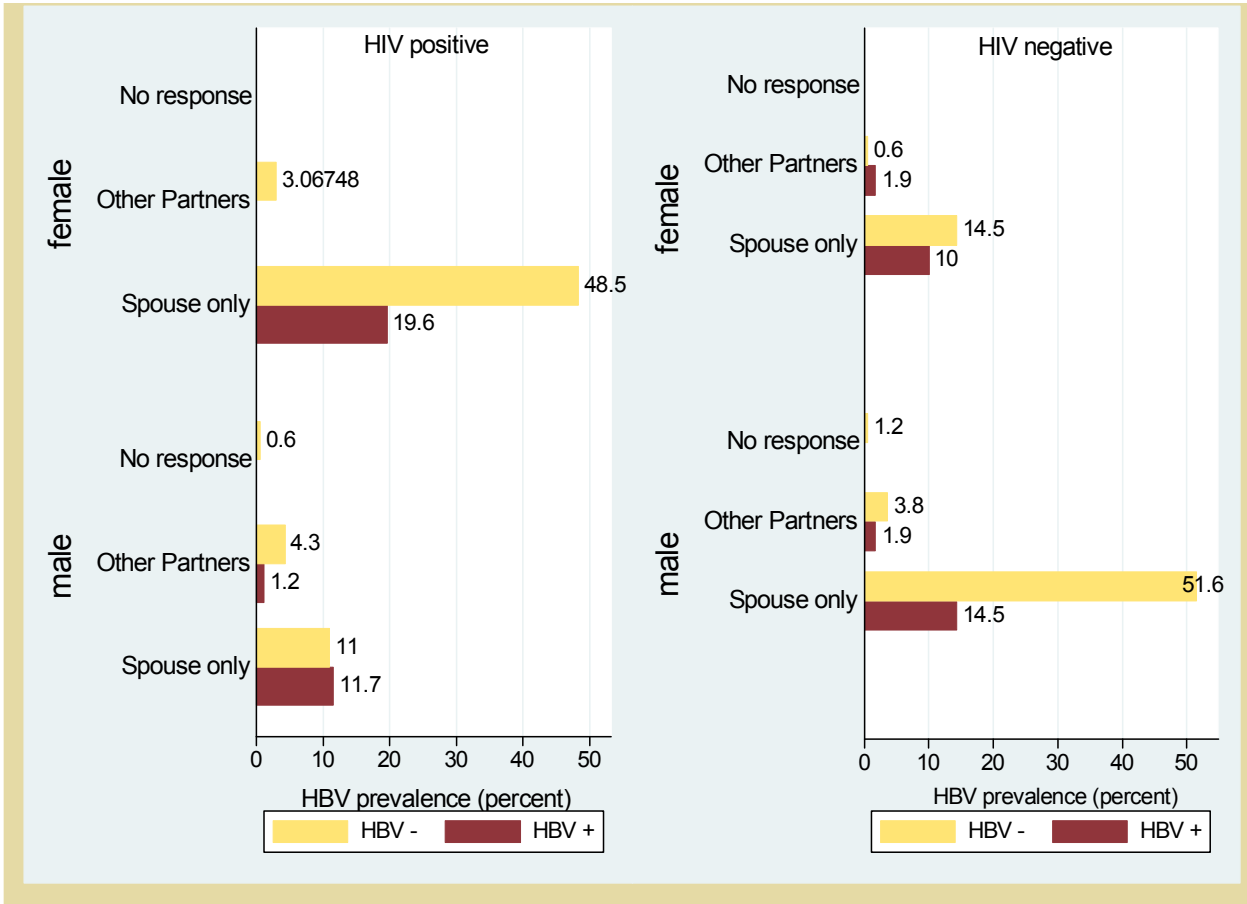


Figure 4.14: Charts showing sexual partners among HIV discordant couples stratified by sex.

A total of 15 participants out of 161 of all HIV positive participants had sexual partners other than their spouse since they were diagnosed with HIV. Of these, 4(27%) participants had one other sexual partner, 8(53%) participants had 2 other sexual partners, 2 (13%) participants had 3 other partners and 1(6%) participant refused to respond to the question.

Among the HIV negative participants, a total of 14 participants out of 161 of all HIV negative participants had other sexual partners other than their study partner since knowledge of HIV discordance. About 6 (44%) participants had one other partner, 5 (38%) participants had 2 other sexual partners, 1 (7.14%) participant had 3 other sexual partners. 1(7.14%) participant refused to respond to the question.

There was no statistically significant difference in HBV prevalence and the number of sexual partners for HIV negative participants ($p>0.05$) and HIV positive participants ($p>0.05$) (Figure 4.15).

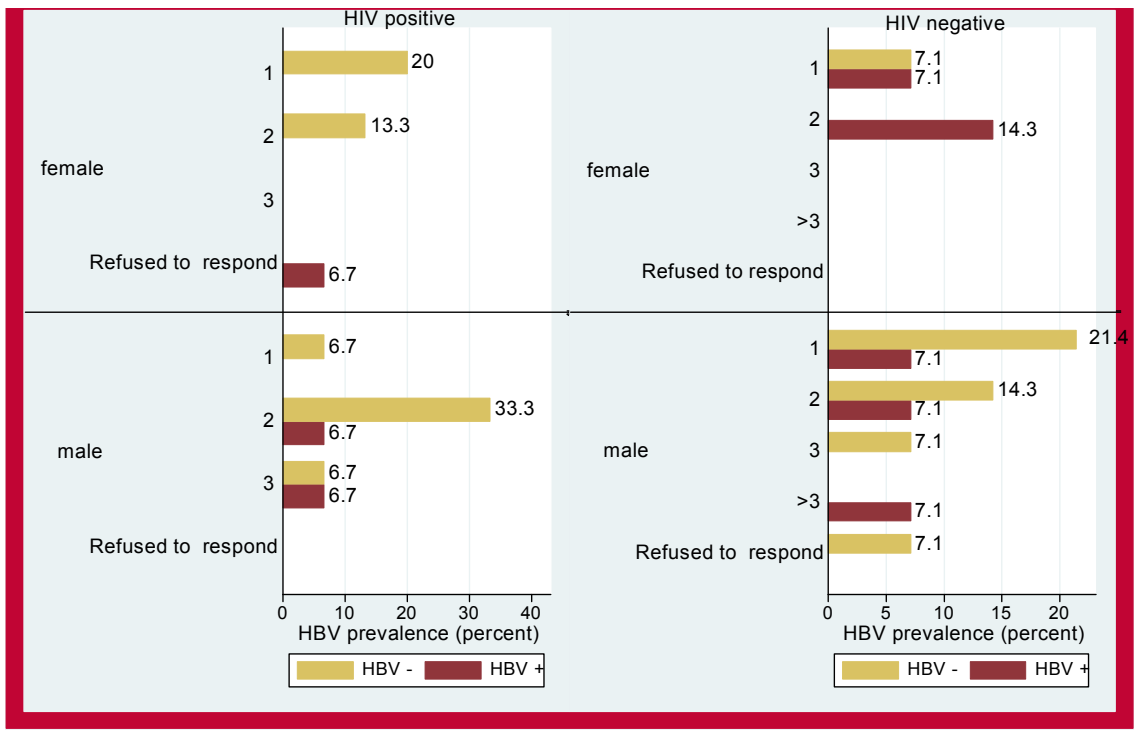


Figure 4.15: Prevalence of HBV among HIV positive and HIV negative participants having other sexual partners other than study partner, stratified by sex.

(b) Condom use among HIV discordant participants.

Among the HIV positive participants, 124 (77%) participants reported that they always wore a condom, 12(7.5%) participants never wear a condom and 25 (15.5%) participants sometimes wore a condom.

Among the HIV negative participants, 126 (78%) participants always wore a condom, 12(7.5%) participants never wore a condom and 23 (14%) sometimes wore a condom (Figure 4.16).

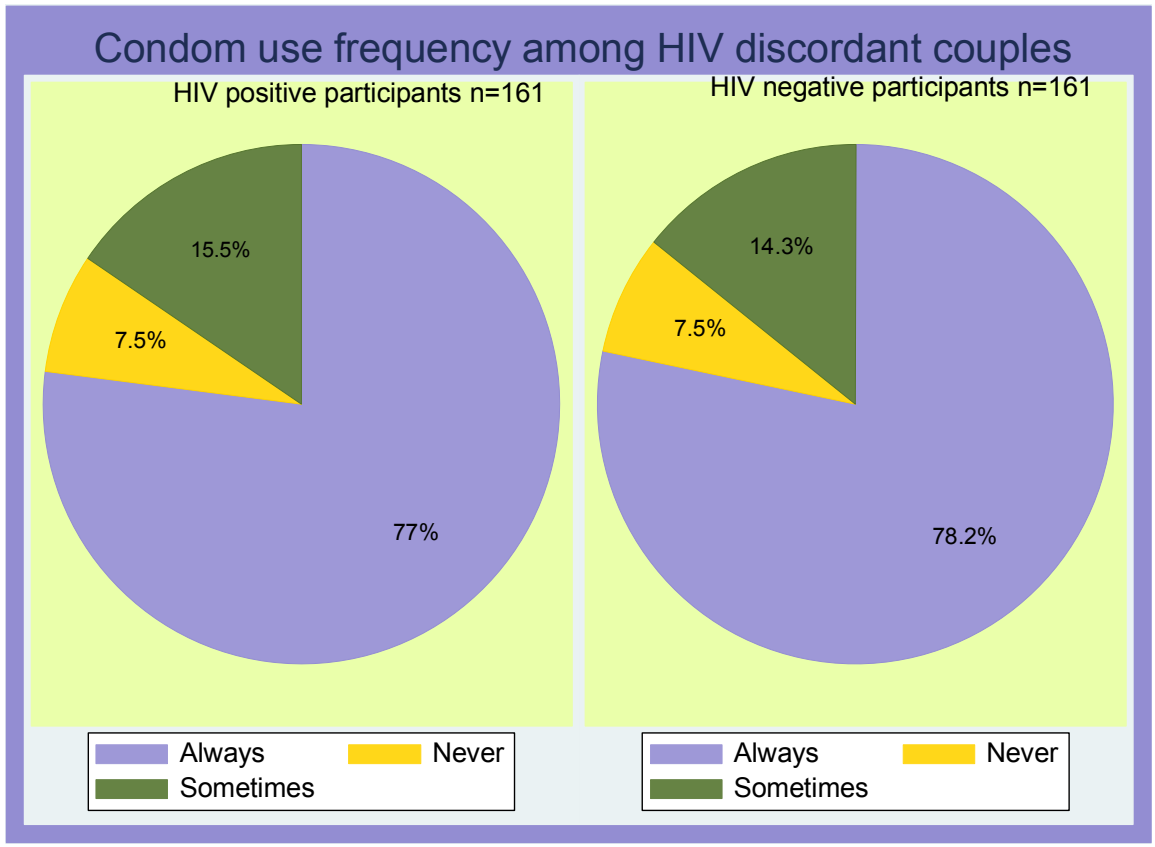


Figure 4.16: Frequency of condom use by HIV positive and negative participants.

There was no statistically significant difference between condom use and HBV status among the HIV negative group ($p>0.05$) and the HIV positive group (>0.05).

Among those who reported that they always wore a condom, HIV positive females had a higher prevalence of HBV of 15.5% than the HIV positive males whose prevalence was 11.2%.

Among the partner participants, the males had a higher prevalence rate than the females of 12.4% and 10.4 % respectively (Fig 4.17).

The difference in HBV prevalence between male and female was not statistically significant. ($p>0.05$) ($p=0.3$ for partner participants as well as 0.7 for index participants)

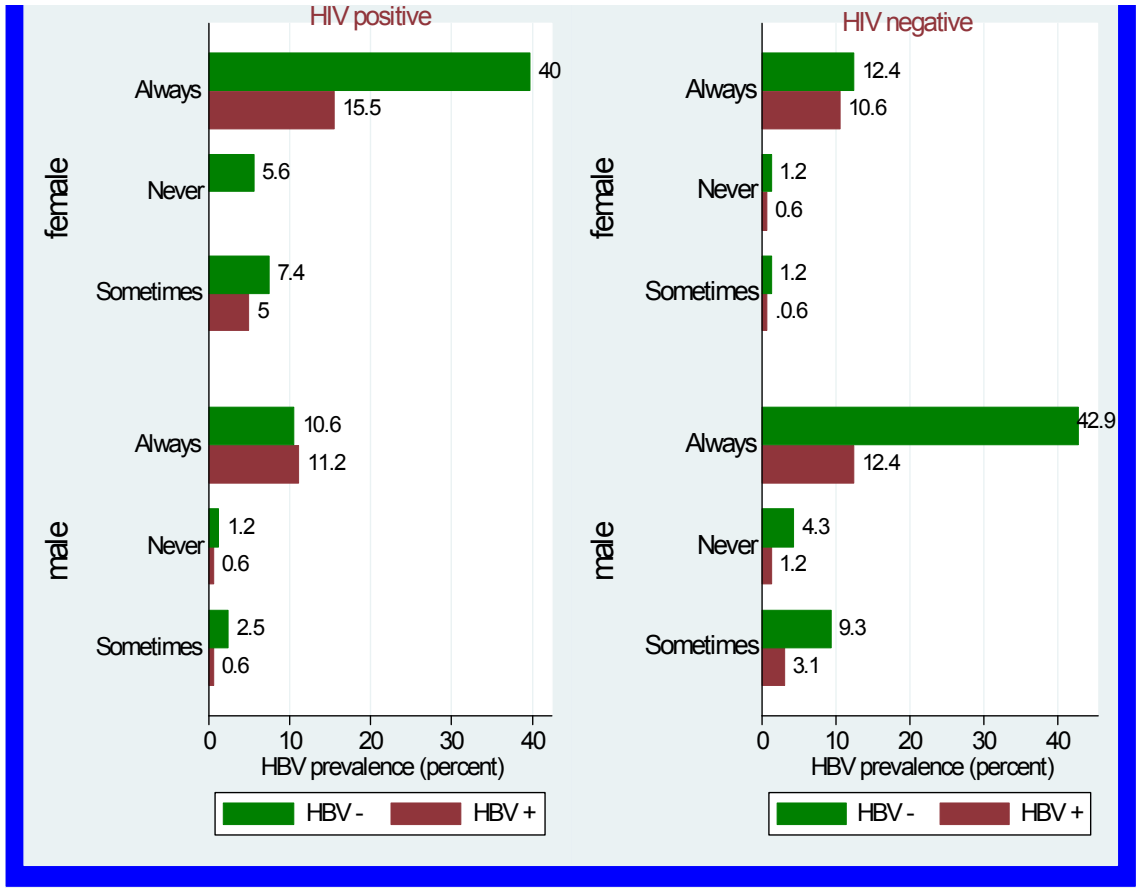


Figure 4.17: Prevalence of HBV by condom use among HIV discordant couples.

(c) Risk factors.

The risk factors which were analyzed in this study include,

- Use of illicit injection drugs.
- Sharing of needles.
- Blood transfusion.

Concerning overall risk, 3 (1%) participant reported to have used injection illicit drugs, 15(5%) participants had shared a needle in their life and 16(5%) participants had a blood transfusion.

(i) Use of illicit injection drugs.

None of the females in the whole population used any drugs, while 2.5% of HIV negative males reported that they had ever used illicit injection drugs. Overall, over 90% of the population reported to never having used illicit injection drugs.

There was no association between illicit injection drug use and HBV status among the HIV discordant couples (p>0.05)

(ii) Sharing of needles.

The participants were asked if they had ever shared a needle in their lives. HBV prevalence among those who had ever shared a needle was less than 1%, with the highest prevalence being 0.6% among HIV positive males. There was no association between sharing needles and HBV status among the HIV discordant population (p>0.05)

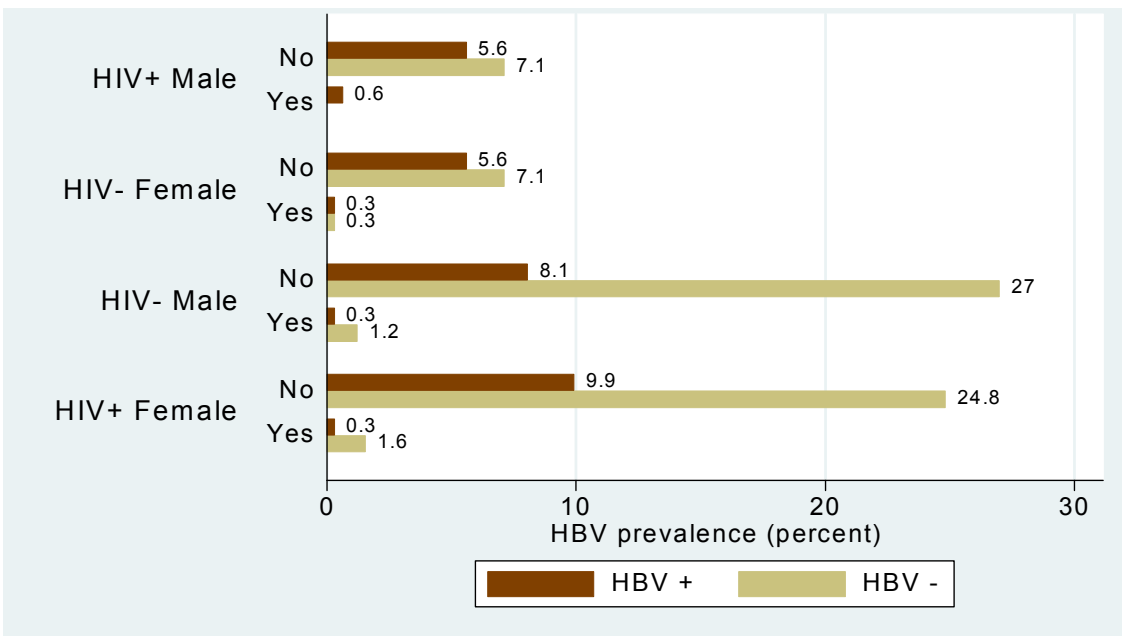


Figure 4.18: Graph showing sharing of needles by HBV status HIV discordant couples.

(iii) Blood transfusion.

The prevalence of HBV among those who have ever had a blood transfusion was less than 1%. The highest prevalence is 9.7% among HIV positive females who reported that they had never had a blood transfusion. Of the participants who reported that they had ever had a blood transfusion, HBV prevalence was 0.6% for both HIV negative and HIV positive females. Of the males who reported that they had ever had a blood transfusion, none had a positive marker for HBV (Fig 4.19). There was no association between blood transfusion and HBV prevalence ($p>0.05$)

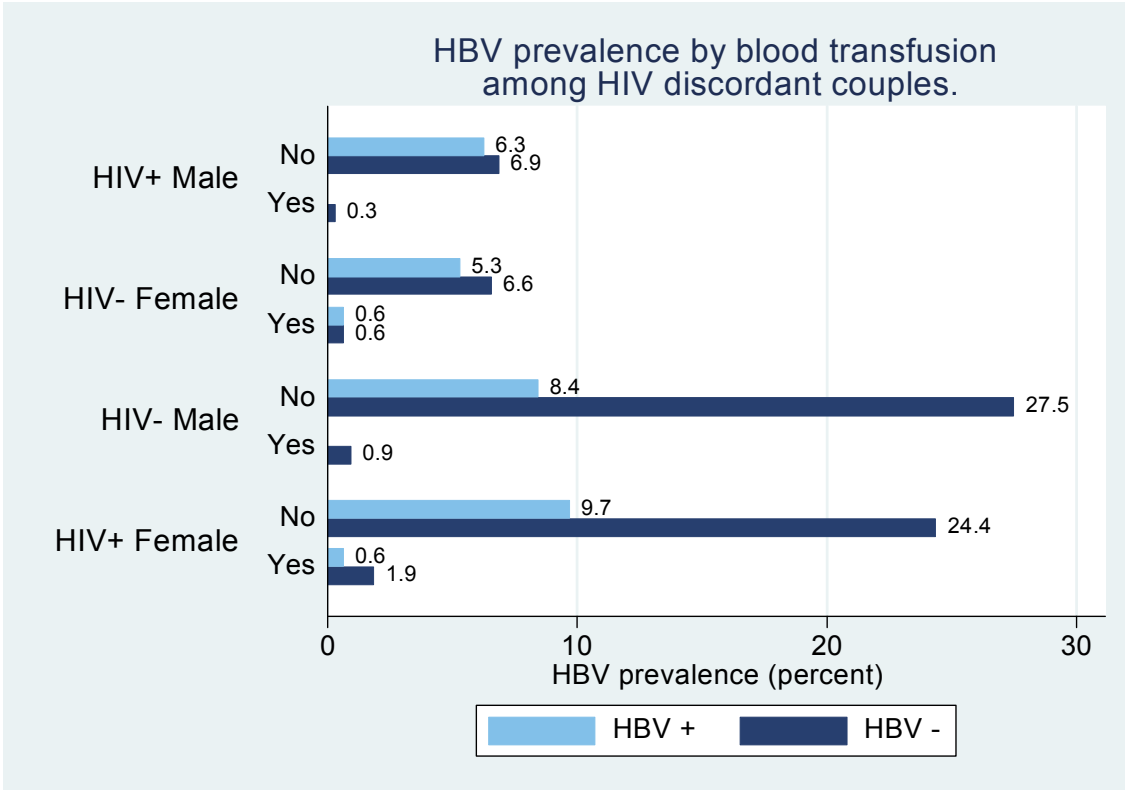


Figure 4.19: Graph showing blood transfusion by HBV status among HIV discordant

A risk scoring variable was generated by combining the sexual behavior and risk factors namely:

1. Number of sexual partners since knowledge of discordance.

2. Frequency of condom use

3. Risk from blood transfusion, sharing needles and illicit injection drug use.

A score of one was awarded for each of the following responses: Participants with more than one sexual partner, never using or sometimes using a condom, and a “Yes” answer to any of the questions on blood transfusion, sharing a needle or illicit injection drug use. A participant who answered “No” to any of the above mentioned questions, had one sexual partner or always used a condom was not included in the risk score as their score would be zero. The scoring system therefore was limited to those with history of risk behavior predisposing them to HBV infection.

This was computed to give risk level of 1 to 3, of which 2 and 3 were considered High risk while a score of 1 was considered Low risk. The risk levels were cross tabulated with HBV to determine HBV prevalence among the Low risk and the High risk groups.

There was a higher prevalence of HBV among the High risk group (33%) compared to the low risk group (26%). This difference, however, was not significant ($p=0.5$) (Figure 4.20).

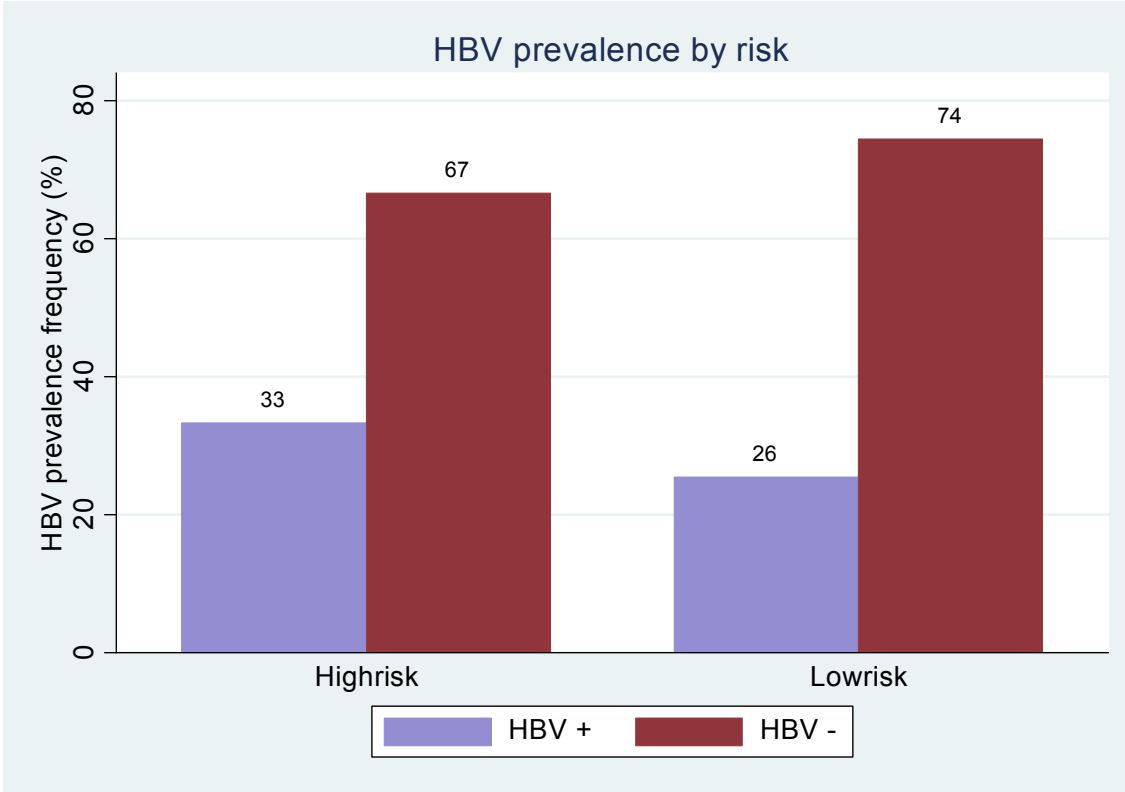


Figure 4.20: HBV prevalence by risk factors scoring system

CHAPTER 5 : DISCUSSION, CONCLUSION, RECOMMENDATIONS

5.1 Discussion

5.1.1 Prevalence of HBV

The prevalence of HBV in this study included a positive marker of HBV indicating either a current or previous infection.

The overall prevalence of active or previous HBV infection in this study is 31%. Active infection prevalence was 1% and prevalence for previous infection of HBV was 30%. While this study did not use other markers for active or previous hepatitis infection, it employed the use of HBsAg and HBsAb which has been found to have specificity of about 97-99% and a sensitivity of 97-98% (Scheiblauer, 2010).

The prevalence of active HBV among the HIV positive participants is lower in this study than in a study done at Aga Khan University Hospital which found a co-infection prevalence

of active HBV infection with HIV-1 at 6% (Nelson, 2008) and a prevalence rate of 20.6% in a study done in Nigeria (Oswaldo, 2007). The reason for the difference in prevalence between these studies and the current study is because these studies mainly analyzed active HBV infection while the current study analyzed both active and previous HBV infection.

According to WHO, 70% of HIV-1-infected people have a blood marker of past or present HBV infection (WHO, Hepatitis B. Geneva, 2002). Among the HIV positive participants in this study, only 29% (46/161) had a positive marker for HBV infection. The study also showed that 61/161(38%) couples were discordant for HBV, meaning one participant in the couple had a positive marker for HBV. These findings compared with the distribution in a study done in New Jersey, USA where 67% of all the couples were discordant for HBV (Poblete R, 1992). Furthermore the distribution contrasted with Pobletes study as those concordant negative were 50% while concordant positive were 12% in this study compared to 33% and 14% respectively in Pobletes' study (Poblete R, 1992). The reason for this variance could be difference in sampling and distribution of participants between the two studies.

The difference in the prevalence of HBV among females (32.3%) and males (29.2%) was not statistically significant. This compares with a similar study done in Thika to determine the prevalence of HBV among HIV-1 discordant couples where the difference in HBV prevalence was not significant between males and females. (Ngure., 2009). However, in this study, couples containing a HIV negative male have are 3 times more likely to have a higher prevalence of HBV than couples with a HIV positive male.

The HIV positive females have the highest HBV prevalence rate of 10.2%. A study conducted in Tanzania to determine the association of HBV and HIV in different populations showed an increased prevalence of HBV in HIV-1 infected females compared to their HIV negative female counterparts **(**66.7% vs. 49%; p =0.01)**,** suggesting that young girls and women of reproductive age group (15-35 years) may have acquired HBV through heterosexual intercourse also leading to HIV transmission (JF Shao, 1993).

Similarly, among the HIV positive participants, there is a significant difference in HBV prevalence with the female having a 0.4 times more likely to have a higher prevalence of HBV than males, while among HIV negative participants, males are 2-3 times more likely have a significantly higher prevalence rate than the HIV negative females. As discussed above the HIV positive female is more likely to be HBV positive as well. HIV negative males are more likely to be HBV positive than HIV negative females, a situation that may be explained by other factors such as male sexual behavior of multiple sexual partners compared to women (Kinsey, 1979), thus exposing the male to greater chances of contracting HBV infection.

5.1.2 Association between HBV and HIV

A chi square test was conducted between HBV prevalence and HIV status. There was no association found. This is consistent with a study done in Tanzania to determine if there is an association between HIV status and HBV among different population groups. Though HBV and HIV have common risk factors, these studies show that having HBV doesn't increase chances of having HIV and vice versa.

However, HIV positive people have 3-6 times higher chance of progressing to chronic Hepatitis than HIV negative participants. (Kukka, 2004). Also patients who have HIV before they get HBV have a lower chance of clearing their Hepatitis B especially if they have severe immune deficiency (Levine OS et al, 1995).

5.1.3 Association of HBV and Various Socio-Demographic Characteristics

(a) Age.

There was a significant association of HBV prevalence and increasing age, meaning that older participants were more likely to have a positive marker for HBV ($p<0.01$). This is not surprising given that this study used previous and active HBV markers and would include cumulative figures. These findings are replicated in a study to determine the HBV prevalence in Kenya (Ogutu, 1990) (Greenfield et al., 1986). Another study in the USA showed that HBV infection was positively associated with older age (Samuel MC, Doherty PM, Bulterys M, Jenison SA et al, 2001).

(a) ***Education level.***

More than half (52%) of the discordant population in this study had attained primary education. The lowest prevalence of HBV was seen among those who have never been to school. This is in contrast to a study on the prevalence of HBV in Iran which showed that the level of education attained was inversely related to the prevalence of HBV infection (35% prevalence among illiterates and 15% prevalence among subjects with at least a high school education) (Amini, 1993). Similar findings to the Iran study were seen in yet another study where education level lower than secondary school was a risk factor for HBV acquisition (Vahid T, 2005).

More females showed a higher prevalence in those who have attained primary education, while for males, the highest prevalence was among those who have attained secondary and tertiary education. This may be explained by the fact that more females had attained up to primary level - 61.5%, compared to 36% of females with secondary and tertiary education. Similarly, more males had attained secondary and tertiary level education (53%) compared to those who attained only primary education (43%). However the difference in HBV prevalence and education level was not statistically significant.

(b) Employment state.

More females (38%) had no employment compared to males (2%). The highest prevalence of HBV was seen among those who are self-employed for both male and female**.** In a similar study, it seems that being unemployed was a marker of other factors (such as low socioeconomic status) and not in itself a direct risk factor (Vahid T, 2005). This therefore means that unemployment is not a risk factor for HBV acquisition.

The difference in HBV prevalence in this study was not significant.

(c) Marital status.

More than half (55.6%) of the study population was living together (co-habiting) without officially being married. A small proportion (2.2%) had married more than one partner. Co-habiting is a big factor for HIV infection as most co-habiting partners rarely use condoms

(KAIS, 2007). The survey stated that condom use at last sex was low among marital/cohabiting relationships with 4.2% and 5.9% condom use reported by women and men respectively. In contrast, among non-marital/non-cohabiting partnerships 35.7% and 52.6% condom use reported by women and men respectively.

The KAIS study findings were replicated in a behavioral survey in Uganda which noted that there are more cohabiting couples who are discordant for HIV than there are cohabiting couples who are both infected with HIV. This is because the vast majorities of these co-habiting couples do not mutually know their HIV status and are therefore not empowered to take action to prevent further spread of the disease (Uganda HIV/AIDS Sero-behavioural Survey, 2006.) By way of HBV being transmitted the same was as HIV, this poses as a significant factor to consider.

The difference in HBV prevalence in this study was not significant.

5.1.4 Knowledge of HBV

Knowledge on HBV is grossly inadequate with only 8% of the study population who had ever heard of HBV having adequate knowledge. Little data is available on knowledge of HBV among HIV discordant couples. Nonetheless, a study to determine knowledge of HBV among health care and public health professionals in China corroborated the findings in this study (Chao J, 2010). It found out that knowledge about HBV was inadequate, even among such highly trained health professionals. Chaos's results on knowledge of HBV agreed with the results acquired from the HIV discordant couples whereby 75% of 200 participants did not know that HBV infection is caused by a virus, and of those who thought they knew the cause of HBV, 14% gave the wrong answer. Similarly only 3% knew the modes of HBV transmission while only 11% knew prevention methods of HBV. An overwhelming 96% of the discordant couples did not have adequate knowledge on complications of HBV compared to 29% of the participants in the study conducted in China.

HIV positive participants had significantly higher HBV knowledge adequacy compared to HIV negative participants ($p<0.02$). However there was no significant difference in knowledge adequacy when cross tabulated with HBV status and sex ($p> 0.05$).

This may be explained by the source of knowledge as documented by the KAIS 2007 survey which found that among those who had heard of AIDS, 44.2% of women and 57.9% of men

reported the radio was their most common source of information on HIV/AIDS with an additional 24.5% of women and 17.5% of men reported they most often gathered information from service providers e.g. health workers and teachers (KAIS, 2007). HIV positive participants are more likely to be interested in HIV discussion and more likely to assimilate it than HIV negative participants. They are also more likely to have contact with a health worker or teacher. In the survey, those who self-reported as positive had significantly more adequate knowledge of HIV and other STIs (such as HBV) than those who self-reported as negative (KAIS, 2007) . Most information on HIV is nowadays coupled with information on sexually transmitted infections- one of which is HBV infection.

5.1.5 Sexual Behavior

This study looked at sexual partners and use of condoms by the study participants. No female HIV positive participant reported having a sexual partner other than the study partner. There was no significant difference in prevalence of HBV among participants with more than one sexual partner than those with only the study partner. On condom use, 7.5% HIV negative and 7.5% HIV positive participants reported that they never use condoms.

The findings are consistent with that of a Uganda survey of HIV discordant couples who did not use condoms despite knowledge of HIV discordance. The study found that of 36,000 couples tested, 96 percent of those in sexually active HIV discordant relationships did not use condoms during their last sexual encounter (Tumwesigye E et al., 2008.)

More HIV negative participants reported that they always use a condom compared to HIV positive participants who reported that they use a condom only sometimes.

There was no association between condom use and HBV prevalence. This compares with a study which showed that neither drug use nor sexual behavior appeared to be risk factors for Hepatitis infections (Nelson, 2008).

5.1.6 Risk Factors

The risk factors which were analyzed in this study include use of illicit injection drugs, sharing of needles and blood transfusion.

No females reported having ever used injection illicit drugs. The prevalence of HBV among those who reported that they have ever shared a needle was the same for HIV negative male, female and HIV positive females. It was highest at 0.6% among the HIV positive male. A study conducted to determine risk factors for HBV showed that blood transfusion, sharing of needles and use of illicit injection drugs contribute significantly to HBV infection (W O Phoon, 1998).

Of the participants who reported that they have ever had a blood transfusion, HBV prevalence was equal for both HIV negative and HIV positive females. Of the males who reported that they have ever had a blood transfusion, none had a positive marker for HBV. These findings concur with those from a study which showed that neither drug use nor sexual behavior appeared to be risk factors for Hepatitis infections (Nelson, 2008). There was no association between illicit injection drug use, sharing needles and blood transfusion and HBV status among the HIV discordant couples.

5.2 Conclusions

The overall HBV prevalence in this study was 31% with only 1% prevalence of active infection and 30% prevalence of previous infection. This study shows that there is no significant association between HBV prevalence and all socio-demographic characteristics with the exception of age. A significant association of age with HBV prevalence was found ($p<0.01$). However, there was no association between HBV and HIV status, risk factors, sexual behavior ($p>0.05$).

A couple of a HIV positive female and HIV negative male had a higher prevalence of HBV than a couple of a HIV negative female and a HIV positive male. This may be because females are more likely than males to get HIV infection and similarly HBV infection, due to physiological reasons, such as, the viral load in semen is higher than in vaginal mucus, the vaginal membrane is thinner than penile tissue, semen remains longer in the vagina and young women are more prone to micro lesions. Socio-economic reasons include having a greater likelihood to accept pain and discomfort, having social pressure to bear children, being vulnerable as adolescents, lacking knowledge in sexual issues, and being unable to express their opinions on these topics.

Knowledge of HBV was found to be grossly limited in the study population with a significant difference being witnessed between the HIV positive participants and HIV negative participants with more HIV positive participants(13%) than HIV negative participants (3.7%) having adequate knowledge of HBV infection ($p<0.05$). This may be explained by the fact that HIV positive participants have more contact with a health care worker who may educate the participant on HIV and STIs such as HBV.

5.3 Recommendations

Knowledge of HBV is exceptionally lacking with only 8% of the study population having adequate knowledge. It is therefore recommended that a lot more health education on HBV should be available to citizens. Since HBV is spread the same way as HIV, the prevention measures will be the same as for HIV and as such it will not be a financial impediment. The health education can be carried out at a national level under NASCOP with the use of the media, newspapers and magazines, as well at a local level in hospitals and health centers by well-informed health workers. Sexual education on HIV provided should include HBV infection, its complications, transmission and prevention measures. Emphasis should be given to the females as they are more vulnerable to sexually transmitted diseases due to their physical anatomy. This was evidenced by more HIV positive females having a marker for HBV in this study. Equally, they should be educated on ways of protecting themselves such use of condoms, in particular female condoms.

HIV positive patients should be routinely tested for HBV as treatment modalities are different for a HBV/HIV co-infected person. HBV vaccine should be available to all HIV positive people and their partners once they are tested for HIV. As the literature shows, HIV positive people co-infected with HBV have higher mortality and morbidity rates than those not co-infected with HBV, especially after starting HAART. This service should be extended to all the HIV discordant couples who have great benefit for preventive measures.

With the purpose of fully capturing the sexual behavior and risk factors, a more detailed prospective study should be undertaken to critically examine and correlate these co-factors with HBV prevalence. This would also determine any sero-conversion from HBV negative to HBV positive state of any of the couples. Similarly, a qualitative follow-up study on

knowledge, attitudes and practices among discordant couples to determine why HIV females have a higher prevalence of HBV as this study showed is recommended. Moreover, incorporation of HBV infection in subsequent national surveys such as the Kenya Aids Indicator Survey would provide much needed data to adequately inform policy makers, thereby paving the way for policy formulation and incorporation of best practices in the area of HIV/HBV management in Kenya.

In addition, a study whose research question is on the prevalence of HBV among HIV-1 discordant heterosexual couples may be done using ideal liver function tests and HBV diagnostic assays.

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APPENDICES

Appendix A- Questionnaire -English Version

(The information on Question 1-5 of this part will be extracted from the participants file)

1. Participant ID __ __/ __ __ __/ __ __

2. HIV status (Tick one)
(a)Positive
(b)Negative
3. HBV status (Tick one)
(a)Negative
(b)HBsAg Positive
(c)HBsAb Positive
4. Age (years) _____ _____
5. Sex (Tick one)
(a)Male
(b)Female

(The following questions are interviewer administered to the participants)

HIV and HBV status.
6. What is your HIV status?
(a) Positive
(b) Negative
(c) I don't know

7. What is your Hepatitis B Virus status?
(a) Positive
(b) Negative
(c) I don't know.

Socio demographic Characteristics
8. Where do you live?

_____

9. What is your education level? (Tick one)
(a) Never been to school
(b)Primary level
(c)Secondary level

(d)Tertiary Education

10. What is your occupation? (Tick one)

(a) Employed (i) Permanent employment

(ii) Casual employment

(b)Self-employed Specify_____

11. What type of marriage are you in? (Tick one)

(a) Married in church with one partner

(b) Married with more than one partner

(c) Co-habiting

(d) Customary Marriage

12. How long have you been with your study partner?

Specify_____

Knowledge of Hepatitis B

13. Have you ever heard of Hepatitis B infection?

(a) Yes (Go to question 14)

(b) No (Skip question 14)

14. When did you first hear about Hepatitis B infection?(Insert year) __ __ __ __

15. When did you first hear about HIV infection? (Insert year) __ __ __ __

16. What causes Hepatitis B infection? (Tick all that apply)

(a)Bacterial Infection (i) Yes (ii) No (iii) I don't know

(b)Viral Infection (i) Yes (ii) No (iii) I don't know

(c)Protozoa Infection (i) Yes (ii) No (iii) I don't know

(d)Fungal Infection (i) Yes (ii) No (iii) I don't know

(e)Other Specify_____

17. How is Hepatitis B acquired (Tick all that apply)

(a)Air borne (i) Yes (ii) No (iii) I don't know

(b)Blood and blood products (i) Yes (ii) No (iii) I don't know

(c)Sexually transmitted (i) Yes (ii) No (iii) I don't know

(d)Deep kissing (i) Yes (ii) No (iii) I don't know

(e)Sharing utensils (i) Yes (ii) No (iii) I don't know

(f)Sharing injections (i) Yes (ii) No (iii) I don't know
(g)Mother to child transmission (i) Yes (ii) No (iii) I don't know
(h)Other Specify_____

18. How can HBV infection be prevented (Mark all that apply)
(a) Wearing a condom with every sexual contact(i) Yes (ii) No (iii) I don't know
(b)Isolating utensils (i) Yes (ii) No (iii) I don't know
(c)Vaccination (i) Yes (ii) No (iii)I don't know
(d)Not sharing needles (i) Yes (ii) No (iii) I don't know
(e)Screening before blood transfusion (i) Yes (ii) No (iii) I don't know
(f)Antiviral treatment to those with HBV (i) Yes (ii) No (iii) I don't know
(g)Other
Specify_____

19. Which organ in the body is affected by HBV? (Tick all that apply)
(a)Heart (i) Yes (ii) No (iii) I don't know
(b)Liver (i) Yes (ii) No (iii) I don't know
(c)Kidneys (i) Yes (ii) No (iii) I don't know
(d)Other Specify_____

20. What are the complications of HBV infection (Tick all that apply)
(a)TB (i) Yes (ii) No (iii) I don't know
(b)Meningitis (i) Yes (ii) No (iii) I don't know
(c)Liver cancer (i) Yes (ii) No (iii) I don't know
(d)HIV (i) Yes (ii) No (iii) I don't know
(e)Other Specify_____

Risk factors
21. Have you ever used injection illicit drugs?
(a) Yes
(b) No

22. Have you ever shared a needle? (Tick one)
(a)Yes
(b)No

23. Have you ever had a blood transfusion? (Tick one)
(a)Yes
(b)No

Sexual behavior

24. How many times have you had sex in the past one month?

(a)With spouse only Specify._____

(b) With other partner Specify._____

25. How many sexual partners have you had in the last one month?

(a) Spouse only

(b) Other partners Specify._____

26. How many sexual partners have you had since 2005?

(a) Spouse only

(b) Other partners Specify._____

Question 27, 28 and 29 are interview administered to the Index participant only.

27. How often do you use a condom since you were diagnosed with HIV (Tick one)

(a)Always

(b)Sometimes

(c)Never (Skip to question 29)

28. Which type of condom do you use?

(a) Male condom

(b)Female condom

29. How many sexual partners have you had since diagnosis with HIV (Tick one)

(a) Spouse only

(b) Other partners Specify._____

Questions 30, 31 and 32 are interview administered to the Partner participant only.

30. How often do you use a condom since knowledge of discordance? (Tick one)

(a) Always

(b)Sometimes

(c)Never (Skip to question 32)

31. Which type of condom do you use?

(a) Male condom

(b)Female condom

32. How many sexual partners have you had since knowledge of discordance.(Tick one)

(a) Spouse only

(b) Other partners Specify._____

Appendix B- Questionnaire- Kiswahili Version

(Habari kuhusu Swali 1-5 wa sehemu hii kutolewa kutoka faili ya washiriki)
1. ID ya mshiriki __ __ / __ __ __ / __ __

2. Hali ya HIV (Weka alama moja)
(a) Positive
(b) Negative
3. Hali ya HBV (Weka alama moja)
(a) Negative
(b) HBSag Positive
(c) HBSab Positive
4. Umri (miaka) _____ _____
5. Jinisia (Weka alama moja)
(a) Mwanaume
(b) Mwanamke

(Maswali yafuatayo yataulizwa washiriki)
Hali ya HIV na HBV
6. Hali yako ya HIV ni gani?
(a) Positive
(b) Negative
(c) Sijui

7. Hali yako ya Hepatitis B ni gani
(a) Positive
(b) Negative
(c) Sijui.

Kijamii, kidemografia na tabia
8. Unaishi Wapi? _____

9 Umeelimika mpaka kiwango gani? (Weka alama moja)
(a) Sijaenda shule
(b) Msingi
(c) Sekondari
(d) Elimu ya chuo kikuu
10. Unafanya kazi gani? (Weka alama moja)
(a) Kuajiriwa (i) Kazi ya kudumu
(ii) Kibarua
(b) Kujiajiri Eleza_____

11. Uko kwenye ndoa ya aina gani? (Weka alama moja)
(a) Walioolewa kwa mpenzi moja kanisani.
(b) Walioolewa zaidi ya mpenzi mmoja
(c) Kuishi pamoja
(d) Ndoa ya mila

12. Umekuwa na mpenzi wako miaka mingapi? Eleza. _____

Ujuzi wa ugonjwa wa Hepatitis B

13. Je, umewahi kusikia juu ya ugonjwa wa Hepatitis B?
(a) Ndio (Nenda Swali 14)
(b) La (Ruka swali 14)

14. Mara yako ya kwanza kusikia kuhusu maambukizi ya Hepatitis B ilikuwa lini? (Andika mwaka) __ __ __ __.

15. Mara yako ya kwanza kusikia kuhusu maambukizi ya virusi vya HIV ilikuwa lini? (Andika mwaka) __ __ __ __

16. Nini husababisha maambukizi ya Hepatitis B? (Weka alama zote zinazotumika)

(a) Maambukizi ya bakteria	(i) Ndio	(ii) La	(iii) Sijui
(b) Maambukizi ya virusi	(i) Ndio	(ii) La	(iii) Sijui
(c) Maambukizi ya protozoa	(i) Ndio	(ii) La	(iii) Sijui
(d) Maambukizi ya vimelea	(i) Ndio	(ii) La	(iii) Sijui
(e) Nyingine	Eleza_____		

17. Je, Hepatitis B inaambukizwa kwa njia gani? (Weka alama zote zinazotumika)

(a) Angani	(i) Ndio	(ii) La	(iii) Sijui
(b) Damu na bidhaa za damu	(i) Ndio	(ii) La	(iii) Sijui
(c) Kwa njia ya ngono	(i) Ndio	(ii) La	(iii) Sijui
(d) Kubusu	(i) Ndio	(ii) La	(iii) Sijui
(e) Kutumiana vyombo na mgonjwa	(i) Ndio	(ii) La	(iii) Sijui
(f) Kutumia sindano moja na mgonjwa	(i) Ndio	(ii) La	(iii) Sijui
(g) Mama kwa mtoto wake	(i) Ndio	(ii) La	(iii) Sijui
(h) Nyingine	Eleza_____		

18. Ni kwa njia gani ambazo unaweza kuzuia kuenea kwa ugonjwa wa Hepatitis B? (Weka alama kwa zote zinazotumika)

(a) Kuvaa kondomu kila wakati	(i) Ndio	(ii) La	(iii) Sijui
(b) Kutotumia vyombo pamoja na mgonjwa	(i) Ndio	(ii) La	(iii) Siju
(c) Chanjo	(i) Ndio	(ii) La	(iii) Sijui
(d) Kutotumia sindano moja pamoja na mtu mwingine	(i) Ndio	(ii) La	(iii) Sijui
(e) Kupima damu kabla ya kuongezewa damu	(i) Ndio	(ii) La	(iii) Sijui
(f) Matibabu kwa wale walio na Hepatitis B.	(i) Ndio	(ii) La	(iii) Sijui
(g) Nyingine	Eleza_____		

19. Ni kiungo kipi mwilini kinachoathiriwa na ugonjwa wa Hepatitis B?(Weka alama zote zinazotumika)

(a) Moyo	(i) Ndio	(ii) La	(iii) Sijui
(b) Ini	(i) Ndio	(ii) La	(iii) Sijui
(c) Figo	(i) Ndio	(ii) La	(iii) Sijui

(d) Nyingine Eleza_____

20. Je, ni madhara gani yanayotokana na ugonjwa wa HBV?
(Weka alama zote zinazotumika)

(a) Kifua Kikuu	(i) Ndio	(ii) La	(iii) Sijui
(b) Meningitis	(i) Ndio	(ii) La	(iii) Sijui
(c) Kansa ya Ini	(i) Ndio	(ii) La	(iii) Sijui
(d) Ukimwi	(i) Ndio	(ii) La	(iii) Sijui

(e) Nyingine Eleza_____

Tabia zinazoongeza uwezekano wa kupata ugonjwa wa hepatitis.

21. Je, umewahi kutumia madawa ya kulevya ya sindano?
(a)Ndio
(b) La

22. Je, umewahi kutumia sindano moja pamoja na mtu mwingine? (Weka alama moja)
(a) Ndio
(b) La

23. Umewahi kuongezewa damu? (Weka alama moja)
(a) Ndio
(b) La

Uhusiano wa kimwili.

24. Umefanya mapenzi mara ngapi katika kipindi cha mwezi mmoja?
(a) Mume ama mke wako tu Andika mara ngapi._____
(b) Wapenzi wengine Andika mara ngapi._____

25. Umekuwa na wapenzi wangapi katika mda wa mwezi mmoja uliopita?
(a)Mume ama mke tu.
(b)Wapenzi wengine Andika wangapi._____

26. Umekuwa na wapenzi wangapi tangu 2005?
(a) Mume ama mke tu
(b) Wapenzi wengine Andika wangapi._____

Swali 27, 28 na 29 yataulizwa kwa <u>mshiriki Index</u> tu.

27. Unatumia kondomu mara ngapi tangu utambuliwe na virusi vya HIV? (Weka alama moja)
(a) Kila wakati
(b) Wakati mwingine
(c) Sijawahi tumia (Ruka hadi swali 29)

28. Unatumia aina gani ya kondomu?
(a) Kondomu ya kiume
(b) Kondomu ya kike

29. Umekuwa na wapenzi wangapi tangu utambuliwe uko na virusi vya HIV? (Weka alama moja)
(a) Mume au mke tu
(b) Wapenzi wengine Andika wangapi._____

Maswali 30, 31 na 32 yataulizwa kwa <u>mshiriki Partner</u> tu.

30. Unatumia kondomu mara ngapi tangu utambuwe kwamba mpenzi wako ako na virusi vya HIV? (Weka alama moja)
(a) Kila wakati
(b) Wakati mwingine
(c) Sijawai tumia (Ruka hadi swali 32)

31. Unatumia aina gani ya kondomu?
(a) Kondomu ya kiume
(b) Kondomu ya kike

32. Umekuwa na wapenzi wangapi tangu utambuwe kwamba mpenzi wako ako na virusi vya HIV? (Weka alama moja)
(a) Mume au mke tu
(b) Wapenzi wengine Andika wangapi._____

Appendix C- Informed Consent Form

TITLE	PREVALENCE AND CO-FACTORS OF PREVIOUS OR ACTIVE HEPATITIS B INFECTION AMONG HIV-1 DISCORDANT HETEROSEXUAL COUPLES					
SCOPE	This informed consent form is for enrolled participants in the Pre-exposure Prophylaxis study, and will be read to them by a qualified counselor before answering the questionnaire.					
VERSION	1.0	DATE	12TH APRIL 2010	SITES	NAIROBI.	THIKA.

Investigator: Dr. Esther N. Njuguna,

Tel 0721-514509, Email: nyamz39@yahoo.com

Address- 59791-00200 Nairobi, Kenya

Sponsor: Dr. Esther N. Njuguna,

This Informed Consent Form has two parts:

• Information Sheet (to share information about the study with you)

• Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form.

Part 1: Information Sheet

Introduction

The study is a partial requirement for the Masters in Public Health from the University of Nairobi. It will be conducted in Nairobi and Thika clinics and will take approximately 9 months including the duration it will take from collection of data and data analysis. This study is nested within the Partners Pre-Exposure Prophylaxis study.

You will be given information and invited to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please the counselor to stop as you go through the information and they will take time to explain. If you have questions later, you can call the investigator at any time.

Purpose of the study

The study primarily aims to determine the number of people with HIV and Hepatitis Infection and the knowledge they have of Hepatitis infection. It also aims to determine their socio-demographic characteristics, if there is any association between HIV and Hepatitis B infection and different sexual and risk behavior.

This knowledge will help us in making certain recommendations regarding HIV and Hepatitis B co-infection so as to improve health care.

Type of Research Intervention

This research will involve your participation on a one-on –one questionnaire interview with a qualified counselor and will take about twenty minutes of your time.

Participation Selection

You are being invited to take part in this research because we feel that your experience as part of a HIV discordant couple can contribute much to our understanding and knowledge of HIV/Hepatitis B co-infection. Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change. You are free to decline participation of this study at any time.

Procedures

You will be provided with a questionnaire. You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer for the counselor to write it down. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except the research investigators have access to your details. The interview will take place in the study clinic where the Pre-exposure prophylaxis study is currently taking place.

No samples will be collected for this study.

Duration

The study will take nine months during which time we will collect and analyze the data. Following the interview, no other follow-up will be done. However, you will be notified of the results once the study is finalized.

Risks

We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the interview. If you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question or for refusing to take part in the interview.

Benefits

There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent HIV/Hepatitis B co-infection in the community.

Confidentiality

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the research team who will have access to the information.

Sharing Results

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and other HIV- discordant couples in the parent study before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.

Who to contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Dr. Esther N. Njuguna Tel: 0721-514509,

Email nyamz39@yahoo.com

Dr. J. Kiarie Tel: 0733-377128,

Email jkiarie@swiftkenya.com

Principal Investigator Pre-Exposure Prophylaxis Study- Nairobi

Dr. Nelly Mugo Tel-072-3914057

Email rwamba@csrtkenya.org

Principal Investigator Pre-Exposure Prophylaxis Study- Thika.

This proposal has been reviewed by the Kenyatta National Hospital/University of Nairobi Ethics and Review Committee (KNH/UON ERC) which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact

The Chairman,

Kenyatta National Hospital/University of Nairobi Ethics and Review Committee

P.O.BOX 20723

Nairobi, Kenya.

Part II: Certificate of consent.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate 1

1 A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ Thumbprint of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that a questionnaire will be administered to the participant.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____(Day/month/year)

Appendix D-Dummy Tables For Data Analysis

Table 5.1: Socio-demographic characteristics Among HIV–1 discordant couples.

Characteristics (Modified from Kenya Aids Indicator Survey 2007)	Male				Female			
	Index		Partner		Index		Partner	
	HIV + HBV+	HIV+ HBV-	HIV- HBV+	HIV- HBV-	HIV + HBV+	HIV+ HBV-	HIV- HBV+	HIV- HBV-
Age n=322 <24 25-34 35-44 45-54 55-64								
Sex n=322 Male Female								
Education Level n=322 Never been to school Primary level Secondary level Tertiary Education								
Marital Status n=322 Married with one partner Married with more than one partner Co-habiting								

Occupation n=322 Employed Self employed Other								

Table 5.2: Knowledge and sexual behavioral characteristics among HIV–1 discordant couples.

Characteristics (Modified from Kenya Aids Indicator Survey 2007)	Male				Female			
	Index		Partner		Index		Partner	
	HIV + HBV+	HIV+ HBV-	HIV- HBV+	HIV- HBV-	HIV + HBV+	HIV+ HBV-	HIV- HBV+	HIV- HBV-
<u>Knowledge of HBV and transmission =322</u> <20% 21-40% 41-60% 61-80% 81-100%								
<u>Risk Factors n=322</u> Shared a needle Never shared a needle Have had a blood transfusion								
<u>Sexual behavior n=322</u> (a)Partners since diagnosis • Spouse only • 2 partners								

• 3 partners • >3 partners (b) Use of condoms since knowledge of HIV(Index) n=161 • Always • Sometimes • Never (c) Use of condoms since knowledge of discordance n=161 (Partner) • Always • Sometimes • Never								

Table 5.3: Chi square table of analysis of socio demographic characteristics and HBV Prevalence

Characteristics (Modified from Kenya Aids Indicator Survey 2007)	Male HBV Prevalence		Female HBV Prevalence	
	Index	Partner	Index	Partner
Age n=322 <24 25-34 35-44 45-54 55-64				
Sex n=322 Male Female				
Education Level n=322 Never been to school Primary level Secondary level Tertiary Education				
Marital Status n=322 Married with one partner Married with more than one partner Co-habiting				
Occupation n=322 Employed Self employed Other				

Table 5.4: Chi square table of analysis of knowledge and sexual behavioral characteristics and HBV Prevalence

Characteristics (Modified from Kenya Aids Indicator Survey 2007)	Male HBV Prevalence				Female HBV Prevalence			
	Index		Partner		Index		Partner	
<u>Knowledge of HBV and transmission =322</u> <20% 21-40% 41-60% 61-80% 81-100%								
<u>Risk Factors n=322</u> Shared a needle Never shared a needle Have had a blood transfusion								
<u>Sexual behavior n=322</u> (a)Partners since diagnosis • Spouse only • 2 partners • 3 partners • >3 partners (b) Use of condoms since knowledge of HIV(Index) n=161 • Always								

• Sometimes • Never (c) Use of condoms since knowledge of discordance n=161 (Partner) • Always • Sometimes • Never								

Appendix E: Study Work Plan

This study was scheduled for 8 months in 2010, during which period the following plan was followed.

	Jan	Feb	March	Apr	May	June	July	Aug	Sept	Oct.
Proposal writing	❖									
Submission to ERC		❖	❖	❖						
Feasibility Study and testing of tools, training of research assistants				❖						
Data collection and data clean up.				❖	❖	❖	❖	❖	❖	
Data analysis									❖	
Report writing										❖
Submission of report.										❖

Table 5.5: Table showing work plan for the study.

Appendix F- Budget Estimation

Table 5.6: Table showing budget estimation for the study.

Description	Amount	Quantity	Total
Transport to Thika	Kshs 200	15 trips (to and fro)	6,000
Printing of questionnaires	Kshs 5 per page	4 pages per questionnaire for 322 questionnaires	6,440
Salaries of assistant data collectors	Kshs 100 per questionnaire	322 questionnaires	32,200
Supervisors allowance	Kshs 5000	3	15,000
Use of computer software Epi Info and SPSS	Kshs 10,000	1	10,000
Data analysis and presentation	15,000	1 data assistant	15,000
Emergency Money	20,000	-	20,000
Total Amount			104,640

Material support and equipment included a computer fully supported by a windows operating system with software in STATA version 11.1 and Access data base.

Appendix G- Knowledge Of HBV on Specific Questions Asked.

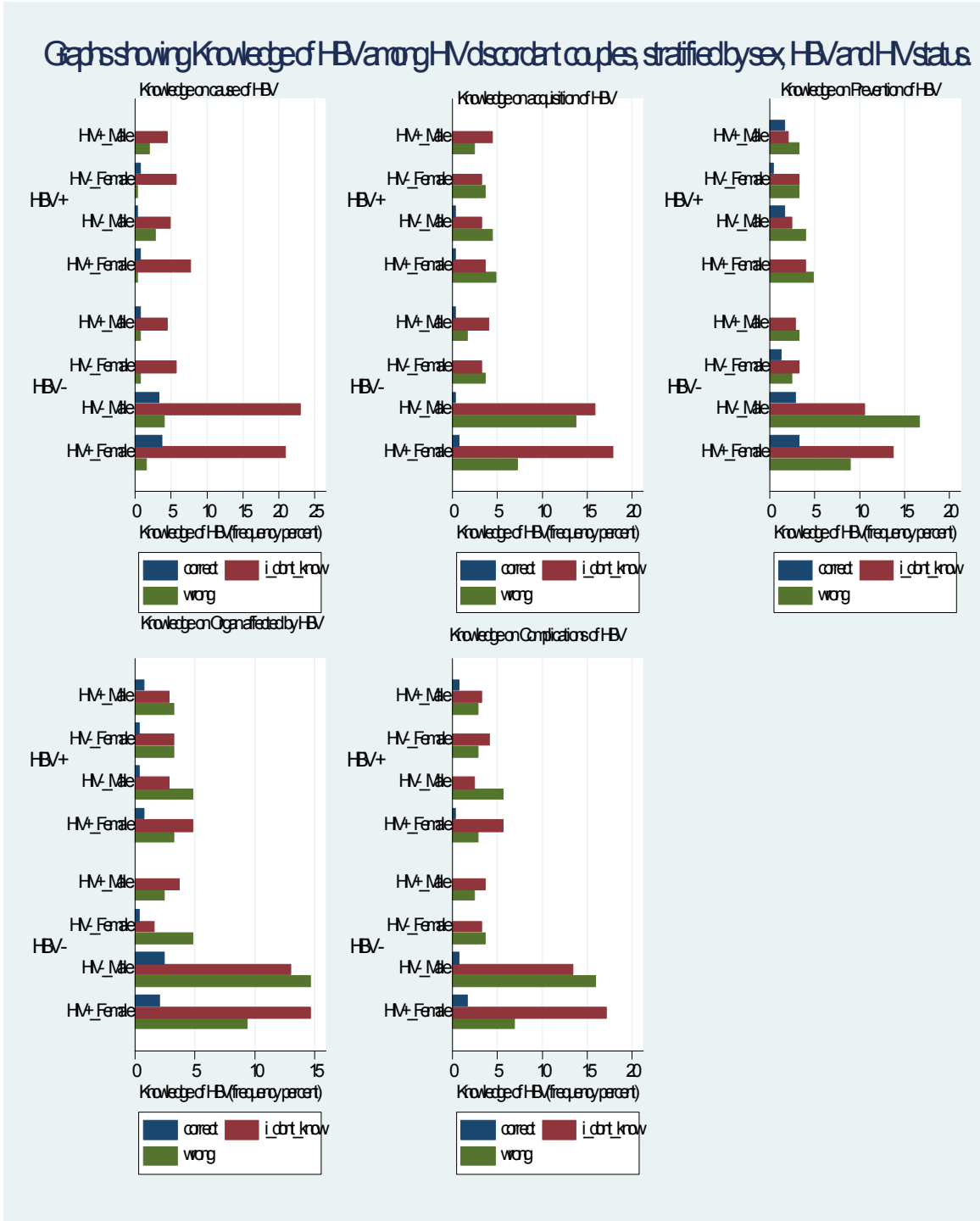

Figure 5.1: Graphs showing knowledge of HBV, stratified by sex, HBV status and HIV status.

Appendix H- Enrollment Numbers and Dates

Enrollment Number	Date
51/331/06	**30/8/2010**
51/331/14	30/8/2010
51/028/07	30/8/2010
51/028/18	30/8/2010
51/316/06	30/8/2010
51/316/10	30/8/2010
51/372/15	30/8/2010
51/372/03	30/8/2010
51/376/07	31/8/2010
51/376/18	31/8/2010
51/435/03	31/8/2010
51/435/15	31/8/2010
51/415/13	31/8/2010
51/415/08	31/8/2010
51/123/09	31/8/2010
51/123/11	31/8/2010
51/212/00	31/8/2010
51/212/17	31/8/2010
51/409/17	30/8/2010
51/409/00	30/8/2010
51/436/19	31/8/2010
51/436/04	31/8/2010
51/395/02	1/9/2010
51/395/16	1/9/2010
51/078/19	1/9/2010
51/078/04	1/9/2010
51/351/10	1/9/2010
51/351/05	1/9/2010
51/192/12	1/9/2010
51/192/01	1/9/2010
51/003/08	1/9/2010
51/003/13	1/9/2010
51/257/04	1/9/2010
51/257/19	1/9/2010
51/098/06	1/9/2010
51/098/14	1/9/2010
51/062/18	1/9/2010
51/062/07	1/9/2010

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51/378/05	1/9/2010
51/378/10	1/9/2010
51/315/14	1/9/2010
51/315/06	1/9/2010
51/295/06	2/9/2010
51/295/14	2/9/2010
51/007/06	2/9/2010
51/007/14	2/9/2010
51/379/02	2/9/2010
51/379/16	2/9/2010
51/380/11	2/9/2010
51/380/09	2/9/2010
51/317/00	3/9/2010
51/317/17	3/9/2010
51/356/16	3/9/2010
51/356/02	3/9/2010
51/439/10	3/9/2010
51/439/05	3/9/2010
51/146/18	6/9/2010
51/146/07	6/9/2010
51/052/10	6/9/2010
51/052/05	6/9/2010
51/381/17	6/9/2010
51/381/00	6/9/2010
51/111/15	6/9/2010
51/111/03	6/9/2010
51/345/13	6/9/2010
51/345/08	6/9/2010
51/010/14	6/9/2010
51/010/06	6/9/2010
51/403/07	6/9/2010
51/403/18	6/9/2010
51/110/16	6/9/2010
51/110/02	6/9/2010
51/128/13	6/9/2010
51/128/08	6/9/2010
51/440/03	6/9/2010
51/440/15	6/9/2010

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51/094/17	7/9/2010	**51/365/03**	10/9/2010
51/100/11	7/9/2010	**51/199/10**	13/6/2010
51/100/09	7/9/2010	**51/199/05**	13/9/2010
51/108/19	7/9/2010	**51/285/00**	13/9/2010
51/108/04	7/9/2010	**51/285/10**	13/9/2010
51/220/14	7/9/2010	**51/404/08**	13/9/2010
51/220/06	7/9/2010	**51/404/13**	13/9/2010
51/384/05	7/9/2010	**51/319/04**	13/9/2010
51/384/10	7/9/2010	**51/319/19**	13/9/2010
51/377/13	8/9/2010	**51/269/03**	13/9/2010
51/377/08	8/9/2010	**51/269/15**	13/9/2010
51/087/08	8/9/2010	**51/113/18**	14/9/2010
51/087/13	8/9/2010	**51/113/07**	14/9/2010
51/320/16	8/9/2010	**51/059/01**	14/9/2010
51/320/02	8/9/2010	**51/059/12**	14/9/2010
51/093/05	9/9/2010	**51/420/07**	14/9/2010
51/093/10	9/9/2010	**51/420/18**	14/9/2010
51/131/10	9/9/2010	**51/325/05**	14/9/2010
51/131/05	9/9/2010	**51/325/10**	14/9/2010
51/243/15	9/9/2010	**51/116/14**	15/9/2010
51/243/03	9/9/2010	**51/116/06**	15/9/2010
51/114/13	9/9/2010	**51/421/04**	15/9/2010
51/114/08	9/9/2010	**51/421/19**	15/9/2010
51/195/03	9/9/2010	**51/148/10**	15/9/2010
51/195/15	9/9/2010	**51/148/05**	15/9/2010
51/224/04	10/9/2010	**51/069/04**	15/9/2010
51/224/18	10/9/2010	**51/069/19**	15/9/2010
51/302/05	10/9/2010	**51/149/16**	15/9/2010
51/302/10	10/9/2010	**51/149/02**	15/9/2010
51/342/02	10/9/2010	**51/274/09**	15/9/2010
51/342/16	10/9/2010	**51/274/11**	15/9/2010
51/222/01	10/9/2010	**51/150/08**	15/9/2010
51/222/12	10/9/2010	**51/150/13**	15/9/2010
51/266/11	10/9/2010	**51/057/03**	16/9/2010
51/266/09	10/9/2010	**51/057/15**	16/9/2010
51/324/18	10/9/2010	**51/363/17**	16/9/2010
51/324/08	10/9/2010	**51/363/00**	16/9/2010
51/364/07	10/9/2010	**51/327/04**	16/9/2010
51/364/18	10/9/2010	**51/327/19**	16/9/2010

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51/109/08	16/9/2010	**53/392/00**	23/9/2010
51/109/13	16/9/2010	**53/392/17**	23/9/2010
51/392/13	16/9/2010	**53/278/07**	23/9/2010
51/392/08	16/9/2010	**53/278/18**	23/9/2010
51/155/04	16/9/2010	**53/317/03**	23/9/2010
51/155/19	16/9/2010	**53/317/15**	23/9/2010
53/048/07	20/9/2010	**53/277/05**	23/9/2010
53/048/18	20/9/2010	**53/277/10**	23/9/2010
53/210/00	20/9/2010	**53/432/06**	23/9/2010
53/210/17	20/9/2010	**53/432/14**	23/9/2010
53/146/10	20/9/2010	**53/217/13**	23/9/2010
53/146/05	20/9/2010	**53/217/08**	23/9/2010
53/069/01	20/9/2010	**53/467/08**	23/9/2010
53/069/12	20/9/2010	**53/467/13**	23/9/2010
53/400/04	22/9/2010	**53/427/07**	23/9/2010
53/400/19	22/9/2010	**53/427/18**	23/9/2010
53/147/00	22/9/2010	**53/388/12**	23/9/2010
53/147/17	22/9/2010	**53/388/01**	23/9/2010
53/231/01	22/9/2010	**53/216/07**	24/9/2010
53/231/12	22/9/2010	**53/216/18**	24/9/2010
53/330/17	22/9/2010	**53/443/02**	24/9/2010
53/330/00	22/9/2010	**53/443/16**	24/9/2010
53/073/18	22/9/2010	**53/280/06**	24/9/2010
53/073/07	22/9/2010	**53/280/14**	24/9/2010
53/318/00	22/9/2010	**53/215/12**	24/9/2010
53/318/17	22/9/2010	**53/215/01**	24/9/2010
53/173/13	22/9/2010	**53/331/09**	24/9/2010
53/173/08	22/9/2010	**53/331/11**	24/9/2010
53/387/19	22/9/2010	**53/281/13**	24/9/2010
53/387/04	22/9/2010	**53/281/08**	24/9/2010
53/076/06	23/9/2010	**53/468/05**	24/9/2010
53/076/14	23/9/2010	**53/468/10**	24/9/2010
53/259/15	23/9/2010	**53/431/17**	24/9/2010
53/259/03	23/9/2010	**53/431/09**	24/9/2010
53/276/15	23/9/2010	**53/036/11**	24/9/2010
53/276/03	23/9/2010	**53/036/09**	24/9/2010
53/389/17	23/9/2010	**53/214/19**	24/9/2010
53/389/00	23/9/2010	**53/214/04**	24/9/2010
53/391/06	23/9/2010	**53/092/05**	27/9/2010
53/391/14	23/9/2010	**53/092/19**	27/9/2010

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53/218/05	27/9/2010	**53/304/11**	4/10/2010
53/218/10	27/9/2010	**53/304/09**	4/10/2010
53/332/15	27/9/2010	**53/230/10**	4/10/2010
53/332/03	27/9/2010	**53/230/05**	4/10/2010
53/149/04	28/9/2010	**53/300/10**	4/10/2010
53/149/19	28/9/2010	**53/300/05**	4/10/2010
53/053/04	28/9/2010	**53/163/12**	4/10/2010
53/053/19	28/9/2010	**53/163/01**	4/10/2010
53/324/00	28/9/2010	**53/109/00**	5/10/2010
53/324/17	28/9/2010	**53/109/17**	5/10/2010
53/284/07	28/9/2010	**53/399/09**	5/10/2010
53/284/18	28/9/2010	**53/399/11**	5/10/2010
53/333/14	28/9/2010	**53/344/03**	5/10/2010
53/333/06	28/9/2010	**53/344/15**	5/10/2010
53/018/04	28/9/2010	**53/341/05**	5/10/2010
53/018/19	28/9/2010	**53/341/10**	5/10/2010
53/078/01	28/9/2010	**53/309/14**	5/10/2010
53/078/12	28/9/2010	**53/309/06**	5/10/2010
53/141/16	28/9/2010	**53/345/17**	6/10/2010
53/141/02	28/9/2010	**53/345/00**	6/10/2010
53/470/06	28/9/2010	**53/024/04**	6/10/2010
53/470/14	28/9/2010	**53/024/19**	6/10/2010
53/390/13	28/9/2010	**53/478/02**	6/10/2010
53/390/08	28/9/2010	**53/478/16**	6/10/2010
53/079/00	28/9/2010	**53/313/16**	7/10/2010
53/079/17	28/9/2010	**53/313/02**	7/10/2010
53/080/03	30/9/2010	**53/394/02**	7/10/2010
53/080/15	30/9/2010	**53/394/16**	7/10/2010
53/334/19	30/9/2010	**53/007/09**	8/10/2010
53/334/04	30/9/2010	**53/007/11**	8/10/2010
53/151/09	30/9/2010	**53/424/11**	8/10/2010
53/151/11	30/9/2010	**53/424/09**	8/10/2010
53/335/12	30/9/2010	**53/273/01**	11/10/2010
53/335/01	30/9/2010	**53/273/12**	11/10/2010
53/433/15	30/9/2010	**53/316/13**	12/10/2010
53/433/03	30/9/2010	**53/316/08**	12/10/2010
53/244/08	30/9/2010	**53/171/10**	13/10/2010
53/244/13	30/9/2010	**53/171/05**	13/10/2010
53/162/17	4/10/2010	**53/275/19**	13/10/2010
53/162/00	4/10/2010	**53/275/04**	13/10/2010

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53/404/00	14/10/2010
53/404/17	14/10/2010
53/224/05	15/10/2010
53/224/10	15/10/2010
53/479/10	15/10/2010
53/479/05	15/10/2010

Appendix I- Correct Responses to Questions on Knowledge of HBV

The text box below summarizes the questions and correct responses as asked to the participants.

Data in context.

Assessment of HBV knowledge based on the correct response to the following questions.

Category	Question	Correct Response
(1) Cause of HBV	What causes Hepatitis B infection	Viral Infection
(2) Acquisition of HBV	How is Hepatitis B acquired	Blood and blood products Sexually transmitted Deep kissing Mother to child transmission
(3) Prevention of HBV	How can HBV infection be prevented	Wearing a condom with every sexual contact Vaccination Not sharing needles Screening before blood transfusion Antiviral treatment to those with HBV
(4) Organ affected	Which organ in the body is affected by HBV?	Liver
(5) Complications of HBV.	What are the complications of HBV infection	Liver cancer