

**DETERMINANTS OF SUSTAINED VIROLOGICAL SUPPRESSION IN HIV-1  
INFECTED FEMALE SEX WORKERS IN THE SEX WORKER OUTREACH  
PROJECT (SWOP), NAIROBI COUNTY**

By;

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**DECLARATION**

**STUDENT**

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

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### **DEDICATION**

I dedicate this work to my family and classmates Sylvia, Henry and Nelson for their undying support and encouragement throughout my studies.



## TABLE OF CONTENTS

DECLARATION .....	ii
ACKNOWLEDGEMENT .....	ii
DEDICATION .....	iii
TABLE OF CONTENTS.....	v
LIST OF TABLES .....	viii
LIST OF FIGURES .....	ix
ABBREVIATIONS .....	x
DEFINITION OF TERMS .....	xi
ABSTRACT.....	xii
CHAPTER ONE .....	1
INTRODUCTION .....	1
1.1 Background of the study .....	1
1.2 Problem statement.....	2
1.3 Justification .....	3
1.4 Broad objective .....	3
1.4.1 Specific objectives .....	4
CHAPTER TWO .....	5
LITERATURE REVIEW .....	5
2.1 Human Immunodeficiency Virus (HIV).....	5

2.2 Transmission of HIV.....	5
2.3 Prevention of HIV.....	6
2.4 Antiretroviral Therapy .....	6
2.5 Virologic Suppression.....	7
2.6 Key populations .....	8
2.7 Sex workers.....	8
2.8 Sex Workers and ART .....	9
2.9 Sex Workers Outreach Project, Kenya (SWOP).....	9
METHODOLOGY .....	10
3.1 Study design.....	10
3.2 Study site.....	10
3.3 Study population .....	10
3.3.1 Inclusion criteria .....	11
3.4 Sample size determination .....	11
3.5 Sampling method .....	13
3.6 Data collection and analysis.....	13
3.7 Ethical considerations .....	14
CHAPTER FOUR.....	15
RESULTS .....	15
4.1 Socio-demographic features of women sex workers .....	15

4.2 Association between FSW profile and virological failure .....	20
CHAPTER FIVE .....	23
5.1 DISCUSSION.....	23
5.2 CONCLUSION.....	26
REFERENCES .....	27

## LIST OF TABLES

Table 1: Socio-demographic features of the women sex workers .....	16
Table 2: Antiretroviral therapy start regimen .....	19
Table 3: Simple log binomial models- Association between the FSW profile and the risk of virological failure.....	20
Table 4: Multiple regression- log binomial model: Association between FSW profile and Virological failure.....	21



## **LIST OF FIGURES**

Figure 1: Distribution of the study participants' age by exposure status .....	16
Figure 2: Distribution of average number of sex acts FSW have per week .....	17
Figure 3: Tuberculosis history distribution in the exposed and unexposed groups .....	18
Figure 4: Virology status of FSW in the exposed and unexposed group.....	19

## ABBREVIATIONS

AIDS -	Acquired Immunodeficiency Syndrome
ART -	Antiretroviral Therapy
HIV -	Human Immunodeficiency Virus
MSM -	Men who have Sex with Men
PHDA-	Partners for Health and Development in Africa
PLWH -	People Living With HIV
RNA -	Ribonucleic Acid
STI -	Sexually Transmitted Infections
SWOP -	<i>Sex Workers Outreach Programme</i>
TB -	Tuberculosis
VL -	Viral Load

## **DEFINITION OF TERMS**

Viraemia	Presence of HIV in bloodstream
Viral suppression	Reducing the function and replication of a HIV
Epidemic	Rapid spread of HIV infection disease to a large number of people in a given population within a short period of time,
Virological failure	It occurs when antiretroviral therapy (ART) fails to suppress and sustain a person's viral load to less than 100 copies/MI due to drug resistance, drug toxicity, and poor treatment adherence

## ABSTRACT

The goal of anti-retroviral therapy is to stem the replication of HIV virus to a point below which drug fighting mutation do not emerge, restore and preserve immune function, reduce AIDS-related events and improve the life span of the patient. By the end of 2016, there were 1.5 million PLWH in Kenya, with 59% on ART. Nairobi carries the highest population of sex workers, a key population in HIV transmission. The rate of viral suppression among PLWH on ART (74%) in Nairobi County stands at 41%. For a County with approximately 39,494 sex workers whose HIV prevalence is high (29.3% among female sex workers and 18.2% among male who have sex with men) relative to the County prevalence, there's need to improve the rate of viral suppression.

The objective of the study was to determine factors influencing sustained viral load suppression in female sex workers initiated into care at the sex worker outreach project in Nairobi. This was a retrospective cohort study using secondary data collected from HIV positive female sex workers initiated into care at SWOP City clinic between 1<sup>st</sup> January, 2014 and 1<sup>st</sup> January, 2015. The outcome of interest was the virological status of the patient after two years from the time of initiation into care.

The study findings indicated that having history of tuberculosis infection (OR=2.40, P<0.001) and not consistently using condoms use when having sex with clients/partners (OR=2.11, P=0.002) significantly increases the risk of virological failure among female sex workers who had previously achieved complete viral suppression.

Special attention should be accorded to HIV positive sex workers with history of tuberculosis and appropriate changes in course of treatment done should they present symptoms of emerging drug resistance to sustain suppressed viral replication. There's also need for continuous training on how to negotiate for condom use among HIV positive sex workers receiving HIV treatment.

## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background of the study

Granich et al. (2009), propose that expanded contact to ART treatment can lead to elimination of the HIV virus from the body of a human being. The therapy significantly reduces morbidity and mortality rates among HIV-infected persons (INSIGHT START Study Group, 2015; TEMPRANO ANRS Study Group et al, 2015).

At the end of 2015, approximately 17 million [15.1 million-17.8 million] people were accessing antiretroviral medicine, which translates to 46% (43-50%) global ART coverage (UNAIDS, 2016). In 2016, 19.5 million out of the 36.7 million people globally were accessing antiretroviral therapy, an improvement from the estimates in 2015 (UNAIDS, 2017). The greatest improvement in ART coverage has been reported in the Eastern and Southern Africa. As of 2015, South Africa was leading with 3.4 million people with access and Kenya had 900,000 PLWH.

The success of ART is defined by sustained virological suppression, immunologic recovery among other clinical benefits. Bello, et al (2016) reports that following maximal and durable suppression of plasma viral load, there is delay in prevention and preservation or improvement in CD4 T lymphocyte (CD4) cell numbers all of which are important treatment goals. With increasing ART coverage, AIDS-related mortality has dropped significantly by 48% from the peak in 2005. An estimated 7.6 million AIDS-related deaths globally were averted between 1995 and 2013, (UNAIDS, 2014). Achieving viral load reduction to lower limits of detection of currently used assays (VL<50 copies/ml) usually occurs within the first 12 to 24 weeks of

therapy (Bello, et al., 2016). Despite evidence indicating that viral replication continues in patients with undetectable viraemia, achieving and maintaining a VL<50 copies/ml is associated with long-term virological suppression and sustained immunological benefits (Palmer et al, 2008). Studies however suggest this is hard to achieve, occurring in 60%-80% and about 85% of HIV patients in cohort studies and clinical trials respectively (Theo, 2014).

Ambrosioni, (2011) add that there is need to monitor viral suppression in guiding HIV programs on the normative levels of population level in order to suppress the virus and define desirable levels of clinic and program performance. That, there is also need estimate viral suppression rates in establishing and improving mathematical models of strategies that can be followed to ensure ART treatment success.

## **1.2 Problem statement**

The main objective of anti-retroviral therapy is to suppress the replication of HIV virus to a minimal level that drug resistance mutations may not emerge, restore and preserve immune function, reduce AIDS-related events and improve the life span of the patient. There are about 36.7 million PLWH worldwide, with sub-Saharan Africa carrying the greatest burden. As of 2016, 51% of PLWH in Eastern and Southern Africa were on ART but only 45% had achieved viral suppression. In the same period, of the 1.5 million PLWH in Kenya, 59% were on ART but data on the viral suppression is not available.

The main factor to control when addressing an infectious disease epidemic is the rate of transmission of the disease which is a function of the infected population size and the rate of transmission. In the case of HIV/AIDS disease one of the key populations to focus on in controlling the spread of HIV infection is sex workers because they are a hub of HIV infection

and key drivers in the transmission owing to their nature of work. One of the strategies to control the rate of HIV transmission is ensuring those carrying the virus have suppressed levels of the plasma HIV RNA. The rate of viral suppression among PLWH on ART (74%) in Nairobi County stands at 41% (Ogaro,2017). For a County with over 39,000 sex workers whose HIV prevalence is high (29.3% among female sex workers and 18.2% among male who have sex with men) relative to the County prevalence, there's need to improve the rate of viral suppression.

### **1.3 Justification**

Studies have been done to investigate factors influencing the virological response among HIV infected patients on ART and have reported factors such as adherence, baseline viraemia, duration of treatment and risk behavior. These studies mainly focused on the general population of patients, with a few on high risk groups like pregnant women and pediatrics. This study sought to establish factors associated with sustained virological suppression in sex workers infected with HIV. The study population was drawn from sex workers on follow-up in the Sex Worker Outreach Program (SWOP), Nairobi. The findings of this study may be useful to the project managers to evaluate the performance of the project in controlling HIV disease in this population and serve as a basis for designing strategies to achieve at least 90% viral suppression in this group.

### **1.4 Broad objective**

To evaluate determinants of sustained virological suppression in HIV-1 infected patients in SWOP-Kenya

### **1.4.1 Specific objectives**

1. To describe the socio-demographic and clinical profile of HIV-1 infected sex workers in SWOP-Kenya.
2. To establish the virological response of HIV-1 infected sex workers in SWOP-Kenya
3. To establish factors associated with sustained viral suppression in HIV-1 infected sex workers in SWOP-Kenya



## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1 Human Immunodeficiency Virus (HIV)**

Walker, (2013) reports HIV has is one of the world's most serious health and development challenges facing humanity. In 2016, 36.7 million people were living with the virus; this was an increase from 33.2 million in 2010 as a result of continuing new infections and also people living longer with the virus. In the World approximately 1.0 million People died of AIDS related illnesses in 2016; this recorded a 48% decrease since 2005 UNAIDS, (2017). However, deaths have declined partially due use of antiretroviral treatment. HIV virus still remains the leading cause of many recorded deaths in the World. A good number of Women also in their reproductive age also die as a result of this disease (Miruka, 2016). According to Conen, et all (2011), in 2016 there were 1.8 million new infections recorded and in a single day the world recorded 5,000 new infections. However, there has been significant decline in the number of new infections since mid-1990s.

#### **2.2 Transmission of HIV**

The spread of HIV from one person to the other is called HIV transmission; this is according to AID Sinfo report of 2015. Dessie, (2016) reports that HIV can be transmitted in certain body fluids from an infected person, this can also occur if these fluids come in contact with a mucous membrane or damaged tissue, it can also by direct injection into the bloodstream. Walker, (2013), adds that the virus is also spread from an HIV-infected woman to her child during pregnancy, childbirth or breastfeeding. This process is referred to us mother-to-child transmission of HIV. (Miruka, 2016).

The main way of transmitting the virus more especially in sub-Saharan Africa is through unprotected heterosexual intercourse (Steen *et al*, 2015). There is a high risk for persons with multiple sex partners and concurrent sexually transmitted infection, for instance, they can expose themselves to herpes simplex type 2 (HSV-2) (Chen *et al*, 2007). A big number of newly recorded HIV infections are mostly attributed to long-term heterosexual relationships in the World

### **2.3 Prevention of HIV**

According to Walker, (2013), several prevention measures are used to combat HIV whereas new vaccines are researched by various researchers (UNAIDS, 2016). Research finding shows that providing HIV treatment to people with HIV reduces the risk of transmission to their negative partners. Pre-exposure antiretroviral prophylaxis (PrEP) is becoming a more effective HIV prevention strategy in individuals at high risk for HIV infection. In 2015, WHO recommended PrEP as a form of prevention for high-risk individuals (WHO, 2015). In 2016, the UN Political Declaration on HIV/AIDS stated PrEP research and development should be accelerated in order to combat the spread of the virus (UN, 2016). There is need to use a combination of prevention measures, and sustaining efforts over time in combating the epidemic. However, access to prevention has remained limited (Ntozi, 2003).

### **2.4 Antiretroviral Therapy**

The advent of potent combination therapy improved steadily the use of ART to treat HIV infection in 1996(Arg *et al*, 2016). ART is highly effective in the prevention of HIV transmission in the world (Cohen *et al*, 2011). In 2012, 9.7 million people in developing countries were on ART (Fettig *et al*, 2016). This development has helped people living with HIV that has resulted in an increase in the number of PLHIV (Ambrosioni *et al*, 2011)

The primary goals of HAART is to obtain and maintain a complete HIV RNA suppression (Hammer *et al*, 2008). Failure to this move, it results in the development of drug resistance, the risk of both horizontal and vertical viral transmission can also be recorded (Castilla *et al*, 2005). The long-term clinical benefits of earlier suppression are not clear while the achievement of earlier suppression reduces the length of time one carries detectable virus (Staszewski *et al*, 1999). It is important to identify factors that predict time to virological suppression in order to optimize therapeutic success.

## **2.5 Virologic Suppression**

According to AIDinfo, (2015), Virologic suppression occurs when ART reduces an individual's viral load to an undetectable level. The reduction does not necessarily mean that a patient is free from the virus but the virus still remains in the body. If ART is discontinued, the person's viral load returns to a detectable level. ART aims at achieving the optimum goal for people infected with HIV in order to maintain continuous maximal virological suppression (O'Connor *et al*, 2017). People who start treatment are able to achieve virological suppression within a period of 3–6 months (Boender *et al*, 2015; McMahon *et al*, 2013).

To allow timely discovery of treatment failures, WHO (2013) recommended use of viral load testing as the gold standard to monitor patients response to ART. Establishment of the virological suppression status among patients enrolled on ART is important for timely detection of treatment failures detection of patients in need of more intensive obedience support and minimizes maturity of drug resistance and unnecessary switch to expensive and limited ART regimen option (Bulage at al, 2017).

## **2.6 Key populations**

According to WHO (2014) key populations are people or a group of people who are vulnerable to and most-at-risk for HIV. This group may include men who have sex with men, transgender people, people who inject drugs and sex workers. Analysis of data available to UNAIDS suggests that more than 90% of new HIV infections in central Asia, Europe, North America, the Middle East and North Africa in 2014 were among people from key populations and their sexual partners (Pustil, 2016). In the Asia and Pacific region, Latin America and the Caribbean, people from key populations and their sexual partners accounted for nearly two thirds of new infections. In sub-Saharan Africa, key populations accounted for more than 20% of new infections, and HIV prevalence among these populations is often extremely high. In Kenya, these groups often have poor contact to and low uptake of health services due to criminalisation and stigmatisation of their behaviour (WHO, 2017).

## **2.7 Sex workers**

The HIV epidemic continued to have a far reaching impact on transgender sex workers as well as male and female (Bekker *et al*, 2015). Studies indicates that female sex workers (FSWs) are more likely to live with the Virus than other women (Baral *et al*, 2012), 15% of female HIV infections were attributed to sex workers in 2011 with the big number recorded in sub-Saharan Africa (17.8%)(Prüss-Ust *et al*, 2013). In West African countries substantial proportions of new infections (10–32%) occurred as a result of sex work. In Uganda, Swaziland, and Zambia, 7–11% of new infections were due to sex work sex-worker clients, and clients' regular partners (Gouws *et al*, 2012).

The high rate of change of sexual partners facilitates not only rapid acquisition, but also onward transmission to other clients; this leads to seeding multiple new streams of infection (Steen *et al*,

2015). Sex work often overlaps with drug-injecting populations. Men who have sex with men and transgender persons expand transmission potential beyond heterosexual networks. Heterogeneity of sexual behaviour and conditions under which sex work takes place influences to a great extent the high percentage of vulnerability and risk in sex work (Shahmanesh *et al*, 2008) (WHO *et al*, 2013).

## **2.8 Sex Workers and ART**

Higher HIV burden has made sex workers to be among the ones in need of antiretroviral therapy (ART) (Baral *et al*, 2012). The numerous benefits of ART are, however, reliant on successful engagement in HIV care and treatment, including linkage to care shortly after HIV diagnosis, retention in pre-ART care, timely initiation onto ART, and optimal ART adherence for viral suppression (Lancaster *et al*, 2017). Sex workers living with HIV must be linked to care and initiate treatment to receive the individual immunological and clinical benefits of ART, such as viral suppression. Further, the evidence supporting ART for-treatment-as-prevention sex workers who are virally suppressed highly decreases the likelihood for ongoing transmission (Cohen *et al.*, 2011; Gardner *et al.*, 2011).

## **2.9 Sex Workers Outreach Project, Kenya (SWOP)**

SWOP works closely with the University of Manitoba and University of Nairobi in promoting health, safety and wellbeing of sex workers (WHO, 2017). The target area has approximately 30,000 sex workers, and the plan has grown from three to nine service sites since 2008. It works closely with the National AIDS and STI Control Programme (NASCO) of the Ministry of Health and it uses peer-led, hotspot-based mobilization and outreach services to provide HIV and sexually transmitted infection prevention and care services that are acceptable to sex workers.

## **CHAPTER THREE**

### **METHODOLOGY**

#### **3.1 Study design**

The aim of this study was determine factors influencing sustained virological suppression. A retrospective cohort study design was adopted with two years observation period. The main exposure was frequency of condom use ('consistency') during sexual intercourse with clients/partners. The exposed group included those sex workers that reported not using condoms consistently during sex with their clients/partners.

#### **3.2 Study site**

The study was conducted at the University of Nairobi, Institute of Tropical and Infectious Diseases using secondary data from Partners for Health and Development in Africa (PHDA)-SWOP, Kenya.

#### **3.3 Study population**

This study compared risk virological failure between the exposed and unexposed group of HIV-1 infected female sex workers, following initial complete viral suppression. The study population was drawn from HIV-1 infected female sex workers, who were on ART and on follow-up in SWOP since January, 2014. It comprised the two groups- exposed group and unexposed group based on consistency of condom use.

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.

### **3.3.1 Inclusion criteria**

- Must have been a HIV-1 infected female sex worker on ART
- Should have been on follow-up in SWOP for at least two years with virological monitoring records
- Must have achieved viral suppression, <1000 copies/ml after ART initiation within the first 6 months
- **Exposed group-** Patients who do not use condoms regularly when having sex
- **Unexposed group-** Patients who regularly use condoms with clients/partners during sex

### **3.4 Sample size determination**

The main outcome of this study was the virological status of the participants one year after achieving viral suppression. This outcome was evaluated in term of probability to have sustained virological suppression. Relative risk was used to compare the probability between the two groups. Therefore sample was calculated using the formula by Fleiss (1981) and was corrected for small sample size in a specific category;

$$n = \frac{\left[ Z_{\alpha/2} \sqrt{(1 + 1/m)\bar{p}(1 - p)} + Z_{\beta} \sqrt{\frac{P_0(1-P_0)}{m+p_1(1-p_1)}} \right]^2}{(p_0 - p_1)^2}$$

$$\bar{p} = \frac{p_1 + mp_0}{m + 1}$$

$$n_c = \frac{n}{4} \left( 1 + \sqrt{1 + \frac{2(m + 1)}{nm|p_0 - p_1|}} \right)^2$$

Where,

**n**: Minimum sample size required in the exposed group

**n<sub>c</sub>**: Continuity-corrected sample size

**Z<sub>α/2</sub>**: Standard normal distribution critical value at α (type I error) - probability of detecting a false effect for a two sided test (**α=0.05; Z<sub>α/2</sub>=1.96**)

**Z<sub>β</sub>**: Standard normal distribution critical value at β (type II error) - probability of failing to detect a true effect (**β=0.2; Z<sub>β</sub>=0.84**)

**p<sub>0</sub>**: Probability of event in unexposed group which can be estimated as the population prevalence of event under investigation (**p<sub>0</sub>**) =0.41 based on the rate of viral suppression among HIV patients on ART in Nairobi County (Ogaro, 2017)

**p<sub>1</sub>**: Probability of event in the exposed group (**p<sub>1</sub> = RR \* p<sub>0</sub>**) where **RR** is expected relative risk (**RR=1.5**)

**m**: Number of unexposed subjects per exposed subject (**m=1**)

Using this formula and the defined parameters values, we obtained n<sub>1</sub>= 150 exposed patients and also n<sub>2</sub>=150 unexposed patients; what give us a total minimum sample size of n= 300



### **3.5 Sampling method**

The participants were selected based on the exposure status of the patient. A complete list of exposed and unexposed patients in SWOP with follow-up records on virology was established. Simple random sampling method was used to select participants in each population.

### **3.6 Data collection and analysis**

Secondary data was retrieved from SWOP database using records from 2010 to 2016 and stored in Microsoft Excel 2013. Data was cleaned, coded and analysed using STATA version 13 SE.

Data cleaning was done by checking for presence of extreme values and missing values. For extreme values, clinic files were reviewed to verify and replace in case of transcription errors. For missing values, proportion of missing values was calculated and pattern of missingness evaluated as whether missing at random or not. If the proportion of missing data was more than 5% and not randomly missing, multiple imputations with m more equal to 5 was used to fill them.

Univariate analysis was done to describe the variables. For quantitative data, histograms were used to show the distribution of data; appropriate measures of central tendency were reported in tables. For categorical data, bar/pie charts were used to show the distribution; frequencies and proportions were reported in tables.

Simple regression using log binomial model was done to evaluate the crude effect of baseline patient characteristics on the risk of virological failure. The crude relative risk and corresponding p-values were reported.

Multiple regression using log binomial model was fitted to evaluate the adjusted effect of patient characteristics (history of tuberculosis, consistency of condom use) that were significant in the

simple regression model adjusting with demographic characteristics (age, marital status). The adjusted relative risk and the corresponding confidence interval were reported.

**Log binomial model was used to estimate the relative risk:**

$$\log(P) = \sum e^{\beta X_i}$$

Where,  $\beta$  is the effect of predictor  $X_i$  (e.g. condom use) on the risk of virological failure

$e^{\beta}$  = Relative risk when time (t) is constant

**P**= Risk for an exposed female with hiv-1 to not sustained virological suppression

### **3.7 Ethical considerations**

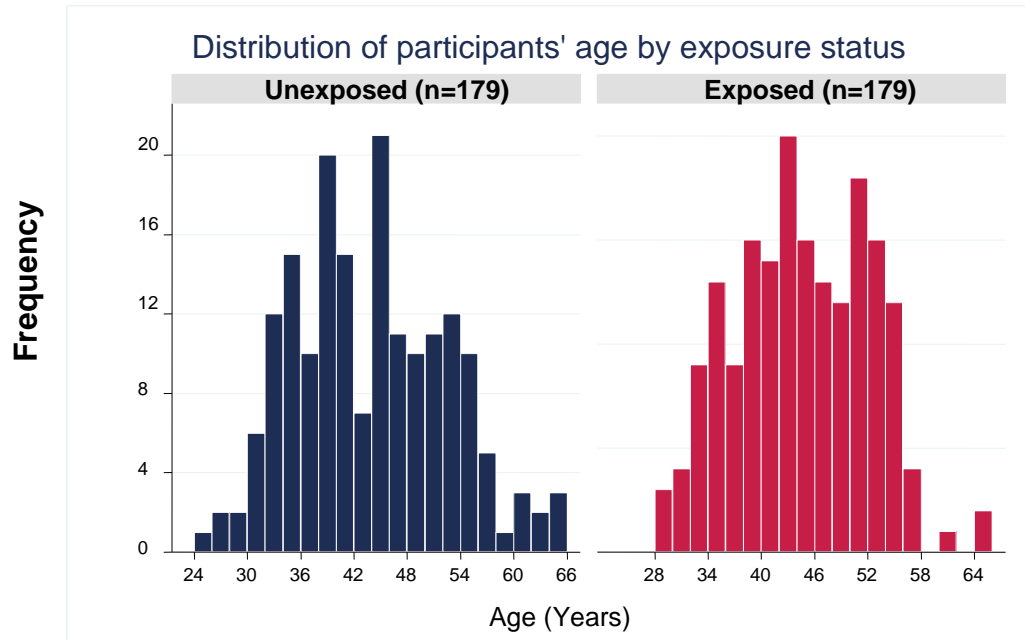
The research proposal was submitted to UoN/KNH research and ethical committee for clearance and approval. Further authorization was sort from SWOP to use their data before the research was conducted. Information obtained from the SWOP database was treated with utmost confidentiality. All data collected was used for this study alone.

## **CHAPTER FOUR**

### **RESULTS**

#### **4.1 Socio-demographic features of women sex workers**

A total of 358 female sex workers in care with suppressed HIV viral loads were sampled from SWOP City clinic database based on their exposure status (Condom use during sex). These patients had been initiated into ART between 1<sup>st</sup> January, 2014 and 31<sup>st</sup> January, 2015 and were confirmed to have achieved complete viral suppression (<1000 viral copies/ml of blood) 6 months post initiation. The exposed group comprised of the female sex workers who did not use protection (condoms) “consistently” during their sex acts whereas the unexposed included those that consistently used protection when having sex. The study participants were followed for a period of 2 years from the time they were declared to have achieved complete viral suppression and their final viral load noted.



**Figure 1: Distribution of the study participants' age by exposure status**

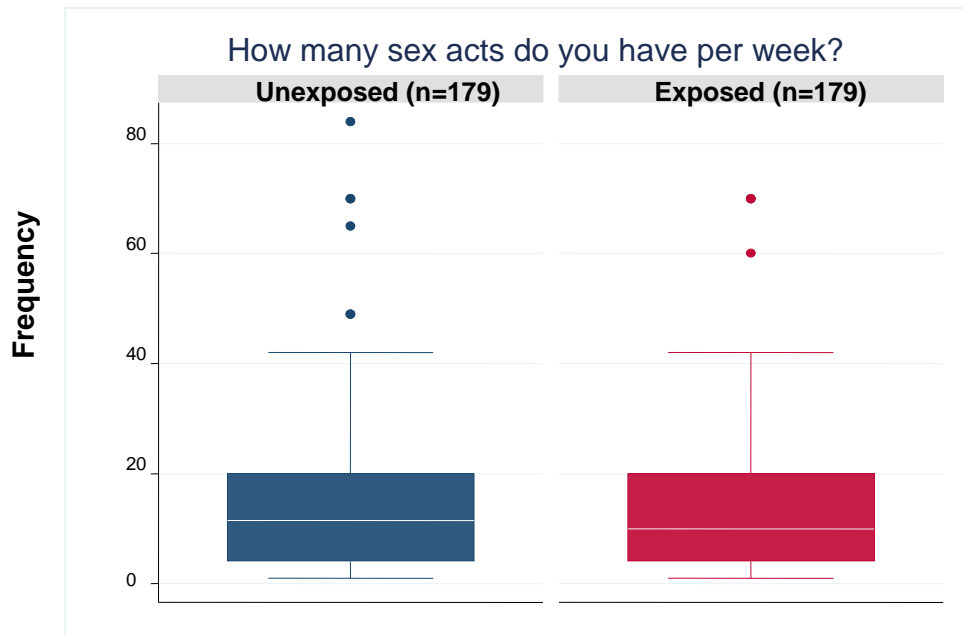
The female sex workers in this study were aged between 24 years and 65 years. The age distribution appeared similar between the exposed and unexposed group

**Table 1: Socio-demographic features of the women sex workers**

Variable	Category	Exposed n (%)	Unexposed n (%)
<b>Marital status</b>	Single	105 (59.7)	126 (71.6)
	Married	47 (26.7)	34 (19.3)
	Divorced/separated	18 (10.2)	13 (7.4)
	Widowed	6 (3.4)	3 (1.7)
<b>Education level</b>	Primary	38 (21.8)	59 (33.3)
	Secondary	100 (57.5)	83 (46.9)
	Tertiary	33 (19.0)	29 (16.4)
	Other	3 (1.7)	6 (3.4)
<b>Engage in sex under alcohol influence</b>	Yes	51 (28.8)	62 (34.8)
	No	126 (71.2)	116 (65.2)
<b>Drug use</b>	Yes	66 (36.9)	52 (29.1)
	No	113 (63.1)	127 (70.9)
<b>Family planning use</b>	Yes	34 (20.1)	25 (14.4)
	No	135 (79.9)	149 (85.6)

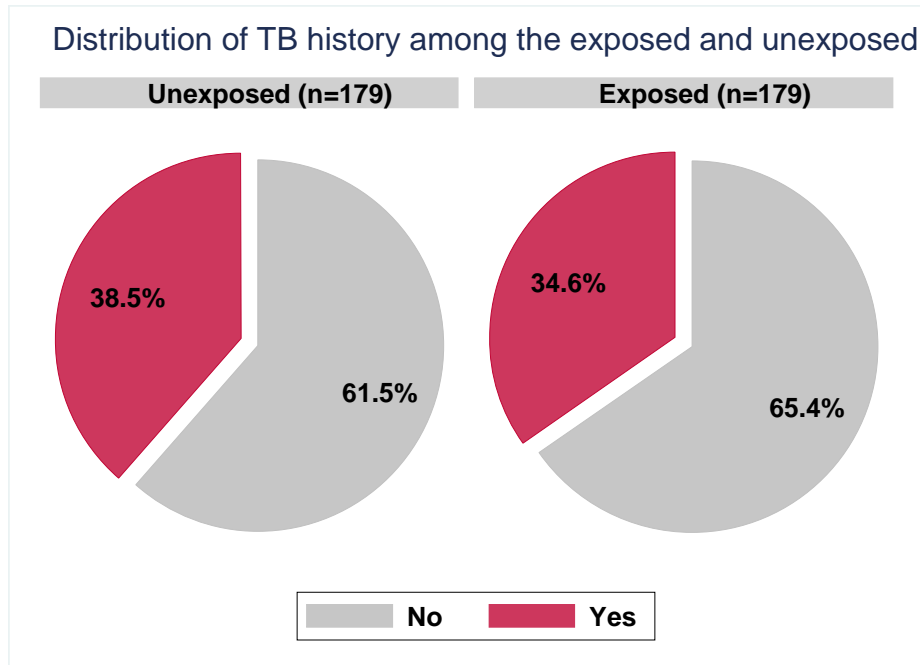
At least half of these FSW in the exposed (59.7%) and unexposed (71.6%) groups were single. There were more married FSW in the exposed group compared to the unexposed group. More than half of the FSW had attained at least secondary level of education in the exposed (76.5%) and unexposed group (63.3%). While the proportion of FSW who engaged in sex under the influence of alcohol was higher in the unexposed group (34.8%) than the exposed group (28.8%), the proportion of those who abuse drugs was higher in the exposed (36.9%) than the unexposed group (29.1%). The distribution of family planning use in the two groups was similar with a high proportion (almost 80%) not using any family planning method.

On average, the FSW in this study have between 1 and 84 sex acts per week with 50% doing at least 12 sex acts in the unexposed group and 10 sex acts in the exposed group.



**Figure 2: Distribution of average number of sex acts FSW have per week**

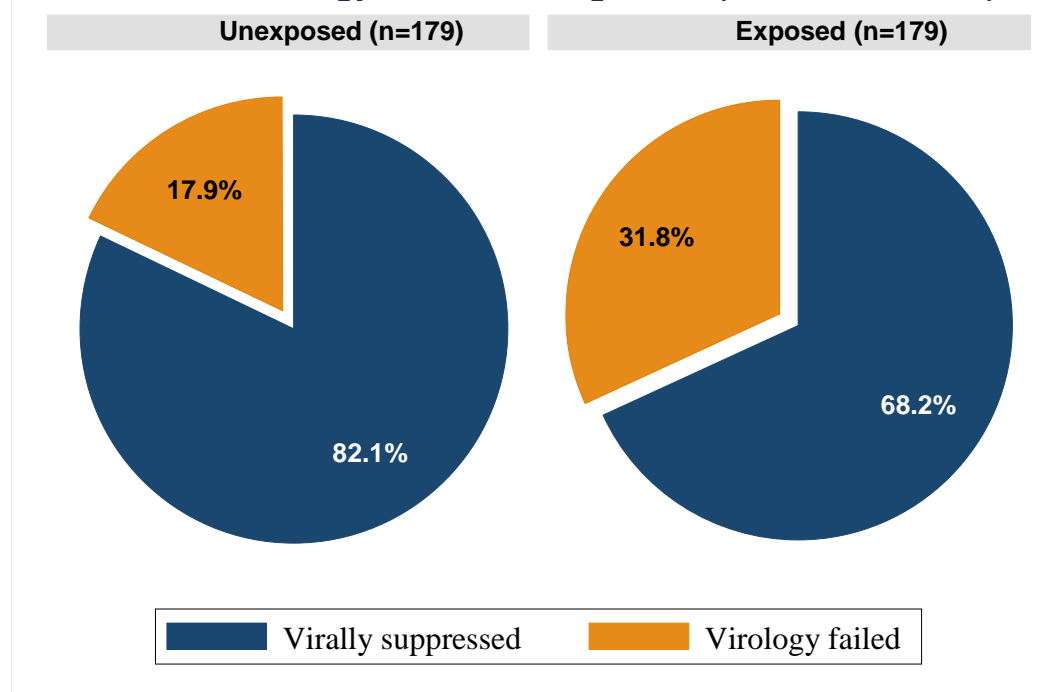
The distribution of sex acts done by FSW per week was similar between the two groups.



**Figure 3: Tuberculosis history distribution in the exposed and unexposed groups**

Among the FSW in the unexposed group, 38.5% had a history of TB infection. This proportion was higher compared to the proportion with previous history of TB infection in the exposed group

Distribution of virology status among the exposed and unexposed



**Figure 4: Virology status of FSW in the exposed and unexposed group**

At the end of the follow-up period, majority of the FSW had maintained viral load suppression in the exposed and unexposed groups. The proportion with virological failure was 1.78 times higher in the exposed group (31.8%) relative to the unexposed group (17.9%).

**Table 2: Antiretroviral therapy start regimen**

Start regimen	Exposed n (%)	Unexposed n (%)
AZT+3TC+EFV (>15YRS ADULT)	10 (5.6)	11 (6.2)
AZT+3TC+NVP (>15YRS ADULT)	39 (21.8)	33 (18.4)
TDF+3TC+EFV (>15YRS ADULT)	87 (48.6)	88 (49.2)
TDF+3TC+NVP (>15YRS ADULT)	38 (21.1)	39 (21.8)
d4T+3TC+NVP (>15YRS ADULT)	5 (2.8)	8 (4.5)

The table 2 shows the distribution of ART start regimen prescribed for FSW in care.

## 4.2 Association between FSW profile and virological failure

Log binomial model was used to evaluate the crude and adjusted effect of the socio-demographic characteristics, sexual practices, alcohol and substance use, and history of tuberculosis and antibiotic use on the risk of virological failure for a FSW who had achieved complete viral suppression. Table 3 shows the simple regression models outputs.

**Table 3: Simple log binomial models- Association between the FSW profile and the risk of virological failure**

Variable	Category	Crude RR	Std. error	95% CI (RR)	P-value
<b>Marital status</b>	Single (base)				
	Married	1.30	0.31	[0.81; 2.08]	0.282
	Separated/Divorced	0.68	0.32	[0.27; 1.69]	0.282
<b>Highest Education level</b>	Primary (base)				
	Secondary	1.29	0.33	[0.77; 2.14]	0.330
	Tertiary	1.12	0.38	[0.58; 2.17]	0.742
<b>Engage in sex under alcohol influence</b>	Yes (base)				
	No	1.00	0.23	[0.64; 1.57]	0.998
<b>Drug intake</b>	Yes (base)				
	No	0.83	0.18	[0.54; 1.28]	0.409
<b>Antibiotic use</b>	Yes (base)				
	No	0.93	0.20	[0.61; 1.41]	0.730
<b>Use condom consistently</b>	Yes (base)				
	No	1.78	0.40	[1.16; 2.75]	0.009*
<b>TB treatment history</b>	No (base)				
	Yes	2.44	0.52	[1.60; 3.71]	<0.001*
<b>Average sex acts/week</b>		0.99	0.01	[0.98; 1.01]	0.699
<b>Age of participant</b>		0.99	0.01	[0.96; 1.02]	0.410



Individually, only condoms use frequency when having sex and history of TB treatment, were found to have a significant effect on the risk of virological failure in a FSW who had previously attained viral suppression.

A FSW on ART who does not use protection consistently when having sex has 78% (RR= 1.78; 95% CI [1.16; 2.75]) increased risk of virological failure relative to one that uses condoms consistently when having sex. A FSW with history of tuberculosis treatment has 2.44 times increased risk (RR=2.44; 95% CI [1.60; 3.71]) to have virological failure relative to one with no previous history of TB treatment.

A multiple regression using log binomial model was fit to evaluate the adjusted effect of a FSW's age, education level, condom use and history of tuberculosis on the risk of virological failure for a FSW who had achieved complete viral suppression. The fitted model was significant (Log-likelihood=-444.95, LR chi2=29.7, p-value=0.0018). The Table 4 shows the model output.

**Table 4: Multiple regression- log binomial model: Association between FSW profile and Virological failure**

Variable	Category	Adjusted RR	95% CI (RR)	P-value
<b>Highest Education level</b>	Primary (base)			
	Secondary	1.02	[0.60; 1.72]	0.949
	Tertiary	0.72	[0.34; 1.55]	0.406
<b>Use condom consistently</b>	Yes (base)			
	No	2.11	[1.32; 3.40]	0.002*
<b>TB treatment history</b>	Yes (base)			
	No	2.40	[1.52; 3.77]	<0.001*
<b>Age of FSW</b>		0.99	[0.96; 1.02]	0.460

Adjusting for the effect of education level, age of the FSW, and history of TB treatment, a FSW who does not use protection consistently has 2.1 fold increased risk (RR=2.1; 95% CI [1.32; 3.40]) to experience virological failure following successful viral suppression. This effect size is higher compared to the effect size estimated in the unadjusted model (RR=1.78). Further, a FSW with history of TB treatment has 2.4 times increased risk for virological failure compared to a FSW with no history of TB treatment after adjusting for the effect of other covariates in the model.

## CHAPTER FIVE

### 5.1 DISCUSSION

Sustained viral load suppression is a key to long-term healthy living for people infected with HIV. The primary objective of ART is to suppress the virus in the body to levels that cannot be detected which in turn leads to recovery of the immune system, reduced opportunistic infections and mitigates the development of acquired immunodeficiency syndrome (AIDS) (Bello, 2016). Sustained viral suppression is an indicator of good response to HIV treatment. Many patients, upon starting treatment, achieve viral suppression within three to six months, but face challenges maintaining the suppression of the replication of the virus to a HIV RNA level of <1000 copies/ml or below detectable levels (Nettles et al, 2005).

The study sought to investigate the determinants of sustained virological suppression in HIV positive female sex workers undergoing treatment at SWOP. The baseline characteristics of 358 HIV infected female sex workers in care were retrieved from the records and association with virological response to treatment after two years of follow-up evaluated. The initial viral load after six months of ART in this sample ranged between ‘below Lower Detection Limit (LDL)’ and 650 viral copies/ml. At the end of the two year follow-up period, 75.1% had sustained viral suppression (below LDL). Virological failure was 24.9%.

The regression analysis using cox proportional hazard model with constant time showed that history of Tuberculosis infection and failure to use protection consistently when having sex were significant factors associated with increased risk of virological failure following successful suppression of viral replication.

A female sex worker with history of tuberculosis infection was found to 2.4 times increased risk of failed viral suppression. This finding agrees with the results reported in a study done by Edson et al, (2014) in which patients with a previous diagnosis of tuberculosis infection were found to have 2.9 times great risk of virologic failure. Tuberculosis is a common opportunistic infection in HIV infected patients and an indicator of clinical progression HIV infection and a compromised immune system (Walker et al, 2013). Tuberculosis accelerates the course of HIV induced disease by activating viral reproduction and accentuating the decline of T CD4<sup>+</sup>cell. First time infection can also increase the risk of latent tuberculosis reactivation, a new infection progression or re-infection to active disease, escalating the risk of the emergence of HIV resistant strains to the usual antiretroviral therapy (Von Reyn et al, 2011). Attention must therefore be given to patients with previous diagnosis of tuberculosis when conducting HIV treatment and follow-up to reduce the incidence of virologic failure.

Consistent condom use remains an effective barrier to HIV transmission not just from the infected to non-infected but also necessary to prevent multiple infections and among those already infected (Shewamene et al, 2015). Multiple infections with different strains of the virus and other secondary sexually transmitted infections can lead to ART drug resistance (Dessie et al, 2011) hence virological failure. Consistent condom use, which was the main exposure variable in this study, is associated with reduced risk of virological failure. A HIV positive sex worker who does not consistently use condoms during sexual intercourse had 2.1 times increased risk of virological failure adjusting for education level, age and history of tuberculosis infection. FSW in SWOP are trained on safe sex and how to negotiate for condom use when dealing with the sexual partners and/or clients, however, from the data it's evident that the consistent condom use is still not being adequately implemented. A study done in Uganda by Ntozi et al, (2003)

reported that the use of condoms by FSW was situational such that sometimes customers would offer to pay extra for unprotected sex or would force them to have sex without condoms if they refused. There's need for economic empowerment of these highly vulnerable women and provide continuous safe sex education to address this problem.

None of the socio-demographic characteristics of FSW were statistically associated with the risk of virological failure occurrence. In terms of marital status, majority of the female sex workers in the sample were single. Though not statistically significant, the regression showed that a married FSW was had a 30% increased risk of virological failure compared to one who is single. Contrary to the findings of this study, age was significantly associated with virological failure in adults according to a study conducted in Nyanza Kenya (Sang & Miruka, 2016). The study found that a patient who is younger than 40 years was 2.3 times likely to experience virological failure compared to one who is 40 years or older adjusting for other patient characteristics.

Engaging in sex under the influence of alcohol and/or drugs was not significantly associated with the risk of virological failure occurrence. This finding agrees with the claim that drinking alcohol does not increase the risk of treatment failure (Conen, 2013). However, patients are heavy drinkers should be monitored for drug adherence which is a known risk factor for ART failure, since heavy drinkers are reported to be more likely to interrupt their antiretroviral therapy compared to non/light drinkers. The frequency of sex acts a female sex worker has per week has no significant effect on the risk of a woman experiencing virological failure. A HIV infected sex worker with history of antibiotic use has the same risk of having virological failure and one without history of antibiotic use in the course of HIV treatment.

## **5.2 CONCLUSION**

The study showed that history of tuberculosis infection and failure to consistently use condoms during sexual intercourse were positively and significantly associated with the risk of a HIV infected female sex worker in care experiencing virological failure. HIV infected sex workers that have previously been treated for tuberculosis should be monitored closely and appropriate changes in course of treatment done should they present symptoms of emerging drug resistance to sustain suppressed viral replication, thus improving their health. There's also need for continuous training on how to negotiate for condom use and increase awareness about the importance of using condom as a powerful means of promotion regular condom use among HIV positive sex workers receiving HIV treatment.

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## **APPENDIX: CONSENT FORM**



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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.

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- 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

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