

**HIV-1 INFECTION ACQUISITION AMONG MSM ENROLLED IN SEX WORKER  
OUTREACH PROJECT (SWOP), NAIROBI COUNTY.**

By

Dr. Yvonne N. Munyao

W62/81060/2015

*A thesis submitted to the University of Nairobi in partial fulfilment for the Degree of Master  
of Science in Medical Statistics.*

Nov 2017

**DECLARATION**

**STUDENT**

I declare that this research proposal is my original work and has not been presented for a degree or any other award in any other University.

**Signature** ..... **Date** .....

Dr. Yvonne N. Munyao

W62/81060/2015

**Supervisors**

This research proposal has been submitted for examination with our approval as the University supervisors.

**Signature**..... **Date** .....

Dr. Anthony Karanja

Institute of Tropical and Infectious Diseases

University of Nairobi

**Signature**..... **Date** .....

Ms Anne Wang'ombe

Institute of Tropical and Infectious Diseases University of Nairobi

## **DEDICATION**

To my husband Dr. Mike Sangoro, my parents Mr. & Mrs Mulinge , thank you for your support and encouragement, I do not take it for granted.

## **ACKNOWLEDGMENT**

First and for most I give thanks to God Almighty, for his favour in my life till this day, with him all things are possible.

To My family I am forever grateful for your moral and financial support during the course of my studies till the completion of my studies.

To my lecturers, Thank you for being patient with me, mentoring and supervision as I was writing my thesis.

Last and not least, my colleagues Sylvia Onyanha and Mian Anatole , whose support and encouragement enabled me to finish my thesis on time.

## Table of Contents

DECLARATION .....	ii
DEDICATION .....	iii
ACKNOWLEDGEMENT .....	iv
ABBREVIATIONS .....	vii
ABSTRACT.....	8
INTRODUCTION .....	10
1.1    Background of the study .....	10
1.2    Problem statement .....	11
1.3    Justification .....	11
1.4    Broad objective .....	12
1.4.1    Specific objectives .....	12
CHAPTER TWO .....	13
LITERATURE REVIEW .....	13
2.1    Human Immunodeficiency Virus .....	13
2.2    HIV transmission.....	13
2.3    HIV progression .....	14
2.4    Epidemiology of HIV.....	15
2.5.1    Female sex workers.....	16
2.5.2    People who inject drugs .....	17
2.5.3    Men who have sex with men (MSM) .....	17
2.6    Risk factors for HIV infection.....	18

2.7	Strategies towards eradication of HIV .....	20
2.7.1	Global approach .....	20
2.7.2	Challenges in addressing HIV epidemic .....	22
CHAPTER THREE .....		24
METHODOLOGY .....		24
2.0	Study design .....	24
2.1	Data Source .....	24
2.2	Study population .....	24
2.3	Determination of Sample Size.....	25
2.4	Sampling method.....	25
2.4.1	Inclusion criteria .....	26
2.5	Data collection and analysis .....	26
2.6	Ethical considerations .....	27
CHAPTER FOUR.....		28
RESULTS .....		28
CHAPTER FIVE .....		37
DISCUSSION.....		37
SUMMARY, CONCLUSION AND RECOMMENDATIONS.....		37
REFERENCES .....		39

## **ABBREVIATIONS**

FSW	Female sex workers
MSM	Men who have sex with Men
PIWD	People who inject drugs
UNAIDS	United Nations programme on HIV and AIDS
WHO	World health organization
NACC	National AIDS Control Council
CD4	Cluster of Differentiation 4
RNA	Ribonucleic acid
LVCT	Liverpool voluntary counselling and testing
PCP	Pneumonocytis Carinii Pneumonia
ART	Antiretroviral Therapy
NASCOP	National AIDS and STI control programme
USA	United States of America
CDC	Centre for Disease Control

## **ABSTRACT**

HIV incidence among MSM has increased in many regions in recent years threatening the progress towards ending the epidemic by 2030 despite prevention, treatment and care programs funded to reverse the HIV epidemic. To meet the targeted 75% reduction in HIV infections among key populations by 2020, adequate approaches need to be adopted that specifically address the key population needs. According to NACC report (2014) approximately 55% of MSM were receiving targeted HIV prevention, management and care interventions by the Ministry of Health and programmes such as SWOP and LVCT. Out of the 1011 MSM enrolled into SWOP by 2014, 447 were living with HIV and 111 of the sero-negative turned positive within a span of 3 years while the number of new infections in both female and male sex workers within the same period was 23 and 9 suggesting gaps in the HIV prevention strategies and/or implementation approach. The aim of the study was to screen all possible factors that increase the risk of MSM enrolled in SWOP acquiring HIV-1 infection and weight the effects of the identified factors. The findings of this study will serve as a guide for the SWOP implementers in coming up with targeted intervention strategies to avert this epidemic.

The study objective was to determine risk factors that are associated with acquisition of HIV-1 infection in MSM enrolled in SWOP between 2005 and 2015. A case control study design was adopted to investigate factors contributing to increased risk of HIV-1 infection among men who have sex with men enrolled in SWOP. The MSM were recruited from enrolment records of the period between 1<sup>st</sup> January, 2015 and 31<sup>st</sup> January, 2016.

A total of 324 men who have sex with men (MSM) were selected for this study. These men were enrolled into SWOP between 1<sup>st</sup> January, 2015 and 31<sup>st</sup> January, 2016 and were HIV negative at



the time of enrolment. 81/324 (25.0%) men had turned sero-positive (Cases) by 1<sup>st</sup> February, 2017 while the rest remained negative (Controls).

The study findings shows only history of foul smelling penile/anal discharge was found to be significant (OR=0.41, P=0.031), Therefore making it a significant risk factor of HIV acquisition among MSM.

Therefore there is need for targeted interventions for MSM who also have history of STI. Future interventions tailored towards MSM should have a comprehensive approach that combines behavioural, medical and structural interventions.

## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background of the study

In the World, approximately 36.7 million people were HIV+ as at end of 2015, HIV control remains a major public health challenge for W.H.O. The majority consisting of men who have sex with men, female sex workers and people who use intravenous drugs represent a mainstay group of focus in HIV prevention programmes. This is because of they are highly stigmatized making them fearful to access health care, their higher vulnerability to HIV infection and prevalence rates compared to the general population (UNAIDS, 2016). Among the programs funded to address the HIV epidemic in this hard to reach and marginalized group is the Sex worker Outreach Project (SWOP) based in Nairobi Kenya. SWOP offers biomedical, behavioural and structural intervention to sex workers and their families through their outreach and clinical teams.

This study will focus on MSM because they are the most stigmatized key populations in the world with a disproportionately higher risk of HIV infection compared to other key and general populations. MSM are reported to be 24 times more likely to be infected with the HIV virus as compared to the population globally (UNAIDS, 2016). In Nairobi Kenya, there are about 11, 042 MSM (10,000-22,222) according to a study by Okal et al., (2016). The HIV prevalence in this population was three times higher the national prevalence at 18.2% in 2010 (UN, 2011).

High number of HIV infections among MSM has been connected with a number of factors mainly due to the high prevalence of unprotected anal sex in this group. Other factors include high prevalence of STIs, low HIV testing and sexual health check-up frequency ranging from

25%-45% across the world, having multiple sex partners, alcohol and substance abuse (Bourne & Harm Reduction International, 2012) as well as legal factors such as criminalizing same-sex conduct which results in MSM being fearful of accessing HIV care services centers because they fear if their sexual identity and orientation is discovered they will be prosecuted.

## **1.2 Problem statement**

Despite the prevention, treatment and care programs funded to reverse the HIV epidemic, the HIV incidence among MSM has been increasing in all regions in recent years threatening the progress towards ending the epidemic by 2030. To meet the targeted 75% reduction in HIV infections among key populations by 2020, adequate approaches need to be adopted that specifically address the key population needs. According to NACC report (2014) approximately 55% of MSM were receiving targeted HIV prevention, treatment and care interventions by the Ministry of Health and programmes such as SWOP and LVCT. Out of the 1011 MSM enrolled into SWOP by 2014, 447 were living with HIV and 111 of the sero-negative turned positive within a span of 3 years while the number of new infections in both female and male sex workers within the same period was 23 and 9 suggesting gaps in the HIV prevention strategies and/or implementation approach. The aim of the study was to screen all possible factors that increase the risk of MSM enrolled in SWOP acquiring HIV-1 infection and weight the effects of the identified factors.

## **1.3 Justification**

The findings of this study will serve as a guide for the SWOP implementers in coming up with targeted intervention strategies to avert this epidemic since there are not many studies on MSM. Due to stigma and prosecution in some countries, MSM have become unreachable and highly marginalised thus creating a need for more studies on them.

## **1.4 Broad objective**

To determine factors related with HIV-1 infection acquisition among MSM enrolled in SWOP between 2005 and 2015.

### **1.4.1 Specific objectives**

1. To describe the profile of MSM enrolled in SWOP.
2. To identify the causes of factors associated with HIV-1 acquisition among MSM in SWOP.

## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1 Human Immunodeficiency Virus

HIV infects and attacks the cells of the immune system of a human being by destroying their function (MS Cohen et al, 2011). HIV attacks the CD4 cells which help the immune system to fight infections. When CD4 cells decline below a critical level, cell-mediated immunity is compromised, increasing the susceptibility of the body to opportunistic infections. If the HIV infection is not diagnosed on time it progresses to AIDS.

HIV-1 and HIV-2 are the two types of HIV that exist. HIV-1 is the most virulent, infective and is the cause of most infections worldwide (Gilbert *et al*, 2003) although HIV-2 is the less virulent, less infectious and is largely confined to West Africa (OT Campbell-Yesufu *et al*, 2011). Infection with The HIV-2 virus has a slower progression to immune deficiency and has a lesser chance of mother to child transmission (Jaffar *et al*, 2004). Due relevancy, we will restrict our discussion only to the HIV-1 virus.

#### 2.2 HIV transmission

Transmission can be through sexual intercourse, mother to the newborn child and blood transmission. Of all these modes, sexual transmission is the commonest mode of transmission due to semen, vaginal fluid, blood, and pre ejaculation. Unprotected sex therefore, puts an individual at a very high risk of getting the virus. .

There are also high chances of transmitting the virus from the mother to child when maternal HIV transmission can occur either at birthing process or when breast feeding. In this case, HIV

positive women are advised to give birth via C-sections to greatly reduce the chance of HIV transmission to the child.

### **2.3 HIV progression**

It takes an average of about 10 years for a person with HIV -1 to develop full blown AIDS but the rate of the disease progression in every infected person varies individually and depends on so many factors like age, degree of immune activation, socioeconomic status and host genetics.(Kuritzkes *et al*, 2005).

The first stage of primary progression of HVI commences during infection and lasts for a few weeks. At this point, the person's immune system is unable to launch an attack against the virus that is replicating throughout the body. The individual may be asymptomatic or may have flu-like symptoms, but would typically not recognize this as potentially being due to HIV. There is recorded decrease in the person's immune system marker at this point, CD4 cells also becomes low with an increase in viral load (HIV) (Oster, 2011).

According to Minkoff, (1987) the second stage referred to as "quiet period" because the individual is asymptomatic which lasts for many years. The CD4 count goes up than in initial infection stage and the viral load goes down. The third stage is marked by viral load increase while CD4 count goes down that makes a person to commence showing minor infection frequent signs like, general weakness, headache, weight loss, diarrhoea, and various skin diseases.

The final stage is full blown AIDS in which the individual's CD4 count is below 200 and/or the individual has contracted at least one opportunistic infection, such as tuberculosis. It is worth noting that HIV can be transmitted during any of the four stages, hence the need to get tested even though one may seem healthy (Kuritzkes *et al*, 2005).

## **2.4 Epidemiology of HIV**

Since the HIV epidemic began, close to 78 million people have been infected with the virus and almost 35 million deaths have so far been recorded (UNAIDS). In Kenya we have two types of epidemic: the generalized and the concentrated (National AIDS Control Council, 2014). The epidemic is common among the general population with a high concentration among key populations. Kenya's HIV epidemic has the following characteristics; the adult population of ages (15-49years) is mostly generalised with a 6% HIV prevalence reported as of 2013 (Kenya HIV Estimates, 2014).

## **2.5 HIV-1 in key population**

Key population is a group of people who are in danger to HIV infection; they include drug users, men who have sex with men, and transgender people. According to UNAIDS, People who inject drugs, female sex workers, men who have sex with men, and transgender women are respectively 19 times, 22 times, 14 times and 49 times more likely to acquire HIV compared to general adult population. About 40-50 % of all new HIV infections occur between individuals in key populations and their immediate partner based on UNAIDS estimates (2016). This category of people is often extremely hard to reach for critical testing, care and treatment services. Globally, the rates of key populations accessing safe, effective and quality HIV and AIDS services are extremely low, while stigma and discrimination are high.

HIV prevalence and incidence in Kenya is mostly among key populations (KPs) with higher risk of HIV acquisition and transmission than the rest of the population because of their risky societal and sexual practices (NACC, 2014: Kenya AIDS Response Progress Report). The identified KPs in Kenya are both men who have sex with men, male and female sex workers and people who

use intravenous drugs (Kenya AIDS Strategic Framework, 2014/15). HIV-1 prevalence among MSM, FSWs, and PWID is at average estimated to be 18.2%, 29.3%, and 18.7%, respectively in Nairobi (NASCO, 2014) and between 26.4% to 40.0% among MSWs in Nairobi, and 19.7% in Mombasa (Baral *et al*, 2015). The analysis of intravenous drug use in Nairobi and Coast provinces has shown that prevalence of HIV virus in PWID is at an estimation of 17% in males and 47% in females. (UNODC, 2012). In addition to that, the results of mapping done showed that there was an estimate of 133,675 urban female sexual workers in the whole country but different regions had significant differences in their numbers, ranging from a high of 29,000 FSWs in Nairobi Province to low of 2,000 in North Eastern Province (NACC, NASCO, 2012). It was noted about 19,000 people identified themselves as MSM, and about 18,000 people identified themselves as PWID (NASCO, 2013). The figures indicated show that there is a gap in targeted and strategic HIV prevention programmes to KPs and to geographic regions of priority so as to address this heterogeneous epidemic (Bhattacharjee *et al*, 2015).

### **2.5.1 Female sex workers**

There exists a linear correlation between HIV risk and number of sex partners for men and women (Chen *et al*, 2007). HIV prevalence on average is higher among FSW (28%) than women with no history of paid sex (17%). The frequency is also higher among men who reported sex with an FSW than those who did not report this risk (Chen *et al*, 2007).

On the other hand, Female sex workers are part of an important sub-population in the epidemiology of HIV infection. They are a vital population with a major HIV frequency of about 29.3% compared to the general population. Almost 68% of the FSWs tested for HIV discern



their results in the last 3 months. 86% of sex workers reported use of condom with their most recent client (UNAIDS 2014).

### **2.5.2 People who inject drugs**

It's approximated that about 12.7 million people worldwide are intravenous drug users (Gap Report, 2014). It is estimated that 1.7 million also live with HIV and injecting drug use has been recorded in many countries of the World. When heroin injection is introduced in a new environment HIV transmission increases very fast. HIV prevalence among people who inject drugs is higher than the rest of the adult population. People who inject drugs bear a 28 times higher prevalence, ranging from 1.3 to more than 2 000 times higher HIV prevalence in 74 countries.

HIV-1 virus is highly associated with drug users' injectors intravenously who accounts for about 30% of the new HIV-1 infection outside of sub-Saharan Africa (GARPR) data. Syringe sharing and drug preparation materials are not the only risk behaviours for HIV infection because, individuals who inject drugs are also likely to get and pass on HIV through unsafe sexual deeds. Compared with the general population in a country, intravenous drug users have a greater risk of AIDS related death. Although the rate of mortality is different as per the social- economic atmosphere present.

### **2.5.3 Men who have sex with men (MSM)**

Beyeret et al, (2011) highlights on various categories of MSM that includes, heterosexually identified men, male sex workers, bisexual men, gay-identified men, men engaging in sex in all male settings such as prisons, and the rich and wide array of traditional identities.

In North Africa, sub-Saharan Africa and Middle East, data for HIV infections on MSM are only emerging (Mumtaz et al, 2011) and the epidemic is gradually spreading to other countries of the World. The high HIV prevalence is being noted among MSM throughout the world despite heavy investments in time, money and resources being poured into research, treatment and care programs targeted at MSM.

In many developed countries, the overall HIV epidemic trends are declining except in MSM where they are highly using active antiretroviral therapy (HAART), this is called re-emergent epidemics in MSM (Sullivan *et al*, 2009). Since 2001 the USA has had an estimate of about 8% yearly increase in HIV infections among MSM (CDC, 2008). Among the key populations MSM have the highest HIV infection rates in Africa, Asia and Latin American. (Beyrer *et al*, 2010). There is little data that exists on the role of MSM in the HIV epidemic in Africa.

## **2.6 Risk factors for HIV infection**

Since HIV epidemic was discovered in the early 1980s, the risk factor for HIV transmission has been due to unprotected anal sex between men (Geibel *et al*, 2012). A good number of studies assess the probability of HIV spread via anal and vaginal sex (Baggaley *et al.*, 2010; Boily *et al.*, 2009). However, study analysis infers that the per-act probability or risk of HIV infection from unprotected anal sex is 18 times more than unprotected vaginal sex (Grulich and Zablotska, 2010). The practice of anal sex in MSM and the gastrointestinal tropism of HIV-1 (Katsidis, 2011), makes it a very risky mode of HIV transmission among MSM.

Other risk factors for HIV-1 acquisition in MSM which may differ individually are; unprotected anal sex, multiple partners, intravenous use of drugs, initial partner high viral load, also in USA, African-American are also a risk factor. Men practicing unprotected receptive anal intercourse

(URAI) with their partners are about twice the HIV vulnerability of men who only practice unprotected insertive anal intercourse (UIAI) (Geibel *et al*, 2012).

In America, 46 of 595 young MSM aged between (12–24 years) and more than 10% (64 of 595) admitted to have recently used ATS (Freeman *et al*, 2011). Of the Young MSM drug users some of them also admitted to practicing highly risky sexual acts like having sex with HIV negative individual, sex with other intravenous drug users, and having numerous sexual partners (Freeman *et al*, 2011).

Sero-adaptation strategy is used as a deterrent approach based on self and partner HIV status (McFarland *et al*, 2011). Sero-sorting, a sero-adaptation method is having sex with only sex partners who have similar HIV sero-status as you and sero-positioning means the choice of sexual acts to be conducted between the sexual partners will depend on their HIV sero-status. There is no evidence to support them as HIV prevention methods and if not careful they might mislead the MSM not to use condoms. (Gorbach *et al*, 2011). Intentionally not using condoms or bare backing which in 2004 was defined as “intentional condom less anal sex in HIV-risk contexts” (Carballo-Dieiguez *et al*, 2004). HIV concordant sex partners who engage in bare backing were also noted to have the highest STIs transmission rate and also likely to contact rare super infections that include HIV variants that are also drug resistant. (Paz-Bailey *et al*, 2004 and Smith *et al*, 2005).

A 2009 meta-analysis of US studies (Crepaz *et al*, 2009) indicated that many MSM who knew their HIV status also tried to protect their sexual partners from getting the infection, furthermore it was also noted that sex without use of condoms was common between HIV-positive sexual

partners was at 30% (95% CI 25–36). It was also found that MSM of ethnic minority were less likely to practice risky sexual practices than other MSM (Crepaz *et al*, 2009).

In high-income environment, ethnic and racial minority MSM bear unbalanced load of HIV (Millett *et al*, 2006), higher rates of untreated STIs has also been recorded in black MSM (OR 1.64, 95% CI 1.07–2.53), and HIV-1 sero-positive black MSM are less likely to know their sero-status and less likely to be treatment compliant by taking their ARVs (0.43, 0.30–0.61) in comparison with white MSM (, Oster *et al*, 2011, Millett *et al*, 2007).

MSM has different subsets, of importance is young MSM engaged in sex while intoxicated with alcohol or stimulants and those that conduct transactional sex are likely to have more sexual partners than the rest of the MSM. (Van Greisen *et al*, 2009.) Since acute HIV infection among MSM is very high which in turn increases the incidence of the disease because acute infections are more infectious (CDC: Acute HIV infection, 2008).

Among MSM most STIs and HIV infections go hand in hand, especially herpes simplex virus type 2, syphilis and human papilloma virus anal infections and some oropharyngeal STIs in cases where oral sex is also performed. (Chin-Hong *et al*, 2009). Hepatitis C virus is also transmitted through sex and may indicate HIV co-infection among MSM (Urbanus *et al*, 2009). The stigmatization , secrecy surrounding MSM in different societies make it difficult for them to access treatment and care if they contract STIs making them more susceptible . (Fay *et al*, 2011).

## **2.7 Strategies towards eradication of HIV**

### **2.7.1 Global approach**

The Coordinating Board of UNAIDS programme called on UNAIDS to support various countries to come up with new targets for HIV treatment and the momentum is now coming up

towards a new target on HIV treatment for a new final determined but achievable target. By the year 2020, nearly 90% of HIV+ persons will know their HIV status, 90% of HIV+ persons will receive continued antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have viral therapy.

### **2.7.2 Antiretroviral therapy (ART)**

Increased ease of use and access to ART has considerably reduced HIV-related complications and deaths (UNFPA, 2015). Right to use in resource-limited environments can be inclusive but ART services are now accessible to many people to provide ART to men who persons with HIV is as achievable and useful. Outreach work plays a core role of linking men with HIV to treatment that are sensitive and proficient. It has been found out that early and effective treatment increases chances of preventing HIV transmission in a big percentage (Mumtazi, 2011). There are no readily available clinical ART guidelines tailor-made to infected men however; due to stigma and discrimination they regularly present themselves belatedly for treatment. As precedence, ART should be offered to all persons with severe or complex HIV clinical disease and individuals with CD4 count  $\leq 350$  cells/mm<sup>3</sup>. It should also be initiated in all HIV+ positive persons with CD4 count between 350 and  $\leq 500$  cells/mm<sup>3</sup> regardless of WHO clinical stage. It is provided to all HIV positive individuals regardless of WHO clinical stage or CD4 cell count.

Okal, (2013), adds that men who have sex with men worries about ART but the understanding of current community indulgent on ART is imperative to attend to concerns, fears or misconceptions (MSMGF, 2016). In counselling it is important to kick off with ART before feeling unwell or having symptoms. Adherence, maintaining a suppressed viral load and the advantage of ART in reducing risk of HIV transmission is also critical. HIV positive men who

have sex with men should be put on ART regardless of CD4 cell count or clinical stage of their infection (UNFPA 2015).

### **2.7.2 Challenges in addressing HIV epidemic**

Interventions targeting key populations is difficult to mount, given the survival of societal denial and social prejudice to these populations and criminalization of their behaviours e.g., same sex relations, sex work or drug use.

Homosexuality is still criminalized in 78 countries in the World. Criminalization has encouraged issues of human rights abuses, discrimination, stigma and violence that have worsened health disparities for men who indulge in sex and their communities (Kelly et al, 2002). Exclusion of men who have sex with men from national AIDS planning processes has contributed to inadequately funded, inaccessible, and poorly targeted programs (FFAR, 2012). Total global investment in HIV prevention programs for men who have sex with men is less than 2% (Ayala et al, 2011). HIV treatment coverage and effectiveness among men who have sex with men is nearly impossible to ascertain since governments remain reluctant to reliably and responsibly collect, disaggregate, and report data (FFAR, 2012). According to UNAIDS (2014), 14 of 45 Sub-Saharan African countries reported to investing in programs that target MSM and only 2 countries that reported to having domestic budget and investment towards MSM programs. In helping to reduce the spread of the infection, there is need to provide safe spaces, social support, promote community coherence as well as encouraging participation and inclusion of all persons with HIV.

### **2.7.3 Sex Worker Outreach Project (SWOP) - Kenya**

The SWOP project is under the Kenya Aids Control Program consisting of ten health clinics and drop-in centres in Nairobi providing health care services to key populations and their families. The project has reached out to more than 20,000 female sex workers, 2,000 male sex workers and 1,000 drug users.

SWOP offers various information services on safer sex practices, to her clients, they also provide information condoms by demonstrating on how to use them effectively. They conduct screening and treatment of STS and risk reduction counselling services as well as HIV testing and counselling services. They also provide ARV and HIV basic care to patients as well as family planning information. SWOP provides cervical cancer screening and referral, TB screening and referrals, post-exposure prophylaxis (PEP) and emergency contraceptive provision, and psychosocial support and referral.

## **CHAPTER THREE**

### **METHODOLOGY**

#### **2.0 Study design**

A case control study design was adopted to investigate factors contributing to increased risk of HIV-1 infection among men having same sex with men enrolled in SWOP.

The cases were sero-positive MSM who were sero-negative at the time of enrolment into SWOP. The controls were MSM who were still sero-negative and must have been enrolled into the program at the same period. The observation period was one year from the date of enrolment. The MSM were recruited from enrolment records of the period between 1<sup>st</sup> January, 2015 and 31<sup>st</sup> January, 2016.

#### **2.1 Data Source**

The study used secondary cohort data for MSM enrolled into SWOP city clinic between 1<sup>st</sup> January, 2015 and 31<sup>st</sup> January, 2016

#### **2.2 Study population**

This study focused on MSM in SWOP city clinic that were sero-negative at the time of enrolment. SWOP is a project under Kenya AIDS control program that employs peer led networks to reach out to sex workers as a community engagement strategy. Since the establishment in 2005, the program has enrolled a total of 25,000 female sex workers and 1000 male sex workers and 1011 MSM in their 10 clinics within Nairobi. The clinics provide services such as HIV testing, counselling and treatment, family planning, cervical cancer screening, STI and TB treatment, general health care and support to control the spread of disease within these key populations



### 2.3 Determination of Sample Size

The size of the sample will be determined using the sample size formula calculation in case control studies (Rosner, 2010) based on power.

$$n \geq \frac{\bar{P}(1 - \bar{P}) \left(1 + \frac{1}{c}\right) (Z_{\alpha} + Z_{\beta})^2}{(P_1 - P_0)^2}$$

$\bar{N}$  is estimated minimum sample size for cases

$$\bar{P} = \{(P_1 + P_0) / (1 + C)\}$$

$C$  is the ratio of controls to cases = 3:1

$Z_{\alpha}$  is the critical value at  $\alpha$ -level of significance (Type I error ( $\alpha$ ) = 0.05;  $Z_{\alpha/2}$  = 1.96)

$Z_{\beta}$  is the critical value for the desired power (Type II error ( $\beta$ ) = 0.2;  $Z_{\beta}$  = 0.84)

$P_1$  is the proportion of exposed among cases ( $P_1 = (P_0 * OR) / [1 + P_0(OR-1)]$ )

**OR** is the expected odds ratio (how many times exposure is expect to raise the risk of getting infected with HIV) = 1.8 (A study done in South Africa found reported 0.21 odd ratio of HIV infection between a sex worker who uses Condoms most frequently and one who uses less frequently (Dunkle et al, 2005); from consultations with SWOP team, an odd ratio of 1.8 was considered significant)

$P_0$  = Proportion of exposed (MSM that do not consistently use condoms during sex) among controls = 0.47 (based on SWOP report MSM in April, 2017).

Using the above formula, the minimum sample size required was 81 cases and 243 controls

### 2.4 Sampling method

Given the few number of new cases that emerged from the MSM that had been enrolled between January, 2015 and January, 2016, all the cases were selected for the study.

For each case, three controls were selected randomly from the list of MSM who were still sero-negative one year post enrolment.

#### **2.4.1 Inclusion criteria**

- Must be a man who has sex with men enrolled in SWOP and was HIV-1 sero-negative at the time of enrolment with complete follow-up records
- Cases: Should be have contracted HIV infection after enrolment
- Controls: should be still be HIV negative after enrolment and follow-up period.

#### **2.5 Data collection and analysis**

Secondary data was retrieved from SWOP city clinic database using records from 2015 to 2017 and stored in Microsoft Excel 2013 sheets. Cleaning, coding and analysis was done using STATA version 13 SE.

Exploratory data analysis was done to describe and summarize the variables. For quantitative data, histograms were used to show the distribution of data; appropriate measures of central tendency (mean, Median, mode) and dispersion (standard deviation, inter-quartile range) were be reported in tables. For categorical data, bar/pie charts were used to show the distribution; frequencies and proportions were reported in tables.

Regression analysis was done to evaluate the association between the suspected risk factors and HIV-1 infection status of the selected MSM. Odds ratios and standard errors, corresponding confidence intervals were be reported.

Binary logistic regression model

$$\ln \frac{p}{1-p} = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots + \beta_k X_k$$

Where:

$\beta_0$ =Intercept

$\beta_1, \beta_2, \dots, \beta_k$  =Coefficients for covariates  $X_1, X_2, \dots, X_k$

p= probability of acquiring HIV infection

## **2.6 Ethical considerations**

Ethical approval was sought granting me permission to use the SWOP database (see appendix).

All the information obtained from the SWOP database will be treated with utmost confidentiality.

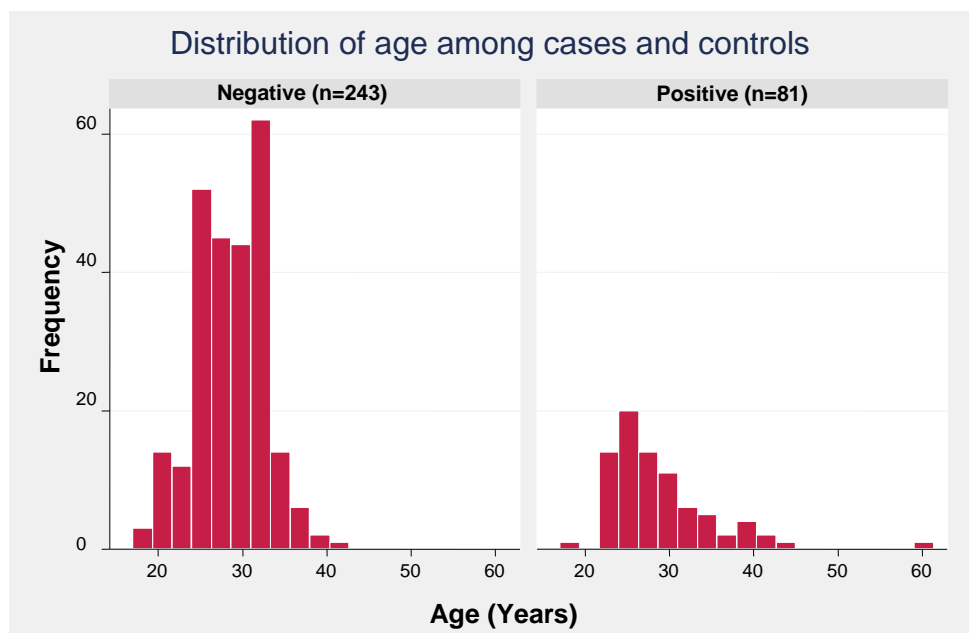
All data collected will be used for this study alone.

## CHAPTER FOUR

### RESULTS

A total of 324 men who have sex with men (MSM) were selected for this study. These men were enrolled into SWOP between 1<sup>st</sup> January, 2015 and 31<sup>st</sup> January, 2016 and were HIV negative at the time of enrolment. 81/324 (25.0%) men had turned sero-positive (Cases) by 1<sup>st</sup> February, 2017 while the rest remained negative (Controls).

The histograms below show the age distribution of the participants among the control group and case group



**Figure 1: Distribution of participants' age by HIV status**

The age distribution among the controls was normal (Shapiro-W=0.995, p-value=0.506) with a mean (SD) of 26.4 years (4.2 years). The age distribution among the cases was right skewed.

Their aged ranged from 18 years to 59 years with more than half above 28.9 years (median) of age.

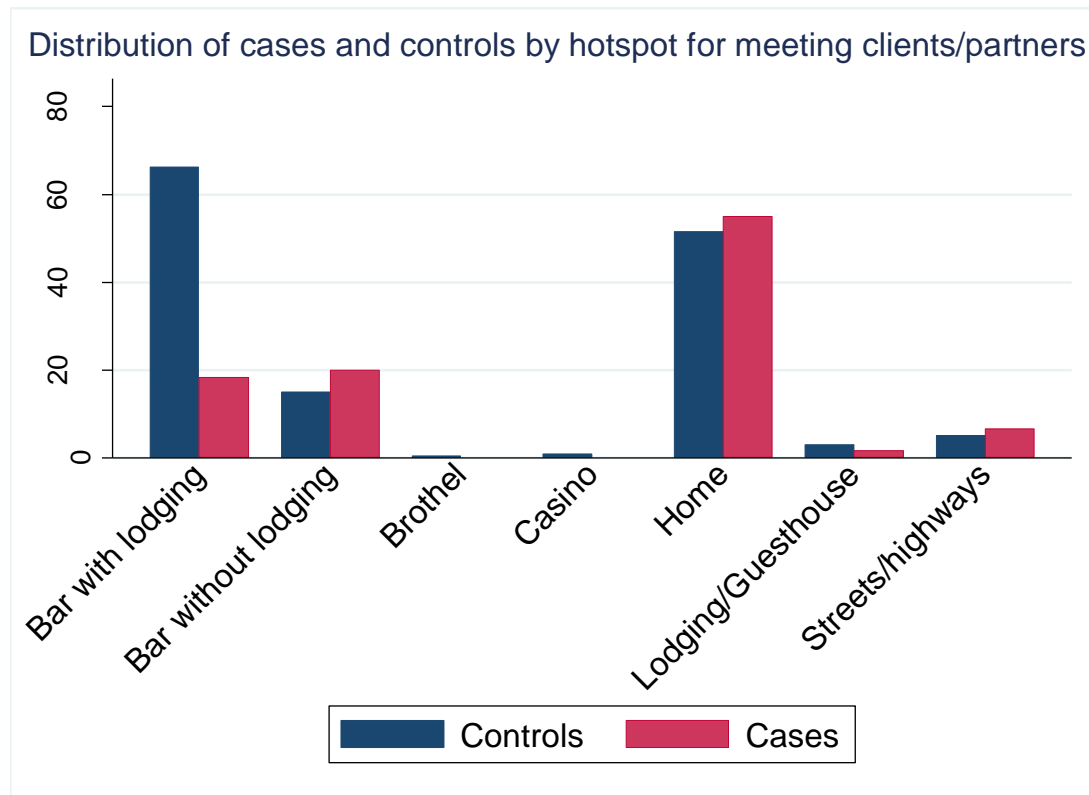
**Table 1: Social characteristics of the men in the control and case group**

VARIABLE	CATEGORY	CASES n (%)	CONTROLS n (%)
<b>Marital status</b>	Single	67 (83.8)	210 (86.4)
	Married	8 (10.0)	13 (5.3)
	Divorced	-	6 (2.5)
	Separated	5 (6.3)	14 (5.8)
<b>Highest Education level</b>	Primary	5 (6.5)	25 (10.2)
	Secondary	39 (50.6)	124 (51.0)
	Tertiary	30 (39.0)	80 (32.9)
	Never attended school	3 (3.9)	14 (5.8)
<b>Have female sexual partners?</b>	Yes	49 (60.5)	122 (50.2)
	No	32 (39.5)	121 (49.8)
<b>Have sex with men for money?</b>	Yes	28 (35.0)	111 (45.7)
	No	52 (65.0)	132 (54.3)

The distribution of MSM by their marital status at enrolment was similar among cases and controls. More than at least 80% in both groups were single. There was 89.6% (69/81) of the cases had attained at least secondary level of education whereas among the controls this group represented 84.0% (204/243).

The study also sought to understand the MSM's sexual practices. Among the cases 60.5% (49/81) had female sexual partners whereas among the controls 50.2% (122/243) had female sexual partners. Among the cases almost one third (35.0%) reported having sex with men for money whereas among the controls there were almost half (45.7%)

The participants were further asked to list the hotspots where they often meet their partners or clients. The figure 2 shows the distribution of their responses.

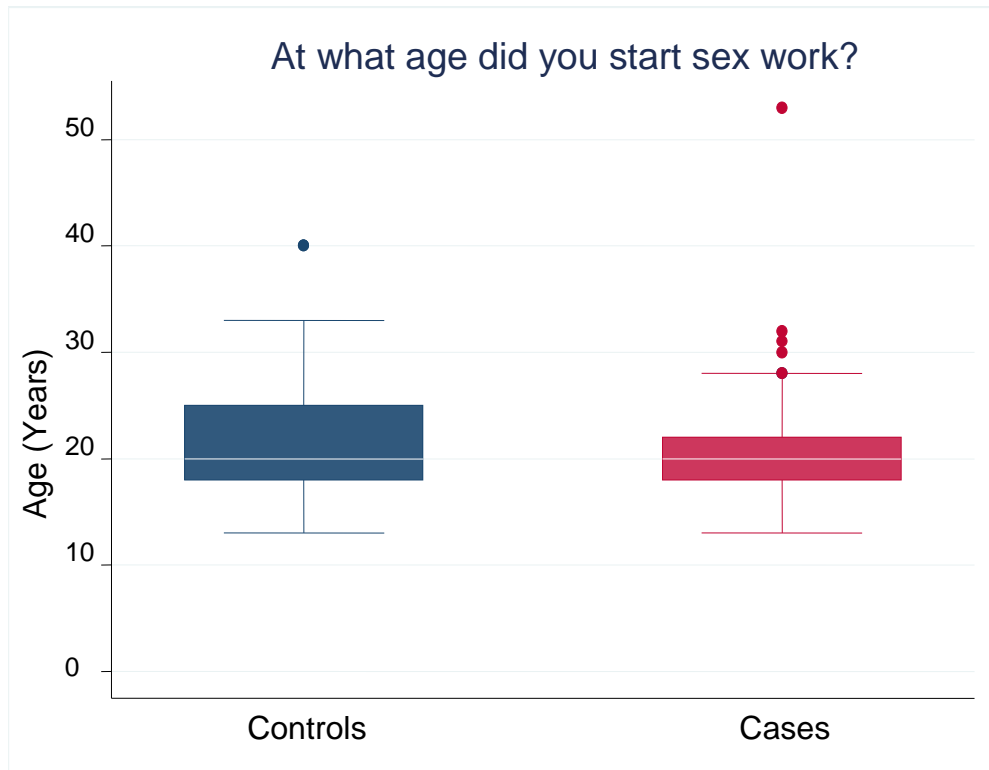


**Figure 2: Distribution of cases and controls by hotspots for meeting clients/partners**

The study found that most of the MSM met their clients or partners at bars with lodging and/or homes. Most controls meet their clients/partners at bars with lodging and/or at home whereas most of the cases meet theirs at home.

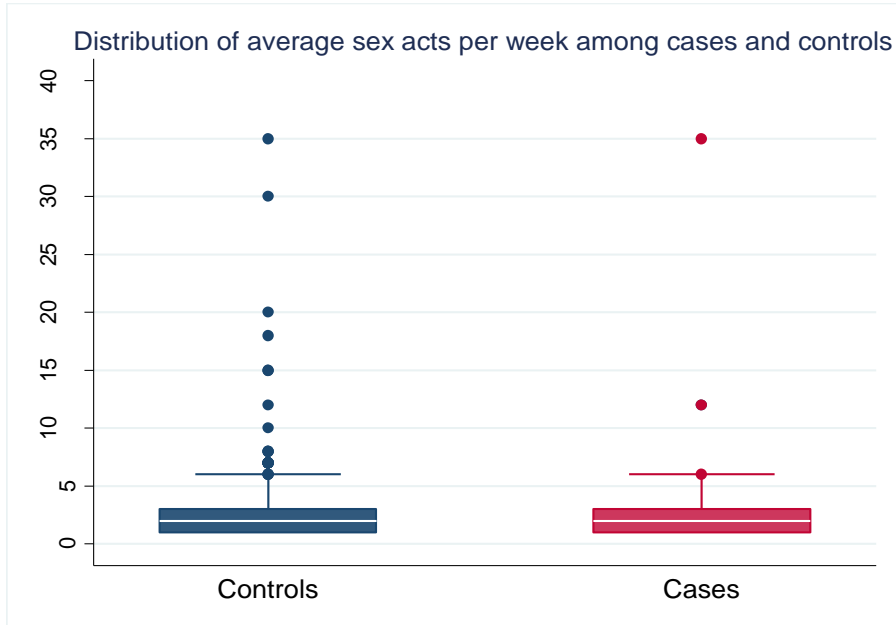
The study revealed that more than half of the cases and controls started their sex activities at the 20 years as shown in the figure 3.

There was no significant difference in the starting age for sex work between the cases and the controls (K-sample median test;  $\chi^2=0.581$ ,  $p\text{-value}=0.446$ ).

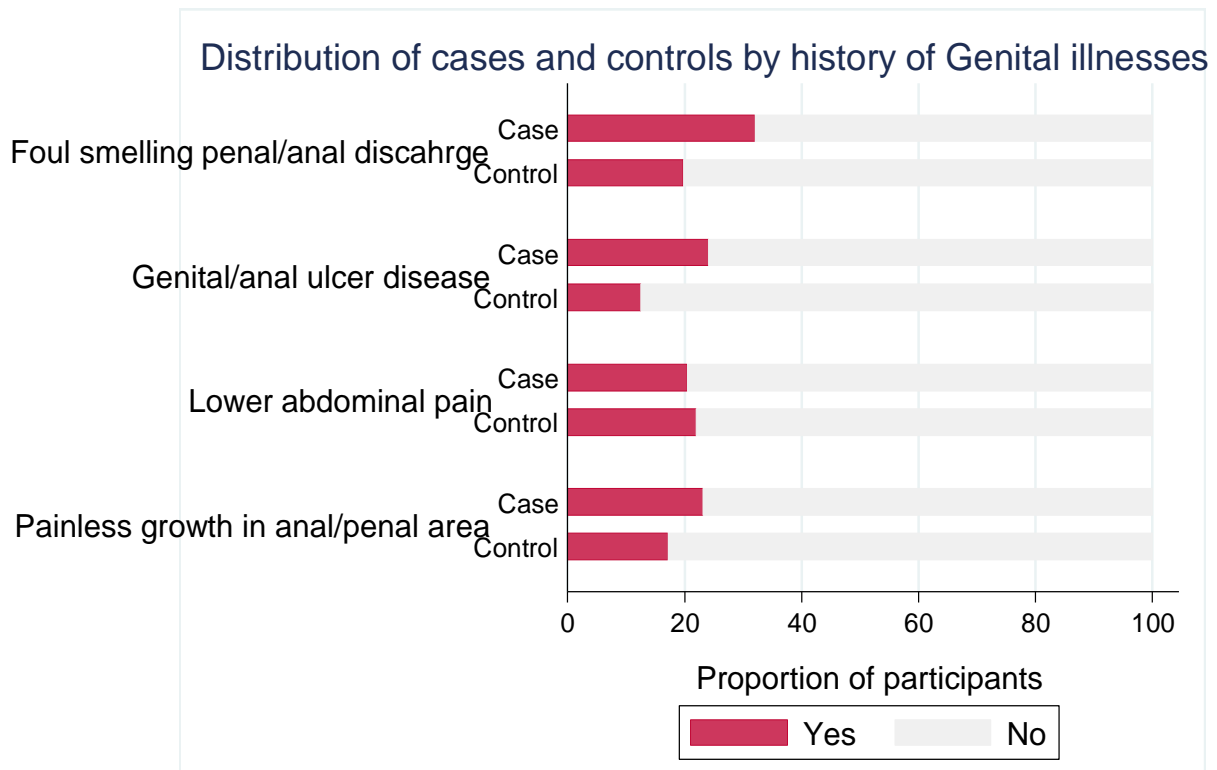


**Figure 3: Distribution of age when MSM started sex work**

The distribution of average sex acts per week among the cases and controls was similar. The sex acts/week ranged between 1 act and 35 sex acts with a median of 2 acts in both groups



**Figure 4: Average number of sex acts per week among cases and controls**

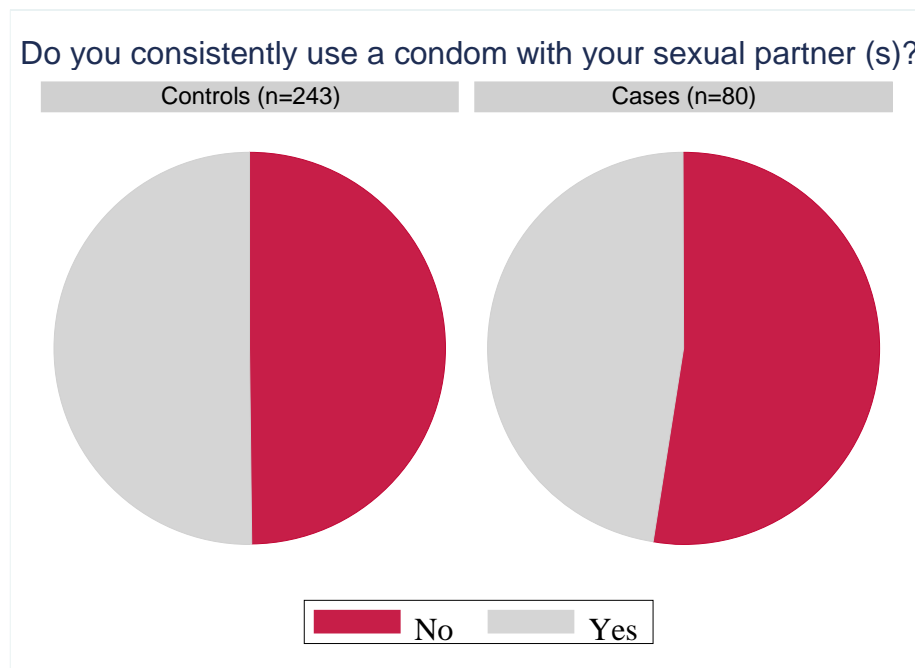


**Figure 5: History of genital illnesses and abdominal pain among cases and controls**



The figure 5 showed that the proportion of cases with history of foul smelling penal/anal discharge, genital/anal ulcer disease and painless growth in anal/penal area was slightly higher compared to the proportion among the controls.

Asked if they consistently used condoms with their sexual partners, the proportion of cases who reported consistently using condoms was slightly higher compared to the proportion among the controls as shown in Figure 6.



**Figure 6: Condom use consistency among cases and controls**

SWOP offers training on condom negotiation to the sex workers enrolled in the program as a strategy to improve condom use among this group, thus reducing the risk of HIV infection.

**Table 2: Condom use practices among cases and controls**

VARIABLE	CATEGORY	CASES n (%)	CONTROLS n (%)
<b>How often do you negotiate for condom use with casual clients</b>	Sometimes	15 (34.9)	33 (20.9)
	Always	27 (62.8)	112 (70.9)
	Never	1 (2.3)	13 (8.2)
<b>How often do you negotiate for condom use with regular clients</b>	Sometimes	21 (38.9)	45 (27.4)
	Always	26 (48.1)	101 (61.6)
	Never	7 (13.0)	18 (11.0)
<b>How often do you negotiate for condom use with boyfriend</b>	Sometimes	18 (33.3)	60 (33.3)
	Always	19 (35.2)	80 (44.4)
	Never	17 (31.5)	40 (22.2)
<b>What do you do if a client refuses to use CD</b>	Continue having sex	7 (11.7)	38 (19.6)
	Refuse sex	45 (75.0)	150 (77.3)
	Charge more	8 (13.3)	6 (3.1)

At enrolment, the MSM were asked about their condom use negotiation practises. From the responses, it was evident that majority of them often negotiate with their clients to use condoms but at varying frequencies. With casual clients, 62.8% of the cases always negotiated with clients whereas among the controls 70.9% always negotiated on condom use. For regular clients, the proportion that always negotiated for condom use among the controls was about 1.3 times higher than the proportion among the cases. Negotiation frequency for condom use with boyfriends was similar between the cases and the controls.

**Table 3: Sex practices among the cases and controls that have sex for money**

VARIABLE	CATEGORY	CASES n (%)	CONTROLS n (%)
<b>What time of day do you do sex work?</b>	Day	7 (20.0)	11 (7.5)
	Night	22 (62.9)	98 (67.1)
	Day & Night	6 (17.1)	37 (25.3)
<b>Do you engage in sex under alcohol/</b>	Yes	39 (49.4)	142 (58.4)

<b>Drug influence?</b>	No	40 (50.6)	101 (41.6)
<b>Apart from sex work, do you have</b>	Yes	23 (63.9)	66 (48.2)
<b>Other sources of income?</b>	No	13 (36.1)	71 (51.8)

More than half of the MSM, who have sex for money, reported doing their sex work at night; the distribution in terms of time when they engage in sex work was similar among the cases and controls.

Among the cases, 49.4% reported engaging in sex under alcohol/drug influence whereas among the controls the proportion was estimated at 58.4%. The proportion of cases who had other sources of income besides sex work was higher compared the proportion among the controls.

A multiple binary logistic regression models were fit to evaluate the adjusted effect of the sexual practices, condom use, socio-demographic characteristics and history of genital illness on the risk of a MSM acquiring HIV infection. The model was significant (Log likelihood=-136.06, LL chi2=25.20, p-value=0.04)

**Table 4: Adjusted effect of probable risk factors on risk of HIV infection**

Variable	Category	Adjusted OR	95% CI (OR	P-value
	Single (base)			0.284
<b>Marital status</b>	Married	1.34	[0.45; 3.96]	
	Separated	0.86	[0.24; 3.05]	
	Primary (base)			0.841
<b>Highest Education level</b>	Secondary	1.24	[0.40; 3.82]	
	Tertiary	1.72	[0.54; 5.49]	
	Never attended school	1.23	[0.23; 6.63]	

<b>Have female sexual partners?</b>	Yes (base)			
	No	0.74	[0.39; 1.41]	0.303
<b>Have sex with men for money?</b>	Yes (base)			
	No	1.49	[0.76; 2.90]	0.085
<b>Engage in sex under alcohol?</b>	Yes (base)			
	No	1.66	[0.89; 3.09]	0.181
<b>Use of condom consistently</b>	Yes (base)			
	No	0.77	[0.42; 1.40]	0.109
<b>History of genital ulcer</b>	Yes (base)			
	No	0.45	[0.18; 1.12]	0.097
<b>History of penile/anal foul smelling discharge</b>	Yes (base)			
	No	0.41	[0.19; 0.87]	0.031*
<b>History of penile/anal growth</b>	Yes (base)			
	No	0.97	[0.38; 2.48]	0.429
<b>Average sex acts/week</b>		0.97	[0.89; 1.05]	0.362
<b>Age of participant</b>		1.04	[0.98; 1.10]	0.704

From the multiple regression analysis, only history of foul smelling penile/anal discharge was found to be significant. MSM with no history of foul smelling penile/anal discharge was 58% less likely to get infected with HIV compared to one with history of this condition, after adjusting for the effect of other covariates in the model. This effect size was lower than the estimated effect size in the simple logistic regression model.

## **CHAPTER FIVE**

### **DISCUSSION**

Using the multiple regression analysis, only history of foul smelling penile/anal discharge was found to be a risk factor for MSM contracting HIV. This is similar to findings of a study done in Cameroon (Ju Nyeong Park, 2011). In addition MSM who have sex for money was found not to be a significant risk factor for contracting HIV. This is contrary to a study carried out in Nigeria (Lung Vu et al., 2010) and in Malawi (Stefan Baral, 2008) that showed a significant association with HIV infection among MSM.

Though not statistically significant, it was noted that more than half of the MSM who contacted HIV were above 28 years. This could suggest the older the person, the more risky their sexual practices are, it is associated with increased number of sexual partners and increased HIV exposure. Similar findings found in the study done in Nigeria (Lung Vu et al., 2010) found older age to be significantly associated with HIV-1 virus infection among MSM.

In addition MSM who engage in sexual acts with female were noted to be at higher risk of contracting HIV than MSM though not statistically significant but significant in a study done in Nigeria (Lung Vu et al., 2010) where MSM who have sex with women are not comfortable with their sexual identity and are unlikely to disclose to their female partners and reluctance to access health care facilities thus increasing the Risk for HIV infection.

### **SUMMARY, CONCLUSION AND RECOMMENDATIONS**

The study results have highlighted the risk factors that are associated with HIV infection among MSM in Nairobi, Kenya. Analysis of the findings have shown that there is an association between history of foul smelling penile/anal discharge and HIV infection among MSM in

Nairobi. Though not statistically significant there is also other risk factors to be considered i.e. older age, MSM who have sex with female which also increase the risk of HIV infection. MSM in Kenya are at a high risk of acquiring and transmitting HIV due to the risky sexual behaviours they engage in. Therefore my recommendations are that, there is need for targeted interventions for MSM who also have history of STI. Future interventions tailored towards MSM should have a comprehensive approach that combines behavioural, medical and structural interventions. This information is important to the health Care Stakeholders and policy makers involved in HIV programs and public health in Kenya.

## REFERENCES

1. **Baggaley RF, White RG, Boily M. (2010)** HIV Transmission Risk through Anal Intercourse: Systematic Review, meta-analysis and implications for HIV prevention. *Int J epidemiol.*; 39:1048-63.
2. **Baral SD, Friedman MR, Geibel S, Rebe K, Bozhinov B, Diouf D, et al. (2015)** Male sex workers: practices, contexts, and vulnerabilities for HIV acquisition and transmission. *Lancet* 385: 260–273.
3. **Beyrer C, Baral S, Walker D, Wirtz A, Johns B, Sifakis F (2010).** The expanding epidemics of HIV-1 among men who have sex with men in low and middle income countries: diversity and consistency. *Epidemiol Rev.*; 32:137–51.
4. **Beyrer C, Baral SD, van Griensven F, et al (2012).** Global epidemiology of HIV infection in men who have sex with men. *Lancet.*; 380(9839):367–77.
5. **Beyrer C. (2010)** Global prevention of HIV infection for neglected populations: men who have sex with men. *Clin Infect Dis.*; 50 (suppl 3):S108–13.
6. **Beyrer, C.; Wirtz, A.; Walker, D.; Johns, B.; Sifakis, F.; Baral, S. (2011)** The global HIV epidemics among men who have sex with men. Washington, DC: *The World Bank*.
7. **Beyrer, C.; Wirtz, A.; Walker, D.; Johns, B.; Sifakis, F.; Baral, S. (2011)** The global HIV epidemics among men who have sex with men. Washington, DC: *The World Bank*.
8. **Bhattacharjee P, McClarty LM, Musyoki H, Anthony J, Kioko J, Kaosa S, et al. (2015)** Monitoring HIV Prevention Programme Outcomes among Key Populations in Kenya: Findings from a National Survey. *PLoS ONE* 10(8): e0137007.

9. **Boily MC, Baggaley RF, Wang L et al. (2009)** Heterosexual risk of HIV-1 infection per sexual act: Systematic Review and Metaanalysis of Observational Studies. *Lancet infect Dis.*; 9:118–29.
10. **Bourne, A. & Harm Reduction International (2012)** 'Drug use among men who have sex with men: Implications for harm reduction'
11. **Carballo-Diequez A, Bauermeister J. (2004)** “Barebacking”: intentional condomless anal sex in HIV-risk contexts. Reasons for and against it. *J Homosex.*; 47:1–16. [PubMed: 15189783]
12. **CDC. (2009)** Acute HIV infection—New York City, 2008. *Morb Mortal Wkly Rep.*; 58:1296–99.
13. **Chen L, Jha P, Stirling B, et al (2007)**. Sexual risk factors for HIV infection in early and advanced HIV epidemics in sub-Saharan Africa: systematic overview of 68 epidemiological studies. *PLoS One.* ; 2(10):e1001.
14. **Chin-Hong PV, Husnik M, Cranston RD, et al. (2009)** anal human papillomavirus infection is associated with HIV acquisition in men who have sex with men. *AIDS.*; 23:1135–42.
15. **Crepaz N, Marks G, Liau A, et al. (2009)** Prevalence of unprotected anal intercourse among HIVdiagnosed MSM in the United States: a meta-analysis. *AIDS.*; 23:1617–29.
16. **Des Jarlais DC, Arasteh K, Hagan H, McKnight C, Perlman DC, Friedman SR (2009)**. Persistence and change in disparities in HIV infection among injection drug users



in New York City after large-scale syringe exchange programs. *American Journal of Public Health.*; 99:S445–S451.

17. **Elford J, Bolding G, Davis M, Sherr L, Hart G. (2007)** Barebacking among HIV-positive gay men in London. *Sex Transm Dis.*; 34:93–98.
18. **Fay H, Baral S, Trapence G, et al. (2011)** Stigma, health care access, and HIV knowledge among men who have sex with men in Malawi, Namibia, and Botswana. *AIDS Behav.*; 15:1088–97.
19. **Freeman P, Walker BC, Harris DR, et al. (2011)** Methamphetamine use and risk for HIV among young men who have sex with men in 8 US cities. *Arch Pediatr Adolesc Med.*; 165:736–40.
20. **Geibel S, Temmerman M, Luchters S. (2012)** Same-sex sexual behavior of men in Kenya: Implications for HIV prevention, programs, and policy. *FVV in ObGyn*, 4 (4): 285-294
21. **German D, Sifakis F, Maulsby C, et al (2011).** Persistently high prevalence and unrecognized HIV infection among men who have sex with men in Baltimore: the BESURE Study. *J Acquir Immune Defic Syndr.*; 57:77–87.
22. **Gilbert P.B, McKeague IW, Eisen G, Mullins C, Gueye-NDiaye A, Mboup S, Kanki PJ (2003).** Comparison of HIV-1 and HIV-2 infectivity from a prospective cohort study in Senegal. *Statistics in Medicine.* 22 (4): 573-593.
23. **Goodreau SM, Peinado J, Goicochea P, et al. (2007)** Role versatility among men who have sex with men in urban Peru. *J Sex Res.*; 44:233–39.

24. **Gorbach PM, Weiss RE, Jeffries R, et al. (2011)** Behaviors of recently HIV-infected men who have sex with men in the year postdiagnosis: effects of drug use and partner types. *J Acquir Immune Defic Syndr.*; 56:176–82.
25. **Grulich A, Zablotska I. (2010)** Commentary: probability of HIV transmission through anal intercourse. *Int J Epidemiol.*; 39:1064–65.
26. **Grulich AE, Zablotska I. (2010)** Commentary: Probability of HIV transmission through anal intercourse. *Int J epidemiol.*;39:1064-5.
27. **Hahn, B.H., Shaw, G.M., De Cock, K.M., and Sharp, P.M.(2000).** AIDS as a zoonosis: scientific and public health implications. *Science.* 287:607–614.
28. **Halkitis PN, Wilton L, Wolitski RJ, Parsons JT, Hoff CC, Bimbi DS. (2005)** Barebacking identity among HIV-positive gay and bisexual men: demographic, psychological, and behavioral correlates. *AIDS.*; 19 (suppl 1):S27–35.
29. **Jaffar S., Grant, A.D.,Whitworth, J., Smith, P.G., and Whittle, H. (2004).** The natural history of HIV–1 and HIV–2 infections in adults in Africa: a literature review [erratum 2004, 82:571]. *Bull. World Health Organ.* 82:462–469.
30. **Johnson W, Diaz R, Flanders W, et al (2008).** Behavioral interventions to reduce risk for sexual transmission of HIV among men who have sex with men. *Cochrane Database Syst Rev.*;3:CD001230.
31. **Kaltsidis H, Cheeseman H, Kopycinski J, et al (2011).** Measuring human T cell responses in blood and gut samples using qualified methods suitable for evaluation of HIV vaccine candidates in clinical trials. *J Immunol Methods.*; 370:43–54.

32. **Kelly JA, Amirkhanian YA, McAuliffe TL, et al (2001).** HIV risk behavior and risk-related characteristics of young Russian men who exchange sex for money or valuables from other men. *AIDS Educ Prev.*; 13:175–88.
33. **Kelly JA, Amirkhanian YA, McAuliffe TL, et al. (2002).** HIV risk characteristics and prevention needs in a community sample of bisexual men in St Petersburg, Russia. *AIDS Care*; 14:63–76.
34. **Koblin B, Husnik M, Colfax G, et al (2006).** Risk factors for HIV infection among men who have sex with men. *AIDS.*; 20:731–39.
35. **Kuritzkes DR, Walker BD( 2007).** HIV-1 pathogenesis and clinical manifestations. In: Knipe DM, Hawley PM, eds. *Fields virology. 5th ed. Philadelphia, PA: Lippincott Williams & Wilkins*: 2187–214.
36. **Lemey, P., et al. (2003).** Tracing the origin and history of the HIV-2 epidemic. *Proc. Natl. Acad. Sci. U. S. A.* 100:6588–6592.
37. **Levy JA (1993).** Pathogenesis of HIV infection. *Microbiol Rev*; 57:183-289.
38. **McFarland W, Chen YH, Raymond HF, et al. (2011)** HIV seroadaptation among individuals, within sexual dyads, and by sexual episodes, men who have sex with men, San Francisco, 2008. *AIDS Care.*; 23:261–68.
39. **Millett GA, Flores SA, Peterson JL, Bakeman R (2007).** Explaining disparities in HIV infection among black and white men who have sex with men: a meta-analysis of HIV risk behaviors. *AIDS.*;21:2083–91.

40. **Millett GA, Peterson JL, Wolitski RJ, Stall R (2006)**. Greater risk for HIV infection of black men who have sex with men: a critical literature review. *Am J Public Health.*; 96:1007–19.
41. **Minkoff H, Nanda D, Menez R, Fikrig S (1987)**. Pregnancies resulting in infants with Acquired Immunodeficiency Syndrome or AIDS Related Complex. *Obst Gynecol*; 69:285-287.
42. **MSMGF (2016)**. Strategic Plan (2016-2021)
43. **Mumtaz G, Hilmi N, Akala FA, et al (2011)**. HIV-1 molecular epidemiology evidence and transmission patterns in the Middle East and North Africa. *Sex Transm Infect.*; 87:101–06.
44. **NACC (2014)** Kenya AIDS Strategic Framework 2014/15-2018/19. Nairobi: Government of Kenya.
45. **NACC, NASCOP (2014)**. Kenya HIV Estimates, 2014. Nairobi: National AIDS Control Council and National AIDS and STI Control Programme.
46. **NASCOP (2013)**. Kenya Most At Risk Populations Size Estimate Consensus. Nairobi: *National AIDS and STI Control Programme, Government of Kenya*.
47. **NASCOP (2014)**. 2010–2011 Integrated Biological and Behavioural Surveillance Survey among Key Populations in Nairobi and Kisumu, Kenya. Nairobi: Government of Kenya, Ministry of Public Health and Sanitation.
48. **National Aids Control Council (2014)** Kenya AIDS Response Progress Report

49. **National AIDS Control Council (2014)**. Kenya AIDS Response Progress Report 2014: Progress towards Zero.
50. **Okal J., Geibel S., Muraguri N., Musyoki H., Tun W., Broz D., Kuria D., Kim A., Oluoch T., Raymond, H. F. (2013)**. Estimates of the size of key populations at risk for HIV infection: men who have sex with men, female sex workers and injecting drug users in Nairobi, Kenya. *Sexually Transmitted Infections*, 89(5), 366–371.
51. **Oster AM, Wiegand RE, Sionean C, et al (2011)**. Understanding disparities in HIV infection between black and white MSM in the United States. *AIDS*.; 25:1103–12.
52. **Paz-Bailey G, Meyers A, Blank S, et al (2004)**. A case-control study of syphilis among men who have sex with men in New York City: association With HIV infection. *Sex Transm Dis*.; 31:581–87.
53. **Pronyk PM, Harpham T, Morison LA, et al (2008)**. Is social capital associated with HIV risk in rural South Africa? *Social Science & Medicine* (1982).; 66(9):1999-2010.
54. **Reeves JD, Doms RW (2002)**. Human Immunodeficiency Virus Type 2. *Journal of General Virology*. 83 (Pt 6): 1253-65.
55. **Rosenberg ES, Sullivan PS, Dinunno EA, Salazar LF, Sanchez TH (2011)**. Number of casual male sexual partners and associated factors among men who have sex with men: results from the National HIV Behavioral Surveillance system. *BMC Public Health*.; 11:189.
56. **Sharp, P.M., Shaw, G.M., and Hahn, B.H. (2005)**. Simian immunodeficiency virus infection of chimpanzees. *J. Virol.*79:3891–3902.

57. **Smith DM, Richman DD, Little SJ. ( 2005)** HIV superinfection. *J Infect Dis.*; 192:438–44.
58. **Sullivan P, Hamouda O, Delpuch V, et al(2009).** Reemergence of the HIV epidemic among men who have sex with men in North America, western Europe, and Australia, 1996–2005. *Ann Epidemiol.*; 19:423–31.
59. **UNAIDS (2011).**Global HIV/AIDS response: epidemic update and health sector progress towards universal access-*Progress report*
60. **UNAIDS (2016)** 'Prevention Gap Report'
61. **United Nations (2011)** ‘International Covenant on Civil and Political Rights: List of issues to be taken up in connection with the consideration of the third periodic report of Kenya (CCPR/C/KEN/3)’
62. **United Nations Development Programme (2014).** Key Populations Definition
63. **UNODC (2012)** Rapid Situational Assessment of HIV Prevalence and Risky Behaviours among Injecting Drug Users in Kenya. Nairobi: United National Office on Drugs and Crime.
64. **Urbanus AT, van de Laar TJ, Stolte IG, et al. (2009)** Hepatitis C virus infections among HIV-infected men who have sex with men: an expanding epidemic. *AIDS.*; 23:F1–7.
65. **USAID (2015)** Key Populations: Targeted Approaches Toward An AIDS-free Generation.

66. **van Griensven F, de Lind van Wijngaarden JW, Baral S, Grulich A. (2009)** The global epidemic of HIV infection among men who have sex with men. *Curr Opin HIV AIDS.*; 4:300–07.
67. **Vogel DL, Wade NG, Wester SR, Larson L, Hackler AH (2007).** Seeking help from a mental health professional: the influence of one’s social network. *Journal of Clinical Psychology.*; 63(3):233-45.
68. **Wang K, Brown K, Shen SY, Tucker J (2011).** Social network-based interventions to promote condom use: a systematic review. *AIDS and Behavior.*; 15(7):1298-308.
69. **Wiebel, WW (1990).** Identifying and gaining access to hidden populations. In: Lambert, EY., editor. *The Collection and Interpretation of Data from Hidden Populations.* National Institute on Drug Abuse; Rockville, MD: DHHS Publication Number (ADM) 90-1678 ed., pp. 4-11
70. **Dunkle KL, Beksinska ME, Rees VH, Ballard RC, Htun Y, Wilson ML. (2005)** Risk factors for HIV infection among sex workers in Johannesburg, South Africa. *Int J STD AIDS* : 16(3):256-61



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

KNH-UoN ERC  
Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)  
Website: <https://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: [@UONKNH\\_ERC](https://twitter.com/UONKNH_ERC) [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)



KENYATTA NATIONAL HOSPITAL  
P O BOX 20723 Code 00202  
Tel: 7263900-9  
Fax: 725272  
Telegrams: MEDSUP, Nairobi

Ref. No.KNH/ERC/R/42

20<sup>th</sup> March 2017

Dr. Joshua Kimani  
Co-Investigator  
UNITID  
College of Health Sciences  
University of Nairobi

Dear Dr. Kimani

Re: Approval of Annual Renewal – Use of clinical data care database by the University of Nairobi/University of Manitoba Research team to evaluate HIV prevention, care and treatment in Kenya (P258/09/2008)

Refer to your communication dated March 10, 2017.

This is to acknowledge receipt of the study progress report and hereby grant annual extension of approval for ethical research protocol P258/09/2008.

The approval dates are 18<sup>th</sup> February 2017 - 17<sup>th</sup> February 2018 .

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.

Protect to discover



- 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.

Kindly ensure that the study is renewed annually within the period required by KNH-UoN ERC.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Yours sincerely,



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

c.c. The Principal, College of Health Sciences, UoN  
The Director CS, KNH  
The Chairperson, KNH-UoN ERC