# Risk of HIV Infection among Men Aged 50 to 75 Years Using Erectile Dysfunction Drugs Attending Kenyatta National Hospital

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## DECLARATION

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

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## DEDICATION

I dedicate this work to the glory of the Almighty God who opens doors for me when hopelessness surrounds me. I also dedicate this research paper to my parents for giving me relentless support and hope to finish this paper. I sincerely thank them for their support through out my study. May God reward them abundantly.

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **AIDS** | Acquired Immunodeficiency Syndrome |
| **CCC** | Comprehensive Care Center |
| **CDC** | Center for Disease Control |
| **cGMP** | cyclic Guanosine Monophosphate |
| **CI** | Confidence Interval |
| **ED** | Erectile Dysfunction |
| **EDD** | Erectile Dysfunction Drug |
| **EDMs** | Erectile Dysfunction Medications |
| **EMEA** | European Medicines Agency |
| **ERC** | Ethical Review Committee |
| **FDA** | Food and Drug Administration |
| **JKUAT** | Jomo Kenyatta University of Agriculture and Technology |
| **HIV** | Human Immunodeficiency Virus |
| **KDHS** | Kenya Demographic and Health Survey |
| **KEMRI** | Kenya Medical Research Institute |
| **KNH** | Kenyatta National Hospital |
| **MoH** | Ministry of Health |
| **MMAS** | Massachusetts Male Aging Study |
| **MSM** | Men Who Have Sex with Men |
| **NASCOP** | National AIDS and STI Control Programme |

| | |
|---|---|
| **NHSLS** | National Health and Social Life Survey |
| **OM** | Older Men |
| **OR** | Odds Ratio |
| **PDE-5** | Phosphodiesterase type 5 |
| **SD** | Standard Deviation |
| **SPSS** | Statistical Package for Social Sciecnes |
| **SSA** | Sub-Saharan Africa |
| **STDs** | Sexually Transmitted Diseases |
| **STI** | Sexually Transmitted Infection |
| **UNAIDS** | United Nation Program on HIV/AIDS |
| **US** | United States |
| **USA** | United States of America |
| **VCT** | Voluntary Counseling and Testing |
| **WHO** | World Health Organization |

## DEFINITION OF OPERATIONAL TERMS

| | |
|---|---|
| **Cases:** | Men aged between 50 and 75 years, who were diagnosed as HIV sero positives at the VCT and HIV positive at CCC of Kenyatta National Hospital. |
| **Controls:** | Men aged between 50 and 75 years, who came for HIV counseling and testing and other purposes to the Hospital, and diagnosed as HIV sero-negatives. |
| **Erectile dysfunction**: | The inability to develop and maintain an erection for satisfactory sexual intercourse or activity in the absence of an ejaculatory disorder such as premature ejaculation. |
| **Erectile dysfunction drugs**: | Drugs that are used for sexual enhancement in erectile dysfunction men by inhibiting the phosphodiesterase type 5 inhibitors (PDE5) enzyme. |
| **Men having sex with men:** | Gays and bisexual men, as well as men who may not identify as gay/bisexual but engage in sexual activity with same-sex partners. |
| **Older men:** | Men aged 50 years and above. |
| **Phosphodiesterase-5 inhibitor:** | Category of drugs that relieve erectile dysfunction (impotence) in men. |
| **HIV:** | Human immunodeficiency virus, a retrovirus that causes AIDS. |

## ABSTRACT

Erectile dysfunction drug (EDD) use has gained popularity among older men for enhancement and treatment of erectile dysfunction in recent years. Increased number of sexual partners and sexual activity due to EDD use concerns about the rising rate of HIV infection among older men. Men who use EDD for erectile dysfunction are found to be two to three times more likely to have sexually transmitted diseases, particularly HIV than non-users. In Kenya, the prevalence of HIV among men of age 50 to 54 years has increased from 5.7% in 2003 to 9.1% in 2008/09. This study aimed at determining the association between EDD use and risk of HIV infection among men aged 50 to 75 years. Unmatched case-control study was conducted among men of 137 HIV positive (cases) and 137 HIV negative (controls). A pre-tested semi-structured questionnaire was administered where information regarding socio-demographic characteristics, EDD use, sexual behavior, and confounding factors in EDD use and HIV infection were collected. Pearson's chi-square test (P-value <0.05) and odds ratio with corresponding 95% confidence interval were computed to establish the association between the dependent variable (HIV status) and independent variables (Key independent variable being EDD use). Binary logistic regression analysis was performed to adjust for confounding factors in the relationship between HIV status and EDD use.

Out of 137 cases, 18(13.1%) used EDD before they tested HIV +ve compared to 8(5.8%) of the controls. Even though the use of erectile dysfunction drugs was found to be significantly associated with serum HIV positivity in bivariate analysis (OR= 2.44; 95%CI: 1.04-5.93; P=0.039), it was not significant after adjustment for other factors at the multivariate analysis (AOR=1.52; 95%CI: 0.43-5.34; P=0.519). Multiple logistic regression revealed the following factors as independent predictors of HIV: presence of sexually transmitted diseases (AOR=5.96; 95%CI: 2.43–14.63; P<0.001), taking alcohol (AOR=6.85; 95%CI: 3.22–14.56; P<0.001) and having multiple sexual partners (AOR=21.69; 95%CI: 8.82–53.33; P<0.001). Although this study shows that there is an increased risk of HIV infection among older men using EDD in bivariate analysis, it was not sustained at multivariate analysis. The study however highlights the need for the Ministry of Health and other concerned stakeholders to prompt screening and treatment of STDs, increase awareness of using condoms and educate about the effects of taking alcohol on HIV infection.

# CHAPTER ONE

# 1.0 INTRODUCTION

## 1.1 Background Information

Erectile dysfunction drugs (EDDs) or phosphodiesterase type 5 (PDE-5) are approved pharmacotherapies for the treatment of erectile dysfunction (ED) in men (Lue, 2000). ED is the persistent inability to achieve and maintain an erection sufficient for satisfactory sexual performance (Ibara *et al,* 2002). It is a common medical problem and is estimated to affect 34 million men in the United States (US) and more than 150 million men worldwide (Young *et al,* 2002). It is age associated, with prevalence rates ranging from 5% to 9% for men 18–39 years, 11–18% for men 40–59 years, and 44–70% for men 60 years and older (Laumann *et al,* 1999). In Kenya, although no epidemiological study has been carried out, erectile dysfunction is presumed to be common among older men.

Erectile dysfunction drugs are selective and highly effective peripheral vasodilator drugs that have been available worldwide since the late 1990s. In recent years EDDs have gained widespread popularity among older men (Lindau *et al,* 2007). Three agents in this class namely sildenafil®, tadalafil® and vardenafil® are currently available worldwide. The introduction of EDD has revolutionized the treatment of ED and has brought relief to many millions of men with erectile dysfunction. The effectiveness and ease of use of EDDs have made them an increasingly popular drug of abuse among men without a medical indication. Although generally regarded as effective and safe, these drugs have also been associated with increased rates of high-risk sexual behaviour and HIV transmission in some men (Rosen *et al,* 2006). Since 1998, EDDs have been extending the sex life of many older individuals and, at the same time, may be extending the HIV epidemic into older age groups (Khalaf & Levinson, 2003). This has raised public health concerns, as EDD use has been associated with increased sexual risk behaviors.

The increasing rate of HIV infection among older adults has led to recent research and public discourses highlighting the need to focus on older people in the fight against HIV/AIDS (Simone & Appelbaum, 2008). Contrary to common beliefs that HIV/AIDS

only affects the youth, literature shows that older adults are increasingly being infected by or living with it (Martin *et al,* 2008). The use of sex enhancing medications such as Viagra and other herbal products commonly used in less developed nations contribute to high risk of HIV infection in older adults (Simone & Appelbaum, 2008).

In Kenya, HIV infection indicates an increased prevalence from 5.7% (KDHS, 2003) to 9.1% (KDHS, 2008/2009) in 50 to 54 year old males. Given that the growing evidence for the increasing incidence of sexually transmitted diseases (STDs), including HIV/AIDS, diagnosed at an older age (Ory & Mack, 1998), ED drugs have received attention for their possible contribution to these trends (Schmid *et al,* 2009).

### 1.2 Problem statement

HIV infection is becoming a continuous concern in men aged 50 years and above (Smith & Christakis, 2009). New diagnoses of HIV are rising among older men (50 years and above), compared with younger age groups (Nguyen & Holodniy, 2008). The global or local HIV community has focused on people aged 15–49 years, often with less attention on the older people. In Kenya, although not capturing all men 50 years and above, HIV infection indicate an increased prevalence among 50 to 54 year old males.

With the advent of effective pharmacotherapy for erectile dysfunction, the risk of STDs, including HIV is a possible consequence, especially in the older population (Karlovsky *et al,* 2004). These drugs have the potential to increase sexual activity in older people and this, combined with the lack of awareness and infrequent use of condoms, may contribute to increased risk of STIs including HIV (Potts *et al,* 2004).

Given the increasing HIV infection among older men and the growing use of pharmacologic treatments for ED, there was a need to investigate the association of EDD use and HIV infection among older men.

### 1.3 Justification

There is increased number of sexual partners among EDD users (Cachy *et al,* 2004) and about a two fold rate in sexually transmitted infections (STIs), including HIV infection (Jackson, 2005; Kim *et al,* 2002). It has been also indicated that in samples of men who have sex with men (MSM), using EDDs are between two and six times greater than

non-users to engage in unprotected anal intercourse with a partner of unknown or serodiscordant HIV status (Swearingen & Klausner, 2005). Since EDDs are associated with risky sexual behaviour, some have argued that EDDs should be classified as controlled substances (Swearingen & Klausner, 2005).

Although the clinical efficacy of EDD has been well documented, there was no documented data on the use of erectile dysfunction drug and risk of HIV infection among older Kenyan men. Therefore, this study was aimed to investigate the relationship between EDD use and HIV infection among older men aged 50 to 75 years.

### 1.4 Research Questions

1. What is the prevalence of erectile dysfunction drug use among HIV positive (cases) and HIV negative (controls) men aged 50 to 75 years?
2. What is the risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs?

### 1.5 Null Hypothesis

There is no difference in prevalence of HIV among men aged 50 to 75 years using EDDs and non-users.

### 1.6 General Objective

To determine the risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs at VCT and CCC of Kenyatta National Hospital.

### 1.7 Specific Objectives

1. To determine the prevalence of EDD use among HIV positive (cases) and HIV negative (controls) men aged 50 to 75 years attending Kenyatta National Hospital.
2. To compare the prevalence of EDD use between HIV positive and HIV negative men aged 50 to 75 years attending Kenyatta National Hospital.

### 1.8 Significance of the study

The information generated by this study will be disseminated to relevant authorities in the Ministry of Health (MoH) and other relevant agents to help initiation of prevention strategies against HIV infection among older men. In part, it is also expected to serve as baseline information for those who may wish to make further research on the area.

### 1.9 Scope of the study

The aim of the study was to investigate the association of EDD use and HIV infection among men aged 50 to 75 years attending Kenyatta National Hospital using case control study. The target population of this study was cosnsisted of HIV positive (137) and HIV negative (137) men aged 50-75 years attending VCT and CCC of Kenyatta National Hospital. They were recruited in the study consecutively as they come to the respective departments of the hospital. Data was collected using pre-tested semi-structured questionnaire through trained health providers (counselors). Odds ratio which is usually approximate to the relative risk was calculated to determine the risk of HIV infection and EDD use as well as the other predisposing factors of HIV.

### 1.10 Limitations of the study

For some study participants, it was difficult to recall all the details accurately as it is case control study (recall bias). Another important limitation was reliability of participants' response to the questionnaire. However, collecting data with trained interviewers (counsellors) and anonymity facilitated participants in disclosing information.

# CHAPTER TWO

# 2.0 LITERATURE REVIEW

## 2.1 Epidemiology of erectile dysfunction

Erectile dysfunction (ED) is one of the most common chronic diseases affecting men over the world and is also the most frequently diagnosed sexual dysfunction in the older male population (Smith *et al,* 2007). It is defined as inability to achieve and maintain an erection sufficient to permit satisfactory sexual intercourse. It refers to a problem during any phase of the sexual response cycle (excitement, plateau, orgasm and resolution) that prevents the individual or couple from experiencing satisfaction from sexual activity. The causes of ED are numerous but generally fall into two categories, organic or psychogenic (Neelima & Edelman, 2001).

The severity, prevalence and incidence of ED increase with age. The prevalence of erectile dysfunction in the Massachusetts Male Aging Study (MMAS) was 52% of males aged 40 to 70 years (Mock, 2000). In the world database, the reported ED prevalence for different countries varies between 3% and 71% according to the age (Lewis, 2011; Selvin *et al,* 2007). This variability of ED prevalence across different studies has been attributed to methodological factors in data collection such as the survey delivery method and the type of ED measure. For example in Thailand 37.5% of men 40-70 years (Kongkanand, 2000), in Australia 33.9% of men 40-69 years (Chew *et al,* 2008), in Italy 12.8% of all men (Parazzini *et al,* 2000), in Singapore 51.3% overall prevalence (Tan *et al,* 2003), in Morocco 54%, which increases with age (Berrada *et al,* 2003), in Nigeria 57.4% among patients attending primary care clinics (Afolayan & Yakubu, 2009), in Germany 19.2% of men aged 30-80 years (Braun *et al,* 2000), in Turky 69.2% population based (Akkus *et al,* 2002), in Korea 32.4% among men (Ahn *et al,* 2007) and in Portugal the prevalence of ED is 29%, 50%, and 74% in men aged 40 to 49 years, 50 to 59 years, and 60 to 69 years, respectively (Teles *et al,* 2007). However, in Kenya, no studies have been carried out on prevalence of erectile dysfunction among men.

## 2.2 Oral pharmacotherapy of ED

The mechanism of action for EDD is through the inhibition of the enzyme phosphodiesterase type 5 and allowing the action of cyclic Guanosine Monophosphate (cGMP), which maintains the relaxation of the smooth muscles of the corpus cavernosa (Mostafa, 2008) and this leads to penile erection (Lue, 2000). Three agents in this class namely sildenafil, tadalafil and vardenafil have been approved by the European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA) for treatment of ED.

### 2.2.1 Sildenafil (*Viagra*)®

Sildenafil, launched in 1998, was the first PDE5 inhibitor available on the market. Efficacy is defined as an erection with rigidity sufficient for vaginal penetration. Sildenafil is effective from 30 to 60 minutes after administration. It is administered in 25, 50 and 100 mg doses. The recommended starting dose is 50 mg and should be adapted according to the patient's response and side-effects (Moncada *et al,* 2004). After 24 weeks in a dose-response study, improved erections were reported by 56%, 77% and 84% of men taking 25, 50 and 100 mg of sildenafil, respectively, compared to 25% of men taking placebo (Goldstein *et al*, 1998).

### 2.2.2 Tadalafil (*Cialis*)®

Tadalafil, licensed for the treatment of ED in February 2003, is effective from 30 minutes after administration with peak efficacy after about 2 hrs (Porst *et al*, 2003). It is administered in 10 and 20 mg doses. The recommended starting dose is 10 mg and should be adapted according to the patient's response and side-effects. In pre-marketing studies, after 12 weeks of treatment and in a dose-response study, improved erections were reported by 67% and 81% of men taking 10 mg and 20 mg of tadalafil compared to 35% of men in a control placebo group (Brock *et al,* 2002).

### 2.2.3 Vardenafil (*Levitra*)®

Vardenafil, commercially available from March 2003, is effective from 30 minute after administration. It is administered in 5, 10 and 20 mg doses. The recommended starting dose is 10 mg and should be adapted according to the patient's response and side-

effects. In vitro, it is 10 fold more potent than sildenafil, though this does not necessarily mean greater clinical efficacy (Bischoff & Schneider, 2001). After 12 weeks in a dose-response study, improved erections were reported by 66%, 76% and 80% of men taking 5 mg, 10 mg and 20 mg of vardenafil, respectively, compared with 30% of men taking placebo (Porst *et al*, 2001).

### 2.3 Prevalence and distribution of EDDs

Pharmacologic treatments for ED have gained widespread popularity among middle-aged and older men in recent years, driven largely by the high prevalence of erectile difficulties in this population (Lindau *et al*, 2007). More than 25 million men in the United States and worldwide have obtained sildenafil prescriptions to treat ED caused by various organic and psychogenic factors (Harte & Meston, 2011). Recreational use of PDE-5 inhibitors in Britain has shown a significant increase over time since the licensing of sildenafil from 3.2% in 1999 to 17% in 2003 (McCambridge *et al*, 2006). In Taiwan sales on PDE5 inhibitors retrieved from International Market Services Health, between 1999 and 2011, shows 5.9-fold increase and over 90% of PDE5 inhibitors were purchased in pharmacies without a prescription (Tsai & Jiann, 2014). Recent rates of recreational use among college-aged men have ranged from 5.3% - 12.7% of undergraduates (Harte & Meston, 2011) to 9% - 21.5% of medical students (Bechara *et al*, 2010; Korkes *et al*, 2008). Recreational PDE5 inhibitor use is greater among gay and bisexual populations, ranging from 26.3% to 37.5% (McCambridge *et al*, 2006; Nettles *et al*, 2009).

Erectile dysfuntion drugs may be obtained via prescription from a health care provider or from friends, or the black market (Sanchez & Gallagher, 2006). They are commonly obtained through both licit and illicit channels. For example, in one survey in the United Sates, over 86% of respondents reporting recreational EDD use obtained them from the friends, dealers or pharmacies and 1.3% through physician prescriptions (Harte & Meston, 2011). In a study carried out by Bechara *et al.* (2010) to evaluate the recreational use of Viagra among 379 men, 69 men reported using Viagra recreationally, 75.4% reported obtaining it from a friend and 17.4% from a pharmacy without a prescription. A 2005 review of all scientific and journal abstracts from USA and international conferences on STDs found 56–83% of MSM obtained their EDD

from sources other than physicians (Swearingen & Klausner, 2005). A number of studies report EDD misuse as a recreational drug or in combination with "club drugs" (methamphetamines, ecstasy, cocaine) (Mussachio *et al*, 2006; Benotsch *et al*, 2002).

In Kenya, EDDs are available in all level 5 pharmacies, that is, those in provincial and higher district level hospitals and in many local pharmacies. The price of EDD ranges from 0.80 to 3.80 US dollars depending on the strength of generics. People are able to obtain them from pharmacists without any prior prescription or checkup by a doctor.

### 2.4 Erectile dysfunction drug use and risk of HIV

Erected dysfunction drugs have been linked to high-risk sexual behaviour in some groups of men at increased risk for STDs transmission, including HIV (Spindler *et al*, 2007). EDD users report higher rates of unprotected intercourse (Swearingen & Klausner, 2005), higher number of sexual partners (Cachy *et al*, 2004), and present with elevated rates of sexually transmitted infections (Kim *et al*, 2002). Recreational EDD users are about twofold rate more likely to have sexually transmitted infections (STIs), including HIV infection (Jackson, 2005*;* Kim *et al*, 2002). A recent study in US found that widowhood in older men, but not older women, was associated with higher rates of STDs, especially after the introduction of EDDs in 1998 (Smith & Christakis, 2009). It is also reported that the use of sex enhancing medications such as Viagra and other herbal products commonly used in less developed nations contribute to high risk of HIV infection in older adults (Simone & Appelbaum, 2008). EDDs provide enhanced erections and it is plausible that condoms become more tight-fitting. Tight-fitting condoms have been associated with breakage (Crosby *et al*, 2007).

In 2005 a review of scientific and journal abstracts on STDs by Swearingen and Klausner among MSM revealed that increased odds of unprotected anal sex with a partner of unknown or serodiscordant HIV status ranged from 2.0 to 5.7 times (mean = 3.9) for sildenafil users versus non-users. The risk of sildenafil use and STD diagnosis among HIV-positive men who have sex with men was 1.92 (P =0.05), and the odds of sildenafil use among those newly HIV infected was 2.5 (95% CI 1.1– 4.1) (Swearingen & Klausner, 2005).

Focusing more specifically on HIV transmission among anonymous male repeat clients at HIV clinic in San Francisco California, showed that HIV incidence was significantly higher among Viagra users compared to non-users (4.4 HIV incidences per 100 person years vs. 1.2 per 100 person years, P<0.001). In multivariate analysis, Viagra users were twice more likely to be diagnosed with HIV than non- users (OR 2.5, 95%CI = 1.5-4.1), with particularly high risk among MSM using both Viagra and amphetamines (Loeb *et al,* 2004).

In a community-based convenience sample of men who have sex with men (MSM) in San Francisco, found a strong relationship between EDDs use and risky sexual behavior as well as a significant association with combined and illicit drug use (Chu *et al,* 2003). Among MSM, those who use EDD are between two and six times greater to engage in unprotected anal intercourse with a partner of unknown or serodiscordant HIV status than nonusers of EDDs (Swearingen & Klausner, 2005). Regardless of the mechanism of action, the association between EDDs use and a higher prevalence level of HIV has been noted in recent surveys, with some exceptions, in studies with convenient samples of gay and bisexual men in the United States and the United Kingdom (Rosen & Kostis, 2004). In a study carried out among gay men in Australia, only use of Viagra was significantly predictive of HIV infection after controlling for sexual risk behaviors (Prestage *et al,* 2009).

There is frequent use of alcohol and/or illicit substances taken concomitantly with EDDs in USA such as, but not limited to, methamphetamines, methyl-enedioxy-methamphetamine (MDMA, ecstasy), cocaine, alkyl nitrites (poppers), and ketamine (Fisher *et al,* 2006; Kim *et al,* 2002). Furthermore, concurrent use of illicit drugs and erectile dysfunction medications (EDMs) may potentiate high-risk sexual behavior by increasing social disinhibition while simultaneously enhancing sexual performance by decreasing the post-orgasmic refractory period; this may facilitate the ability to have more sexual partners in a short period of time.

While erectile dysfunction is common and EDDs are widely distributed in developing countries (Ibara *et al,* 2002) no study has been conducted on their possible impact on the HIV epidemic, although their use in industrialized countries has been associated with risky sexual practices (Khalaf & Levinson, 2003).

## 2.5 Epidemiology of HIV infection among older adults

In the global response to the HIV epidemic, the significant and rapidly increasing number of older adults with HIV is gaining recognition as one of the most important challenges for the coming years (Negin *et al,* 2012). Older people with HIV/AIDS are often invisible, isolated and ignored. Studies on HIV at old age are in their infancy globally, and in Africa in particular (Negin *et al,* 2012).

In USA, case reporting from 2003 to 2006 shows the proportion of older HIV-positive individuals has increased from 20% to 25% and numbers of cases have risen in all 5-year age bands from 45 years to 65 years and 11% of 2006 incident cases are in older individuals (Hall *et al,* 2008). In world health organization's (WHO) European Region, 8% of reported cases in 2005 are older adults (ECDC, 2007). As of June 2006, 8% of HIV cases and 12% of AIDS patients were 50 years or older in Canada (PHAC, 2006).

In China according to the National Centre for AIDS/STD Control and Prevention, 483 new HIV infected aged 60 and older were diagnosed in 2005, accounting for 2.2% of the total that year. The number has surged to 3,031 in 2010, or nearly 9% of the total that year. The new trend was related to many factors, including a longer sexually active period of Chinese men and better economic conditions.

The rate of growth in absolute size of the older population will be fastest in sub-Saharan Africa (UNPD, 2011); the region that also accounts for 67% of all HIV prevalence (UNAIDS, 2010). Research on HIV infection and sexual behaviour in Sub-Saharan Africa (SSA) typically focuses on individuals aged 15–49 years under the assumption that both become less relevant for older individuals. In SSA, HIV among older adults has largely been ignored, though there has been some emerging interest in this topic (Mills *et al,* 2011). A recent study estimated that there are three million HIV positive people in SSA aged 50 and older representing more than 14% of those over the age of 15 infected (Negin & Cumming, 2010) suggesting that increased attention is warranted for older age groups. The common stereotype is that older people don't have sex or use drugs. However, the available data often do not include how the pandemic is affecting the older population.

In Kenya, the only African country with two fully nationally representative DHS datasets for older adults (2003 and 2008/2009), there is evidence of increased prevalence from 5.7 to 9.1% in 50–54 year old males respectively (KDHS, 2003; KDHS, 2008/09).

### 2.6 Impact and burden of HIV infection in older adults

Acquired immunodeficiency syndrome (AIDS) is unique in human history in its rapid spread and the extent and depth of its effects. Since the first AIDS case was diagnosed in 1981, the world has struggled to cope with the extraordinary dimensions of this disease. Early efforts to mount an effective response were fragmented, piecemeal, and vastly under-resourced. Few communities recognized the dangers ahead, and even fewer were able to provide an effective response. As of 2009, 28 years later, approximately 32 million people have died and 33.3 million people (range: 31.4–35.3 million) globally were living with HIV. In 2009, still about 1.8 million people died of AIDS-related causes, similar to 1.9 million deaths due to AIDS in 2001 (UNAIDS, 2010). The impact of HIV/AIDS goes far beyond individual suffering and death. The high case fatality rate can have a major impact on families. As studies have shown in other parts of the world, the impact of HIV/AIDS on a household's income and family structure is disastrous (UNAIDS, 2010).

HIV infection at older ages has important health implications. Data from high income countries indicate that HIV infected adults aged over 49 have poorer prognoses than their younger counterparts (Somarriba *et al,* 2010). HIV infection causes the immune system to decline through the depletion of $CD4^+$ T cells. However ageing itself is associated with declining functionality of the immune system (immunosenescence). Older individuals have fewer $CD4^+$ cells and are less able to produce new $CD4^+$ cells. There is evidence that immunosenescence is accelerated in HIV-infected individuals as they age, exacerbating HIV (Somarriba *et al,* 2010). $CD4^+$ reconstitution in response to treatment in adults aged 55 years and older has been found to be significantly lower than in younger adults (Goetz *et al,* 2001). Even with highly active antiretroviral therapy, the time from HIV infection to AIDS or death is shorter in older individuals than younger adults (Schneider *et al,* 2005).

As a person ages, involution of the thymus occurs, and resultant thymic volumes are significantly lower in persons 45 years and older as compared to younger persons (Kalayjian *et al,* 2003). Moreover, the production of naive T cells declines with increasing age and thymic output is only minimal after age 55 (Naylor *et al,* 2005). Increased age is further associated with diminished T cell functionality, reduced memory T cell populations, and fewer numbers of properly functioning $CD8^+$ cytotoxic T cells (Effros, 2004). Not only are CD4 cell counts significantly lower in HIV-infected young and older adults when compared to their age-matched controls, but HIV-infected older subjects have the lowest counts (Kalayjian *et al,* 2003).

Since the introduction of ART, there have been conflicting data on mortality outcomes for older individuals. A decade after the introduction of ART, a French study reported a 1.5 times increased mortality risk in patients aged over 50 years at time of ART initiation compared with younger patients (Grabar *et al,* 2006). Similar to this and other resource-rich countries, African studies have reported a positive association between increasing age at ART initiation and either AIDS or mortality (Lawn *et al,* 2009).

Cause-specific mortality data are largely lacking in SSA, and vital registration systems do not have detailed mortality causes (Kahn *et al,* 2006). In a verbal autopsy study in rural Kenya, HIV was the cause of death in 27% of people aged 50 years or older and was the leading cause of death up to the age of 70 years (Negin *et al,* 2010). Recent publications from Europe and North America show that age associated non-HIV related diseases, such as cardiovascular disease, non-AIDS-defining cancers, hepatitis, hyperlipidemia, diabetes and kidney and liver disease, are growing causes of death in people living with HIV, while AIDS-defining causes continue to fall due to ART (De Wit *et al,* 2008).

# CHAPTER THREE

# 3.0 MATERIALS AND METHODS

## 3.1 Study area

The study was conducted at the Voluntary Counseling and Testing (VCT) and Comprehensive Care Center (CCC) of Kenyatta National Hospital (KNH). KNH is the largest teaching and research hospital in Kenya with an average of 600,000 outpatient visits and 89,000 inpatients annually. It serves the local population as well as referrals from other parts of Kenya and neighboring countries. It has a comprehensive center for voluntary counseling and testing and a comprehensive care center that handles HIV/AIDS patients, dispensing of antiretroviral medicine, monitoring viral load, and HIV testing and counseling. Approximately 20,000 HIV patients receive their medication at the CCC with an average daily attendance rate of 200 patients.

## 3.2 Study design

The study design was a hospital based unmatched case-control. The study intended to establish whether there was an association between HIV infection and EDD use among men aged 50 to 75 years. It was unmatched by individual but matched by group (50 – 75 years). It is often used to identify factors that may contribute to a medical condition by comparing subjects who have that condition/disease (cases) with subjects who do not have the condition/disease but are otherwise similar (controls). By definition, a case-control study is always retrospective because it starts with an outcome then traces back to investigate exposures. Case-control studies determine the relative importance of a predictor variable in relation to the presence or absence of the disease by calculating odds ratio which is usually approximate to the relative risk.

## 3.3 Study period

This study was conducted between January and April of 2014.

### 3.4 Study population

The cases comprised of HIV positive men aged 50 to 75 years attending CCC and VCT center. The controls comprised of men aged 50 to 75 years confirmed to be HIV negative at VCT center.

#### 3.4.1 Inclusion criteria

**Cases:**

- Men aged 50 to 75 years diagnosed with HIV at VCT center of KNH.
- Men aged 50 to 75 years receiving care and support at CCC of KNH and tested HIV positive while they were within the age range of 50 to 75 years.
- Those who consented

**Controls:**

- Men aged 50 to 75 years confirmed to be HIV negative at VCT center of KNH
- Those who consented

#### 3.4.2 Exclusion criteria

**Cases:**

- Men aged less than 50 or more than 75 years diagnosed with HIV at CCC and VCT center of KNH.
- Those who refused to consent

**Controls:**

- Men confirmed to be HIV negative aged less than 50 or more than 75 years.
- Those who refused to consent

### 3.5 Sample size determination

The sample size was determined using the formula of Casagrande *et al.* (1978):

$$n = \frac{\{Z_{1-\alpha/2}\sqrt{[2P(1-P)]} + Z_{1-\beta}\sqrt{[P_1(1-P_1)+P_2(1-P_2)]}\}^2}{(P_1-P_2)^2}$$

Where;

$\alpha$ = Type I error (0.05)

$\beta$ = Type II error (0.10)

At 95% confidence, $Z_{1-\alpha/2} = 1.96$

At 90% power, $Z_{1-\beta} = 1.28$

$P_1$= Since the prevalence of EDD use among HIV positives was not known an assumed proportion of 50% was used

$P_2$= Since the prevalence of EDD use among HIV negatives was not known an assumed proportion of 30% was used

$P = \frac{P_1 + P_2}{2}$

$$n = \frac{\{1.96\sqrt{[2(0.4)(1-0.4)]} + 1.28\sqrt{[0.5(1-0.5)+0.3(1-0.3)]}\}^2}{(0.5-0.3)^2}$$

$$n = \frac{\{1.96\sqrt{0.48)} + 1.28\sqrt{0.2116}\}^2}{0.04}$$

$$n = \frac{\{2.226\}^2}{0.04} \quad = 124$$

The sample size was 124 cases and 124 controls. Allowing for 10% attrition the sample size was adjusted to 137 cases and 137 controls. The ratio of cases to controls was 1:1.

### 3.6 Sampling

Men aged 50 to 75 years confirmed to be HIV positive attending CCC at KNH and those diagnosed to be HIV positive at KNH VCT center were recruited consecutively as cases and men aged 50 to 75 years confirmed to be HIV negative at VCT center were recruited consecutively as controls. They were part of the study after consent was sought and obtained from both cases and controls. Age was used by the data collectors to filter the participants during VCT process and follow-up at CCC. Every man meeting the inclusion criteria was included in the study until the desired number was attained.

### 3.7 Data collection tool

Data was collected using a pre-tested semi-structured questionnaire for both cases (Appendix 3) and controls (Appendix 5). The structured questionnaire was also translated into Swahili. During structured interviews, participants were asked about their

background information, EDDs use, sexual behavior and confounding factors in the EDD use and HIV infection. Furhtermore, cases were asked whether they had ever used EDD and the confounding factors before they knew their HIV positive status.

To ensure confidentiality and reliability of the response health care providers (counselors) working in the VCT and CCC of KNH were recruited to collect the data as participants have more trust towards them. Eight counselors from VCT center and four counselors from CCC of the hospital were enrolled for data collection. They were given training before the study commenced, whereby they were exposed to the objectives of the study and the general questions to be asked. Moreover, quality assurance was maintained through monitoring and supervising of data collection activities on daily basis.

Pre-testing of the questionnaire was conducted among 7 cases and 7 controls. The aim of this pre-testing was to check the extent to which questions were understood by the interviewee and to identify areas for modifications and corrections. In addition, the exercise was done to ensure validity and reliability and also to familiarize research assistants (counselors) with data collection tools.

### 3.8 Dependent variable

HIV sero-status (HIV sero-positivity or sero-negativity) among men aged 50 to 75 years was considered as the outcome or dependent variable.

### 3.9 Independent variables

Erectile dysfunction drug use, socio demographic charactersitics (age, residence, religion, marital status, occupation, level of education, circumcision status and sex orientation, type of sex partner, sexual desire and erectile dysfunction), injection drug use, taking alcohol/drunk, history of sexually transmitted diseases, multiple sexual partners and condom use were considered as independent variables.

### 3.10 Data management and analysis

Data captured in questionnaires was double entered into a computer database designed using MS- Excel application. Regular file back-up was done to avoid any loss or tampering. Data was analysed using a Statistical Package format (SPSS version 20.0).

Descriptive analysis was done for the demographic variables in both cases and controls using frequencies and proportions. Pearson's Chi-square test was used to establish the association between the dependent variable (HIV status) and independent variables in order to determine which ones had significant association. Unadjusted and adjusted Odds ratio (OR) with corresponding 95% confidence interval was estimated. The level of statistical significance was set at P-value <0.05. Binary logistic regression analysis was performed to adjust for confounding factors in the relationship between HIV status and EDD use. The significant factors with P-value <0.05 at bivariate analysis were subjected to binary logistic regression by specifying *'backward conditional'* method with removal at P<0.05.

### 3.11 Ethical considerations

The consent of the respondents was sought and obtained before administration of the questionnaire (Appendix 1). The participants were informed that their participation was voluntary and they could withdraw from the study at any time without giving any reason. The findings were treated with confidentiality and for the purpose of this research only. The objectives and results of the study were explained to the study participants. The participants were informed that the research did not pose any potential risk and their identities and personal particulars were kept confidential. Approval for data collection was sought from KNH and Scientific and Ethical clearance was sought and obtained from KEMRI Scientific Steering Committee (Appendix 7) and Ethical Review Committee (Appendix 8).

# CHAPTER FOUR

## 4.0 RESULTS

A total of 274 men aged between 50 to 75 years consented to participate in the study and were interviewed using a pre-tested semi-structured questionnaire. Of the 274 participants 137 were HIV positive represented cases and 137 HIV negative participants represented controls.

### 4.1 Socio-demographic characteristics of cases and controls attening KNH

Table 4.1 illustrates some of the selected socio-demographic characteristics among cases and controls. The table shows that cases were statistically significantly (P<0.001) younger than controls within the age range of 50-58 years. With respect to level of education, cases had significantly (P<0.006) higher level of education, where 73(53.3%) had attained secondary level of education compared to 48(35.0%) controls. Majority of the study participants were married 232(84.7%) with more controls 126(92%) being married compared to cases 106(77.4%) (P<0.001). However, there were more widowers 19(13.9%) among cases than controls 5(3.6%). Most of the respondents were self-employed 171(62.4%). However, significantly more controls 37(27.0%) were unemployed compared to cases 14(10.2%) (P<0.001). In regard to ability for erection, 118(43.1%) of the respondents reported that they sometimes get and keep an erection, with more cases 71(51.8%) had this experience compared to controls 47(34.3%) (P= 0.008).

**Table 4. 1: Distribution of socio-demographic characteristics of cases and controls attending KNH, 2014**

| Socio-demographic Characterstics | Total, n(%) | Cases, n(%) | Control, n(%) | $\chi^2$ value | df | p value* |
|---|---|---|---|---|---|---|
| | n=274 | n=137 | n=137 | | | |
| **Age in years** | | | | | | |
| 50-58 | 172(62.8%) | 112(81.8%) | 60(43.8%) | 52.25 | 2 | < **0.001** |
| 59-66 | 62(22.6%) | 23(16.8%) | 39(28.5%) | | | |
| 67-75 | 40(14.6%) | 2(1.5%) | 38(27.7%) | | | |
| **Level of education** | | | | | | |
| No formal education | 22(8.0%) | 4(2.9%) | 18(13.1%) | 18.87 | 3 | < **0.001** |
| Primary | 98(35.8%) | 40(29.2%) | 58(42.3%) | | | |
| Secondary | 121(44.2%) | 73(53.3%) | 48(35.0%) | | | |
| Higher/University | 33(12.0%) | 20(14.6%) | 13(9.5%) | | | |
| **Marital status** | | | | | | |
| Single | 4(1.5%) | 2(1.5%) | 2(1.5%) | 12.64 | 3 | **0.006** |
| Married | 232(84.7%) | 106(77.4%) | 126(92.0%) | | | |
| Divorced | 14(5.1%) | 10(7.3%) | 4(2.9%) | | | |
| Widower | 24(8.8%) | 19(13.9%) | 5(3.6%) | | | |
| **Occupation** | | | | | | |
| Unemployed | 51(18.6%) | 14(10.2%) | 37(27.0%) | 17.44 | 2 | < **0.001** |
| Civil servant | 36(13.1%) | 23(16.8%) | 13(9.5%) | | | |
| Self-employed | 171(62.4%) | 87(63.5%) | 84(61.3%) | | | |
| Retired | 16(5.8%) | 13(9.5%) | 3(2.2%) | | | |
| **Religion** | | | | | | |
| Christian | 261(95.3%) | 131(95.6%) | 130(94.9%) | 4.115 | 4 | 0.391 |
| Muslim | 9(3.3%) | 4(2.9%) | 5(3.6%) | | | |
| Hindu | 1(0.4%) | 1(0.7%) | 0(0%) | | | |
| Traditional | 1(0.4%) | 1(0.7%) | 0(0%) | | | |
| No religion | 2(0.7%) | 0(0%) | 2(1.5%) | | | |
| **Level of sexual desire** | | | | | | |
| Low sexual desire | 118(43.1%) | 57(41.6%) | 71(44.5%) | 1.812 | 2 | 0.404 |
| Moderate sexual desire | 108(39.4%) | 59(43.1%) | 49(35.8) | | | |
| High sexual desire | 48(17.5%) | 21(15.3%) | 27(19.7%) | | | |
| **Ability to get and keep an erection** | | | | | | |
| Always able to get and keep an erection | 104(38.0%) | 41(29.9%) | 63(46.0%) | 9.612 | 2 | **0.008** |
| Sometimes able to get and keep an erection | 118(43.1%) | 71(51.8%) | 47(34.3%) | | | |
| Never able to get and keep erection | 52(19.0%) | 25(18.2%) | 27(19.7%) | | | |

df= Degree of Freedom, *Significant P Value Bolded

### 4.2 Residence of cases and controls attending KNH, 2014

Most 95(69.3%) of the cases were residents of Nairobi compared to 61(44.5%) in controls as shown in Figure 4.1.

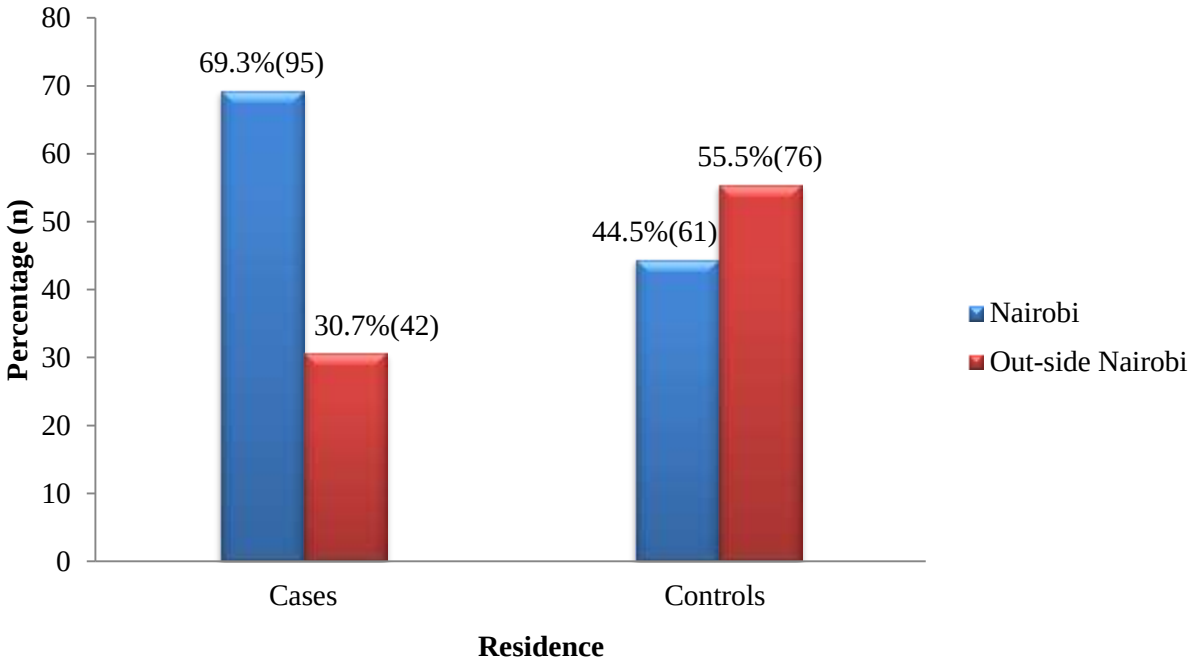


**Figure 4. 1: Residence of cases and controls attending KNH, 2014**

### 4.3 Frequency of EDD use among cases and controls attending KNH, 2014

Figure 4.2 below reveals that out of 137 cases (HIV +ve men) 18(13.1%) were using EDD compared to 8(5.8%) among 137 conrols (HIV –ve men).

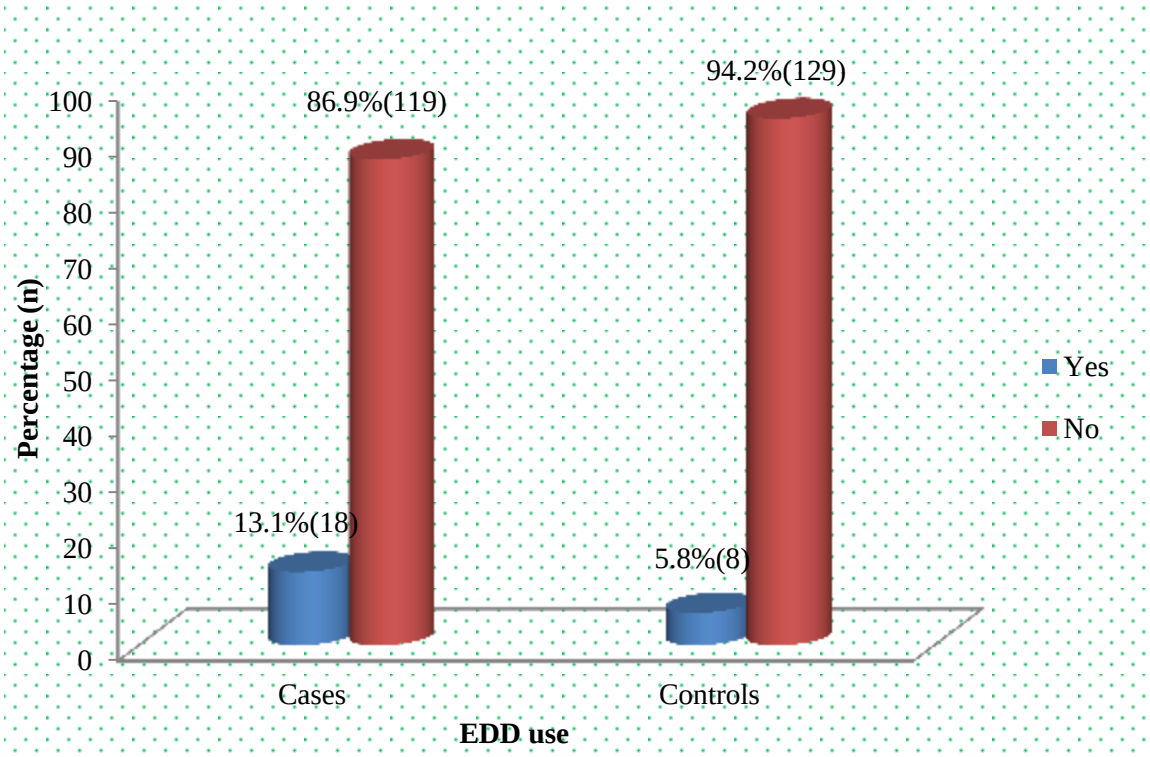


**Figure 4. 2: Frequency of EDD use among cases and controls attending KNH, 2014**

### 4.4 Bivariate analysis of EDD use and predisposing factors of HIV infection among cases and controls

Table 4.2 shows bivariate analysis of EDD use and predisposing factors for HIV in relation to HIV sero-status (cases or controls). In regard to EDD use, there was a significant increase in proportion of EDD use among cases 18(13.1%) compared to the controls 8(5.8%) (OR= 2.44; 95%CI: 1.04-5.93; P=0.039).

The table further indicates that cases were less likely to have been circumcised 119(86.9%) than controls 130(94.9%), (OR=0.36; 95%CI: 0.14-0.88; P=0.021). Presence of sexually transmitted diseases were more among cases 67(50.8%) compared to the controls 13(9.8%), (OR=9.52; 95%CI: 4.89-18.53; P<0.001). The use of alcohol/drunkenness was also examined and it was high among cases 100(73.0%) compared to controls 21(15.3%) (OR= 14.93; 95%CI: 8.21-27.16; P<0.001). Having multiple sexual partners was significantly higher in cases 128(93.4%) than controls 39(28.5%), (OR= 35.74; 95%CI: 16.53-77.27; P<0.001). There was significant lesser use of condoms all the time during having multiple sexual partners among cases 4(3.1%) than 15(38.5%) in controls, (OR= 0.052; 95%CI: 0.02-0.18; P<0.001). However, there was no significant difference with respect to using injection drugs (OR= 3.05; 95%CI: 0.31-29.64; P=0.314) and sex orientation (being heterosexual or homosexual) (OR= 2.02; 95%CI: 0.18-22.48; P=0.562) among cases and controls.

**Table 4. 2: Bivariate analysis of EDD use and predisposing factors of HIV among cases and controls**

| Variable | Total | Cases | Control | OR (95% CI) | p value* |
|---|---|---|---|---|---|
| | n(%) | n(%) | n(%) | | |
| **Erectile dysfunction drug use** | | | | | |
| Yes | 26(9.5%) | 18(13.1%) | 8(5.8%) | **2.44(1.04-5.93)** | **0.039** |
| No | 248(90.5%) | 119(86.9%) | 129(94.2%) | | |
| **Circumcision status** | | | | | |
| Circumcised | 249(90.9%) | 119(86.9%) | 130(94.9%) | **0.36(0.14-0.88)** | **0.021** |
| Un-circumcised | 25(9.1%) | 18(13.1%) | 7(5.1%) | | |
| **Sex orientation** | | | | | |
| Heterosexual | 271(98.9%) | 136(99.3%) | 135(98.5%) | 2.02(0.18-22.48) | 0.562 |
| Homosexual | 3(1.1%) | 1(0.7%) | 2(1.5%) | | |
| **Sexually transmitted diseasses** | | | | | |
| Yes | 80(30.2%) | 67(50.8%) | 13(9.8%) | **9.52(4.89-18.53)** | **< 0.001** |
| No | 185(69.8%) | 65(49.2%) | 120(90.2%) | | |
| **Taking alcohol/drunkenness** | | | | | |
| Yes | 121(44.2%) | 100(73.0%) | 21(15.3%) | **14.93(8.21-27.16)** | **< 0.001** |
| No | 153(55.8%) | 37(27.0%) | 116(84.7%) | | |
| **Use of injection drugs** | | | | | |
| Yes | 4(1.5%) | 3(2.2%) | 1(0.7%) | 3.05(0.31-29.64) | 0.314 |
| No | 270(98.5%) | 134(97.8%) | 136(99.3%) | | |
| **Multiple sexual partners** | | | | | |
| Yes | 167(60.9%) | 128(93.4%) | 39(28.5%) | **35.74(16.53-77.27)** | **< 0.001** |
| No | 107(39.1%) | 9(6.6%) | 98(71.5%) | | |
| **Use of Condom** | | | | | |
| All the time | 19(11.4%) | 4(3.1%) | 15(38.5%) | **0.05(0.02-0.18)** | **< 0.001** |
| Sometimes | 50(29.9%) | 42(32.8%) | 8(20.5%) | 1.02(0.41-2.59) | 0.751 |
| Never | 98(58.7%) | 82(64.1%) | 16(41.0%) | **Reference** | |

OR= Odds Ratio, CI= Confidence Interval, *Significant P Value Bolded

### 4.5 Multivariate analysis of EDD use and other predisposing factors of HIV

Multiple regression analysis was performed in order to identify factors associated with HIV sero-positivity (Table 4.3). Five (5) factors that associated with HIV sero-positivity at P<0.05 during bivariate analysis were considered together in a multiple regression analysis. These include: (1) EDD use, (2) circumcision status, (3) presence sexually transmitted diseases, (4) taking alcohol/drunkenness, and (5) having multiple sexual practices. Upon fitting these factors using binary logistic regression and specifying *'backward conditional'* method with removal at P<0.05, three (3) factors remained in the final analysis (Table 4.3). These are having had history of sexually transmitted diseases (AOR=7.87; 95% CI: 2.73 – 22.73; P<0.001), taking alcohol/drunkenness (AOR=7.11; 95% CI: 2.94 – 17.23; P<0.001), engaging in multiple sexual practices (AOR=19.33; 95% CI: 6.45 – 57.96; P<0.001).

However, after adjusting for other factors, EDD use was not significantly associated with HIV sero-positivity (AOR= 1.52; 95%CI: 0.43- 5.34; P=0.519) (Table 4.3).

**Table 4. 3: Multivariate of EDD use and other predisposing factors of HIV**

| Variables/factors | AOR | 95% CI | | p value* |
|---|---|---|---|---|
| | | Lower | Upper | |
| **Full model** | | | | |
| **Erectile dysfunction drug use** | | | | |
| Yes | 1.52 | 0.43 | 5.34 | 0.519 |
| No | 1.00 | | | |
| **Circumcision status** | | | | |
| Circumcised | 0.32 | 0.09 | 1.14 | 0.078 |
| Un-circumcised | 1.00 | | | |
| **Sexually transmitted diseases** | | | | |
| Yes | 5.92 | 2.40 | 14.58 | **<0.001** |
| No | 1.00 | | | |
| Taking alcohol/drunk | | | | |
| Yes | 7.73 | 3.57 | 16.76 | **<0.001** |
| No | 1.00 | | | |
| **Multiple sexual partners** | | | | |
| Yes | 20.82 | 8.35 | 51.89 | **<0.001** |
| No | 1.00 | | | |
| **Reduced model** | | | | |
| **Sexually transmitted diseases** | | | | |
| Yes | **5.96** | **2.43** | **14.63** | **<0.001** |
| No | 1.00 | | | |
| **Taking excessive alcohol/drunk** | | | | |
| Yes | **6.84** | **3.22** | **14.56** | **<0.001** |
| No | 1.00 | | | |
| **Multiple sexual partners** | | | | |
| Yes | **21.69** | **8.82** | **53.33** | **<0.001** |
| No | 1.00 | | | |

AOR= Adjusted Odds Ratio, CI= Confidence Interval, *Significant P Value Bolded

### 4.6 Age at onset, frequency, reason and sexual desire in cases and controls among those using EDD attending KNH, 2014

Table 4.4 summarizes the distribution of age at onset, frequency, reason and sexual desire in cases and controls among those using EDD. Among those who were using EDD, 11(42.3%) started using EDD while they were 45 to 50 years old. Majority 22(84.0%) indicated that they were using EDD to treat erectile dysfunction with 17(94.4%) among cases compared to 5(62.5%) among controls. Others 3(11.5%), reported that they used EDD to experiment or satisfy their partners with 1(5.6%) among cases and 2(25.0%) among controls. Sildenafil (Viagra) was one of the most 16(61.5%) used type of EDD however, 7(26.9%) did not know the type of EDD they have used. Most 18(69.2%) of respondents indicated high level of sexual desire after using EDD. Majority 24(92.4%) of the participants (cases and controls) were using EDD sometimes.

**Table 4. 4: Distribution of age at onset, frequency, reason and sexual desire in cases and controls among those using EDD attending KNH, 2014**

| Variable | Total, n(%) | Cases, n(%) | Control, n(%) |
|---|---|---|---|
| **Age at onset of using EDD** | | | |
| 45-50 | 11(42.3%) | 10(55.6%) | 1(12.5%) |
| 51-55 | 6(23.1%) | 6(33.3%) | 0(0.0%) |
| 56-60 | 6(23.1%) | 2(11.1%) | 4(50.0%) |
| 61-65 | 1(3.8%) | 0(0.0%) | 1(12.5%) |
| 66-70 | 2(7.7%) | 0(0.0%) | 2(25.0%) |
| **Reason for using EDD** | | | |
| To treat erectile dysfunction | 22(84.6%) | 17(94.4%) | 5(62.5%) |
| Counteract effects of drugs/alcohol | 1(3.8%) | 0(0.0%) | 1(12.5%) |
| Other (experimenting or satisfy partner) | 3(11.5%) | 1(5.6%) | 2(25.0%) |
| **Type of EDDs use** | | | |
| Sildenafil (Viagra)® | 16(61.5%) | 11(61.1%) | 5(62.5%) |
| Tadalafil (Cialis) ® | 3(11.5%) | 3(16.7%) | 0(0.0) |
| Don't know | 7(26.9%) | 4(22.2%) | 3(37.5%) |
| **Frequency of EDD use** | | | |
| Always/often | 1(3.8%) | 1(5.6%) | 0(0.0%) |
| Sometimes | 24(92.4%) | 16(88.9%) | 8(100.0%) |
| No response | 1(3.8%) | 1(5.6%) | 0(0.0%) |
| **Level of sexual desire after using EDD** | | | |
| High sexual desire | 18(69.2%) | 11(61.1%) | 7(87.5%) |
| Moderate sexual desire | 5(19.2%) | 4(22.2%) | 1(12.5%) |
| Low sexual desire | 3(11.5%) | 3(16.7%) | 0(0.0%) |

EDD= Erectile dysfunction drug

### 4.7 Access to EDD among those using EDD attending KNH, 2014

In relation to access of EDD, 15(58%) of the respondents obtained the EDD from pharmacies without prescription and 7(27%) through friends but only 4(15%) obtained through Doctor's prescription (Figure 4.3).

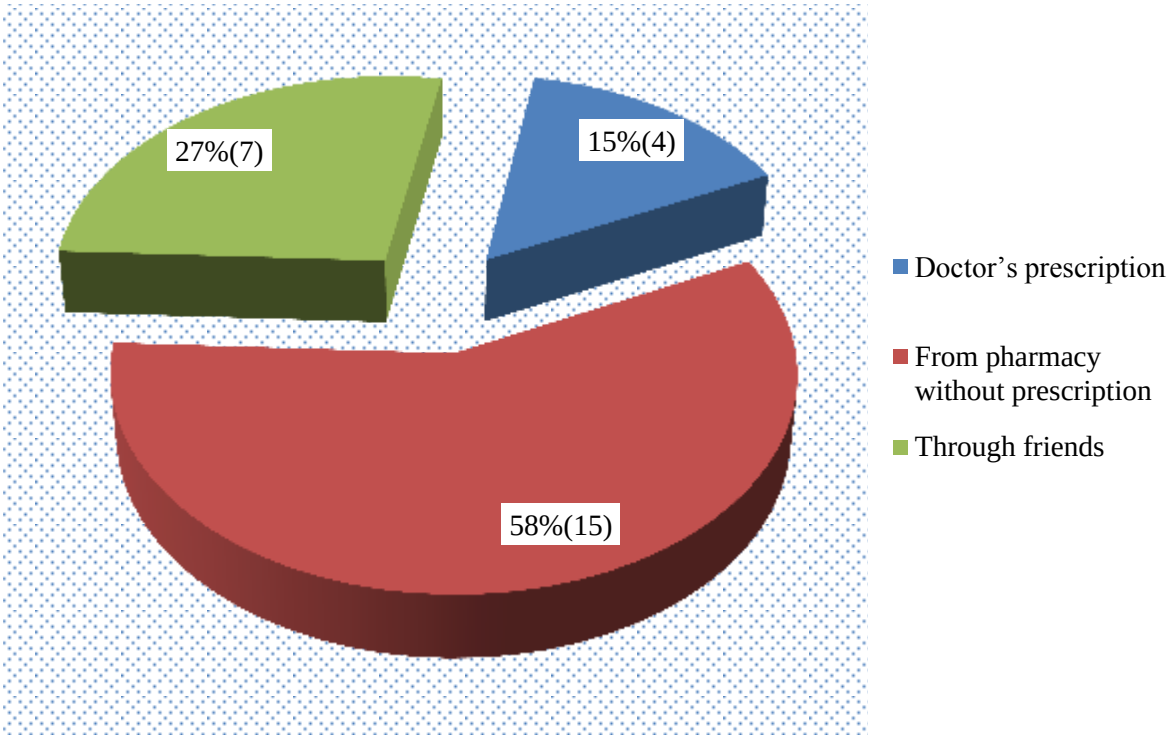


**Figure 4. 3: Distribution of access to EDD among those using EDD attending KNH,**

### 4.8 Drugs/alcohol used with EDD among cases and controls attending KNH, 2014

Analysis of use of concomitant recreational substances revealed alcohol to be the only substance used concomitantly with EDD 9(34.6%) as depicted in Figure 4.4.

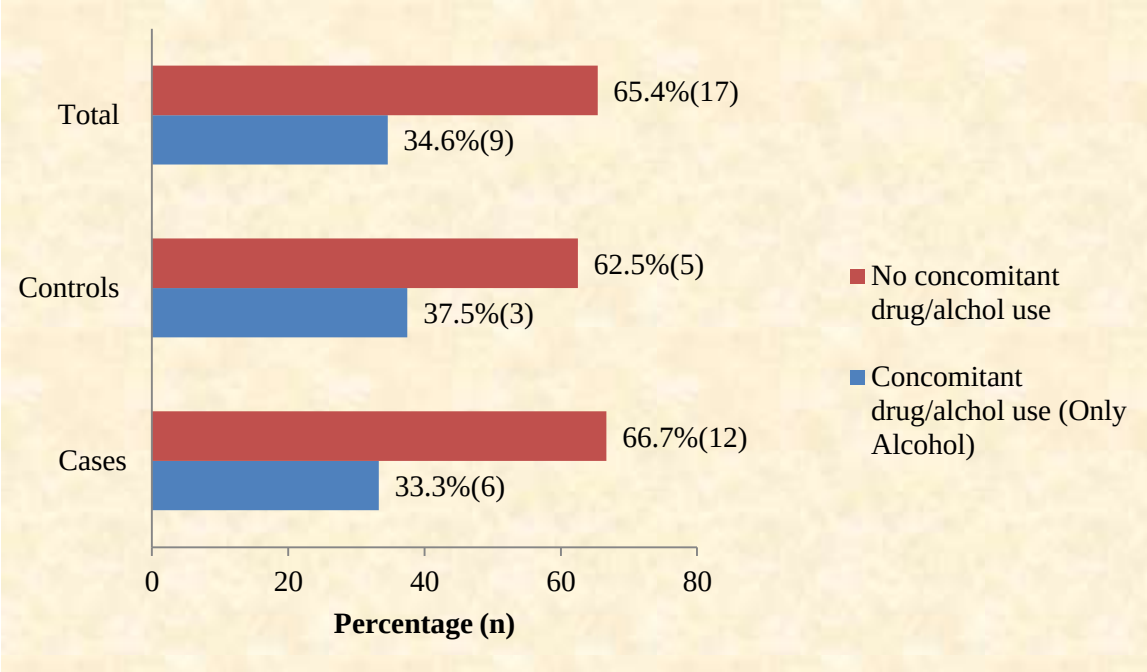


**Figure 4. 4: Distribution of recreational drugs/alcohol used concomitantly with EDD**

# CHAPTER FIVE

# 5.0 DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

## 5.1 Discussion

In Kenya HIV infection indicates an increased prevalence from 5.7% (KDHS, 2003) to 9.1% (KDHS, 2008/2009) in 50 to 54 year old males. Since the introduction of EDD (Viagra) in 1998, the sex life of many older men has been extending and, at the same time, may be extending the HIV epidemic into older age groups (Khalaf and Levinson, 2003). Although EDDs are generally regarded as effective and safe, they have been associated with increased rates of high-risk sexual behaviour (Rosen *et al*, 2006) and increasing incidence of STDs, including HIV/AIDS, diagnosed at an older age (Ory & Mack, 1998; Schmid *et al,* 2009). Moreover, WHO in 2009 proposed that one reason for the increasing incidence of HIV infection among older men is the use of impotence treatments that have allowed men to have more sexual partners (WHO, 2009). This study hence sought to establish the risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs at VCT and CCC of Kenyatta National Hospital, Kenya.

### 5.1.1 Socio-demographic characteristics of cases and controls

Comparison of cases (HIV +ve) and controls (HIV -ve) with regard to demographic characteristics showed that there was statistically significant difference between cases and controls with respect to age ($P < 0.001$), educational status ($P = 0.006$), marital status ($P < 0.001$), occupation ($P < 0.001$) and ability to keep an erection adequate for satisfactory intercourse ($P = 0.008$). However, there was no significant difference in relation to religion and level of sexual desire.

Surprisingly, a statistically significant number of men with educational level of secondary school and above were found to be HIV sero-positives. This is against the fact that people that are more knowledgeable could take care of HIV infection, as they easily understood both the transmission and prevention methods. Hence knowledge alone, as seen in this study, may not be protective unless behavioral change is attained. The unemployment was also significantly higher in controls than in cases. This could be because cases were significantly younger than controls within the age range of 50 to 75

years. However, as expected among the cases there were significantly more widowers and divorced men than controls.

### 5.1.2 EDD use and risk of HIV infection among cases and controls

This study has revealed that using EDD has increased proportion and risk of HIV infection among men aged 50 to 75 years in the bivariate analysis (OR= 2.44; 95%CI: 1.04-5.93; P=0.039). It has been reported that use of EDD appeared to be linked to high-risk sexual behaviour among men having sex with men (Swearingen & Klausner, 2005) and enabled older men to rejuvenate their sexual activity. However, after controlling for confounding factors, the association of EDD use with serum HIV positivity was found to be insignificant (AOR= 1.52; 95%CI: 0.43- 5.34; P=0.519). Hence the finding of this study supports the null hypothesis which states that 'there is no difference in prevalence of HIV among men aged 50 to 75 years using EDDs and non-users.'

There is however some evidence that Viagra is used more by MSM than by heterosexual men, although there is a finding that heterosexual men who take Viagra are more likely to have insertive anal intercourse with women (Fisher *et al*, 2006). Viagra users were more than twice more likely to be diagnosed with HIV than non- users (OR 2.5, 95% CI 1.5-4.1) in a multivariate analysis at HIV clinic in San Francisco CA, with particularly high risk among MSM using both Viagra and amphetamines (Loeb *et al*, 2004). Similarly in a search carried out using all scientific and journal abstracts from USA and international conferences, showed that the risk of HIV infection among MSM using sildenafil (Viagra) was 2.5 (95%CI: 1.1–4.1) (Swearingen & Klausner, 2005). Furthermore, in a study conducted among gay men in Australia, only use of Viagra was significantly predictive of HIV infection after controlling for sexual risk behaviors (Prestage *et al*, 2009) and there was a replication of these findings in a US study conducted in Chicago and Los Angeles among MSM (Carey *et al*, 2008).

In this study among all those who were using EDD, most indicated that they had experienced high sexual desire (56.3%) and moderate sexual desire (21.9%) after using EDD. Likewise other studies have shown that EDD use increases high-risk sexual behaviour (Rosen *et al*, 2006; Cachy *et al*, 2004). Regarding to access of EDD, 80.7% obtained them from pharmacies and friends (53.8% from pharmacy without prescription and 26.7% through friends) which is comparable to a survey done in the United States,

in which over 86% of respondents obtained them from the friends, dealers or pharmacies and 1.3% through physician prescriptions (Harte & Meston, 2011). Moreover, in Taiwan sales on PDE5 inhibitors retrieved from International Market Services Health, between 1999 and 2011, shows over 90% of PDE5 inhibitors were purchased in pharmacies without a prescription (Tsai & Jiann, 2014). Therefore, obtaining EDD from pharmacy without prescription and friends are among the most commonly reported places.

### 5.1.3 Other factors associated with HIV infection among the respondents

The presence of sexually transmitted infections (STIs) was one of the most important risk factors associated with HIV infection (AOR=5.96; 95% CI: 2.43 – 14.63; P<0.001). Similar to this finding, the association between HIV and herpes simplex virus type 2 was found significant after controlling for multiple sex partners, paying for sex, and history of STIs (AOR= 8.0; 95%CI= 4.8-13.1) among 224 HIV-negative and 191 HIV-positive male factory workers in Zimbabwe (Gwanzura *et al,* 1998). There are several biological mechanisms thought to account for the synergy between HIV and STI epidemics. Infections that disrupt the epithelial surface of the genital tract may increase acquisition through facilitating the access of HIV-1 to target cells under epithelial surface thus increasing the probability that HIV-1 is able to establish a systemic infection. Ulcers in both partners can facilitate blood to blood contact and thereby transmission, while STI in the HIV infected partner can increase viral shedding in the genital tract (Fox & Fidler, 2010). Furthermore, inflammatory STDs recruit activated CD4 cells to the surface of the genital tract, increasing the pool of cells susceptible to HIV infection (Corey *et al,* 2004). Thus, STDs treatment is an important HIV prevention strategy in the general population.

In this study reported alcohol consumption/drunkenness was significantly associated with HIV sero-positivity (AOR=6.84; 95% CI: 3.22 – 14.56; P<0.001). This is comparable to a meta-analysis carried out by Baliunas *et al.* (2010) on alcohol consumption and risk of incident HIV infection where the overall alcohol consumption increased the risk of HIV (RR 1.98, 95% CI 1.59-2.47). The main reason for this association is that alcohol can act directly on the brain to reduce inhibitions and diminish risk perception (Fisher *et al,* 2007).

Engaging in multiple sexual practices was also significantly associated with HIV sero-positivity (AOR=21.69; 95% CI: 8.82 – 53.33; P<0.001). This is consistent with the pooled sub-Saharan Africa sample that men who had two or more overlapping partners in the past 12 months were significantly more likely to be HIV-infected than those who had only one lifetime sexual partner (AOR=2.87, P<0.001) (Mishra & Simona, 2009). Therefore, it can be concluded that having multiple sexual partners is the main route of HIV transmission among older men.

In contrast to the industrialized world where the epidemic of HIV is reported to be entrenched among homosexual men and injecting drug users (Thomas, 2001), they were not significantly associated with serum HIV positivity in this study (OR= 2.02; 95%CI: 0.18-22.48; P=0.562) and (OR=3.05; 95%CI: 0.31-29.64; P=0.314) respectively. HIV transmission by non-sterilized injecting equipment and intravenous drug use has not been documented as a major mode of HIV transmission in Africa. Little is known about the practice of anal intercourse in sub-Saharan Africa, but there is a taboo on it and it is believed to be uncommon.

Even though circumcision was significantly protective at the bivariate analysis (OR= 0.36; 95% CI: 0.14-0.88; P=0.021), it was not significant after adjustment was made for other variables at multivariate analysis (AOR= 0.32; 95% CI: 0.09-1.14; P=0.078). The findings of this study contradict to a number of studies conducted principally among African populations finding an association between circumcision status and HIV infection (Nasio *et al,* 1996). A recent meta-analysis of randomized controlled trials suggested that circumcision reduces a man's risk of contracting HIV by around 56% with confidence interval of 40-67% (Mills *et al,* 2008).

In this study use of condoms all the time was found to be protective among those who were engaged in sexual practices with a prostitute or with anyone other than wife (OR= 0.05; 95% CI: 0.02-0.18; P<0.001). Among all respondents engaged in multiple sexual practices, 58.7% had never used condoms, 29.9% used condoms sometimes and only 11.4% used condoms all the time. This suggests that condom use is not popular among older men.

## 5.2 Conclusions

Among the cases 18(13.1%) used EDD compared to 8(5.8%) of the controls. Even though the use of EDD was found to be significantly associated with serum HIV positivity in bivariate analysis (OR= 2.44; 95%CI: 1.04-5.93; P=0.039), it was not significant after adjustment made for other factors at the multivariate analysis (AOR= 1.52; 95%CI: 0.43- 5.34; P=0.519). Therefore, this supports the null hypothesis which states that 'there is no difference in prevalence of HIV among men aged 50 to 75 years using EDDs and non-users.'

Moreover, multiple logistic regression revealed the following factors as independent predictors of HIV infection:

- Presence of sexually transmitted diseases (AOR=5.96; 95%CI: 2.43 – 14.63; P<0.001),
- Taking alcohol/drunkenness (AOR=6.85; 95%CI: 3.22 – 14.56; P<0.001) and
- Having multiple sexual partners (AOR=21.69; 95%CI: 8.82 – 53.33; P<0.001).

## 5.2 Recommendations

Based on the findings of the study, the following recommendations are made:

- A prospective study design (cohort) is recommended to shed more light on the use of EDD and risk of HIV infection.
- It is also necessary to:
    - increase awareness on the need for regular screening and prompt treatment of STDs
    - educate older men about the effects of taking alcohol/drunkenness on HIV infection
    - increase awareness of using available protective methods such as use of condoms all the time, abstinence and having one sexual partner among older men

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## APPENDICES

### Appendix 1: Informed Consent in English

**Informed Consent – risk of HIV and EDD Use Survey**

**Study title:** Risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs attending at Kenyatta National Hospital

**Institutions and Investigators:**

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**Introduction**

At an international level, UNAIDS and other agencies that report on the state of the epidemic, have limited or no data on the number of HIV-infected mature adults (50 years or older) in developing countries, which face the largest burden of HIV. In Kenya, the only African country with two fully nationally representative DHS datasets for older adults (2003 and 2008/2009), there is evidence of increased prevalence from 5.7 to 9.1% in 50–54 year old men.

It is a common belief that elders are not sexually active and a common stereotype is that older people don't have sex or use drugs. These myths and stereotyping that elders are asexual have contributed to the progression of the disease. Despite myths and stereotypes, many seniors are sexually active, and some are drug users and their behaviors can put them at risk for HIV infection (National Association on HIV over Fifty).

There is an urgent need to institute measures, through informed policy decisions based on scientific evidence, to mitigate the current high incidence of HIV infection among older men in the developing world like Kenya. There is however extremely little data on the use of erectile dysfunction drug and risk of HIV among 50 years and above men in developing countries.

This study which proposes to assess the association of EDD use and HIV among the older men is expected to contribute to the scientific basis.

You are being asked to participate in this survey because you are eligible to join the study. If you decide to join the study, you will be asked a series of questions regarding

your socio-demographic information and EDD usage. The interview will last approximately 20 minutes only.

Before you decide if you wish to be in this study, you need to know about any good or bad things that could happen if you decide to join. This form tells you about the study. You can ask any questions you have at any time.

**Being in the study is your choice:**

This consent form gives you information about the study, the risks and benefits, and the process that will be explained to you. Once you understand the study, and if you agree to take part, you will be asked to sign your name or make your mark on this form. You will be given a copy to take home.

Before you learn about the study, it is important that you know the following:

- Your participation in this study is entirely voluntary
- You may decide to withdraw from the study at any time, without facing any consequences

**Purpose of the study:**

The purpose of this study is to determine whether erectile dysfunction drug use may be associated with HIV infection among older men aged 50 to 75. Kenyatta National Hospital is being selected for this study. The study will be using semi-structured questionnaire about erectile dysfunction drug use and related confounding factors.

**What to expect during the interview:**

I will ask you few questions regarding erectile drug and HIV.

**If you choose not to participate or to leave the study:**

You have the choice to not participate in this research study. If you choose not to participate in this study or to leave the study during the interview process, you may do so freely without consequences against you.

**Risks and/or discomforts:**

I do not anticipate any risks or discomforts to you during this study. You will be requested to avail yourself for an interview at a time and place that you are most comfortable. You may become worried or anxious about discussing matters of erectile dysfunction drug and HIV related questions. Every effort will be made to protect your

privacy and confidentiality while you are participating in the study. The interviews will take place in private.

**Benefits to you:**

You may get no direct benefit from the information you provide for this study. However, the results will be used to assist in formulating policies that may initiate prevention strategies against HIV infection among older men.

**Costs to you:**

There is no cost to you for participating in this study apart from your precious time.

**Your records will be private:**

Every effort will be made to keep the information you provide confidential. You will be only identified by a code and personal information from the interview will not be released without your written permission. The information in the questionnaire cannot be identified as belonging to you. You will not be personally identified in any publication about this study. Your records may be reviewed by Ethics Committee at KEMRI.

**Injury because of participating in this study:**

It is unlikely that any form of injury could happen to you as a result of being in this study. It is important that you tell the study staff if you feel that you have been irritated or damaged because of taking part in this study.

**Problems and questions:**

You will be given a copy of this form to take with you. If you have any questions or concerns about your rights as a research participant, please contact to:

The Principal;
College of Health Sciences
Jomo Kenyatta University of Agriculture and Technology
P.O. Box 62200-00200; Nairobi
Tel: 254-67-52711/52181-4
Fax: 254-67-52161
director@itromid.jkuat.ac.ke

**Your rights as a study participant:**

This research has been approved and reviewed by the KEMRI's Scientific Steering Committee. This committee has reviewed this study in order to help protect participants. If you have any questions about your right as research participant you may contact to: The secretary, KEMRI Ethics Review Committee, P.O.Box 54840-00200, Nairobi. Tel: 020-2722541. E-mail address: ERCadmin@kemri.org.

**Your statement of consent and signature:**

If you have read the informed consent, or have had it read and explained to you, and you understand the information and voluntarily agree to join this study, please carefully read the statements below and think about your choice before signing your name:

- I have been given the chance to ask any questions I may have and I am content with the answers to all my questions.
- I know that any information I give will be kept confidential and that I may leave this study at any time.
- If I leave or refuse to be in the study, I understand that there will be no repercussions.
- The name, phone number and address of whom to contact in case of an emergency has been told to me and has also been given to me in writing.
- I agree to take part in this study as a volunteer, and will be given a copy of this informed consent form to keep.

| | |
|---|---|
| …… | …… |
| Participant's name | Participant's signature and date |
| …… | …… |
| Interviewer's name | Interviewers' signature and date |
| …… | …… |
| Researcher's name | Researcher's signature and date |

**Appendix 2: Ridhaa**

**Ridhaa -Hatari ya matumizi ya madawa ya kuongeza nguvu za kiume na kuambukizwa virusi vya ukimwi (VVU).**

**Utafiti kuhusu:**

Hatari ya kuambukizwa VVU miongoni mwa wanaume wenye umri wa miaka 50-75 wenye kutumia madawa ya kuongeza nguvu za kiume katika Hospitali ya Taifa ya Kenyatta.

**Taasisi na wakaguzi:**

| **Mtafiti** | **Taasisi** | **Kuwasiliana na** |
|---|---|---|
| Mr. Michael Habtu | Kenya Medical Research Institute | +254-718092615 |

**Utangulizi**

Katika ngazi ya kimataifa, UNAIDS na mashirika mengine yanayoripoti juu ya hali ya ugonjwa, hawana data juu ya idadi ya watu wazima walioambukizwa VVU (miaka 50 au zaidi) katika nchi zinazoendelea, ambazo zina mzigo mkubwa wa VVU. Katika nchi za Afrika nchini Kenya tu ndio ina datasets mbili mwakilishi DHS (2003 na 2008/2009) kwa watu wazima na kuna ushahidi wa kuongezeka kwa kiwango cha maambukizi 5.7-9.1% katika wanaume wa umri 50-54. Kuna ubaguzi na imani ya kawaida kwamba wazee hawajihusishi sana katika mambo ya ngono na kwamba hawatumii madawa ya kuongeza nguvu za kiume. Hizi imani potofu zimechangia kukua kwa ugonjwa wa VVU. Licha ya hizi hadithi na fikra potofu, wazee wengi hujihusisha katika ngono, na baadhi yao hutumia madawa ya kuongeza nguvu za kiume na tabia yao inaweza kuwaweka hatarini kwa maambukizi ya VVU (National Association on HIV over fifty).

Kuna haja muhimu ya kuanzisha hatua, kwa njia ya maamuzi ya sera ya msingi ya ushahidi wa kisayansi, kupunguza matukio makubwa ya maambukizi ya VVU miongoni mwa watu wa umri mkubwa katika nchi zinazoendelea kama vile Kenya. Hata hivyo kuna data kidogo sana juu ya matumizi ya madawa ya kuongeza nguvu za kiume na hatari ya VVU miongoni mwa watu wa umri wa miaka 50 na juu katika nchi zinazoendelea.

Utafiti huu ambao unapendekeza kutathmini uhusiano kati ya matumizi ya madawa ya kuongeza nguvu za kiume na VVU miongoni mwa wanaume wazee unatarajiwa kuchangia kwa misingi ya kisayansi.

Unaulizwa kushiriki katika utafiti huu. Ukiamua kushiriki katika utafiti, utaulizwa mfululizo wa maswali ya kijamii na matumizi ya madawa ya kuongeza nguvu za kiume. Mahojiano yatadumu takriban dakika 20 tu.

Kabla ya kuamua kama unataka kuwa katika utafiti huu, unahitaji kujua kuhusu jambo lolote nzuri au mbaya linaloweza kutokea ukiamua kuwa katika utafiti huu. Fomu hii anaelezea kuhusu utafiti. Unaweza kuuliza swali lolote wakati wowote.

**Kuwa katika utafiti huo ni uchaguzi wako:**

Fomu hii ya ridhaa inatoa taarifa kuhusu utafiti huu, hatari na faida, na mambo mengine ambayo utaelezewa. Baada ya kuelezewa na kuelewa utafiti, kama utakubali kujihusisha na utafiti huu , utaulizwa kuweka ishara ya jina lako au kufanya alama yako juu ya fomu hii. Utapewa nakala ya kuchukua nyumbani.

Kabla ya kujifunza juu ya utafiti huu, ni muhimu kujua yafuatayo:

- Ushiriki wako katika utafiti huu ni hiari kabisa
- Unaweza kuamua kujiondoa katika jaribio wakati wowote, bila kukabiliwa na madhara yoyote

**Madhumuni ya utafiti:**

Madhumuni ya utafiti huu ni kujua kama matumizi ya madawa ya kuongeza nguvu za kiume yanaweza kuhusishwa na maambukizi ya VVU miongoni mwa wanaume wenye umri wa miaka 50-75. Utafiti huu utafanyiwa katika hospitali ya Taifa ya Kenyatta. Utafiti utakuwa ukitumia dodoso aina ya nusu muundo kuhusu matumizi ya madawa za kuongeza nguvu za kiume na mambo mengine husika.

**Nini cha kutarajia wakati wa mahojiano:**

Utaulizwa maswali machache kuhusu madawa ya kuongeza nguvu za kiume na VVU.

**Ukichagua kutoshiriki au kuondoka kwenye utafiti:**

Una uhuru wa kutoshiriki katika huu utafiti. Ukiamua kutoshiriki au kuondoka kenye utafiti wakati wa mahojiano, unaweza kufanya hivyo kwa uhuru bila madhara dhidi yako.

**Uwezekano wa Hatari**

Sitarajii hatari yoyote kwako wakati wa utafiti huu. Utatarajiwa kufika kwa ajili ya mahojiano wakati na mahali ambapo ni sawa na wewe. Unaweza kuwa na wasiwasi kuhusu kujadili masuala ya madawa ya kuongeza nguvu za kiume na VVU au maswali kuhusiana. Kila juhudi zitafanywa kulinda faragha yako na usiri wakati wewe unashiriki katika utafiti. Mahojiano yatafanyika kwa feraga.

**Faida zinazoweza kutokana na utafiti huu:**

Kunaweza kuwa hakuna faida ya moja kwa moja kutokana na habari utataoa kwa ajili ya utafiti huu. Hata hivyo, matokeo yatatumika kusaidia katika kutunga sera ambazo zinaweza kuanzisha mikakati ya kuzuia dhidi ya maambukizi ya VVU miongoni mwa wanaume wa umri mkubwa.

**Gharama:**

Hakuna gharama kwako kwa ajili ya kushiriki katika utafiti huu mbali na wakati wako.

**Rekodi yako itakuwa siri:**

Kila juhudi zitafanywa kuweka habari utakazotoa siri. Hauhitaji kuandika jina lako na taarifa za kibinafsi ambazo utatoa katika mahojiano hazitatolewa bila idhini yako iliyoandikwa. Habari katika dodoso haiwezi kutambuliwa kama ni yako. Habari zozote binafsi hazitatolewa katika uchapishaji wowote kuhusu utafiti huu. Rekodi yako inaweza kupitiwa na Kamati ya Maadili ya KEMRI.

**Kuumia kwa sababu ya kushiriki katika utafiti huu:**

Hakuna uwezekano kwamba aina yoyote ya kuumia inaweza kutokea kutokana na utafiti huu. Ni muhimu kumweleza wafanyakazi utafiti kama wewe umehisi kukasirika kwa sababu ya kushiriki katika utafiti huu.

**Matatizo na maswali:**

Utapewa nakala ya fomu hii kuchukua na wewe. Kama una maswali yoyote au wasiwasi juu ya haki zako kama mshiriki wa utafiti, tafadhali wasiliana na:

The Principal;
College of Health Sciences
Jomo Kenyatta University of Agriculture and Technology
P.O. Box 62200-00200; Nairobi

Tel: 254-67-52711/52181-4

Fax: 254-67-52161

director@itromid.jkuat.ac.ke

**Haki zako kama mshiriki katika utafiti:**

Utafiti huu umepitishwa na kupitiwa na KEMRI's Scientific Steering Committee . Kamati hii imepitia huu utafiti ili kusaidia kulinda haki za washiriki. Kama una maswali yoyote kuhusu haki yako kama mshiriki wa utafiti unaweza kuwasiliana na: The secretary, KEMRI Ethics Review Committee, P.O.Box 54840-00200, Nairobi. Tel: 020-2722541. E-mail address: ERCadmin@kemri.org.

**Kauli yako ya ridhaa na saini:**

Kama umesoma ridhaa, au kama imesomwa na ukaelezewa , na umeelewa habari na hiari na umekubali kujiunga na utafiti huu, tafadhali kusoma kwa makini maelezo ya hapa chini kabla ya kusaini jina lako:

- Nimepewa nafasi ya kuuliza maswali yoyote na nina uhakika kuhusu majibu ambayo nimepeana.
- Najua kwamba taarifa yoyote nimetoa itakuwa siri na kwamba mimi ninaweza kuondoka kwenye utafiti huu wakati wowote.
- Nikiamua kuondoka au kukataa kuwa katika utafiti, naelewa kwamba hakutakuwa na madhara.
- Jina, namba ya simu na anuani ya kuwasiliana katika kesi ya dharika kuandika.
- Mimi kukubaliana na kuchukua sehemu katika utafiti huu kama kujitolea, na nimepewa nakala ya fomu hii ya ridhaa ya kutunza.

| | |
|---|---|
| …… | …… |
| Jina la mhojiwa | Saini ya mhojiwa na tarehe |
| …… | …… |
| Jina la mhojaji | Saini ya mhojaji na tarehe |
| …… | …… |
| Jina la mtafiti | Saini ya mtafiti na tarehe |

**Appendix 3: Questionnaire for Cases**

| Risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs attending at Kenyatta National Hospital. | | | | |
|---|---|---|---|---|
| **Section I: Background Information** | | | | |
| **No** | **Questions** | **Coding categories** | | **Skip to** |
| 1. | Questionnaire serial number | | | |
| 2. | Data collector's name and signature | | | |
| 3. | Date of interview | Day: _____ | | |
| | | Month:_____ | | |
| | | Year: _____ | | |
| 4. | How old are you? | Year: _____ | | |
| 5. | Where is your location/address? | Nairobi | 1 | |
| | | Outside Nairobi | 2 | |
| 6. | What is your level of attained education? | No formal education | 1 | |
| | | Primary | 2 | |
| | | Secondary | 3 | |
| | | Higher/university | 4 | |
| | | No response | 99 | |
| 7. | What is your occupation? | Unemployed | 1 | |
| | | Civil servant | 2 | |
| | | Self-employed | 3 | |
| | | Other (specify)_____ | 77 | |
| 8. | What is your religion? | Christian | 1 | |
| | | Muslim | 2 | |
| | | Buddhist | 3 | |
| | | Hindu | 4 | |
| | | Traditional | 5 | |
| | | Other (specify):_____ | 77 | |
| | | No religion | 6 | |
| | | No response | 99 | |
| 9. | What is your marital status? | Single | 1 | |
| | | Married | 2 | |
| | | Divorced | 3 | |
| | | Cohabiting | 4 | |
| | | Widower | 5 | |
| | | No response | 99 | |
| 10. | What is your circumcision | Circumcised | 1 | |

| | | | | |
|---|---|---|---|---|
| | status? | Un-circumcised | 2 | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| 11. | What is your sex orientation? | Heterosexual | 1 | |
| | | Homosexual/gay | 2 | |
| | | No response | 99 | |

**Section II: Questions related to erectile dysfunction drug use**

| No | Questions | Coding categories | | Skip to |
|---|---|---|---|---|
| 1. | When did you first find out you were HIV positive? | Year: _____ | | |
| 2. | What was your age by the time you knew your HIV positive status? | Age in years: _____ | | |
| 3. | How do you describe your sexual life? | Casual partner | 1 | |
| | | Steady/Regular partner | 2 | |
| | | No response | 99 | |
| 4. | How would you rate your level of sexual desire? | None at all | 1 | |
| | | Very low | 2 | |
| | | Low | 3 | |
| | | Moderate | 4 | |
| | | High | 5 | |
| | | Very high | 6 | |
| 5. | Many men experience problems with sexual intercourse. How would you describe your ability to get and keep an erection adequate for satisfactory intercourse? | Always able to get and keep an erection | 1 | |
| | | Usually able to get and keep an erection | 2 | |
| | | Sometimes able to get and keep an erection | 3 | |
| | | Never able to get and keep erection | 4 | |
| | | No response | 99 | |
| 6. | Many men use EDDs or sexual enhancement drugs. Have you ever used erectile dysfunction drugs during the period? | Yes | 1 | |
| | | No | 2 | **Q 18** |
| | | No response | 99 | |
| 7. | When did you start using erectile dysfunction drugs? | Before you found HIV + | 1 | |
| | | After you found HIV + | 2 | |
| | | Year: _____ | | |
| 8. | What was the reason using erectile dysfunction drug? | To treat erectile dysfunction | 1 | |
| | | Counteract effects of drugs/alcohol | 2 | |
| | | Other (specify)_____ | 77 | |

| | | | | |
|---|---|---|---|---|
| 9. | What kind of erectile dysfunction drugs were you using? | Sildenafil (Viagra) | 1 | |
| | | Tadalafil (Cialis) | 2 | |
| | | Vardenafil (Levitra) | 3 | |
| | | Sexual enhancement cream | 4 | |
| | | Sexual enhancement herbs | 5 | |
| | | Other (specify)_____ | 77 | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| 10. | How often did you use erectile dysfunction drugs when you had intercourse? | Always/often | 1 | |
| | | Sometimes | 2 | |
| | | Rarely | 3 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 11. | How would you rate your level of sexual desire after using EDD? | Low | 1 | |
| | | Moderate | 2 | |
| | | High | 3 | |
| | | Very high | 4 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 13. | For how long have you been using erectile dysfunction drugs | One day | 1 | |
| | | One week | 2 | |
| | | One month | 3 | |
| | | One year | 4 | |
| | | Two years and above | 5 | |
| | | Other (specify)_____ | 77 | |
| 14. | How did/do you get the erectile dysfunction drugs | Doctor's prescription | 1 | |
| | | From pharmacy without prescription | 2 | |
| | | Through friends | 3 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 15. | When you are taking EDD, were/are you given any advice? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 16. | Have you ever combined an erectile dysfunction drugs with other recreational drugs/alcohol? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 17. | What was/were the recreational substances used concomitantly with erectile dysfunction drugs | Methamphetamines | 1 | |
| | | Cocaine | 2 | |
| | | Marijuana | 3 | |
| | | Heroin | 4 | |
| | | Alcohol | 5 | |
| | | Alkyl nitrites (poppers) | 6 | |

| | | | | |
|---|---|---|---|---|
| | | Khat | 8 | |
| | | Other: _____ | 77 | |
| | | No response | 99 | |
| 18. | Before you found out you were HIV positive, did you have a sexually transmitted disease, such as chlamydia, gonorrhoea, herpes or syphilis? | Yes | 1 | |
| | | No | 2 | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| | | No | 2 | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| 19. | Before you found out you were HIV positive, did you use to take excessive alcohol/drunk? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 20. | Before you found out you were HIV positive, did you use injection drugs? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 21. | Have you ever had sexual practices with a prostitute or with anyone other than your wife or or more than one partner before you found out you were HIV positive? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 22. | If the above question is yes, did you use condom? | All of the time | 1 | |
| | | Some of the time | 2 | |
| | | Very rarely | 3 | |
| | | Never | 4 | |
| | | No response | 99 | |

**Appendix 4: Dodoso kwa ajili ya kesi**

| Hatari ya kuambukizwa VVU miongoni mwa wanaume wenye umri wa miaka 50-75 wanaotumia dawa za kuongeza nguvu za kiume katika Hospitali ya Taifa ya Kenyatta. | | | | |
|---|---|---|---|---|
| **Sehemu ya I: Taarifa za kijamii** | | | | |
| **Nambari** | **Maswali** | **Nambari ya mafumbo ya makundi** | | **Enda kwa** |
| 1 | Nambari ya dodoso | | | |
| 2 | Jina na saini ya mhojaji | | | |
| 3 | Tarehe ya mahojiano | Siku: _____ | | |
| | | Mwezi:_____ | | |
| | | Mwaka: _____ | | |
| 4 | Una umri gani? | Mwaka: _____ | | |
| 5 | Unaishi wapi / anwani? | Nairobi | 1 | |
| | | Nje ya Nairobi | 2 | |
| 6 | Ngazi ya elimu? | Hakuna elimu rasmi | 1 | |
| | | Shule ya msingi | 2 | |
| | | Sekondari | 3 | |
| | | Juu / chuo kikuu | 4 | |
| | | Hakuna majibu | 99 | |
| 7 | Unafanya kazi gani? | Ajira | 1 | |
| | | Mtumishi wa umma | 2 | |
| | | Kujiajiri | 3 | |
| | | Other (Nyingine (taja))_____ | 77 | |
| 8 | Dini yako? | Mkristo | 1 | |
| | | Muislamu | 2 | |
| | | Buddhist | 3 | |
| | | Hindu | 4 | |
| | | Jadi | 5 | |
| | | Nyingine (eleza)_____ | 77 | |
| | | Hakuna dini | 6 | |
| | | Hakuna majibu | 99 | |
| 9 | Nini hadhi yako ya ndoa? | Sijaoa | 1 | |
| | | Nimeoa | 2 | |
| | | Talaka | 3 | |
| | | Kinyumba | 4 | |
| | | Mjane | 5 | |
| | | Hakuna majibu | 99 | |

| | | | | |
|---|---|---|---|---|
| 10 | Nini hadhi yako ya tohara? | Kutahiriwa | 1 | |
| | | Kutotahiriwa | 2 | |
| | | Kutojua | 88 | |
| | | Hakuna majibu | 99 | |
| 11 | Nini hadhi yako ya mapenzi? | Kawaida | 1 | |
| | | Mashoga /shoga | 2 | |
| | | Hakuna majibu | 99 | |

**Sehemu ya II: Maswali kuhusiana na matumizi ya madawa za kuongeza nguvu za kiume**

| **Nambari** | **Maswali** | **Nambari ya mafumbo ya makundi** | | **Enda kwa** |
|---|---|---|---|---|
| 1. | Ni wakati gani ulijua mara ya kwanza kuhusu hali yako ya HIV? | Mwaka: _____ | | |
| 2. | Ulikuwa umri gani wakati ulijua hali yako ya HIV? | Umri katika miaka: _____ | | |
| 3. | Unasema vipi kuhusu maisha yako ya ngono? | Wapenzi wengi | 1 | |
| | | Mpenzi mmoja | 2 | |
| | | Hakuna majibu | 99 | |
| 4. | Unasema vipi kuhusu hisia zako za kimapenzi? | Hakuna hisia | 1 | |
| | | Chini kabisa | 2 | |
| | | Chini | 3 | |
| | | katikati | 4 | |
| | | Juu | 5 | |
| | | Juu kabisa | 6 | |
| 5. | Wanaume wengi huwa na matatizo na kujamiiana. Jinsi gani unaweza kuelezea uwezo wako wa kupata na kuweka Erection ya kutosha kwa ajili ya ngono ya kuridhisha? | Daima na uwezo wa kupata na kuweka Erection | 1 | |
| | | Kawaida na uwezo wa kupata na kuweka Erection | 2 | |
| | | Wakati mwingine uwezo wa kupata na kuweka Erection | 3 | |
| | | Kamwe na uwezo wa kupata na kuweka Erection | 4 | |
| | | Hakuna majibu | 99 | |
| 6. | Wanaume wengi hutumia madawa ya kuongeza nguvu za | Ndiyo | 1 | |
| | | Hapana | 2 | **Q 18** |

| | | | | |
|---|---|---|---|---|
| | kiume. Je, umewahi kutumia madawa haya tangu ujue hali yako? | Hakuna jibu | 99 | |
| 7. | Ulianza lini kutumia madawa ya kuongeza nguvu za kiume? | Kabla ya kujua hali yako | 1 | |
| | | Baada ya kujua hali yako | 2 | |
| | | Mwaka: _____ | | |
| 8. | Ni nini sababu ya kutumia madawa ya kuongeza nguvu za kiume? | Kutibu shida ya erection. | 1 | |
| | | Kukabiliana na madhara ya madawa ya kulevya / pombe | 2 | |
| | | Nyingine (taja) _____ | 77 | |
| 9. | Ni aina gani ya dawa ya kuongeza nguvu za kiume ambayo wewe hutumia? | Sildenafil (Viagra) | 1 | |
| | | Tadalafil (Cialis) | 2 | |
| | | Vardenafil (Levitra) | 3 | |
| | | Sexual enhancement cream | 4 | |
| | | Sexual enhancement herbs | 5 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Sijui | 88 | |
| | | Hakuna majibu | 99 | |
| 10. | Ni mara ngapi wewe hutumia madawa za kuongeza nguvu za kiume ukifanya mapenzi? | Daima / mara nyingi | 1 | |
| | | Wakati mwingine | 2 | |
| | | Mara chache | 3 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 11. | Jinsi gani unaweza kupima kiwango yako ya hamu ya ngono baada ya kutumia madawa ya kuongeza nguvu za kiume? | Asili | 1 | |
| | | Wastani | 2 | |
| | | High | 3 | |
| | | Juu sana | 4 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 12. | Unapo chukua EDD, je unapewa mawaidha yoyote? | Ndio | 1 | |
| | | Hapana | 2 | |
| | | Hakuna majibu | 99 | |
| 13. | Kwa muda gani umekuwa ukitumia madawa za kuongeza nguvu za kiume sasa? | Siku moja | 1 | |
| | | Wiki moja | 2 | |
| | | Mwezi mmoja | 3 | |
| | | Mwaka mmoja | 4 | |
| | | Miaka miwili na juu ya | 5 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 14. | Jinsi gani unaweza kupata hizi | Agizo la daktari | 1 | |

| | | | | |
|---|---|---|---|---|
| | madawa za kuongeza nguvu za kiume? | Kutoka maduka ya dawa bila ya agizo | 2 | |
| | | Kupitia marafiki | 3 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna jibu | 99 | |
| 15. | Umewahi tumia dawa za kuongeza nguvu za kiume pamoja na dawa nyingine za burudani / pombe? | Ndiyo | 1 | |
| | | Hapana | 2 | |
| | | Hakuna majibu | 99 | |
| 16. | Ni dawa gani za burudani zilitumika pamoja na dawa za kuongeza nguvu za kiume? | Methamphetamines | 1 | |
| | | Cocaine | 2 | |
| | | Marijuana | 3 | |
| | | Heroin | 4 | |
| | | Pombe | 5 | |
| | | Alkyl nitrites (poppers) | 6 | |
| | | Miraa | 8 | |
| | | Nyingine: _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 17. | Kabla ya kujua hali yako ya HIV je ulikuwa na ugonjwa wa zinaa, kama vile klamidia, kisonono, kaswende au herpes? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hawajui | 88 | |
| | | Hakuna majibu | 99 | |
| | | Hakuna | 2 | |
| | | Sijui | 88 | |
| | | Hakuna majibu | 99 | |
| 18. | Kabla ya kujua hali yako ya HIV, ulitumia pombe kupindukia au ulikuwa mlevi? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hakuna majibu | 99 | |
| 19. | Kabla ya kujua hali yako ya HIV, ulikuwa unatumia dawa za kulevya za kujidunga? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hakuna majibu | 99 | |
| 20. | Je umefanya mapenzi na makahaba ama wanawake wengine isipokua mke wako? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hakuna majibu | 99 | |
| 21. | Kama swali la juu ni ndio, je ulitumia mipira? | Kila wakati | 1 | |
| | | Saa zingine | 2 | |
| | | Sio sana | 3 | |
| | | sijawahi | 4 | |
| | | Hakuna majibu | 99 | |

**Appendix 5: Questionnaire for Controls**

| Risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs attending at Kenyatta National Hospital. | | | | |
|---|---|---|---|---|
| **Section I: Background Information** | | | | |
| **No** | **Questions** | **Coding categories** | | **Skip to** |
| 1. | Questionnaire serial number | | | |
| 2. | Data collector's name and signature | | | |
| 3. | Date of interview | Day: _____ | | |
| | | Month:_____ | | |
| | | Year: _____ | | |
| 4. | How old are you? | Year: _____ | | |
| 5. | Where is your location? | Nairobi | 1 | |
| | | Outside Nairobi | 2 | |
| 6. | What is your level of attained education? | No formal education | 1 | |
| | | Primary | 2 | |
| | | Secondary | 3 | |
| | | Higher/university | 4 | |
| | | No response | 99 | |
| 7. | What is your occupation? | Unemployed | 1 | |
| | | Civil servant | 2 | |
| | | Self-employed | 3 | |
| | | Other (specify)_____ | 77 | |
| 8. | What is your religion? | Christian | 1 | |
| | | Muslim | 2 | |
| | | Buddhist | 3 | |
| | | Hindu | 4 | |
| | | Traditional | 5 | |
| | | Other (specify):_____ | 77 | |
| | | No religion | 6 | |
| | | No response | 99 | |
| 9. | What is your marital status? | Single | 1 | |
| | | Married | 2 | |
| | | Divorced | 3 | |
| | | Cohabiting | 4 | |
| | | Widower | 5 | |
| | | No response | 99 | |
| 10. | What is your circumcision status? | Circumcised | 1 | |
| | | Un-circumcised | 2 | |
| | | Don't know | 88 | |

| | | | | |
|---|---|---|---|---|
| | | No response | 99 | |
| 11. | What is your sex orientation? | Heterosexual | 1 | |
| | | Homosexual/gay | 2 | |
| | | No response | 99 | |

**Section II: Questions related to erectile dysfunction drug use**

| No | Questions | Coding categories | | Skip to |
|---|---|---|---|---|
| 1. | How do you describe your sexual life? | Casual partner | 1 | |
| | | Steady/Regular partner | 2 | |
| | | No response | 99 | |
| 2. | How would you rate your level of sexual desire? | None at all | 1 | |
| | | Very low | 2 | |
| | | Low | 3 | |
| | | Moderate | 4 | |
| | | High | 5 | |
| | | Very high | 6 | |
| 3. | Many men experience problems with sexual intercourse. How would you describe your ability to get and keep an erection adequate for satisfactory intercourse? | Always able to get and keep an erection | 1 | |
| | | Usually able to get and keep an erection | 2 | |
| | | Sometimes able to get and keep an erection | 3 | |
| | | Never able to get and keep erection | 4 | |
| | | No response | 99 | |
| 4. | Many men use EDDs or sexual enhancement drugs. Have you ever used erectile dysfunction drugs? | Yes | 1 | |
| | | No | 2 | **Q 15** |
| | | No response | 99 | |
| 5. | If the response for the above question is yes when in years | _____ | | |
| 6. | What was the reason using erectile dysfunction drug? | To treat erectile dysfunction | 1 | |
| | | Counteract effects of drugs/alcohol | 2 | |
| | | Other (specify)_____ | 77 | |
| 7. | What kind of erectile dysfunction drugs were you using? | Sildenafil (Viagra) | 1 | |
| | | Tadalafil (Cialis) | 2 | |
| | | Vardenafil (Levitra) | 3 | |
| | | Sexual enhancement cream | 4 | |
| | | Sexual enhancement herbs | 5 | |
| | | Other | 77 | |

| | | | | |
|---|---|---|---|---|
| | | (specify)_____ | | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| 8. | How often did you use erectile dysfunction drugs when you had intercourse? | Always/often | 1 | |
| | | Sometimes | 2 | |
| | | Rarely | 3 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 9. | For how long have you been using erectile dysfunction drugs | One day | 1 | |
| | | One week | 2 | |
| | | One month | 3 | |
| | | One year | 4 | |
| | | Two years and above | 5 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 10. | How would you rate your level of sexual desire after using EDD? | Low | 1 | |
| | | Moderate | 2 | |
| | | High | 3 | |
| | | Very high | 4 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 11. | How did/do you get the erectile dysfunction drugs | Doctor's prescription | 1 | |
| | | From pharmacy without prescription | 2 | |
| | | Through friends | 3 | |
| | | Other (specify)_____ | 77 | |
| | | No response | 99 | |
| 12. | When you are taking EDD, were/are you given any advice? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 13. | Have you ever combined an erectile dysfunction drugs with other recreational drugs/ alcohol? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 14. | What was/were the recreational substances used concomitantly with erectile dysfunction drugs | Methamphetamines | 1 | |
| | | Cocaine | 2 | |
| | | Marijuana | 3 | |
| | | Heroin | 4 | |
| | | Alcohol | 5 | |
| | | Alkyl nitrites (poppers) | 6 | |
| | | Khat | 8 | |
| | | Other: _____ | 77 | |

| | | | | |
|---|---|---|---|---|
| | | No response | 99 | |
| 15. | Did/do you have a sexually transmitted disease, such as chlamydia, gonorrhoea, herpes or syphilis? | Yes | 1 | |
| | | No | 2 | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| | | No | 2 | |
| | | Don't know | 88 | |
| | | No response | 99 | |
| 16. | Did/do you use to take excessive alcohol/drunk? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 17. | Did/do you use injection drugs? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 18. | Have you ever had sexual practices with a prostitute or with anyone other than your wife or more than one partner? | Yes | 1 | |
| | | No | 2 | |
| | | No response | 99 | |
| 19. | If the above question is yes, did you use condom? | All of the time | 1 | |
| | | Some of the time | 2 | |
| | | Very rarely | 3 | |
| | | Never | 4 | |
| | | No response | 99 | |

**Appendix 6: Dodoso kwa ajili ya Udhibiti**

| | | | | |
|---|---|---|---|---|
| Hatari ya kuambukizwa VVU miongoni mwa wanaume wenye umri wa miaka 50-75 wanaotumia madawa za kuongeza nguvu za kiume katika Hospitali ya Taifa ya Kenyatta. | | | | |
| **Sehemu ya I: Taarifa za kijamii** | | | | |
| **Nambari** | **Maswali** | **Nambari ya mafumbo ya makundi** | | **Enda kwa** |
| 1. | Nambari ya dodoso | | | |
| 2. | Jina na saini ya mhojaji | | | |
| 3. | Tarehe ya mahojiano | Siku: _____ | | |
| | | Mwezi:_____ _ | | |
| | | Mwaka:_____ | | |
| 4. | Una umri gani? | Mwaka:_____ | | |
| 5. | Unaishi wapi/ anwani? | Nairobi | 1 | |
| | | Nje ya Nairobi | 2 | |
| 6. | Ngazi ya elimu? | Hakuna elimu rasmi | 1 | |
| | | Kanuni ya | 2 | |
| | | Sekondari | 3 | |
| | | Juu / chuo kikuu | 4 | |
| | | Hakuna majibu | 99 | |
| 7. | Unafanya kazi gani? | Ajira | 1 | |
| | | Mtumishi wa umma | 2 | |
| | | Kujiajiri | 3 | |
| | | (Nyingine (taja))____ | 77 | |
| 8. | Dini yako? | Mkristo | 1 | |
| | | muislamu | 2 | |
| | | Buddhist | 3 | |
| | | Hindu | 4 | |
| | | Jadi | 5 | |
| | | Nyingine (eleza): _____ | 77 | |
| | | Hakuna dini | 6 | |
| | | Hakuna majibu | 99 | |
| 9. | Nini hadhi yako ya ndoa? | Sijaoa | 1 | |
| | | Nimeoa | 2 | |
| | | Talaka | 3 | |
| | | Kinyumba | 4 | |
| | | Mjane | 5 | |
| | | Hakuna majibu | 99 | |
| 10. | Nini hadhi yako ya tohara? | Kutahiriwa | 1 | |

| | | | | |
|---|---|---|---|---|
| | | Kutotahiriwa | 2 | |
| | | Kutojua | 88 | |
| | | Hakuna majibu | 99 | |
| 11. | Nini hadhi yako ya mapenzi? | Kawaida | 1 | |
| | | Mashoga / shoga | 2 | |
| | | Hakuna majibu | 99 | |

**Sehemu ya II: Maswali kuhusiana na matumizi ya madawa za kuongeza nguvu za kiume**

| **Nambari** | **Maswali** | **Nambari ya mafumbo ya makundi** | | **Enda kwa** |
|---|---|---|---|---|
| 1. | Unasema vipi kuhusu maisha yako ya ngono? | Wapenzi wengi | 1 | |
| | | Mpenzi mmoja | 2 | |
| | | Hakuna majibu | 99 | |
| 2. | Unasema vipi kuhusu hisia zako za kimapenzi? | Hakuna hisia | 1 | |
| | | Chini kabisa | 2 | |
| | | Chini | 3 | |
| | | katikati | 4 | |
| | | Juu | 5 | |
| | | Juu kabisa | 6 | |
| 3. | Wanaume wengi huwa na matatizo na kujamiiana. Jinsi gani unaweza kuelezea uwezo wako wa kupata na kuweka Erection ya kutosha kwa ajili ya ngono ya kuridhisha? | Daima na uwezo wa kupata na kuweka Erection | 1 | |
| | | Kawaida na uwezo wa kupata na kuweka Erection | 2 | |
| | | Wakati mwingine uwezo wa kupata na kuweka Erection | 3 | |
| | | Kamwe na uwezo wa kupata na kuweka Erection | 4 | |
| | | Hakuna majibu | 99 | |
| 4. | Wanaume wengi hutumia madawa ya kuongeza nguvu za kiume. Je, umewahi kutumia madawa haya? | Ndio | 1 | |
| | | Hapana | 2 | **Q 15** |
| | | Hakuna jibu | 99 | |
| 5. | Ni nini sababu ya kutumia madawa ya kuongeza nguvu za kiume? | Kutibu erectile dysfunction | 1 | |
| | | Kukabiliana na madhara ya madawa ya kulevya / pombe | 2 | |
| | | Nyingine (taja) _____ | 77 | |

| | | | | |
|---|---|---|---|---|
| 6. | Ni aina gani ya dawa ya kuongeza nguvu za kiume wewe hutumia? | Sildenafil (Viagra) | 1 | |
| | | Tadalafil (Cialis) | 2 | |
| | | Vardenafil (Levitra) | 3 | |
| | | Sexual enhancement cream | 4 | |
| | | Sexual enhancement herbs | 5 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hawajui | 88 | |
| | | Hakuna majibu | 99 | |
| 7. | Ni mara ngapi wewe hutumia madawa za kuongeza nguvu za kiume ukifanya mapenzi? | Daima / mara nyingi | 1 | |
| | | Wakati mwingine | 2 | |
| | | Mara chache | 3 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 8. | Jinsi gani unaweza kupima kiwango chako cha hamu ya ngono baada ya kutumia EDD? | Asili | 1 | |
| | | Wastani | 2 | |
| | | High | 3 | |
| | | Juu sana | 4 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 9. | Kwa muda gani umekuwa ukitumia madawa za kuongeza nguvu za kiume sasa? | Siku moja | 1 | |
| | | Wiki moja | 2 | |
| | | Mwezi mmoja | 3 | |
| | | Mwaka mmoja | 4 | |
| | | Miaka miwili na juu ya | 5 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 10. | Jinsi gani unaweza kupata hizi madawa za kuongeza nguvu za kiume? | Agizo la daktari | 1 | |
| | | Kutoka maduka ya dawa bila ya agizo | 2 | |
| | | Kupitia marafiki | 3 | |
| | | Nyingine (taja) _____ | 77 | |
| | | Hakuna jibu | 99 | |
| 11. | Unapo chukua EDD, je unapewa mawaidha yoyote? | Ndio | 1 | |
| | | Hapana | 2 | |
| | | Hakuna majibu | 99 | |
| 12. | Umewahi tumia dawa za kuongeza nguvu za kiume pamoja na dawa nyingine za burudani / pombe? | Ndio | 1 | |
| | | Hapana | 2 | |
| | | Hakuna majibu | 99 | |
| 13. | Ni dawa gani za burudani zilitumika pamoja na dawa za kuongeza nguvu za kiume? | Methamphetamines | 1 | |
| | | Cocaine | 2 | |
| | | Marijuana | 3 | |
| | | Heroin | 4 | |

| | | | | |
|---|---|---|---|---|
| | | Pombe | 5 | |
| | | Alkyl nitrites (poppers) | 6 | |
| | | Miraa | 8 | |
| | | Nyingine: _____ | 77 | |
| | | Hakuna majibu | 99 | |
| 14. | Je ulikuwa/u na ugonjwa wa zinaa, kama vile klamidia, kisonono, kaswende au herpes? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hawajui | 88 | |
| | | Hakuna majibu | 99 | |
| | | Hakuna | 2 | |
| | | Sijui | 88 | |
| | | Hakuna majibu | 99 | |
| 15. | Ulitumia pombe kupindukia au ulikuwa mlevi? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hakuna majibu | 99 | |
| 16. | Je ulikuwa unatumia madawa ya kulevya ya kujidunga? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hakuna majibu | 99 | |
| 17. | Je umefanya mapenzi na makahaba ama wanawake wengine isipokua mke wako? | Ndiyo | 1 | |
| | | Hakuna | 2 | |
| | | Hakuna majibu | 99 | |
| 18. | Kama swali la juu ni ndio, je ulitumia mipira? | Kila wakati | 1 | |
| | | Saa zingine | 2 | |
| | | Sio sana | 3 | |
| | | sijawahi | 4 | |
| | | Hakuna majibu | 99 | |

**Appendix 7: Approval Letter by Scientific Steering Committee -KEMRI**

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

ESACIPAC/SSC/101920 31st July, 2013

Michael Fissehaye

Thro'
Director, CPHR
NAIROBI

Forwarded
08/08/2013

REF: SSC No. 2629 (Revised) – Risk of HIV infection among men aged 50 to 75 years using erectile dysfunction drugs attending Kenyatta National Hospital, 2013

Thank you for your letter dated 25th July, 2013 responding to the comments raised by the KEMRI SSC.

I am pleased to inform you that your protocol now has formal scientific approval from SSC.

The SSC however, advises that work on the proposed study can only start after ERC approval.

Sammy Njenga, PhD
SECRETARY, SSC

In Search of Better Health

## Appendix 8: Approval Letter by Ethical Review Committee - KEMRI

# KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-206901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

**KEMRI/RES/7/3/1** **November 06, 2013**

**TO:** **MICHAEL HABTU FISSEHAYE**
**PRINCIPAL INVESTIGATOR**

**THROUGH** **DR. CHARLES MBAKAYA**
**ACTING DIRECTOR, CPHR**
**NAIROBI**

Forwarded 6/11/2013

Dear Sir,

**RE:** **SSC NO. 2629 - (*2ND RESUBMISSION*): RISK OF HIV INFECTION AMONG MEN AGED 50 TO 75 YEARS USING ERECTILE DYSFUNCTION DRUGS ATTENDING AT KENYATTA NATIONAL HOSPITAL. VERSION 3: OCTOBER 26, 2013**

Reference is made to your letter written on 25 October 2013 and received at the KEMRI ERC on 4th November 2013.

This is to inform you that the Committee notes that the following issues raised at the 218th meeting of the KEMRI Ethics Review Committee held on 20th August 2013 have been adequately addressed. Consequently, the study is granted approval for implementation effective this **6th November 2013** for a period of one year. Please note that authorization to conduct this study will automatically expire on **November 05, 2014**.

If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval to the ERC Secretariat by **September 23, 2014**. The regulations require continuing review even though the research activity may not have begun until sometime after the ERC approval.

You are required to submit any proposed changes to this study to the SSC and ERC for review and the changes should not be initiated until written approval from the ERC is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of the ERC and you should advise the ERC when the study is completed or discontinued.

Work on this project may begin.

Yours faithfully,

EAB

**DR. ELIZABETH BUKUSI,**
**ACTING SECRETARY,**
**KEMRI/ETHICS REVIEW COMMITTEE**

## Appendix 9: Approval Letter by Ethics and Research Committee - KNH/UON

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/11 Link:www.uonbi.ac.ke/activities/KNHUoN 17th January, 2014

KENYATTA NATIONAL HOSPITAL APPROVED 17 JAN 2014 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

Michael Habtu Fissehaye
TM 310-2082/2012
JKUAT

Dear Michael

RESEARCH PROPOSAL: RISK OF HIV INFECTION AMONG MEN AGED 50 TO 70 YEARS USING ERECTILE DYSFUNCTION DRUGS ATTENDING AT KENYATTA NATIONAL HOSPITAL, 2013 (P563/11/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 17th January 2014 to 16th January 2015.

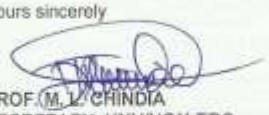
This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. Prof. A.N.Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
Assistant Director/Health Information, KNH
Supervisors: Dr. Yeri Kombe, Kenya Medical Research Institute
Prof. Zipporah Ng'ang'a, JKUAT
Mrs.moses Mwangi, Kenya Medical Research Institute

Protect to Discover