

**EFFECTS OF HIV ORAL PRE-EXPOSURE
PROPHYLAXIS USE ON INCIDENCE OF STIs AND
RISKY SEXUAL BEHAVIORS AMONG FEMALE SEX
WORKERS AT THE DROP-IN CENTERS IN NAIROBI
COUNTY, KENYA**

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**Effects of HIV Oral Pre-Exposure Prophylaxis Use on Incidence of
STIs and Risky Sexual Behaviors among Female Sex Workers at the
Drop-In Centers in Nairobi County, Kenya**

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**A Thesis Submitted in Partial Fulfilment of the Requirements for
the Degree of Master of Science in Epidemiology of the Jomo
Kenyatta University of Agriculture and Technology**

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DECLARATION

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

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DEDICATION

This thesis is dedicated to all persons committed to ending HIV epidemic and eliminating Sexually Transmitted Infections through concerted efforts and proven interventions.

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ABBREVIATIONS AND ACRONYMS

CDC -	Centers for Disease Control
CROI -	Conference on Retroviruses and Opportunistic Infections
DICEs -	Drop in Centers
HAART -	Highly Active Antiretroviral Therapy
HDOH -	Hawaii Department of Health
HIV-	Human Immunodeficiency Virus
IRB -	Institutional Review Board
JKUAT-	Jomo Kenyatta University of Agriculture and Technology
KEMRI -	Kenya Medical Research Institute
KP -	Key Populations
MSM -	Men who have Sex with Men
NASCOP -	National AIDS and STI Control Program
NGOs-	Non-Governmental Organizations
OR-	Odds Ratio
PrEP -	Pre Exposure Prophylaxis
PWID-	People Who Inject Drugs
RC -	Risk Compensation
SERU -	Scientific and Ethical Review Unit

STI - Sexually Transmitted Infections

TDF/FTC - Tenofovir Disoproxil Fumarate and Emtricitabine

VDRL - Venereal Disease Research Laboratory

WHO - World Health Organization

ABSTRACT

Pre-exposure Prophylaxis (PrEP) is effective in prevention of Human Immunodeficiency Virus (HIV) infections among populations at a substantial risk. Approximately 39 million HIV related mortalities have been recorded to date and over 2 million people contract HIV annually, while HIV rate among FSWs estimated to be about 12% globally. World Health Organization (WHO) recommended use of PrEP for HIV prevention in 2012 and by 2020, over 930,000 people worldwide had been initiated on PrEP. However, risk compensation among Female Sex Workers (FSWs) raises concerns about increased risk of sexually transmitted Infections (STIs). While STIs screening is continually done at every PrEP refill visits and cases treated, increased risk of STIs may reduce the prevention benefits of PrEP while increasing STI rates with ultimate impact on economic and health burdens. This study investigated the effects of HIV oral PrEP on the incidences of STIs and risky sexual behaviors among female sex workers in Nairobi. A six months retrospective cohort study was conducted among FSWs comprising of both HIV oral PrEP users and non-PrEP users accessing services at selected Drop-in Centers (DICES) in Nairobi County. Multi stage sampling was employed to select Sub Counties, DICES and participants, to generate a sample size of 168 PrEP users and 168 non-PrEP users. A structured data abstraction tool was used to collect the desired data on STI incidences, condom use and average sexual acts. This data was abstracted from the participant records as documented during monthly routine data collection. Data was analyzed using STATA. Oral PrEP users were found to be 1.8 times at increased risk of STIs ($P=0.005$, 95%CI) than non-PrEP users. Vaginitis (62%) and cervicitis (21%) were the most common STIs identified among FSWs with a composite STI prevalence of 35.4% and pooled STI incidence rate of 14 per 1000 person years. The average number of sexual acts per day was significantly higher among oral PrEP users than non-PrEP users from month two to month six with a 1.0-unit increase in mean sexual acts among PrEP users ($P=.004$, 95%CI). PrEP users were at increased risk of STIs than non-PrEP users with hazard ratio of 1.82 ($P=.005$, 95%CI) and relative risk (RR) of 1.4 ($P=.012$, 95%CI). There was no significant difference in mean condom use between PrEP users and non-users from month one to month five, but a statistically significant difference in mean condom use at month six, 4.3 and 5.0 PrEP and non-PrEP use respectively ($P=0.05$, 95%CI). There was a 0.38 mean reduction in condom use among PrEP users, but statistically insignificant ($P=.179$, 95%CI). This study has demonstrated that: Vaginitis, cervicitis and Pelvic Inflammatory Disease (PID) are the most prevalent STIs among FSWs; PrEP use among FSWs increases likelihood of higher daily sexual acts suggestive of behavioral risk compensation; Use of oral PrEP for HIV prevention increases the risk of STIs among FSWs using oral PrEP; and PrEP use does not influence condom use among FSWs. Prevention counseling should be emphasized during PrEP initiation and throughout PrEP follow up visits

CHAPTER ONE

INTRODUCTION

1.1 Background to the study

Oral Human Immunodeficiency Virus (HIV) Pre Exposure Prophylaxis (PrEP) is a chemoprophylaxis involving use of antiretroviral medicines taken orally to prevent HIV acquisition (Grant *et al.*, 2010). Oral PrEP can reduce the risk of HIV infection by more than 95% among men who have sex with men (MSM) with solid medication adherence (Jenness *et al.*, 2017). Oral PrEP is a major current HIV prevention intervention that has been adopted globally for prevention of HIV among the populations at substantial ongoing risk of acquiring HIV and the World Health Organization (WHO) released a series of recommendations supporting the use of oral PrEP for prevention of HIV among the high risk populations in 2015 (WHO, 2015).

In Kenya, oral PrEP was launched in 2016 and is recommended for use by persons at substantial ongoing risk of acquiring HIV (NASCOP, 2017) including discordant couples, female sex workers (FSW), Men who have sex with men (MSM), people who inject drugs (PWID), Adolescent girls and young women (AGYW), fisher folks and lesbians. Pre Exposure Prophylaxis (PrEP) intervention has become crucial in sex workers as a result of their increased risk to acquire HIV due to multiple sexual partners and inconsistent condom use (Shannon *et al.*, 2015).

Increased incidence of STI has been observed in demonstration studies with some studies recording up to 50% of men initiated on PrEP presenting with STIs within twelve months of follow up (Jenness *et al.*, 2017) (Liu *et al.*, 2016). According to World Health Organization (WHO) Global strategy for prevention and control of Sexually Transmitted Infections 2005-2015 (World Health Organization, 2015), more than 340 million curable STI occur annually in both men and women between the ages of 15 to 49 years with the highest burden seen in South and South East Asia, followed by Sub

Saharan Africa, and Latin America and the Caribbean. Gonorrhea is considered by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), a global health concern due to limited treatment options remaining (Katz *et al*., 2012). Hawaii Department of Health (HDOH) and CDC reported several isolates of *N. gonorrhoeae* with high level resistance to Azithromycin and reduced susceptibility to ceftriaxone (Katz *et al.*, 2012). Gonorrhea is one of the STIs caused by *Neisseria gonorrhoeae* which remains a global Public Health concern basically due to the development of resistant strains.

The use of HIV PrEP has the potential to increase incidences of STIs thereby posing public health concern possibly resulting from different forms of Risk Compensation (RC), including; risky sexual behaviors such as increasing the number of sexual partners, greater clustering of high-risk men associated with MSMs, greater number of sexual acts per day in FSW and reduced condom use with existing partners and/or strangers thereby increasing their vulnerability to STI. A conclusive evidence to show that STI rates are increased by the use of PrEP is however lacking.

1.2 Statement of the Problem

A combination of oral TDF-FTC when taken daily prevent HIV transmission among HIV heterosexual adults (Thigpen *et al.*, 2012) (Jenness *et al.*, 2017). This offers solution to one of the problem affecting the Key populations. Other problems associated with risky sexual practices/behavior including unintended pregnancies and other STIs must be addressed and part of the solution is attributed to consistent and proper condom use. Risk compensation resulting from the use of oral HIV PrEP has been cited to increase the incidence of other Sexually transmitted infections (Montaño *et al.*, 2019). Sexually transmitted infections were identified by the WHO in 2015 to be on the rise, reporting that about 357 million curable STI cases caused by bacteria and protozoa are recorded worldwide annually among men and women between the 15 to 49 years of age (Seale *et al.*, 2017). Syphilis is responsible for up to 40% of perinatal deaths

worldwide and prevalence of syphilis among pregnant women in Africa is estimated to be between 4 to 15% while one in four gonococcal and chlamydial infections result to infertility and annually, 4000 newborn babies become blind as a result of untreated maternal gonococcal and chlamydial infections worldwide (World Health Organization, 2007). Globally, STI constitute an enormous economic and health burden especially in developing countries where they constitute 17% of economic losses due to ill-health (Seale *et al.*, 2017). Kenya National AIDS and STIs Control Program (NASCO) estimate the rate of STI among Female Sex workers to be 22% (NASCO, 2017).

The government of Kenya rolled out PrEP use in 2016 following the WHO 2015 recommendations on oral PrEP use for prevention of HIV. Since then, Kenyan health facilities have implemented PrEP use particularly on the key population and HIV discordant couples as highlighted in the Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya 2017 (NASCO, 2017). This implementation framework focused on the roll out and uptake leaving a bigger void in prevention of other STIs that possibly attribute to risk compensation. Studies have demonstrated up to 20 times higher rates of STIs in gay men using PrEP than gay men in the general population (Montaño *et al.*, 2017). Most of the studies surrounding risk compensation and sexual behavior modification during HIV oral PrEP use have focused majorly on MSM with very limited knowledge on STI risk among FSWs.

What remains unknown is whether HIV oral PrEP use among female Sex workers may increase their risk of acquiring bacterial STI as a result of risk compensation due the fact that the perceived risk of HIV is eliminated by use of HIV Pre Exposure Prophylaxis. There is a demonstrated high likelihood of persons using PrEP to increase risky sexual behavior including inconsistent condom use. This may possibly lead to increased risk of exposure to HIV and other STIs. Risk homeostasis theory posits that a reduction in the perceived risk due to HIV PrEP use, relates with increase in risk-taking behavior. Inconsistent condom use and increased number of sexual acts per day among the female sex workers can conceivably be further compounded by the advent of PrEP as a result of a reduction of the perceived risk of acquiring HIV.

1.3 Justification of the Study

Studies have demonstrated the effectiveness of PrEP in HIV prevention (Thigpen *et al.*, 2012), (Jenness *et al.*, 2017) and as reported by WHO in 2015. Combination prevention involving both condoms use and PrEP can therefore be very promising in the fight against HIV and other STIs. The global strategy for control and prevention of Sexually Transmitted Infection 2006-2015 identifies prevention and control of STI as an integral part of comprehensive sexual and health services that will improve sexual and reproductive health (World Health Organization, 2007).

Limited studies have produced conclusive evidence showing that HIV oral PrEP increases STI rates, while STI rates among FSW PrEP users remain increasingly high. Moreover, many studies have focused on the relationship between HIV PrEP use and incidences of STI among MSM with little studies conducted on FSW (Marcus *et al.*, 2013).

The findings of this study contribute in informing policy makers in HIV prevention program, non-governmental organizations (NGOs) implementing HIV programs and the Ministry of Health (MoH), to advocate for and enhance awareness on combination prevention interventions and behavior adjustment counselling during PrEP initiation and follow up. Consequently, the implemented changes provide ultimate reduction in STI incidences and improved health status among the FSWs.

Moreover, there is an increasing global demand for information regarding risk compensation and the increasing risk of acquiring other STIs among the PrEP users especially among FSWs. The knowledge generated in this study will be useful in contributing to this demand, as well as adding to the national knowledge demand on PrEP use.

Studies on risk compensation following PrEP initiation are generally confounded by a number of factors; Such studies may not generate adequate evidence to infer continuing

sexual behavior patterns among the high risk population outside the study structure; this is partly because, in many studies the inclusion criteria screens out low risk individuals and include high risk individuals whose risk behaviors may have been high enough even before initiating PrEP in order to achieve statistical power for HIV incidence in the different study groups (Liu *et al.*, 2016). Subsequently, in some studies, the time for follow up may not be long enough to quantify the significance of long term outcome (Gift *et al.*, 2017).

The purpose of this study was therefore to determine the rate of STIs and risky sexual behaviors among Female Sex Workers using HIV oral Pre Exposure Prophylaxis while comparing with FSW of the same cohort who do not use PrEP. This study bridges the knowledge gap in the limited studies on risk compensation following PrEP use among FSWs while it also informs PrEP implementers and policy makers on areas of prevention focus and considerations when initiating oral PrEP.

1.4 Research questions

- 1) What STIs affect PrEP and non-PrEP using FSWs in Nairobi?
- 2) What is the effect of PrEP use on average number of sexual acts among FSWs using PrEP in Nairobi?
- 3) What is the effect of PrEP use on the incidence of STIs among PrEP and non-PrEP using FSWs in Nairobi?
- 4) What is the effect of PrEP use on the average condom use among PrEP using FSWs in Nairobi?

1.5 General objective

To determine the effects of HIV oral Pre-Exposure Prophylaxis use, on the incidence of STIs and Risky Sexual Behaviors among Female Sex Workers at the Drop-in Centers in Nairobi County, Kenya.

1.5.1 Specific Objectives

- 1) To determine the STIs affecting PrEP and non-PrEP using FSWs in Nairobi.
- 2) To determine the effect of PrEP use on average number of sexual acts among FSWs using PrEP in Nairobi.
- 3) To determine the effect of PrEP use on the incidence of STIs among PrEP and non-PrEP using FSWs in Nairobi.
- 4) To determine the effect of PrEP use on the average condom use among PrEP using FSWs in Nairobi.

1.6 Conceptual Framework of the Study

The relationship between the PrEP use (Independent variable), and STIs and Sexual behavior outcomes has been illustrated in figure 1.1 below. PrEP use predicts the outcomes in the incidences of STIs resulting from change in sexual behavior due to perceived elimination of HIV risk. PrEP use also can influence the FSWs' choice of the number of sexual acts, which is usually a risk reduction strategy, where FSWs are empowered to reduce sexual acts and explore other sources of income. Perceived elimination of HIV risk by FSWs when using HIV oral PrEP can possibly influence their decision making on condom use. Oral PrEP adherence remains constant as a control variable since the success of oral PrEP strongly depends on users' adherence of at least 85%, and therefore only participants with acceptable level of adherence, measured during refill visits, were considered for inclusion into the study. Moderator variables which includes all the sociodemographic components have the tendency of influencing the dependent variables but are not affected by the independent variable. The moderator variables however are unlikely to influence the STIs outcomes (Figure 1.1).

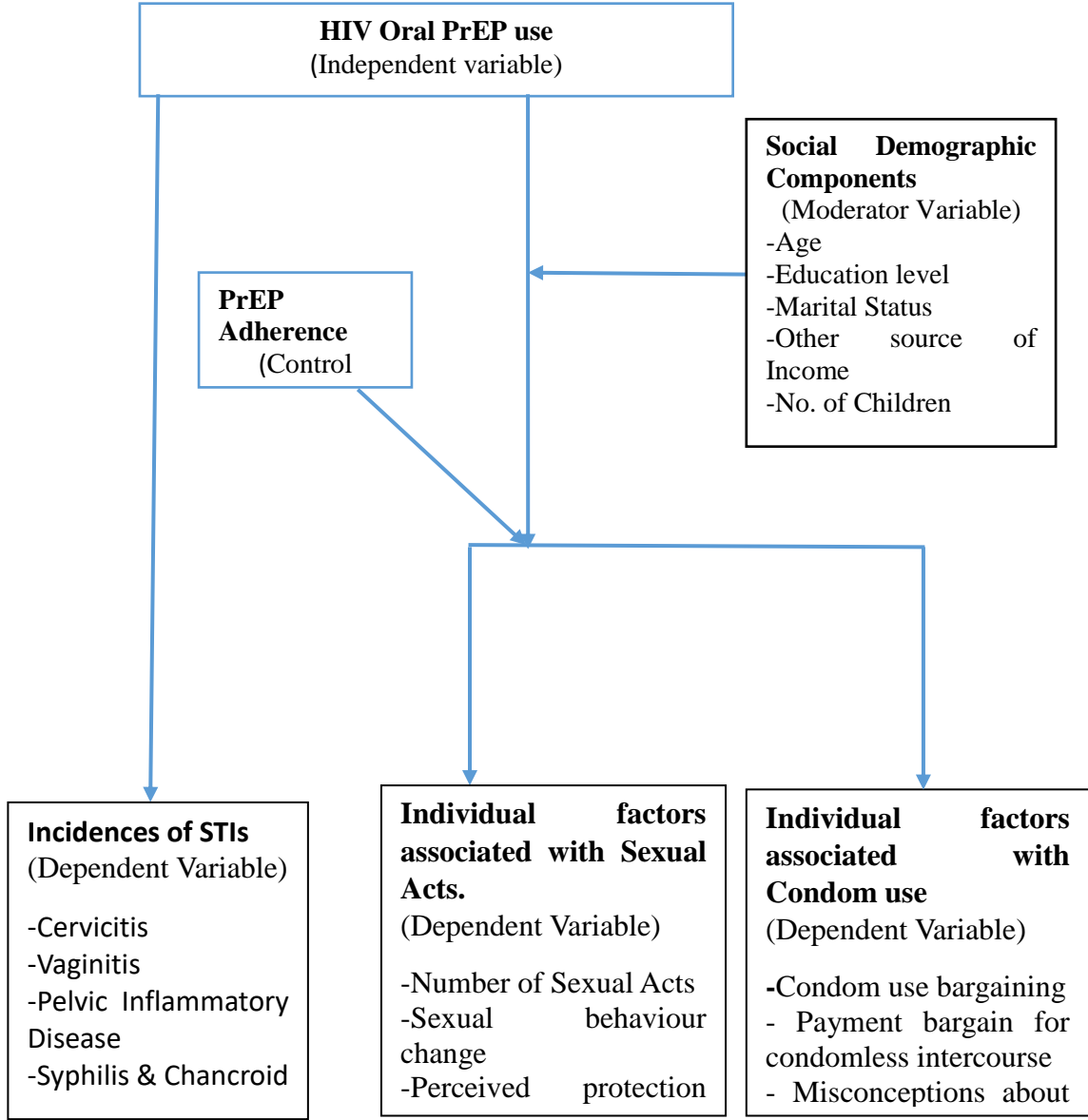


Figure 1.1: Conceptual Framework

CHAPTER TWO

LITERATURE REVIEW

2.1 Pre-Exposure Prophylaxis for HIV

Human Immunodeficiency Virus has had a damaging effect on public Health all over the world with no cure found despite the prevention interventions employed over the years (Mwangi *et al.*, 2019). About 39 million HIV related deaths have been recorded to date and over 36 million persons reported to be living with HIV worldwide with approximately 2 million annual new infections (Pandey *et al.*, 2019)

Oral Pre-Exposure Prophylaxis for HIV prevention is a major biomedical approach towards prevention of HIV among the persons at increased risk of infection who are otherwise healthy but require continued contact with healthcare system (Gabona *et al.*, 2017) (Pyra *et al.*, 2019); the use of Tenofovir disoproxil Fumarate (TDF) and a combination of Tenofovir disoproxil Fumarate and Emtricitabine (TDF/FTC) reduce HIV infection in heterosexual men and women with the TDF/FTC combination commanding up to 75% reduction in HIV-1 infection (Thigpen *et al.*, 2012). The use of oral HIV Pre Exposure prophylaxis has demonstrated a significant reduction in HIV infection among populations at substantial risk of acquiring HIV (McCormack *et al.*, 2016). HIV incidence remained extremely low, while adherence to PrEP medicines remained high among individuals who reported high sexual risk behavior (Liu *et al.*, 2016). Oral PrEP is a single dose pill consisting of a combination of TDF/FTC and its effectiveness is entirely dependent on good adherence (Shea *et al.*, 2019). The use of oral HIV Pre Exposure prophylaxis for prevention of HIV has significantly contributed to reduction of HIV transmission with up to 75% reduction of HIV incidence (Baeten *et al.*, 2012). Pre Exposure Prophylaxis (PrEP) intervention has become crucial in sex workers as a result of their increased risk to acquire HIV due to multiple sexual partners and inconsistent condom use (Shannon *et al.*, 2015).

2.2 Populations at risk of HIV

Populations have been categorized based on their risky behaviors and vulnerabilities to acquiring HIV. Key populations are distinct groups who are at high risk of acquiring HIV infection due to their high risk behavior and include; people in prison and other closed settings, Men who have sex with men, persons who inject drugs, sex workers and transgender people (World Health Organization, 2014). These risky behavior and vulnerabilities in particular populations determine the dynamics of HIV epidemics (Beyrer, 2016). Global HIV prevalence among Sex Workers is estimated to be 12% while in countries with medium and high HIV prevalence in the general population, the HIV prevalence among sex workers is over 30% (Beyrer, 2016). The United Nations General Assembly set a target of three million people to be initiated on PrEP by 2020 but 930,000 people were initiated on PrEP by 2020 (Krishen Samuel, 2021) . Kenya has over 63,000 PrEP initiations, second after South Africa among Countries in the Sub Saharan Africa (Segal *et al.*, 2021). However, small proportion of these are female (Hodges-Mameletzis *et al.*, 2019), while Female sex workers are disproportionately at risk of HIV (Shea *et al.*, 2019).

2.3 Risk Compensation following PrEP Use

Users of HIV Pre-Exposure Prophylaxis have up to 20 times higher rates of STI infections than in HIV seronegative gay men in the general population (Montaño *et al.* 2017). On the contrary, a mathematical modeling study demonstrates that a widespread PrEP use among gay men in US would result to increased STI diagnosis but will fall after a year assuming that 40% of gay men take PrEP and all STIs diagnosed are treated (Jenness *et al.*, 2017). Another Mathematical modeling study demonstrated that 42% of *Neisseria gonorrhoeae* and 40% of *Chlamydia trichomatis* would be prevented in the next 10 years with lower *Neisseria gonorrhoeae* and *Chlamydia trichomatis* incidences being associated with higher PrEP coverage (Jenness *et al.*, 2017). This prevention outcome was attributed to increased STI screening and treatment associated with HIV PrEP program.

The likelihood of acquiring *Neisseria gonorrhoeae*, *Chlamydia trichomatis*, and Syphilis infection among MSM PrEP users is 25.3, 11.2, and 44.6 times respectively, than that of non-PrEP users MSMs (Kojima *et al.*, 2016). Behavioral risk compensation as a result of HIV preventive technologies is apparent and an adjunct behavioral risk reduction intervention alongside the HIV preventive technologies is recommended (Eaton and Kalichman, 2007). No evidence of sexual risk compensation among both participants receiving Emtricitabine/Tenofovir disoproxil Fumarate (FTC/TDF) and the placebo was reported in the the iPrEx study, with participants taking PrEP recording even more receptive anal intercourse before initiating the oral PrEP (Marcus *et al.*, 2013). Meta-analysis and systemic review of 88 studies suggested a pooled prevalence for composite outcome of clamydia, gonorrhea and early syphilis of 23.9% post PrEP initiation and a pooled incidence of 72.2 per 100 person years during PrEP follow up (Ong *et al.*, 2019).

The uptake of PrEP increase while consistency in condom use rapidly decreased and can conceivably undermine PrEP effectiveness (Wise, 2018); similarly, high rates of STIs are diagnosed among HIV uninfected persons using PrEP with decreased mean condom use (Mayer *et al.*, 2014). STI incidence remain the same among PrEP users, however, the incidence of STI remain lower in event driven group than the daily PrEP group (Hoornenborg *et al.*, 2019). Some studies have shown no increase in sexual risk behavior associated with PrEP use while some PrEP users have reported increase in sexual risk behavior including inconsistent condom use, potentially worsening the rising incidence of bacterial STI (Scott & Klausner, 2016). Both HAART initiation and viral suppression do not increase the prevalence of unprotected sex and sexual risk behavior, however, the prevalence rate of unprotected sex increases with an Odds ratio (OR) of 1.8, among persons who believe that HAART initiation and suppressed viral load protects against HIV transmission (Crepaz *et al.*, 2004).

The number of condomless sex with casual partners increase among PrEP users (Hoornenborg *et al.*, 2019). The rate of unprotected sex and the number of sexual partners decreased over 12 months with data pointing effectiveness of the trial associated HIV Prevention counseling and recommended prevention counselling and

messaging on different population subgroups (Guest *et al.*, 2008). However, a study among discordant couples recorded decrease in condomless intercourse and decreased in mean number of monthly sexual acts (Ortblad *et al.*, 2020). Reports have indicated a significant decline in the mean number of partners reporting unprotected anal sex while the mean unprotected anal sex episodes remain stable among the HIV negative MSMs, (Liu *et al.*, 2013). insignificant number of the participants have reported both condom and PrEP use highlighting no observable increase in risky sexual practices among those who use condom, Prep or both (Sagaon-Teyssier *et al.*, 2016). An increase in receptive and insertive condomless anal sex act from the baseline have been reported, while the number of anal sex and sex partners remained the same (Hoornenborg *et al.*, 2018).

It has been reported that Post Exposure Prophylaxis (PEP) for prevention of HIV as a result of sexual exposure does not result to increase risky behavior (Martin *et al.*, 2004). One study has reported an equivalent sexual risk behavior to that of the baseline, although it remain significant throughout the trial period, prompting recommendations for vigilant HIV risk reduction counselling and educational process (Bartholow *et al.*, 2005). There was no evidence of risk compensation among the circumcised cohort in a circumcision clinical trial (Kong *et al.*, 2012). In a similar study, significant reduction in risky sexual behavior in both the circumcised and the controls was reported, but longitudinal analysis suggested insignificant difference in the incidences of gonorrhea, chlamydia, and trichomona infections between the circumcised and the uncircumcised (Mattson *et al.*, 2008). Risk compensation (RC) is less likely to negatively impact the prevention benefits of PrEP and on the contrary RC results to increased PrEP intake by indication at the population level, due to increased anal intercourse without condoms among MSMs for whom PrEP is not indicated thereby leading to a subsequent drop in HIV incidences and decrease in percent of infections averted among adherent participants (Jenness, *et al.*, 2017). It has been demonstrated that PrEP use does not significantly change the rates of STI and there is no conclusive evidence that Prep use increase risky sexual behavior (Freeborn & Portillo, 2017). However, the overall STI incidences among a cohort of MSM and transgender women initiated on PrEP were

high but did not increase over time while two individuals became HIV infected during follow up (Liu *et al.*, 2016). Despite the High STI incidences among the participants (90 per 100 person-years

2.4 Sexually Transmitted Infections and HIV infection

The relationship between HIV incidences and the presence of bacterial STI has been recorded to be confounded by sexual risk behavior. This complicates the analysis of the effects of STI on HIV acquisition (Kelley *et al.*, 2015). High HIV incidence has been recorded among individuals with any form of STI. Subsequently, HIV incidences have been observed among individuals with rectal STI, having controlled the confounding issue of behavioral risk factors associated with HIV and STIs. These have underscored the need for routine STI screening and implementation of HIV preventive interventions such as PrEP (Fleming & Wasserheit, 1999), (Kelley *et al.*, 2015)

2.5 Impact of STIs on public health

Among other STIs, *N. gonorrhoea*, *C. trachomatis*, and Syphilis have been associated with increased HIV acquisition probably by reducing the integrity of the mucus membranes, increasing inflammation and the availability of HIV target cells (Fleming & Wasserheit, 1999). This has a direct impact on the control of HIV especially among the populations at high risk of acquiring HIV. Gonorrhoea is considered by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), as a global health concern due to limited treatment options (Papp *et al.*, 2017a).

Gonorrhoea is remains a global Public Health concern due to the development of resistant strains, having 98% of the isolates resistant to ciprofloxacin, penicillin, tetracycline and Azithromycin and two strains showing decreased susceptibility to Ceftriaxone and Cefixime (Kulkarni *et al.*, 2016). Eight *Neisseria gonorrhoea* isolates from seven patients were found to be resistant to Azithromycin and five had reduced susceptibility to

Ceftriaxone in vitro and genetic analysis has indicated a different phylogenetic clade to the contemporary strains (Papp *et al.*, 2017a).

2.6 Bacterial Resistance to Antibiotics

STIs are rapidly developing resistant strains which raises concern on the treatment options left for their prevention and control. Antimicrobial resistance by microorganisms responsible for STIs is on the rise, rates that can further be complicated by failing to address any boulevards that may be responsible for the spread and increase of incidences of STI among MSM, Transgender, female Sex Workers, and Lesbians.

The rates of Gonorrhoea infections in males has been found to be four times higher than in females and higher in 20-24 years age group, those who take alcohol, those with multiple sexual partners and those who use condom less frequently (Ali *et al.*, 2016). *N. gonorrhoea* has been found to be susceptible to Ceftriaxone and Cefoxitin but resistant to Penicillin, Tetracycline and ciprofloxacin (Ali *et al.*, 2016).

Resistance to *Treponema pallidum* infections began in 1960's as was observed in a case who failed to respond to Erythromycin after four weeks therapy but the cutaneous lesions resolved with a lowered VDRL titer results following parenteral penicillin administration (Duncan *et al.*, 1989). Increasing tendency of macrolide resistant *T. pallidum* has been observed in several developed countries posing serious threat to treatment and control of Syphilis (Stamm, 2010).

Chlamydia trachomatis treatment failure rate has been documented to be on the rise (Horner, 2012); Study results have highlighted increased susceptibility to antimicrobial resistance of *Trichomonas vaginalis* as a result of over reliance on nitroimidazoles, metronidazole and tinidazole (Kirkcaldy *et al.*, 2012); *Haemophilus ducreyi* responsible for Chancroid has been found to develop resistance to; tetracyclines, sulphonamides, streptomycin, kanamycin and chloramphenicol (Ison *et al.*, 1998); and *Mycoplasma genitalium* has demonstrated decreased susceptibility to macrolides (Jensen *et al.*, 2008).

Mycoplasma genitalium is a reemerging microorganism responsible for bacterial STI other than the known *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Treponema pallidum*. For this reason it has been suggested to be systematically tested during chronic, recurrent or antibiotic resistant genital infections and in STI high risk populations (Edouard *et al.*, 2017).

Center for Disease Control (CDC) recommend dual antimicrobial therapy for treatment and prevention of *N. gonorrhoeae* due to its increasing resistance to antibiotics, posing Public health concern (CDC, 2015). In Kenya, STI services have been decentralized to primary health care level improving the efficiency in STI service delivery and syndromic approach to case management has been ensued (Moses *et al.*, 2002). Routine STI screening and treatment has been enhanced among the key Populations including FSWs, in Drop-in Centers (Helgar *et al.*, 2018). Dual antimicrobial therapy has been adopted and case management is revised periodically based on the changing treatment needs (NASCO, 2018). A combination of Azithromycin and Cefixime or ceftriaxone are some of the drugs of choice in the management of gonorrhea as highlighted in the Kenya's NASCO STI syndromic management guideline and has been proven to be effective in the management of these infections (NASCO, 2018).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

The study was conducted in Nairobi County at the selected Key Populations Drop-in Centers (DICES) / Prevention Centers located in various Sub Counties, particularly those handling Female Sex Workers. Nairobi is a cosmopolitan city of a population of about four million and is the Kenyan Capital city hosting a huge number of socio-economic and cultural activities including; trading, small and medium enterprises, manufacturing, tourism, education and even commercial sex work. It is located in a geographical area of about 695 square kilometers and comprises of both formal and informal settlement (Appendix 1). It has a total of 17 Sub Counties and 22 Drop-in centers/Prevention Centers. Out of the 17 Sub Counties, nine Sub Counties host the 22 DICES/Prevention centers. The DICES serve both female sex workers and Men who have sex with men while a few DICES serve only female sex workers.

3.2 Study Population

The study Population consisted of Female Sex Workers aged 18 years and above. The FSWs were sampled from seven DICES in three Sub Counties and were residents of Nairobi County for at least six months during which they had been conducting sex work and had been registered in these DICES or prevention centers for at least six months prior to the study. It is estimated that there are over 133,000 female sex workers in Kenya and Nairobi hosts over 29,000 FSWs. The population comprised of both HIV PrEP users and non-PrEP users.

3.2.1 Inclusion Criteria

1. Female Sex workers
2. Signed Consent to participate
3. Being in sex work for at least six months
4. Resident of Nairobi County for at least 6 months
5. Should be 18 years and above.
6. If on oral PrEP, should be a period of at least six months;
7. Adherence to PrEP medicines should have been at least at 85% as recorded in clinic encounter forms
8. Must have been accessing preventive and curative services at the selected DICE for at least six months
9. Complete records on STI treatment, condom use and average number of sexual acts per day recorded at every visit

3.2.2 Exclusion criteria

- i. Female sex workers using oral PrEP but were screened STI positive during enrolment into the DICES/prevention centers cohorts
- ii. Inadequate history for both PrEP and non-PrEP clients
- iii. Any participant who reported accessing HIV and other STIs preventive and curative services at any other DICE/Prevention center or health facility other than the one she had been selected to participate in the study.
- iv. Known HIV positive status.
- v. Use of any other HIV prophylaxis technology.

3.3 Study Design

This was a retrospective cohort study that adopted quantitative methodologies in data collection. It was conducted among the FSWs comprising both HIV oral PrEP users and non- PrEP users.

3.4 Sampling and Sample Size Determination

Haseman formula (Haseman, 1978) that incorporates continuity correction for n' was adopted for sample size calculation in PASS 15.0.5 since the study involves comparison of two populations:

Replacing $\sqrt{2\bar{p}\bar{q}}$ by $\sqrt{2\bar{P}\bar{Q}}$ then solving for n'

$$n' = \frac{\left(z_{\alpha/2} \sqrt{2\bar{P}\bar{Q}} + z_{\beta} \sqrt{P_1 Q_1 + P_2 Q_2} \right)^2}{(P_2 - P_1)^2}$$

Where: $\bar{p} = \frac{1}{2}(p_1 + p_2)$ and $\bar{q} = 1 - \bar{p}$.

$$\bar{P} = \frac{P_1 + P_2}{2}, \text{ and } \bar{Q} = 1 - \bar{P}.$$

n' – is the sample size that ignores continuity correction

P_1 - Proportion of individuals in group 1

P_2 - Proportion of group 2

Q- 1-P

n= total sample size for study group 1 and group 2

$$n = \frac{n'}{4} \left(1 + \sqrt{1 + \frac{4}{n' |P_2 - P_1|}} \right)^2$$

The desired sample size was computed using PASS 15.0.5. The test statistics used was a two-sided Z – test with un-pooled variance. The proportion for population 1 (P1), the group 1 proportion was estimated to be 0.22 and group 2 proportion (P2) 0.38, with 90% power and 5% precision ($e=0.05$). The power was computed using the normal approximation method. The numeric results for the sample size calculation were: n1 168 and n2 168 for population 1 and population 2 respectively with N being 336. No drop out was anticipated and therefore the sample size was not inflated.

$$N1 = 168$$

$$N2 = 168$$

$$n = 336$$

3.4.1 Proportionate samples per DICE/Prevention Center

Samples were collected according to the population per DICE/Prevention Center. Samples were picked proportionate to size in each center by factor 0.0184321685. (Table 3.1)

Table 3.1: Proportionate number of participants per DICE/Prevention center

DICE/Prevention Center	Total Cohort of FSWs	Proportion of participants
Sokoni Arcade	1051	19
Bar Hostess Roysambu	4009	74
Hurlingham DICE	467	10
Jogoo Road	5060	93
Githurai	967	18
Kariobangi	5743	106
Center of Business District	932	16
Totals	18,229	336

3.4.2 Sampling Techniques

A Multi Stage Sampling was used. Nairobi County has a total of 17 Sub Counties but the DICES/Prevention Centers are spread across nine Sub counties. Of the nine sub counties, one third of them were selected by simple random sampling giving three Sub-Counties. Out of the 22 DICES/Prevention Centers in Nairobi County, one third of them which is seven DICES/prevention centers were selected by simple random sampling from the three Sub-Counties. The number of participants per DICE/prevention center was allocated proportionately according to the total numbers of FSWs in each site's cohort.

A simple random sampling was done using the FSWs listing as the sampling frame at the selected sites, to offer each active member of the target population an equal chance of participating in the study. Files at the DICES/prevention centers were arranged according to the key population type and PrEP use. PrEP files and Non-PrEP files were separately sampled equally at the site. The files of the FSWs selected for the study were withdrawn from the shelved and completeness of records verified. Incomplete files and those that did not pass the inclusion/exclusion criteria were dropped and replaced.

3.5 Data collection methods

The files containing records of consented participants were identified and withdrawn from the shelves, and data was collected using the data abstraction tool adopted from the Kenya Ministry of Health (NASCO, 2014). Research assistants were familiarized and

trained on data abstraction tool, abstraction process, documentation and data management before the study commenced. Each data elements listed in the data abstraction tools were obtained from every participant records. A data abstraction tool was filled for each participant.

The clients' unique identifiers on every file were randomly sampled for participation in the study, and equal number of files for both the active PrEP and non-PrEP clients were identified. Each participant was invited to the DICE/Prevention center to give their consent for participation in the study. Once consent was obtained, a systematic six months' retrospective data abstraction from the treatment records of each participant was done, using the data abstraction tool; to identify the cases of STIs, condom use, and the number of sexual acts reported per day, as recorded in the patients past six months' records collected during the routine clinical visits. Specific data elements were abstracted from the records of each participant and one tool was filled for each participant.

Only the participants screened negative for STI during enrolment into the DICEs/prevention centers were eligible to participate in the study in order to eliminate zero-time bias. The participants were to be free from STIs at the time of enrolment at the DICE/Prevention Center, so that an STI free participant was followed up for STI incidence in the cohort of PrEP and non-PrEP female sex workers throughout the study period. The average number of sexual acts per day and average condom use per day were recorded for every participant at the zero-time study period, which was the time at which the participant was enrolled at the DICE/Prevention Center; and same data abstracted from subsequent five months' visits. The starting average number of sexual acts per day and condom use per day at enrolment was estimated using a previous one month records. The incidence density of STI among the female sex worker using HIV oral PrEP was compared to that of those who do not use PrEP.

Data was abstracted from both the client's files and preexisting cohort records. In the records, STI screening had been done to all the female sex workers at the time of

enrolment into the DICEs cohort. STI screening was done using the NASCOP STI treatment algorithm (NASCOP, 2018) and whenever necessary, Laboratory tests were conducted to confirm some diagnosis. The screening results were recorded in the client's files. During the routine STI screening, those screened positive for STIs were offered a standard STI treatment with the aid of the treatment algorithm and followed up for two weeks to ensure a successful treatment. Each episode of STI in an individual participant was considered as a new case, including infections occurring after successful STI treatment completion, as documented in the client file and were recorded as new infection. Successful treatment was defined as complete elimination of clinical symptoms two weeks post cessation of treatment as documented in the patient records.

3.6 Data collection tools

A Quantitative data collection method was adopted. Data was collected using a data abstraction tool (appendix 2) containing data elements that answered the questions on STI incidence, common STIs, condom use and the number of sexual acts per day questions. This data abstraction tool was adopted from the partners implementing HIV prevention among the Key Populations, and modified to suit the data needs of this study. This tool was developed using the Ministry of Health (NASCOP) Key Populations Monitoring and Evaluation tools (NASCOP, 2014). The data abstraction tool is attached in the appendices.

3.7 Validity and Reliability

3.7.1 Validity

The tools used for collecting routine data at the DICEs/Prevention centers are provided by the Ministry of Health (NASCOP) and are only released to implementing partners after passing the required quality check. The ministry of health (NASCOP) monitoring and evaluation experts work hand in hand with the implementing partners to develop the tools which are then piloted in a few facilities and feedback given for necessary

adjustment. The tools are rolled out for use only when the implementing partners and the developers are in agreement that it serves the purpose. The data abstraction tool that was used for data collection in this study was adopted from the implementing partners' data abstraction tool used for program monitoring and evaluation; which has been appraised and passed validity and quality checks during pretesting and implementation phases; therefore, the data collected using this tool was a true reflection of the data of interest.

3.7.2 Reliability

The source documents for the data that was used in this study are the Ministry of Health (NASCO) provided monitoring and evaluation tools that are standard to all the partners implementing prevention services among the key populations, particularly female sex workers. No variation was therefore experienced in the data that was collected. The data officers are routinely taken through refresher trainings in addition to the initial tools roll out training on data capture and all the implementing partners use the same tool for data collection. The data abstraction tool that was used to collect data for this study was standard and was not subject to any modification or alteration at every site.

3.8 Data management and analysis

The participants' records remained under lock and key during the entire study period. Data was analyzed using statistical package STATA (STATA, 2016) and Microsoft excel. Relative risk, Rates, hazard ration and cumulative hazard, were computed as measures of association between PrEP use and STI rates. The rate of STI among the female sex workers who use PrEP was determined and the rate of STI among female sex workers who do not take PrEP was also determined. Relative STI risk was therefore computed to establish whether the use of oral PrEP increases female sex workers risk of acquiring STI using Cox regression model. Consequently, the level of statistical significance of hypothesis was determined at 95% CI and 0.05 level of error. The relationship and association between condom use and PrEP use, as well as that of PrEP

use and number sexual acts were determined using descriptive statistics and linear regression models.

3.9 Ethical considerations

Ethical approval was obtained from the Kenyatta National Hospital- University of Nairobi Ethical Review Committee (KNH-UoN ERC), (appendix 3), before commencing the recruitment of participant. An approval letter was obtained from the JKUAT Board of Postgraduate Studies (BPS) (appendix 4), and the partners implementing prevention services at the DICEs/prevention centers (appendix 5). Informed consent was obtained from all eligible participants after the disclosure of all the information pertaining the study and they were assured of confidentiality of the information collected (appendix 6 and appendix 7). In conforming with ethics principles, participants who tested positive for STI symptomatically or through laboratory diagnosis using standard tests during screening at the cohort entry point were managed using the STI syndromic management algorithm or referred for specialized care accordingly during the routine patient management before the beginning of this study.

CHAPTER FOUR

RESULTS

4.1 Socio-demographic characteristics of FSWs in Nairobi County

A total of 336 participants were consented to participate. Among the respondents, 168 (50%) were HIV Pre-Exposure Prophylaxis (PrEP) users while 168 (50%) were non-PrEP users. The mean age (SD) for FSWs not using HIV PrEP was 27.7 (5.8) years while the mean age (SD) for FSWs using HIV PrEP was 25.4 (5.53) years; and the minimum and maximum age for both the PrEP users and non-PrEP users were 18 and 50 years respectively. On marital status, majority of the respondents, 132(78.6%) PrEP users and 131 (78%) non-PrEP users were single, while the rest of the respondents were either married, divorced or widowed. Majority of the respondents had between 1 to 3 children; 120(71.4%) of non-PrEP user and 98 (58.3%) of PrEP users respectively, while 38 (22.6%) and 63 (37.6%) of non-PrEP and PrEP users did not have children. The highest level of education for half of the non-PrEP using respondents 84(50.6%) was primary school and 80(47.6%) were secondary school drop outs, while 85(51.2%) of PrEP users were secondary school drop outs and 78(47%) were primary school drop outs. All the respondents using PrEP 168(100%) were doing sex work as their sole source of income, while 155(92.3%) of non-PrEP users did sex work as their sole source of income (Table 4.1).

Table 4.1: Socio-demographic characteristics of FSWs in Nairobi County

Characteristics	Frequency (%)	
	Non-PrEP n = 168	PrEP n = 168
Age		
Mean age (SD)	27.72 (6.58)	25.38 (5.53)
Marital Status		
Single	131(78)	132 (78.6)
Married	16(9.5)	14 (8.3)
Divorced/Separated/widowed	21(12.3)	22 (13.1)
Number of Children		
Without children	38 (22.6)	63 (37.5)
1-3 children	120 (71.4)	98 (58.3)
More than 3 children	10 (6)	7 (4.2)
Level of Education		
Primary and <	85 (50.6)	79 (47)
Secondary School	80 (47.6)	86 (51.2)
Tertiary	3 (1.8)	3 (1.8)
Source of Income		
Bar Attendant	6 (3.6)	0 (0)
FSW	155 (92.3)	168 (100)
House help	3 (1.8)	0 (0)
Saloonist	3(1.8)	0(0)

4.2 The STIs affecting female Sex workers, both PrEP and non-PrEP users

The common Sexually Transmitted Infections that were identified among the female sex workers were arranged in order of most common to the least common STIs. Most STIs 62% identified were as a result of Vaginitis, followed by Cervicitis 21%, then Syphilis & Chancroid 11% and PID 7%. Vaginitis was the most commonly experienced STI among both PrEP and non-PrEP respondents (Figure 4.1). Cervicitis was equally

common with 25 cases reported among the respondents. Thirteen cases of syphilis and Chancroid were reported among the respondents. Seven cases of Pelvic Inflammatory Disease (PID) caused by Gonorrhoea and Chlamydia infections were reported, 1% and 3% Non-PrEP and PrEP respectively. A composite prevalence of STIs among FSWs was determined, 35.4% while the pooled incidence rate was 14 per 1000-person years (Figure 4.1)

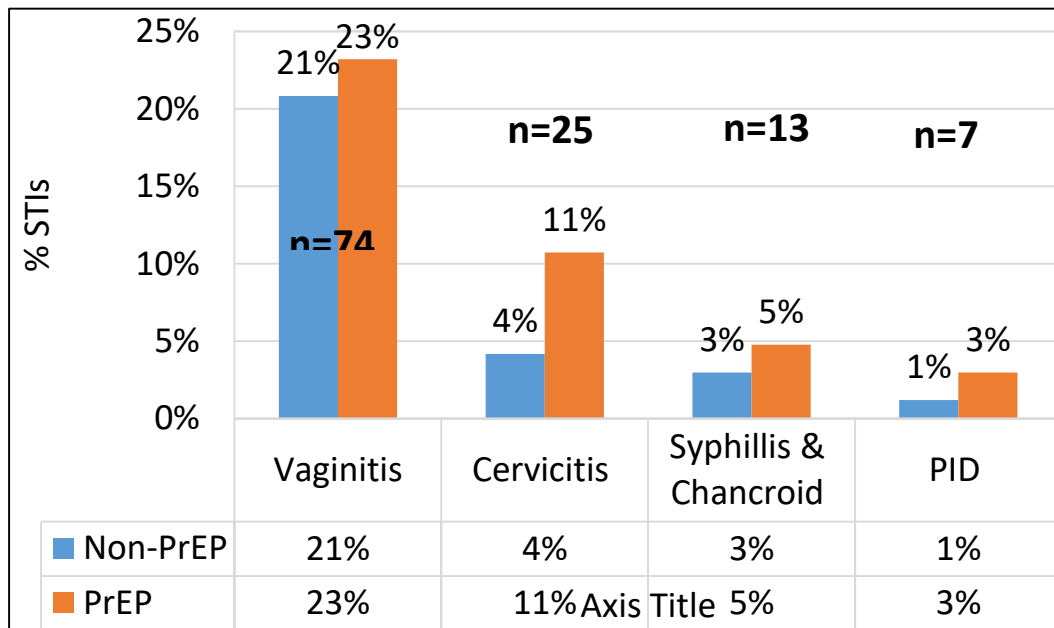


Figure 4.1: Common STIs Identified among the Female Sex workers in Nairobi County

4.2.1 Episodes of STIs among FSWs diagnosed with STIs

During the analysis, data showed that there were some respondents that had multiple episodes of STIs. Generally, most of the respondents diagnosed with STIs had only one episode of STI throughout the study period. Up to 74% of non-PrEP users and 71% of PrEP using FSWs diagnosed with STIs had one Episode of STI throughout the study time. Only 24% of non-PrEP and 23% of PrEP using FSWs diagnosed with STIs had two Episode of STIs, with the second episode observed after treatment and complete recovery from the first STI episode. Very few respondents, 3% of non-PrEP users and

6% of PrEP users diagnosed with STIs had three STI episodes. None of the respondents had over three STI episodes. The multiple STI episodes were recorded as new cases having been treated and declared fully recovered from the previous episode (Figure 4.2).

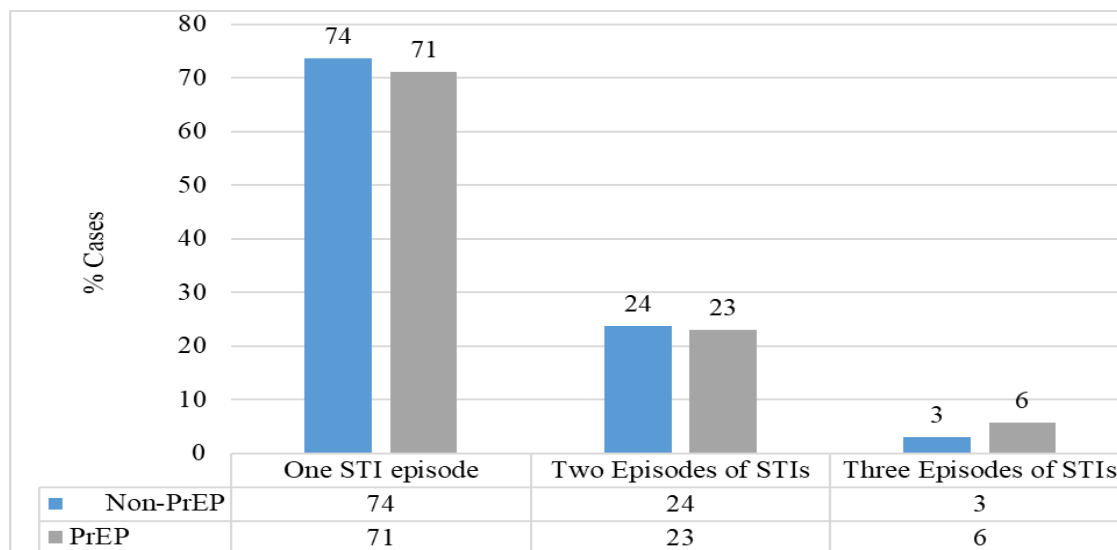


Figure 4.2: Number of STI episodes for every Female Sex Worker diagnosed with STI in Nairobi

4.3 The average number of sexual acts per day among FSWs in Nairobi

Average number of sexual acts per day was recorded for all the FSW at each visit. The mean daily sexual acts among the FSWs using HIV oral PrEP was overly higher from the first visit through to the end of the study period, than the mean daily sexual acts among non-PrEP users. On the first visit, the FSWs using PrEP recorded a 6 mean daily sexual acts compared to 5.3 among non-PrEP users but the difference in the mean daily sexual acts was not statistically significant. In the subsequent visits at months two, three, four, five and six, the difference in mean daily sexual acts between FSWs using PrEP and non-PrEP users was significant ($P=0.017$, $P=0.003$, $P=0.006$, $P=0.003$ and $P=0.036$ respectively, at 95% CI). The trend for mean sexual acts remained fairly the same for both PrEP and non-PrEP users throughout the six months (Table 4.2).

Table 4.2: Sexual acts per day among FSWs in Nairobi County through the study period

Follow up	Non-PrEP mean (SD)	PrEP mean (SD)	t-test Statistic		
			t	df	P
Month 1	5.3 (3.4)	6.0 (4.3)	-1.8	334	0.071
Month 2	4.9 (3.1)	5.8 (4.0)	-2.4	334	*0.017
Month 3	4.9 (3.1)	6.1 (4.0)	3.0	334	*0.003
Month 4	5.0 (3.4)	6.2 (4.4)	-2.7	334	
			*0.006		
Month 5	4.9 (3.1)	6.1 (4.0)	-3.0	334	*0.003
Month 6	5.1 (3.5)	5.9 (3.7)	-2.1	334	*0.036

*t-test statistic significant at 95% confidence level.

4.3.1 Relationship between the average number of Sexual acts and PrEP use among FSWs

The association between the average number of sexual acts per day and PrEP use as well as the association between the average sexual acts per day and socio-demographic components were measured using a bivariate linear regression model. The association between the average number of sexual acts per day and HIV oral PrEP use was significant with data showing that for every unit increase in PrEP use, there was a 1.0 increase in mean sexual acts (P=0.004, 95%CI). The association between the mean number of sexual acts per day and other socio-demographic characteristics on the other hand, were not statistically significant with some characteristics including; age, married, and tertiary education, demonstrating a beneficial relationships suggesting there could be a reduction in mean sexual acts given the increase in age, married status, and tertiary education level. (Table 4.3).

Table 4.3: Association between average sexual acts per day and HIV oral PrEP use across Socio-demographics characteristics

Variables	Coef.	[95% Conf. Interval]		P> z
age	-0.02	-0.07	0.04	0.586
Marital Status				
Single	Ref.			
Married	-0.14	-1.28	1.01	0.811
Divorced/separated /Widowed	0.27	-0.80	1.35	0.619
Without children	Ref.			
Some children	0.53	-0.21	1.25	0.162
Education level				
Secondary School	0.11	-0.58	0.80	0.753
College	-0.36	-3.23	2.52	0.808
University	-3.49	-9.84	2.86	0.282
Non-PrEP	Ref			
PrEP	1.00	0.32	1.67	*0.004

*Significant at 95% confidence level.

4.4 Risk of STIs among PrEP and non-PrEP using FSWs in Nairobi across the study period

Cases of STIs were recorded for all the participants during enrolment and on every visit throughout the study duration. The 336 participants were free from any STI in the beginning of the study at the first month of observation. All the participants who were screened positive for any STI at the entry point were excluded from the study. Generally, higher number of STI cases were observed among FSWs using oral PrEP during fourth month (16), fifth month (21) and sixth month (13); compared to STI cases observed among non-PrEP users, in the fourth month (10), fifth month (8) and sixth month (7) respectively. A significant difference in the incidence of STI cases between the two groups was observed in the fifth month (P=0.012, 95%CI). Cases of STIs in the second and third months were fairly the same in both PrEP users 7 and 13; and non-PrEP users 9 and 14 respectively with no statistical difference (Table 4.4).

Table 4.4: Cases of STIs among FSWs in Nairobi during the study period

Time	Non-PrEP n (%)	PrEP n (%)	Statistic
Month 1	0	0	
Month 2	9 (5%)	7 (4%)	X ² = 0.27, P= 0.60
Month 3	14 (8%)	13 (8%)	X ² = 0.04, P= 0.83
Month 4	11 (7%)	16 (10%)	X ² = 0.97, P= 0.32
Month 5	8 (5%)	21 (13%)	X ² = 6.28, P= 0.012
Month 6	7 (4%)	13 (8%)	X ² = 0.87, P= 0.17

*Chi-square statistic significant at 95% confidence level.

4.4.1 Percentage STI Cases distribution over time

All the respondents were enrolled into the study at time zero with no STI infections. There was no significant difference in percentage STI cases between the FSWs using PrEP and non-PrEP users in the two months that followed. Percentage STI cases among the PrEP users rapidly increased over the months especially between month two and month five, with a slight slump in month six. There was a reduction in percentage STI cases among non-PrEP users from month three through to month six. The Cumulative incidence of STIs among PrEP users was much higher than that of non- PrEP user at (P=0.012, 95% CI) (Figure 4.3)

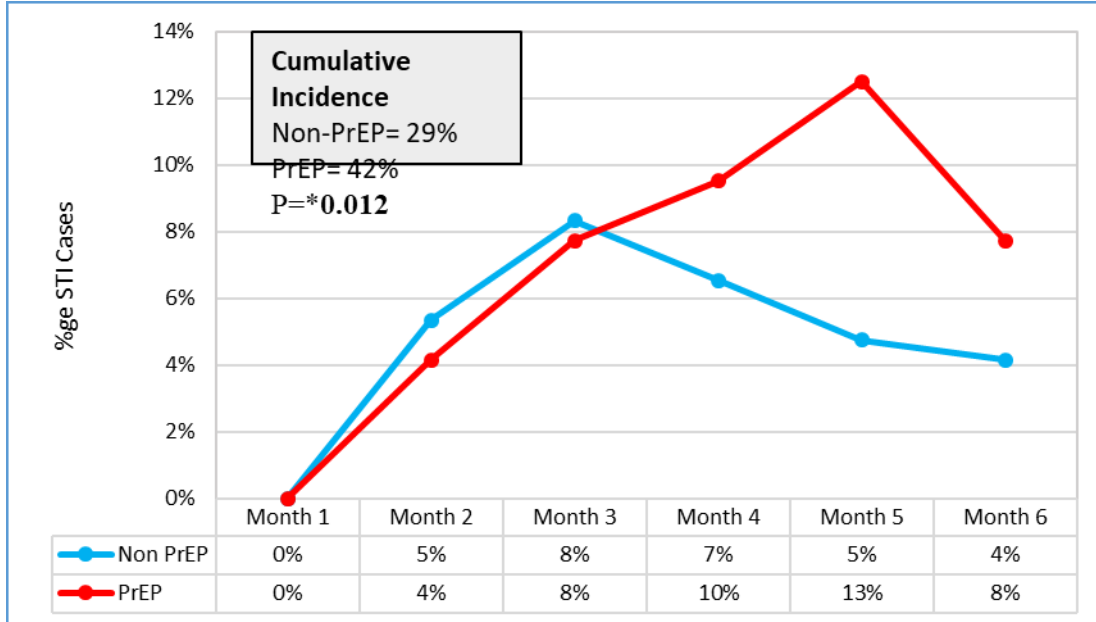


Figure 4.3: Distribution of STI cases through six months cohort among FSWs in Nairobi County

4.4.2 Sexually Transmitted Infections risk among PrEP users

The risk of acquiring STI varied between the FSWs taking oral PrEP and FSWs who do not take PrEP. The STIs Incidence rate among the FSWs who did not use oral PrEP was 11 per 1000 person years while the STIs incidence rate among PrEP users was 16 per 1000 person years. The time at risk for both PrEP and non-PrEP users was 4322 for each group. Pooled incidence rate of STIs among FSWs was 14 per 1000 person years. The hazard ratio for STI between FSWs who did not use oral PrEP and FSWs using oral PrEP for HIV prevention was 1.82 (P=0.005, 95% CI). FSWs taking HIV oral PrEP were up to 1.8 times at increased risk of acquiring STIs than the FSWs who do not take PrEP. The Relative Risk (RR) of STI between FSWs using PrEP and Non PrEP users was 1.4 (P=0.012, 95%CI).

4.4.3 Sexually Transmitted Infections Hazard Estimate between PrEP and non-PrEP users

The risk of contracting STI among FSW over six months was evaluated using Nelson-Aalen cumulative hazard estimate. The blue line on the graph represents non-PrEP users while the red line in the graph represents PrEP users. As illustrated on the graph, the cumulative hazard of STI among the PrEP users at the baseline was very low but constantly increased over time in each month of the cohort with the trend suggestive of a constant increased risk of STI over the study period. STI risk among the non-PrEP users looked considerably lower than that of PrEP users and did not increase so significantly as compared to that of PrEP users over time (Figure 4.4).

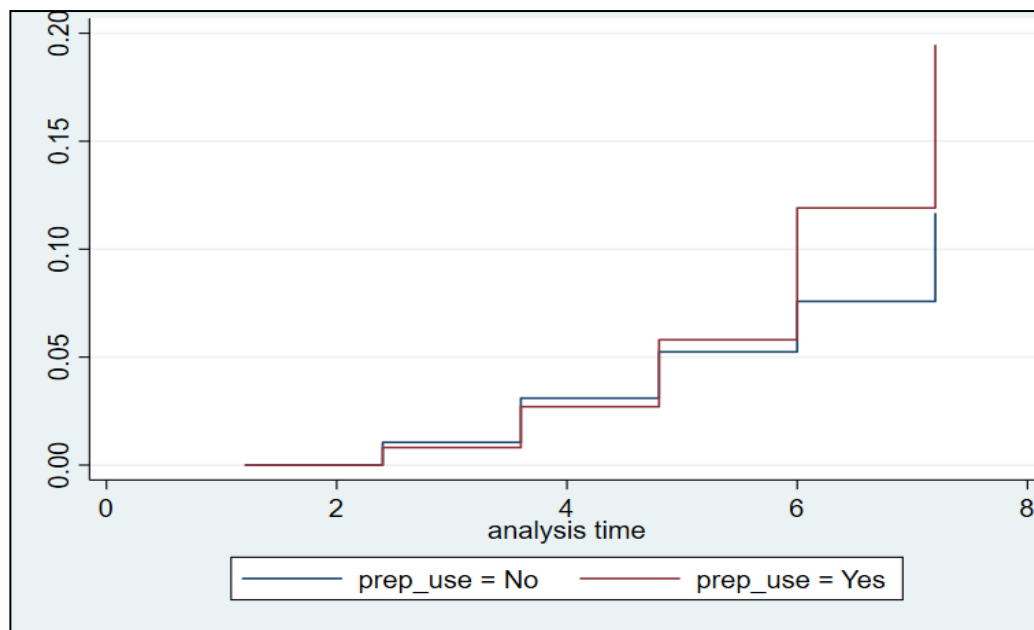


Figure 4.4: Cumulative hazard of contracting STIs between the FSW who used oral PrEP and the FSW who did not use PrEP in Nairobi.

4.4.4 Risk of Sexually Transmitted Infections against PrEP use and across socio-demographic characteristics of FSWs in Nairobi County

A multivariate analysis of STI risk across the socio demographic components and among FSWs using oral PrEP for HIV prevention was measured using a cox regression model. Oral PrEP use increases the risk of STIs by up to 1.8 times (P=.005, 95% CI), when compared to FSWs who do not use PrEP. Divorced/Separated and Widowed FSWs have up to 1.73 (P=.035, 95%CI) and 2.97 (P=.035, 95%CI) times respectively, increased risk of STIs compared to unmarried FSW. There was no significant association observed between age, married FSWs and number of children FSW has and risk of STIs. However, increased number of sexual acts was associated with increased risk of STIs among FSWs (P=.012, 95%CI) (Table 4.5).

Table 4.5: Multivariate analysis of STI risk of FSWs in Nairobi County

STIs	Haz. Ratio	[95% Conf. Interval]		P> z
Age	0.98	0.95	1.02	0.319
Non-PrEP Use				
PrEP Use	1.82	1.20	2.75	*0.005
Marital status				
Single	Ref.			
Married	0.64	0.28	1.48	0.3
Divorced/separated	1.73	1.04	2.89	*0.035
Widowed	2.97	1.06	8.34	*0.039
Without Children	Ref.			
Some children	1.36	0.86	2.16	0.193
No of sexual acts	1.15	1.03	1.28	*0.012

4.5 Condom use among FSWs in Nairobi

Condom use was recorded throughout the study period for all the participants. Both the HIV oral PrEP users and non-PrEP users, used condoms but the mean condoms use among the HIV oral PrEP users, although not statistically significant, was slightly lower than the mean condom use among non-PrEP users from month 1 to month 5. In month 6, there was a significant difference in condom use between non-PrEP and PrEP users at

(P=0.05, 95%CI). In month 1, PrEP users recorded a total of 777 condom use while non-PrEP users recorded 838 condom use; In months 5 and 6, PrEP users recorded 749 and 745 condom use compared to 829 and 852 condom use recorded in non-PrEP user. The mean condom use per day per FSW among PrEP users range between 4.3 to 4.8, while the mean daily condom use per FSW among non-PrEP users range between 4.7 to 5.0 throughout the study period (Table 4.6).

Table 4.6: Mean Condom use among FSWs in Nairobi County

Time	Non-PrEP N=168 PrEP N=168		t-test Statistics
	mean (SD)	mean (SD)	
Month 1	4.9 (3.2)	4.5 (3.4)	t= 1.07, df=334, P=0.283
Month 2	4.7 (2.9)	4.3 (2.8)	t= 1.44, df=334, P=0.252
Month 3	4.8 (3.1)	4.6 (3.0)	t= 0.60, df=334, P=0.55
Month 4	4.9 (3.4)	4.8 (3.3)	t= 0.30, df=334, P=0.763
Month 5	4.8 (3.3)	4.4 (2.8)	t= 1.50, df=334, P=0.135
Month 6	5.0 (3.5)	4.3 (2.9)	t= 1.90, df=334, P= *0.05

*t-test statistic significant at 95% confidence level.

4.5.1 Relationship between Condom use and PrEP use among Female Sex workers in Nairobi

Bivariate analysis of condom-use against socio-demographic components and oral PrEP use was done using Panel data linear regression model. Having one or more children is associated with 0.60 mean increase in condom use (P=.024, 95%CI). There was no significant association between condom use and PrEP use (P=0.179, 95%CI). Being married, tertiary education and oral PrEP use, although statistically insignificant, are associated with decrease in mean condom use, while there was an increased tendency, but not statistically significant, in mean condom use among the FSWs who are either divorced, separated or widowed (P=0.376, 95%CI), (Table 4.7).

Table 4.7: Relationship between Condom use and PrEP use across Sociodemographic Characteristics among Female Sex Workers in Nairobi County

Variable	Coef.	[95% Conf. Interval]		P> z
Age	0.01	-0.03	0.06	0.462
Marital Status				
Single	Ref.			
Married	-0.32	-1.24	0.61	0.502
Divorced/separated/widowed	0.39	-0.48	1.26	0.376
Without Children	Ref.			
Some children	0.69	0.09	1.29	*0.024
Education Level				
Secondary School	-0.13	-0.69	0.43	0.649
College	-1.95	-4.28	0.37	0.099
University	-2.75	-7.89	2.38	0.293
Non-PrEP Use	Ref.			
PrEP Use	-0.38	-0.93	0.17	0.179

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Common Sexually Transmitted Infections affecting female Sex workers

The findings of the study shows that the most prevalent STI affecting Female Sex Workers was Vaginitis which is caused by mixed micro-organisms including; bacteria, yeast and trichomonas, but is predominantly caused by bacterial vaginosis (CDC, 2015), (Papp *et al.*, 2017). Another common STIs seen in this study was cervicitis which can be caused by gonorrhea, chlamydia or trichomonas (Katz *et al.*, 2012); and pelvic inflammatory disease (PID) which is mainly as a result of gonorrhea and chlamydia infections. Meta-analysis and systemic reviews suggested pooled prevalence for composite outcome of chlamydia, gonorrhea and early syphilis of 23.9% (Ong *et al.*, 2019), which agrees with the findings of this study which documented a 35.4% pooled STI prevalence. A few participants were also diagnosed with syphilis and chancroid. These findings are consistent with WHO declaration of gonorrhea as a global health concern. The findings of this study were also coherent with Mayer *et al.*, (2014) findings in which 32.8% of STIs were diagnosed among participants using PrEP for HIV prevention. Studies have demonstrated pooled incidence rate of up to 70 per 100 person-years during PrEP follow-up (Ong *et al.*, 2019) which compares relatively higher with the finding of this study that recorded an STI incidence rate of over 14 per 1000 person years. Most of the respondents diagnosed with STIs had only one episode of STIs and the few repeated episodes were diagnosed as a new infection.

5.1.2 The average number of sexual acts per day, between oral PrEP users and non-PrEP users

The average number of sexual acts per day among the FSWs using HIV oral PrEP was much higher than that of non-PrEP users. This study has demonstrated that PrEP users are more likely to have a much higher average number of sexual acts per day ($P=0.004$, 95%CI) compared to non-PrEP using FSWs, suggestive of behavioral risk disinhibition. This observation is coherent with studies that have pointed out behavioral risk compensation among PrEP users (Marcus *et al.*, 2013). Prevention of HIV using PrEP conceivably poses sexual acts associated behavioral risk disinhibition by encouraging an increase in the number of sexual acts per day among the FSWs using oral PrEP due to perceived HIV risk elimination by PrEP users. Similarly, other studies have suggested an increase in receptive and insertive anal sex among PrEP users (Guest *et al.*, 2008) and (Hoornenborg *et al.*, 2018).

These findings controverts other findings that however, have attributed the decrease in the rate of unprotected sex and the number partners, to trial associated HIV prevention counselling (Liu *et al.*, 2013), (Sagaon-Teyssier *et al.*, 2016) and (Guest *et al.*, 2008). This could conceivably mean that, in the absence of the prevention counselling, risky sexual behavior can possibly be observed. This study also disagrees with another study which demonstrated that the number of sexual acts remains the same among persons using PrEP (Hoornenborg *et al.*, 2019), while it records an opposite out come to the study by (Ortblad *et al.*, 2020), which reported a decrease in mean monthly sexual acts among PrEP users.

5.1.3 Risk of STIs in PrEP and non- PrEP users among female sex workers

In this study, all the participants recorded no STIs at the beginning of the study, but over time, it was observed that STI cases in PrEP users increased steadily until month five where there was a slight slump in cases of STI; whereas, STI cases in Non-PrEP users increased in the first three months but demonstrated a steady decrease from month three

to month six; this finding is similar to a mathematical modeling, which demonstrated a widespread PrEP use among gay men would result in increased STI diagnosis but would fall after a year with assumptions that all STIs diagnosed are treated (Jenness *et al.*, 2017). The slump that was observed in this study in month five could also possibly be explained by other factors other than behavior change, such as scaled up STIs prevention campaigns and prevention counseling.

Cumulative hazard of contracting STIs among the HIV oral PrEP users was very low in the first months but increased consistently over the study period, whereas the cumulative hazard of STI among the non-PrEP users was slightly higher than that of PrEP users at the beginning of the study period, but remained lower with a very slight increase over time compared to that of PrEP users; this observation was similar to (Kojima *et al.*, 2016) meta-analysis in which the STI incidence rate ratio was over 25 times that of non-PrEP users. While (Liu *et al.*, 2016) has demonstrated an overall high STI incidence, which did not increase over time among MSM using PrEP for HIV prevention; this study has also suggested similarly higher STI incidences among PrEP users which increased over time. Also in agreement with this study is (Ong *et al.*, 2019) which similarly demonstrated high composite incidence rate (72.2 per 100-person time) and polled prevalence of STIs of 23.9%. (Nguyen *et al.*, 2018) in his study recorded an increased STI rate in a cohort observed before and after PrEP initiation, and as well compared STI rates between PrEP and PEP users; an observation which was quite coherent with the STI trends observed this study. These findings are however contrary to the findings of (Mattson *et al.*, 2008) which demonstrated insignificant difference in the rate of gonorrhea, chlamydia, and trichomonas infections in a randomized clinical trial between the circumcised and uncircumcised males participants.

The hazard ratio of 1.8 established in this study, ascertained an increased risk of STIs among the FSWs taking oral PrEP compared to non-PrEP users, similar to (Hoornenborg *et al.*, 2019). The statistical significant relationship associating PrEP use and higher STIs risk affirms a conclusive inferences supporting higher rate of STIs among PrEP users compared to non-PrEP users in demonstration studies including; (Montaño *et al.* 2017)

which demonstrated up to 20 time higher rates of STIs among PrEP users than non-PrEP users; also the STIs trend observed in this study was in agreement with (Jenness *et al.*, 2017) which demonstrated in a mathematical modelling that STI diagnosis would increase initially but fall within one year of PrEP. These findings were however quite inconsistent with the findings of (Freeborn & Portillo, 2017).

5.1.4 Condom use among female sex workers using HIV oral PrEP and non- PrEP users

The finding of the study has demonstrated an insignificant association between oral PrEP use and condom use and do not statistically support any difference in the mean condom use between FSWs using PrEP for HIV prevention and non-PrEP users. There was therefore no demonstrable conclusive evidence in this study, supporting decreased condom use among female sex workers using oral PrEP; findings that are coherent with (Crepaz *et al.*, 2004). Other studies have as well reported no conclusive evidence to support reduced condom use among persons using HIV PrEP; (Sagaon-Teyssier *et al.*, 2016) observed no increase in risky sexual practices among PrEP users, and (Marcus *et al.*, 2013) did as well reiterate that there is no significant change in sexual behavior that could be observed when PrEP users were compared with non-PrEP users in the same period of time. (Kong *et al.*, 2012) in his study, also did not find evidence of risk compensation associated with condom use among persons using PrEP for HIV prevention. A cohort of discordant couples (Ortblad *et al.*, 2020), although a population with different sexual behavior to the FSWs, recorded a reduction in condomless intercourse, which vary from this study. However, (Wise, 2018) recorded contrary findings suggesting that while the uptake of PrEP for HIV prevention increased, condom use decreased and further suggested that this could conceivably undermine the prevention benefits of PrEP; while (Mayer *et al.*, 2014) highlighted increase in STI cases as a result of reduced condom use among PrEP users and (Hoornenborg *et al.*, 2019) findings as well demonstrated increased number of condomless sexual acts among persons using oral PrEP.

5.2 Conclusions

- 1) Vaginitis, cervicitis and pelvic inflammatory disease (PID), are the most common Infections identified among the female sex worker. These infections are caused by mixed microorganisms with bacteria, chlamydia and trichomonas the most notable microorganisms. The diagnosis was done syndromically, however, cases of syphilis and chancroid were diagnosed syndromically and a confirmatory test in the laboratory followed, during the clients routine clinical and sick visits. Most FSWs diagnosed with STIs had only one Episode of STI.
- 2) The increase in mean sexual acts among PrEP users suggests behavioral risk compensation associated with increased average number of sexual acts per day. The FSWs who used oral PrEP were more likely to have increased average number of sexual acts per day compared to non-PrEP users. The fact that PrEP use among FSWs increases likelihood of higher average daily sexual acts, therefore jeopardizes the HIV prevention benefits of PrEP and as well increase the PrEP user's exposure to other sexually transmitted infections. The findings suggested that the use of PrEP for HIV prevention plausibly increases the tendency of the PrEP using FSWs to have more sexual acts, this could be conceivably as a result of perceived reduced risk of HIV among PrEP users..
- 3) Use of oral PrEP for HIV prevention increases the risk of STIs among FSWs using oral PrEP. This study has demonstrated a steady increasing trend of STI incidences and cumulative hazard of STIs among the respondents using oral PrEP over the six months study period, whereas the STI incidence rate and cumulative hazard among the non- PrEP respondents has displayed a very slight increase with decrease in incidences as the study progresses over the same period. The statistically significant hazard ratio ($P=.005$, 95%CI) and RR ($P=0.012$, 95%CI) comparing the risk of STIs among PrEP and non-PrEP using FSWs, confirms the increased risk of STIs among the PrEP using FSWs. This evidence therefore infers that the use of oral PrEP for HIV prevention among female sex workers possibly put FSWs at an increased risk of acquiring STIs.

- 4) This study did not find a conclusive evidence to support association between condom use and oral PrEP use among female sex workers. There was no evidence of condom use associated risk compensation as a result of oral PrEP use. This therefore infers that the use of PrEP for HIV prevention does not influence condom use among FSWs.

5.3 Recommendations

5.3.1 Recommendations from the Study

- i. STI prevention counselling as well as screening, should be emphasized during oral PrEP initiation and every time clients visit the clinic for routine PrEP refill follow up; including advocating for combination prevention including condom use alongside PrEP, and reducing the number of sexual acts per day to minimize exposure to infections.
- ii. Emphasis to be made on reduction in the number of sexual acts per day among the FSWs right at the point of enrolment into the prevention program in the DICEs, to minimize their exposure and risk of both HIV and other STIs.
- iii. There is need to tailor STIs prevention intervention among HIV oral PrEP users and other non-PrEP using key populations according to their behavioral profile.
- iv. Promotion of combination Prevention including biological and structural interventions which includes both PrEP and condom use.

5.3.2 Recommendations for further research

- i. Longitudinal cohort study that will run for at least one year to be conducted and diagnosis of sexually transmitted infections done using biological samples collected from the patients and tested in the laboratory. A study where the participants visit would be based on study schedule and not routine clinical appointments.
- ii. More studies involving FSWs are recommended, particularly on risk compensation, and especially in Sub Saharan Africa. Little research has been done on PrEP use among FSWs with most studies focusing on MSMs.

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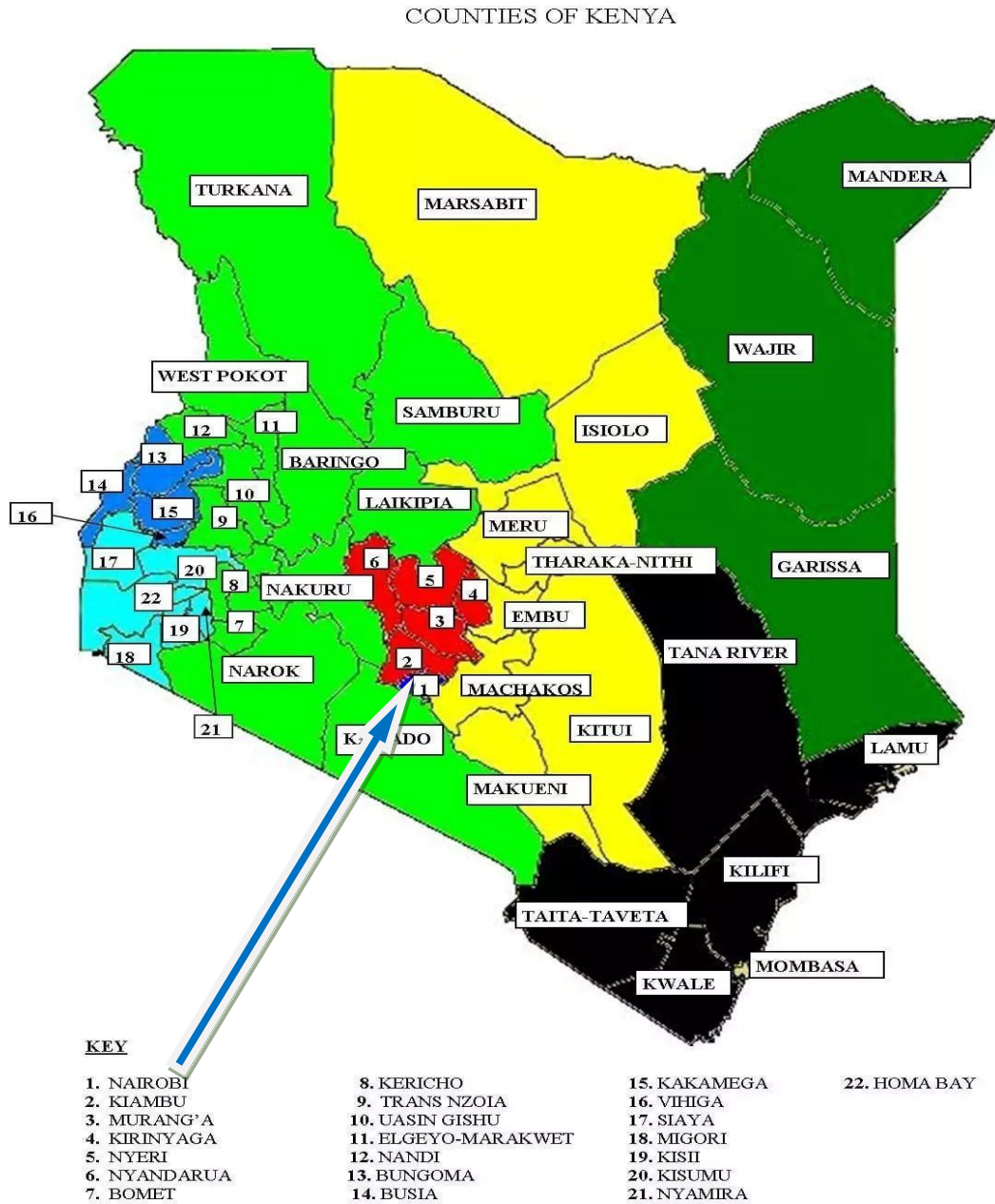
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APPENDICES

Appendix I: Nairobi County in the map of the Republic of Kenya



Appendix II: Data Abstraction Tool

Individual level data

Individual data will be extracted from the registers and or filtered from electronic medical records. The variables to be collected include the following:

Variable	Level and Scale	Source document	Location
Socio-demographics			
Client ID		Cohort register	Client's unique ID (e)
Age in Years	Indicate:	HTS LAB and Linkage Register	Column (E)
Sex	1. Male 2. Female	HTS LAB and Linkage Register	Column (F) M = Male F = Female
Marital status	1. Single 2. Married 3. Divorced/separated 4. Widowed	HTS LAB and Linkage Register	Column (H) S = Single MM = Married Monogamous MP = Married Polygamous D = Divorced/

			separated W = Widowed
Number of children	Indicate:	Patient file	
Level of Education	1.Primary school 2.Secondary School 3.College 4.University	Cohort Register	
Occupation	Indicate:	Cohort register	
HIV Diagnosis			
HIV Status at enrolment	1. Positive 2. Negative 3. Inconclusive	HTS LAB and Linkage Register	Column (R) N = Negative (non – reactive) P = Positive (Reactive) I = Inconclusive
Date tested	Date:	HTS LAB and Linkage Register	Column (B) DD/MM/YYYY
HTS Results	1.Positive	Cohort Register	Column (V)

visit 1	2.Negative		Y = Yes N = No
HTS Results visit 2	1. Positive 2. Negative	Cohort Register	Column (V) Y = Yes N = No
HTS Results visit 3	1. Positive 2. Negative	Cohort Register	Column (V) Y = Yes N = No
HTS Results visit 4	1. Positive 2. Negative	Cohort Register	Column (V) Y = Yes N = No
HTS Results visit 5	1. Positive 2. Negative	Cohort Register	Column (V) Y = Yes N = No
HTS Results visit 6	1. Positive 2. Negative	Cohort Register	Column (V) Y = Yes N = No
STI Diagnosis			
Treated for STI for Initial contact	1. Yes 2. No Name of STI:	Cohort Register	Column (BE) Y = Yes N = No

Treated for STI Visit 2	1. Yes 2. No Name of STI: _____	Cohort Register	Column (BE) Y = Yes N = No
Treated for STI Visit 3	1. Yes 2. No Name of STI: _____	Cohort Register	Column (BE) Y = Yes N = No
Treated for STI Visit 4	1. Yes 2. No Name of STI: _____	Cohort Register	Column (BE) Y = Yes N = No
Treated for STI Visit 5	1. Yes 2. No Name of STI: _____	Cohort Register	Column (BE) Y = Yes N = No
Treated for STI Visit 6	1. Yes 2. No Name of STI: _____	Cohort Register	Column (BE) Y = Yes N = No
Oral HIV PrEP Use (PrEP users only)			

Initiated on PrEP	1. Yes 2. No	Cohort Register	Column (BH) Y = Yes N = No
Date initiated on PrEP	Date:	Cohort Register	
PrEP refill visit 1	1. Yes 2. No	Cohort Register	Column (BI) Y = Yes N = No Column (BH) O = Ongoing
PrEP refill visit 2	1. Yes 2. No	Cohort Register	Column (BI) Y = Yes N = No Column (BH) O = Ongoing
PrEP refill visit 3	1. Yes 2. No	Cohort Register	Column (BI) Y = Yes N = No Column (BH)

			O = Ongoing
PrEP refill visit 4	1. Yes 2. No	Cohort Register	Column (BI) Y = Yes N = No Column (BH) O = Ongoing
PrEP refill visit 5	1. Yes 2. No	Cohort Register	Column (BI) Y = Yes N = No Column (BH) O = Ongoing
Percentage PrEP Adherence (For HIV Oral PrEP users only)			
PrEP adherence One month post PrEP Initiation	Indicate %ge:	PrEP Follow up Visit form.	Page 1 bottom
PrEP adherence Visit 2	Indicate %ge:	PrEP Follow up Visit form.	Page 1 bottom
PrEP adherence	Indicate %ge:	PrEP Follow up Visit form.	Page 1 bottom

Visit 3			
PrEP adherence Visit 4	Indicate %ge:	PrEP Follow up Visit form.	Page 1 bottom
PrEP adherence Visit 5	Indicate %ge:	PrEP Follow up Visit form.	Page 1 bottom
Average Number of Sexual Acts per day			
Sexual acts per day, Visit 1 (At enrolment)	Average number:	Enrolment form	
Sexual acts per day, Visit 2	Average number:	Peer Contact form	
Sexual acts per day, Visit 3	Average number:	Peer Contact form	
Sexual acts per day, Visit 4	Average number:	Peer Contact form	
Sexual acts per day, Visit 5	Average number:	Peer Contact form	
Sexual acts per day, Visit 6	Average number:	Peer Contact form	
Condom use			
Condom	Average number:	Enrolment form	

Use per day, At Enrolment			
Condom Use per day, Visit 1	Average number:	Peer Contact form	
Condom Use per day, Visit 2	Average number:	Peer Contact form	
Condom Use per day, Visit 3	Average number:	Peer Contact form	
Condom Use per day, Visit 4	Average number:	Peer Contact form	
Condom Use per day, Visit 5	Average number:	Peer Contact form	



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Ref: KNH-ERC/A/83

Kennedy Owino Radeny
Reg. No.HSH315-0303/2017
School of Public Health
College of Health Sciences (CoHES)
J.K.U.A.T

Dear Kennedy



6th March, 2019

RESEARCH PROPOSAL: EFFECTS OF HIV ORAL PRE-EXPOSURE PROPHYLAXIS ON INCIDENCE OF BACTERIAL STIs AND RISKY SEXUAL BEHAVIOR AMONG FEMALE SEX WORKERS IN SELECTED DROP IN CENTERS IN NAIROBI COUNTY (P876/12/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 6th March 2019 – 5th March 2020.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious 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.
- 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.
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- 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*).
- 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.

Protect to discover

Appendix III: Ethical Review Committee Approval.

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
The Assistant Director, Health Information, KNH
Supervisors; Dr. Raphael Lihana(KEMRI), Dr. Jackline Nyaberi(School of Public Health, JKUAT)

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OT23- 739603

No reply

**JOMO KENYATTA UNIVERSITY
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FAX: (067)52164. Email: director@bps.jkuat.ac.ke

REF JKU/BPS/HSB315-0303/2017

1ST OCTOBER, 2019

Owino Radeny Kennedy
C/o SOPH
JKUAT

Dear Kennedy

RE: APPROVAL OF RESEARCH PROPOSAL AND SUPERVISORS

Kindly note that your MSc. research proposal entitled: "Effects of HIV oral pre-exposure prophylaxis on incidence of bacterial STIs & risky sexual behavior among female sex workers in selected drop in centers in Nairobi County." has been approved. The following are your approved supervisors:-

1. Dr. Raphael Lihana - KEMRI
2. Dr. Jackline Nyaberi - JKUAT

**PROF. MATHEW KINYANJUI
DIRECTOR, BOARD OF POSTGRADUATE STUDIES**

Copy to: Dean SOPH



JKUAT is ISO 9001:2015 and ISO 14001:2015 Certified
Setting Trends in Higher Education, Research, Innovation and Entrepreneurship



Appendix IV: Board of Post Graduate Studies (BPS) letter of Approval

Appendix V: DICE/Prevention Centers, letter of authorization to collect data

BAR HOSTESS EMPOWERMENT & SUPPORT PROGRAMME (BHESP)

18th April 2019

To Whom It may concern

Ref: AUTHORISATION TO COLLECT DATA FOR ACADEMIC RESEARCH PROJECT.

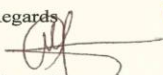
This is to affirm that Mr. Radeny Kennedy has been authorized to collect data for his academic research project that is focusing on; The Effects of HIV oral pre-exposure prophylaxis (PrEP) on incidence of bacterial STIs and risky sexual behavior among female sex workers in selected drop in centers in Nairobi County.

He has been permitted to collect the data relevant to the study from our Roysambu, Jogoo Road and Kariobangi DICES.

Kindly accord him necessary support during this period.

Thank you.

Regards,


Simon Mwangi

BHESP Program Manager



Kasarani - Mwiki Road Near D.O's Place
P.O Box 32821-00600, Nairobi Tel: 020 2608944
e-mail: barhostess@yahoo.com info@bhesp.org www.bhesp.org

Appendix VI: Informed Consent form

Title

To investigate the effects of oral HIV Pre-Exposure Prophylaxis use on the Incidence of STIs and risky sexual behavior among female sex workers in Nairobi County

Principal Investigator: Radeny Kennedy _ Student

-Masters of Science in Medical Epidemiology

-Jomo Kenyatta University of Agriculture and
Technology/ITROMID

- Department- COHES

Supervisors: Dr. Raphael Lihana

Dr. Jackline Nyaberi

Introduction

I am Radeny Kennedy, a student at Jomo Kenyatta University of Agriculture and Technology, undertaking Masters in Medical Epidemiology and currently conducting a study for my master's degree on the effects of HIV oral PrEP use on the rate of sexually transmitted Infections (STIs) and risky sexual behaviors among the female sex workers (FSW) who use HIV Pre-Exposure Prophylaxis (PrEP) when compared to those FSWs who do not use PrEP. I am going to give you information regarding the study and will invite you to participate in the study. You do not have to decide about your participation right now and you can stop me to ask questions about anything you do not understand.

Feel free to consult about participating, with anyone you feel comfortable. Feel free to ask about anything you do not understand anytime.

Purpose of the research

Sexually Transmitted Infections are very common especially among the female sex workers who do not use condoms during the sexual act. It is thought that the use of HIV PrEP can possibly increase an individual's risk of acquiring STIs because of the perceived HIV risk elimination while taking PrEP. The reason we are doing the study is to find out if female sex workers who take HIV oral PrEP are at a higher risk of contracting STIs and indulging in risky sexual behavior than the female sex workers who do not use HIV oral PrEP. Ultimately this research may be used to inform prevention programs how best structures may be put in place to protect female sex workers from HIV and other STIs.

Description of the Study Procedures

If you agree to participate in this study, you will be required to sign a written consent having been informed and understood all you need to know about the study. We will need your past six months data obtained from the clinic records, which will be used for the purpose of the study. You will be requested to come to the clinic just once to give you consent to participate in the study, and on this day, if you wish, your health care providers will offer you the usual services so that you do not have to come back on a later date that particular month for the same services. The usual services offered during your visit can be offered if you wish to take them. This However will not be part of the study but will be part of your routine clinic schedule so that you do not have to come back to the clinic soon.

Participant selection

We are inviting all the female sex workers who come to the selected DICES to participate in this research study investigating the association between HIV PrEP and

incidences of STIs among female sex workers. You were selected as a possible participant because you meet the criteria required for one to participate including; a negative HIV status, 18 and above years of age, and having been conducting sex work for the past six months.

Voluntary Participation

Your participation in this study is exclusively voluntary. It is entirely your choice to or not to participate. You will continue to all the services you have been accessing from this clinic whether you choose to participate in the study or not. If you choose not to participate in this study, you will still receive the routine services that you always get from here. You are also free to stop participating at any time even if you have earlier agreed to participate.

Risks/Discomforts of Being in this Study

There are no reasonable foreseeable risks associated with this study. On this visit for consenting, the participants may wish to access their usual services at the Drop In Centers (DICES)/Prevention centers, this entirely will be dependable on the participant if they wish to take their routine service or not.

Benefits of Being in the Study

There may be no direct benefit to you at the moment but your participation is likely to help find an answer to the research question which in future may inform the programs on the best approach to prevention and control of HIV and other STIs among the female sex workers.

Confidentiality

We will not share the identity of those participating in this study with anyone. Any information collected from you for the purpose of this research shall remain confidential and all the records of this study will be kept under lock and key accessible to the

researchers only. Any information about you will be identified by a number/code and not your names known only to the researchers. Your number will not be shared with anyone except the researchers and your clinician.

Sharing the Results

The knowledge gained through this study will be shared with you through your gatherings before it is made widely available to the public. Personal and confidential information will not be shared. We will hold small meetings in your groups after which we will publish the results so that those interested may learn from our research study.

Right to Refuse or Withdraw

You do not have to take part in this study if you do not wish to and that will not stop you from accessing any of the services you receive from this clinic, you will still have all the benefits you get from this clinic. You may still stop participating in this study anytime you wish without losing any of your right as a client here.

Right to Ask Questions and Report Concerns

In case you have any questions, you may ask now, later or even after the study has started. Feel free to contact me by cell phone at 0723739603.

This proposal has been reviewed and approved by Kenyatta National Hospital-University of Nairobi Ethics Review Committee (KNH-UoN ERC), which is a committee whose task is to ensure that research participants are kept from harm.

PART II: Certificate of Consent

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

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the study procedure.

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

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

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

Appendix VII: Fomu ya Ruhusa (Kiswahili Translation of Informed Consent form)

Kichwa

Kuchunguza madhara ya matumizi ya madawa za kuzuia Virusi Vya Ukimwi (VVU) kabla ya Mfiduo juu ya Matukio ya magonjwa ya magonjwa ya ngono na tabia ya hatari ya ngono kati ya wafanyakazi wa ngono huko Nairobi County

Mtafiti Mkuu: Radeny Kennedy _ Mwanafunzi

-Masters wa Sayansi katika Epidemiology

- Chuo Kikuu cha Jomo Kenyatta Kilimo na Teknolojia / ITROMID

- Idara- COHES

Wasimamizi: Dr Raphael Lihana

Dr Jackline Nyaberi

SEHEMU YA I: Karatasi ya Taarifa

Utangulizi

Mimi ni Radeny Kennedy, mwanafunzi katika Chuo Kikuu cha Kilimo na Teknolojia ya Jomo Kenyatta, akifanya Masters katika Epidemiology ya Matibabu na sasa anaendesha utafiti kwa shahada ya masters juu ya madhara ya matumizi ya PrEP kwa kiwango cha magonjwa ya zinaa (STIs) na hatari tabia za kijinsia kati ya wafanyakazi wa kijinsia (FSW) ambao hutumia Prophylaxis ya Virusi Vya Ukimwi (VVU) (PrEP) ikilinganishwa na wale wa FSW ambao hawatumii PrEP. Nitawapa taarifa kuhusu utafiti na nitakualika kushiriki katika utafiti. Huna budi kuamua kuhusu ushiriki wako sasa na unaweza kuniacha kuuliza maswali kuhusu kitu chochote ambacho hujui. Jisikie huru kushauriana kuhusu kushiriki, na mtu yeyote anayejisikia vizuri. Jisikie huru kuuliza juu ya chochote ambacho hujui wakati wowote.

Kusudi la utafiti

Maambukizi ya ngono ni ya kawaida sana kati ya wafanyakazi wa ngono ambao hawatumii kondomu wakati wa kitendo cha ngono. Inachukuliwa kuwa matumizi ya VVU PrEP inaweza uwezekano wa kuongeza hatari ya mtu binafsi ya kupata magonjwa ya ngono kwa sababu ya kuharibiwa kwa hatari ya UKIMWI wakati wa kuchukua PrEP. Sababu tunayofanya utafiti ni kujua kama wafanyakazi wa ngono wa kike ambao huchukua VVU kwa mdomo PrEP wako katika hatari kubwa ya kuambukizwa magonjwa ya ngono na kujiingiza katika tabia ya hatari ya ngono kuliko wafanyakazi wa jinsia ambao hawapatii VVU kwa mdomo. Hatimaye utafiti huu unaweza kutumika kutangaza mipango ya kuzuia jinsi miundo bora inaweza kuwekwa kuwalinda wafanyakazi wa ngono kutoka kwa wanawake na VVU na magonjwa mengine ya magonjwa ya ngono.

Maelezo ya Utaratibu wa Utafiti

Ikiwa unakubali kushiriki katika somo hili, utahitajika kusaini ridhaa iliyoandikwa baada ya taarifa na kuelewa unahitaji kujua kuhusu utafiti. Tutahitaji data zako za miezi sita zilizopita kutoka kwenye kumbukumbu za kliniki, ambazo zitatumika kwa kusudi la utafiti. Utatakiwa kuja kliniki mara moja tu kukupa idhini ya kushiriki katika utafiti huo, na siku hii, ikiwa unataka, watoa huduma wako wa afya watakupa huduma za kawaida ili usirudi kwenye tarehe ya baadaye ambayo mwezi fulani kwa huduma sawa. Huduma za kawaida zinazotolewa wakati wa ziara yako zinaweza kutolewa ikiwa unataka kuwachukua. Hii hata hivyo haitakuwa sehemu ya utafiti lakini itakuwa sehemu ya ratiba yako ya kliniki ya kawaida ili usipate kurudi kliniki hivi karibuni.

Uchaguzi wa washiriki

Tunakaribisha wafanyakazi wote wa jinsia wa kike ambao wanakuja DICE waliochaguliwa kushiriki katika utafiti huu wa uchunguzi kuchunguza chama kati ya VVU PrEP na matukio ya magonjwa ya ngono kati ya wafanyakazi wa ngono. Ulichaguliwa kama mshiriki anayewezekana kwa sababu unakidhi vigezo vinavyotakiwa kuhusika ikiwa ni pamoja na; hali mbaya ya VVU, 18 na zaidi ya umri wa miaka, na baada ya kufanya kazi ya ngono kwa miezi sita iliyopita.

Kushiriki kwa hiari

Ushiriki wako katika utafiti huu ni pekee kwa hiari. Ni uchaguzi wako kabisa au ushiriki. Utaendelea huduma zote ulizopata kutoka kwenye kliniki hii ikiwa unachagua kushiriki katika utafiti au la. Ikiwa unachagua kushiriki katika utafiti huu, bado utapata huduma za kawaida ambazo unapata kutoka hapa. Wewe pia ni huru kuacha kuhusika wakati wowote hata kama umekubali kushiriki.

Hatari / kutokuwepo kwa Kuwa katika Masomo haya

Hakuna hatari inayohusiana na utafiti huu. Katika ziara hii ya kukubaliana, washiriki wanaweza kutaka kufikia huduma zao za kawaida katika vituo vya (DICEs) / Vikwazo vya kuzuia, hii itakuwa ya kudumu kwa mshiriki ikiwa wanataka kuchukua huduma yao ya kawaida au la.

Faida za Kuwa katika Masomo

Hatuwezi kuwa na manufaa ya moja kwa moja kwa sasa lakini ushiriki wako uwezekano wa kusaidia kupata jibu kwenye swali la utafiti ambalo baadaye litajulisha programu za njia bora zaidi ya kuzuia na kudhibiti VVU na magonjwa mengine ya magonjwa ya ngono kati ya wafanyakazi wa kijinsia .

Usiri

Hatutashiriki utambulisho wa wale wanaoshiriki katika utafiti huu na mtu yeyote. Taarifa yoyote iliyokusanywa kutoka kwako kwa lengo la utafiti huu utabaki siri na kumbukumbu zote za utafiti huu zitahifadhiwa chini ya kufungwa na ufunguo kupatikana kwa watafiti tu. Taarifa yoyote kuhusu wewe itatambuliwa kwa namba / msimbo na si majina yako inayojulikana kwa watafiti tu. Nambari yako haitashirikiwa na mtu yeyote isipokuwa watafiti na daktari wako.

Kushiriki matokeo

Ujuzi uliopatikana kupitia utafiti huu utashirikiwa na wewe kupitia mikusanyiko yako kabla ya kutolewa kwa umma. Maelezo ya kibinafsi na ya siri hayatashirikiwa. Tutafanya mikutano michache katika vikundi vyako baada ya kutangaza matokeo ili wale wanaopendezwa waweze kujifunza kutoka kwa utafiti wetu wa utafiti.

Haki ya Kukataa au Kuondoa

Huna budi kushiriki katika utafiti huu ikiwa hutakii na hiyo haitakuzuia kupata huduma zozote unazopokea kutoka kliniki hii, utakuwa na faida zote unazopata kutoka kliniki

hii. Unaweza bado kuacha kushiriki katika utafiti huu wakati wowote unavyotamani bila kupoteza haki yako yoyote kama mteja hapa.

Haki ya Kuuliza Maswali na Ripoti Mahangaiko

Ikiwa una maswali yoyote, unaweza kuuliza sasa, baadaye au hata baada ya utafiti kuanza. Jisikie huru kuwasiliana na mimi kwa simu ya mkononi saa 0723739603.

Pendekezo hili limepitwa na kupitishwa na Hospitali ya Taifa ya Kenyatta - Chuo Kikuu cha Kamati ya Ukaguzi wa Maadili ya Nairobi (KNH-UoN ERC), ambayo ni kamati ambayo kazi yake ni kuhakikisha kwamba washiriki wa utafiti hawahifadhiwe.

SEHEMU YA II: Hati ya Ruhusa

Nimesoma taarifa iliyotangulia, au imesomezwa. Nimekuwa na fursa ya kuuliza maswali kuhusu hilo na maswali yoyote niliyoyauliza yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari kushiriki kama mshiriki katika utafiti huu.

Jina la Chapisho la Mshiriki _____

Saini ya Mshiriki _____

Tarehe _____

Siku / mwezi / mwaka

Taarifa ya mtafiti / mtu kuchukua idhini

Nimesoma kwa usahihi karatasi ya habari kwa mshiriki anayeweza, na kwa uwezo wangu wote nilihakikisha kuwa mshiriki anaelewa utaratibu wa kujifunza.

Ninathibitisha kwamba mshiriki huyo alitolewa fursa ya kuuliza maswali kuhusu utafiti, na maswali yote aliyoulizwa na mshiriki amejibu kwa usahihi na kwa uwezo wangu mkubwa. Ninathibitisha kwamba mtu huyo hakujazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Nakala ya ICF hii imetolewa kwa mshiriki.

Jina la Magazeti la Mtafiti / mtu anayekubali_____

Sahihi ya Mtafiti / mtu kuchukua kibali_____

Tarehe _____

Siku / mwezi / mwaka

Appendix VIII: Sample Size Determination

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Tests for Two Proportions

Numeric Results for Testing Two Proportions using the Z-Test with Unpooled Variance

H0: $P_1 - P_2 = 0$. H1: $P_1 - P_2 = D_1 \neq 0$.

Target Power	Actual Power*	N1	N2	N	P1	P2	Diff D1	Alpha
0.90	0.90146	168	168	336	0.2200	0.3800	-0.1600	0.0500

* Power was computed using the normal approximation method.

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Report Definitions

Target Power is the desired power value (or values) entered in the procedure. Power is the probability of

rejecting a false null hypothesis.

Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often

(slightly) larger than the target power.

N1 and N2 are the number of items sampled from each population.

N is the total sample size, $N_1 + N_2$.

P1 is the proportion for Group 1 at which power and sample size calculations are made. This is the treatment or experimental group.
P2 is the proportion for Group 2. This is the standard, reference, or control group.
D1 is the difference P1 - P2 assumed for power and sample size calculations.
Alpha is the probability of rejecting a true null hypothesis.

Summary Statements

Group sample sizes of 168 in group 1 and 168 in group 2 achieve 90.146% power to detect a difference between the group proportions of -0.1600. The proportion in group 1 (the treatment group) is assumed to be 0.3800 under the null hypothesis and 0.2200 under the alternative hypothesis. The proportion in group 2 (the control group) is 0.3800. The test statistic used is the two-sided Z-Test with unpooled variance. The significance level of the test is 0.0500.

Definitions

Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").

N1, N2, and N are the evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.

N1', N2', and N' are the number of subjects that should be enrolled in the study in order to end up with N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2'

are calculated by inflating N1 and N2 using the formulas $N1' = N1 / (1 - DR)$ and $N2' = N2 / (1 - DR)$, with

N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., and Wang, H. (2008) pages 39-40.)

D1, D2, and D are the expected number of dropouts. $D1 = N1' - N1$, $D2 = N2' - N2$, and $D = D1 + D2$.

Design Tab

Solve For:	Sample Size
Power Calculation Method:	Normal Approximation
Alternative Hypothesis:	Two-Sided
Test Type:	Z-Test (Unpooled)

Power: 0.90
Alpha: 0.05
Group Allocation: Equal (N1 = N2)
Input Type: Proportions
P1 (Group 1 Proportion|H1): 0.22
P2 (Group 2 Proportion): 0.38

Appendix IX: Publication one-International Journal of Scientific and Research Publications

**International Journal of Scientific and
Research Publications**
ISSN 2250-3153
www.ijsrp.org

Certificate of Publication

This is to certify paper titled "Effects Of HIV Oral Pre-Exposure Prophylaxis On Incidence Of STIS Among Female Sex Workers In Selected Drop-In Centers In Nairobi County" submitted by Author(s) Radeny Kennedy Owino, Raphael Lihana, Jackline Mosinya Nyaberi has been published for September 2020, Volume 10, Issue 9 publication under ISSN 2250-3153.

Signed by:



[J. Prakash]
Publication Head, USRP Inc.
Email: editor@ijsrp.org
www.ijsrp.org

ISSN 2250-3153



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Certificate

Office Code :	M1867	Date :	2021-02-24
MIC No. :	2854	Status :	Published

Article Details

This is to certify that following paper has been published in IOSR Journals.

Article Title :	Behavioral Risk Compensation Ensuing HIV Oral Pre Exposure Prophylaxis Use Among Female Sex Workers In Nairobi, Kenya.
Author's Name :	Kennedy Owino Radeny , Jackline Mosinya Nyaberi, Raphael Lihana , Christian Ochieng
Journal Name :	IOSR Journal of Dental and Medical Sciences
ISSN :	2279-0853
Publisher Name :	International Organization of Scientific Research
Journal Url :	www.iosrjournals.org
Publishing Model :	Open Access Publishing
Review Type :	Blind Peer Review Process
Journal Type :	Indexed Refereed Journal
Volume No. :	20
Issue No. :	02
Article DOI :	10.9790/0853-2002105663



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Appendix X: Publication Two- IOSR Journal of Dental and Medical Sciences

Appendix XI: First Seminar Presentation



In Search of Better Health

KENYA MEDICAL RESEARCH INSTITUTE

KEMRI GRADUATE SCHOOL

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THE 8th SEMINAR PRESENTATION FOR MSc AND PhD STUDENTS FOR SCHOOL OF PUBLIC HEALTH HELD VIRTUALLY ON 10TH JUNE 2020 AS FROM 9.30AM TO 1PM

FACULTY MEMBERS PRESENT	STUDENTS PRESENT
<ol style="list-style-type: none">1. Dr. Elizabeth Echoka- KEMRI/Chairperson2. Dr. Nzioka Mativo -JKUAT3. Dr. Rose Bosire- KEMRI4. Prof Gideon Kikvi- JKUAT5. Dr. Fredrick Kirui- KEMRI6. Dr. Raphael Lihana- KEMRI7. Hillary Imire- Taking Minutes KEMRI	<ol style="list-style-type: none">1. Fridah Muinde2. Peter Saula3. Geoffrey Maitha4. Kennedy Radeny
<p>FACULTY MEMBERS ABSENT WITH APOLOGIES</p> <ol style="list-style-type: none">1. Dr. Violet Wanjihia- KEMRI2. Dr. Jackline Nyaberi- JKUAT	

Echoka.
13.10.2020

Agenda

1. Matters Arising
2. Opening Remarks
3. Seminar Presentations
4. AOB

The meeting began officially at 9.30am with the Chairperson welcoming both the faculty and students and thereafter an opening prayer was made by Hillary Imire after which we proceeded to the presentations by students.

No	Students	Reported that	Agreed that
1	<p>Peter W. Saula- TM 410-0741/2016 PhD in Public Health</p> <p>Title: Outcomes of newborns with surgical conditions at Moi Teaching and Referral Hospital in the context of a structured standards operating procedure for new borns transport</p> <p>Supervisors; Prof Yeri Kombe KEMRI, Prof. Gideon Kikuvi JKUAT Reviewer Dr. Elizabeth Echoka</p>	<ol style="list-style-type: none"> 1. The student is doing his 4th presentation which is the final presentation. 2. There is much improvement as compared with the 3rd presentation. 3. Detailed comments will be sent directly to the student by Dr. Echoka who reviewed the student's thesis. 4. The slides were abit crowded 5. Recommendation was not well organized i.e practice, policy future research needs to be reflected on the thesis. 6. Results – characteristics of participants needs to be in a table. 7. Put characteristics of newborns (more) so that it impacts on the interests. 8. Tables 2a, 2b- what statistics tests were you using? So that results are not exaggerated. 9. How did you assign interventions to the study participants? 10. Quasi experiment was used on the slides cluster randomized control trial; need to look into the methodology. 11. How did you measure the significance between the two propositions? In group A and B on your sides. 12. Need to know the statistical tests that you used. 	<p>Dr. Elizabeth Echoka to share the review comments with the student</p>

Echoka.
 13.10.2020

		<p>13. Specific objectives no. two does not tally with the recommendations no. two</p> <p>14. Clustering needs to be taken into consideration on the analysis</p>	
2.	<p>Fridah Ndunda Muinde- TM 410-0996/2011 PhD Public Health</p> <p>Title Effect of a community-based health education interventions on breast and cervical cancer awareness and screening among women of reproductive age in Kitui county Kenya</p> <p>Supervisors- Dr. Nzioka Mativo- JKUAT, Prof Mohammed Karama- KEMRI, Reviewer Dr. Jackline Nyaberi- JKUAT</p>	<p>1. The student was not audible enough.</p> <p>2. There were challenges with network connectivity.</p> <p>3. There was no difference between objective one and two. Need to relook at it.</p> <p>4. What guided the development of your intervention?</p> <p>5. What is the conclusion of your hypothesis and how did you make your conclusions?</p> <p>6. We need to see more of analytic studies</p> <p>7. Sample calculations was not seen. Need to include.</p> <p>8. Result prevention need to use conventional methods so that we know the significance of the study.</p> <p>9. Results needs to be well presented depending on the significance by showing the actual P -Value.</p> <p>10. Conclusions and recommendations are outside the scope.</p> <p>11. Tables for results were too crowded.</p> <p>12. Review your specific objectives.</p> <p>13. Title has the word "effect" needs to be looked into.</p> <p>14. Cross sectional, hypothesis should be tested.</p> <p>15. The objectives need to be redesigned.</p> <p>16. Results, specific objectives, sample size needs to checked</p>	<p>Dr. Jackline Nyaberi to share the review comments with the student</p>
3	<p>Kennedy Radeny Owino- TM -406-0303/2017 Msc Epidemiology</p> <p>Title Effects of HIV oral pre exposure prophylaxis on incidence of bacterial STIs and risky sexual behaviours among</p>	<p>1. It was well-presented.</p> <p>2. What was the justification for the study?</p> <p>3. Results- There is need to work on the table, it's not very clear.</p> <p>4. What are the values interms of data for using a proportionate of a third?</p>	<p>Dr. Violet Wanjihia to share the review comments with the student</p>

Handwritten signature and date:
12.10.2020


	female sex workers in selected drop- in centres in Nairobi county Supervisors Raphael Lihana-KEMRI, Dr. Jackline Nyaberi JKUAT, Reviewer Dr. Violet Wanjihia	<ul style="list-style-type: none"> 5. Sample size calculations –what informed those assumptions. 6. Findings are not clear. 7. Analytic approach- what is the follow up time for the visits. 8. Conclusions are not related with the results. What do they mean from the findings? 9. Why just the female sex workers? 10. What constitutes risky behavior? 	
4.	Geoffrey Maitha TM 406-0745/2016 PhD Epidemiology Title: Effects of hepatitis B Virus co- infections among HIV Patients attending comprehensive care clinics in Makueni County. Supervisors Prof Gideon Kikuvi JKUAT, Dr. Peter Wanzala KEMRI, Dr. Fredrick Kirui KEMRI	1. The student was not able to present due to challenges with network and audio with the computer	It was agreed that: The student will be given another opportunity to present once he attends a pre-testing for the seminar presentations.

APPROVED FOR ISSUE:

Chairperson: 

Signature:  Date: 13.10.2020.

PUBLIC HEALTH PROGRAMME MSc PROPOSAL PRESENTATION_SEMINAR ONE			
ONLINE: Wednesday 10 th June 2020			
Session Chairperson Dr. Elizabeth Echoka		Rapatour Hillary Imire	
10 th June 2020 (9am to 1pm)			
Time	Presenter	Proposal title	supervisors
9.30am-9.55am	Peter W. Saula- TM 410-0741/2016 PhD in Public Health	Outcomes of newborns with surgical conditions at Moi Teaching and Referral Hospital in the context of a structured standards operating procedure for newborns transport	Prof Yeri Kombe KEMRI, Prof. Gideon Kikui JKUAT Reviewer Dr. Elizabeth Echoka
10.00am-10.30am	Fridah Ndunda Muinde TM 410-0996/2011 PhD Public Health	Effect of a community-based health education interventions on breast and cervical cancer awareness and screening among women of reproductive age in Kitui county Kenya	Supervisors- Dr. Nzioka Mativo- JKUAT, Prof Mohammed Karama- KEMRI, Reviewer Dr. Jackline Nyaberi- JKUAT
10.35am-1100am	Kennedy Radeny Owino TM 406-0303/2017 Msc Epidemiology	Effects of HIV oral pre exposure prophylaxis on incidence of bacterial STIs and risky sexual behaviours among female sex workers in selected drop- in centres in Nairobi county	Raphael Lihana- KEMRI, Dr. Jackline Nyaberi JKUAT, Reviewer Dr. Violet Wanjihia
11.05am to 1130am	Geoffrey Maitha TM 406-0745/2016 PhD in Epidemiology	Effects of hepatitis B Virus co- infections among HIV Patients attending comprehensive care clinics in Makueni County	Prof. Gideon Kikui JKUAT, Dr. Peter Wanzala KEMRI, Dr. Fredrick Kirui KEMRI


13.10.2020

Appendix XII: Second Seminar Presentation



In Search of Better Health

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Minutes of KEMRI Seminar Proposal Presentations held on 13th March 2021_BLENDED

Faculty Members Present		Students Present	
1	Dr. Elizabeth Echoka- KEMRI	1	Aggrey Gisiora Mokaya
2	Dr. Nzioki Mativo- JKUAT	2	Kennedy Radeny
3	Prof. Gideon Kikuvi-JKUAT	3	Fridah Muinde
4	Dr. Raphael Lihana-KEMRI	4	Emelda Namayi
5	Dr. Jackline Nyaberi-JKUAT	5	Elizabeth Mwaniki
6	Dr. Joseph Mutai – KEMRI	6	Raymond Sudoi
7	Dr. Vincent Were- JKUAT	7	Joan Soi
8	Dr. Rose Bosire- KEMRI	8	Evans Obwocha Obarre
		9	Julie

The meeting started at 9:30 am with a word of prayer from Imelda Namayi.

Student Seminar Presentations:

	Description	Comments	Verdict
1	Aggrey Mokaya REG: HSH411-0021/2017 PhD Public Health PhD Seminar 2 <i>Effect of A Teacher-Led Psychoeducation Program On Bullying, Depression, And Suicidality Among Adolescents Attending</i>	1. Need to include descriptive analysis of the factors by control and intervention in the regression 2. Why not collapse the independent variables in the conceptual framework? 3. Risk factors go hand in hand with design 4. Have/incorporate one of the specific objectives to reflect the qualitative approach 5. There is a need to link outcomes/conclusions and	- Make progress on publications - Proceed to seminar 3

Signed: _____

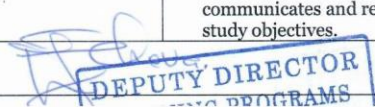
Date: 13th May 2021

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Page 1 of 10

		<p>study? What were the findings and how did they inform the revision of tools?</p> <p>17. Please what are the areas of further research did you find out after doing this study.</p> <p>18. Were any women found to have cervical or breast cancer?</p> <p>19. use conventional methods of stating p-value.</p> <p>20. on justification slide you have 3th...what is that?</p> <p>21. Ever tested or ever sought breast cancer screening? This is not clear in the presentation and needs to come out clearly.</p>	
3	<p>Kennedy Radeny HSH315-0303/2017 MSc. Epidemiology</p> <p>MSc Seminar 2 (4th Presentation)</p> <p><i>Incidence of Bacterial STIs and Risky Sexual Behaviors Among Female Sex Workers Using HIV Oral Pre-Exposure Prophylaxis at Drop-In Centers in Nairobi County.</i></p> <p>Supervisors Dr. Raphael Lihana, KEMRI Dr. Jackline Nyaberi, JKUAT</p>	<p>1. The survival information has now come out clearly. There is marked improvement in the analysis</p> <p>2. The risk factors are now clear and the inferential analysis is now clear.</p> <p>3. The study deals with female sex workers but there are some described as house helps or salonists – these should be people with alternative income</p> <p>4. These numbers are low to include as non-sex workers. This doesn't make sense because the population of the entire study are FSWs.</p> <p>5. Condom use – those who had children were less likely to use condoms yet it is stated that nothing was significant. Needs to be rechecked</p> <p>6. Objective 3 – interpretation needs to be worked on and same to conclusion</p> <p>7. Month 1 has been skipped in the monthly STI cases</p> <p>8. The alignment of the Tables of socio-demographic characteristics is not good. This can be improved.</p> <p>9. For the defense you may need to justify why you chose 90% power instead of 80%</p> <p>10. Otherwise commendable improvements seen</p> <p>11. Positive attitude to the comments given.</p> <p>12. Conceptual framework is unclear. That needs to be discussed so that it communicates and relates to the study objectives.</p>	- Proceed to submit thesis

Signed: _____


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HIV PROGRAMS

Date: 13th May 2021

- Student forums should be organized to sensitize students on the next steps in research and how to receive and work on critique to their work
- A standing postgraduate committee is being put together at graduate school to enhance quality control at the Graduate School
- Supervision guidelines are being developed to address gaps in the supervision process.
- There is a free seminar series on scientific writing: students should attend.

APPROVED FOR ISSUE:

Chairperson: Dr. Elizabeth Echoka

Signature: _____ **Date:** 13th May 2021

DEPUTY DIRECTOR
TRAINING PROGRAMS

Signed: _____

Date: 13th May 2021