

Effects Of HIV Oral Pre-Exposure Prophylaxis On Incidence Of STIs Among Female Sex Workers In Selected Drop-In Centers In Nairobi County.

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Abstract

Pre-exposure Prophylaxis (PrEP) is effective in prevention of Human Immunodeficiency Virus (HIV) infections among populations at a substantial risk. World Health Organization recommends use of PrEP for prevention of HIV, however, risk of sexually transmitted Infections (STIs) raises concern. While STIs screening is continually done at 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 behaviours among female sex workers in Nairobi. Specifically, the study; compared the incidence rate of bacterial STIs and identified the STIs between FSWs taking HIV oral PrEP and non-PrEP user FSWs 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 Centres (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 data on STI incidences. Data was analysed using STATA. Oral PrEP users were found to be 1.7 times higher risk of acquiring STIs ($P=0.064$, 95%CI) than non-PrEP users. Vaginitis (52.1%) and cervicitis (21.8%) were the most common STIs identified among FSWs. Composite STI prevalence of 35.4 and pooled STI incidence rate of 70.8 per 100-person years was observed. This study demonstrated an increasing trend of STIs among FSWs using HIV PrEP; 0%, 7%, 13%, 16%, and 21%, from enrolment to month five, with the most notable STIs being vaginitis, cervicitis and Pelvic Inflammatory Disease (PID). Oral PrEP use does not increase STI risk, however there was a notable increasing trend of STI cases through the six-month study period. STIs prevention counselling should therefore be emphasized during PrEP initiation and throughout PrEP follow up visits.

Index Terms: Drop In Centres, Female Sex Worker, HIV, Pre-Exposure Prophylaxis.

Background

Oral Human Immunodeficiency Virus (HIV) Pre Exposure Prophylaxis (PrEP) is a chemoprophylaxis involving use of antiretroviral medicines to prevent HIV (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, Weiss, *et al.*, 2017). Oral PrEP has been adopted globally for prevention of HIV among the populations at substantial ongoing risk of HIV (WHO, 2015). In Kenya, oral PrEP was launched in 2016 (NASCO, 2017). Pre Exposure Prophylaxis (PrEP) intervention has become crucial among Female Sex Workers (FSW) as a result of their increased risk to acquire HIV due to multiple sexual partners (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 (Jenness, Weiss, *et al.*, 2017), (Liu *et al.*, 2016). Oral PrEP is a major biomedical approach towards HIV control (Gabona *et al.*, 2017) (Pyra *et al.*, 2019). Combination of Tenofovir disoproxil Fumarate and Emtricitabine (TDF/FTC) reduce HIV-1 infection by up to 75% (Thigpen *et al.*, 2012). The use of oral HIV Pre Exposure prophylaxis has demonstrated a significant reduction in HIV infection (McCormack *et al.*, 2016).

Populations have been categorized based on their risky behaviours and vulnerabilities to acquiring HIV. Key populations are distinct groups who are at high risk of acquiring HIV infection due to their high risk behaviour 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 behaviour and vulnerabilities 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

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general population, the HIV prevalence among sex workers is over 30% (Beyrer, 2016). Over 300,000 people have been initiated on PrEP since 2012, 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).

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). A mathematical modelling demonstrated that a widespread PrEP use among gay men in US would result to increased STI diagnosis but will fall after (Jenness *et al.*, 2017). Another Mathematical modelling demonstrated 42% *Neisseria gonorrhoeae* and 40% *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). 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, that of non-PrEP user MSMs (Kojima *et al.*, 2016). Meta-analysis and systemic review of 88 studies has suggested a pooled prevalence for composite outcome of chlamydia, gonorrhea and early syphilis to be 23.9% post PrEP initiation and a pooled incidence of 72.2 per 100 person years during PrEP follow up (Ong *et al.*, 2019).

Gonorrhea 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) and 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 (Kulkarni *et al.*, 2016). Genetic analysis has indicated a different phylogenetic clade to the contemporary strains (Papp *et al.*, 2017a). Resistance to *Treponema pallidum* infections began in 1960's (Duncan *et al.*, 1989). Increasing tendency of macrolide resistant *T. pallidum* has been observed in several developed countries (Stamm, 2010). *Chlamydia trachomatis* treatment failure has been documented (Horner, 2012); 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), (Edouard *et al.*, 2017). 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 ensued (Moses *et al.*, 2002).

Materials and methods

Study Site and population

The study was conducted in Nairobi County at the selected Key Populations Drop in Centres (DICES) / Prevention Centres located in various Sub Counties. Nairobi has a total of 17 Sub Counties and 22 Drop in centres/Prevention Centres. Out of the 17 Sub Counties, 9 Sub Counties host the 22 DICES/Prevention centres. The study Population were female sex workers aged 18 years and above. 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; PrEP users had been on PrEP for at least six months at the time of recruitment. The Female Sex worker must have been in sex work while residing in Nairobi County for at least six months. Both HIV PrEP users and non- PrEP users participated. Adherence to PrEP medicines should have been at least at 85% as recorded in clinic encounter forms. FSWs less than six months' in commercial sex work and PrEP users with less than six months PrEP use were excluded from the study. FSWs not residing in Nairobi County, those using oral PrEP but were screened positive for STI during enrolment into the DICES/prevention centres cohorts and known HIV positive status were excluded. Other exclusions included; inadequate client history, Use of any other HIV prophylaxis technology and any participants accessing HIV and other STIs preventive and curative services at any other DICE/Prevention centre or health facility other than the one she had been selected to participate in the study.

Study Design and Sampling

A retrospective cohort study that employed quantitative data collection methods was conducted among the FSWs comprising both HIV oral PrEP users and non- PrEP users. A multi stage random sampling was espoused. Out of the 9 sub counties hosting DICES, one third were selected by simple random sampling. One third of the 22 DICES/Prevention centres (7 DICES/prevention centres) were selected by simple random sampling. The number of participants per DICE/prevention centre was allocated proportionately according to the total numbers of FSWs in each site's cohort. A simple random sampling was done using the key population listing. Equal number of participants; PrEP users and non-PrEP users were recruited at each site.

Data collection, management and analysis

A Quantitative data collection method was adopted. Data was collected using a data abstraction tool containing data elements that answered the questions on STI incidence and prevalence of bacterial STIs questions. The tool was adopted from the Kenya Ministry of Health (NASCO) Key Populations Monitoring and Evaluation tools (NASCO, 2014).

Research assistants were trained on data abstraction tool, abstraction process, documentation and data management before the study commenced. Each data elements listed in the data abstraction tools was obtained from every participant records. A data abstraction tool was filled for each participant. Equal number of files for the active PrEP and non-PrEP clients were identified. The clients' unique identifiers on every file were randomly sampled for participation. Clients' participants were identified and withdrawn from the shelves. The participants of the respective files were called to the DICE/Prevention centre for consenting. Once consent was obtained, a systematic six months' retrospective data abstraction from the treatment records of each participant was done to identify the incidences of STIs as recorded in the patients past six months' records. Only the clients who were 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. At the time the clients were enrolled at the DICE/Prevention Center, they were free from STIs so that an STI free client were followed up for STI incidences in the cohort of PrEP and non-PrEP female sex workers.

The participants' records remained under lock and key during the entire study period. Data was analyzed using statistical software STATA (STATA, 2016) and Microsoft excel. Relative risk and Rate were determined as measures of association between PrEP use and STI rates. The rate of STI among the female sex workers who use PrEP and that of those who did not use PrEP. Relative STI risk was therefore computed to establish whether the use of oral PrEP increases female sex workers risk of acquiring STI. Consequently, the level of statistical significance of hypothesis was determined.

Ethical considerations

Ethical approval was obtained from the Kenyatta National Hospital- University of Nairobi Ethical Review Committee (KNH-UoN ERC No: P876/12/2018). An approval was obtained from the JKUAT Board of Postgraduate Studies (BPS), and authorisation from the partners implementing prevention services at the DICES/prevention centers. Informed consent was obtained from all eligible participants after the disclosure of all the information pertaining the study. There were no physical risks involved in the study.

RESULTS

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- PrPEP 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 are 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 as illustrated in (Table 4.1), 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 a 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 solely as their occupation while 155(92.3%) of non-Prep users had sex work as their sole occupation, as shown in (Table 1).

Table 1: Socio-demographic characteristics of Female Sex Workers 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 <	84 (50.6)	78 (47)

Secondary School	80 (47.6)	85 (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	1 (1.8)	0(0)

FSW- Female Sex Workers; PrEP- Pre-exposure Prophylaxis

Common bacterial STIs affecting female Sex workers, both PrEP and non-PrEP users

Common Sexually Transmitted Infections that were identified among the female sex workers were arranged in order of most common to the least common STIs. As shown below, vaginitis 62 (52.1%) was the most commonly experienced STI among the respondents. Cervicitis was equally common with 26 (21.8%) cases reported among the respondents. Pelvic Inflammatory Disease (PID) caused by Gonorrhea and Chlamydia infections 10 (8.4%) cases were reported. Five cases of syphilis and Chancroid were also reported among the respondents. Non-bacterial STI cases were as well reported including; Genital warts 9 and Herpes Simples, 7. A composite prevalence of STIs among FSWs was determined to be 35.4% while the pooled incidence rate was 70.8 per 100-person time (Figure 1).

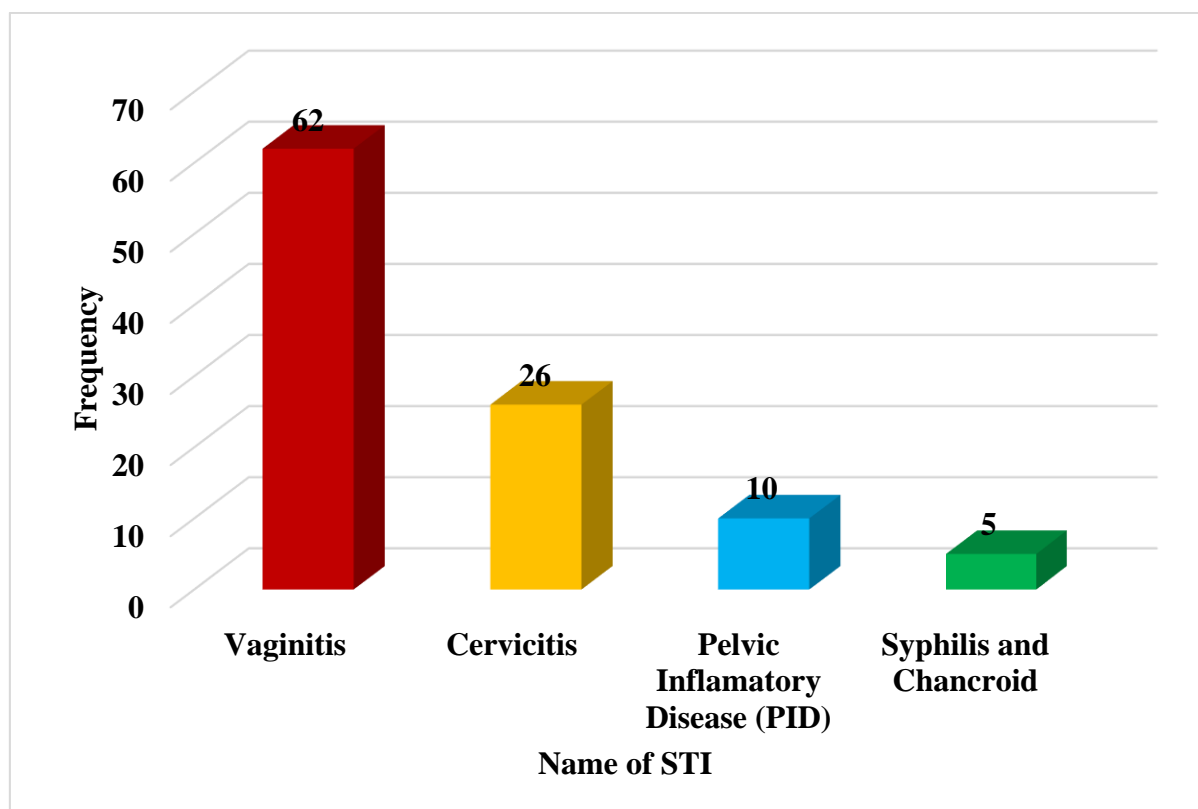


Figure 1: Common STIs Identified among the Female Sex workers in Nairobi County

Risk of STIs among 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. All the 336 participants were free from any STI at the beginning of the study. All the participants who were screened positive for any STI at the entry point were excluded from the study. Generally, higher number or STI cases among FSWs using HIV oral PrEP were observed in visit 4 (16), visit 5 (21) and visit 6 (13); compared to cases observed among non-PrEP users, in Visit 4 (10), visit 5 (8) and visit 6 (7). Cases of STIs in the second and third visits were fairly the same in both PrEP users 7 and 13; and non-PrEP users 9 and 14 with the difference in the STI rates having P-values exceeding 0.05 (Table 2)

Table 2: Risks of STIs among Female Sex Workers in Nairobi County

	Initiated on PrEP (%)		P-value
	No	Yes	
Treated for STI at Baseline			
No	168 (100)	168 (100)	
Yes	0	0	
Treated for STI at Month 2			
No	159 (94.6)	161 (95.8)	0.608
Yes	9 (5.4)	7 (4.2)	
Treated for STI at Month 3			
No	154 (91.7)	155 (92.3)	0.841
Yes	14 (8.3)	13 (7.7)	
Treated for STI at Month 4			
No	158 (94.0)	152 (90.5)	0.221
Yes	10 (6.0)	16 (9.5)	
Treated for STI at Month 5			
No	160 (95.2)	147 (87.5)	0.012*
Yes	8 (4.8)	21 (12.5)	
Treated for STI at Month 6			
No	161 (95.8)	155 (92.3)	0.167
Yes	7 (4.2)	13 (7.7)	

*Chi-square.

STIs- Sexually Transmitted Infections

STI Cases distribution over time

All the respondents were enrolled into the study at time zero with no STI infections. STI cases were observed over six months in both the PrEP and non-PrEP groups. More cases of STI were observed in non-PrEP users than in PrEP users in the first two months, post enrolment but cases among PrEP users increased steadily through to month five with a slight slump in month six. There was a reduction in STI cases among non-PrEP users from month three through to month six, (Figure 2).

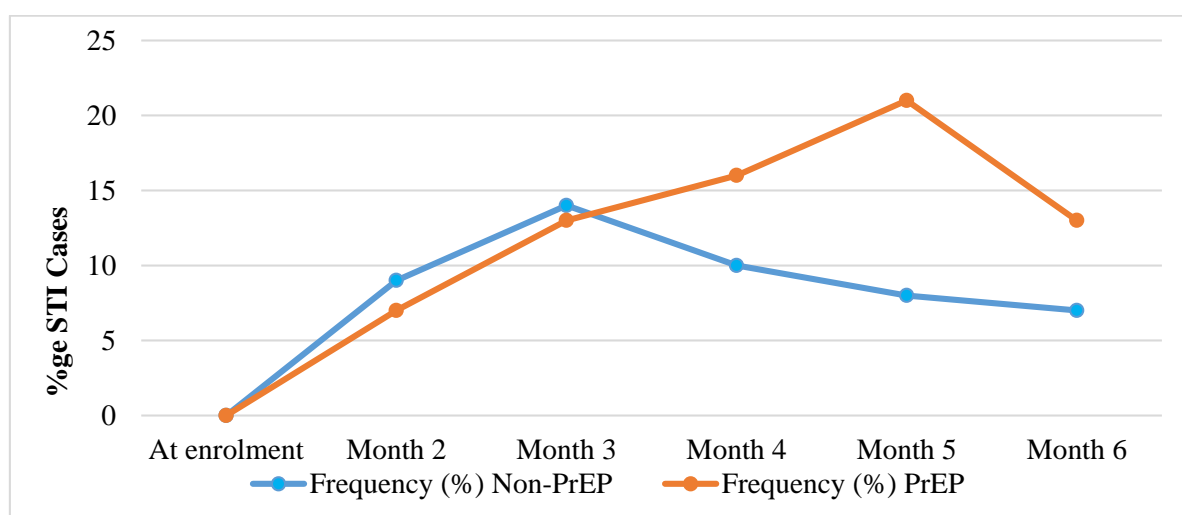


Figure 2: Distribution of STI cases through six months cohort among Female Sex Workers in Nairobi County

Sexually Transmitted Infection risk across socio demographic characteristics of FSWs in Nairobi County

The risk of acquiring STI across the socio demographic components and among the Female sex workers using PrEP for HIV prevention vary. HIV PrEP users are at 1.7 times higher risk of acquiring STIs, with P value of 0.064 at 95% confidence level, compared to female sex workers who do not use PrEP. Female sex workers who are widows are up to 8 times at higher risk of

STIs with P value of 0.002 (95% confidence level); while divorced/separated female sex worker are 3.4 times at higher risk of STI with P value of 0.001 (95% cl). No association was observed between the number of children FSW has and STI rate, however, increased number of sexual acts is associated with increased rate of STI (P value 0.012, 95%cl). This study did not find enough evidence to demonstrated association of condom use and increased STI risk (P 0.49, 95%cl), (Table 3)

Table 3: The risk of acquiring STIs among Female Sex Workers in Nairobi County

Variable	Haz. Ratio	[95% Conf. Interval]		P> z
Age	0.9996828	0.953552	1.048045	0.989
PrEP_use				
No	Ref.			
Yes	1.7085	0.769181	3.03919	0.064
Marital_status				
Married	0.8929631	0.27018	2.951307	0.853
Divorced/separated	3.393102	1.684423	6.835063	0.001
Widowed	8.220776	2.215328	30.50616	0.002
Number of children				
No_sexual_acts	1.150505	1.031008	1.283852	0.012
Condoms_use	0.9522935	0.828166	1.095025	0.493
occupation				
Bar Attendant	0.0308725	0.001777	0.536417	0.017
FSW	0.0683646	0.008699	0.537265	0.011
House help	2.73E-17	0	.	1
Saloonist	0.2722763	0.016813	4.409477	0.36

PrEP- Pre-exposure Prophylaxis; FSW- Female Sex Worker

Sexually Transmitted Infection risk among PrEP users

The risk of acquiring STI vary between the FSWs taking oral PrEP for HIV prevention and FSWs who do not take PrEP. The hazard ratio for STI between FSWs who do not use HIV oral PrEP and FSWs using oral PrEP for HIV prevention is 1.7085 with standard error of 0.494863, Z of 1.85 and P value of 0.064 at 95% Confidence Level. FSWs taking HIV oral PrEP are therefore 1.7 times higher risk of acquiring STIs than the FSWs who do not take PrEP. The significance level of acquiring STI while taking oral PrEP for HIV prevention is 0.064 at 95% confidence interval.

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 risk 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 beyond the study timeline. STI risk among the Non-PrEP users looks considerably lower than that of PrEP users and does not increase so significantly as compared to that of PrEP users (Figure 3).

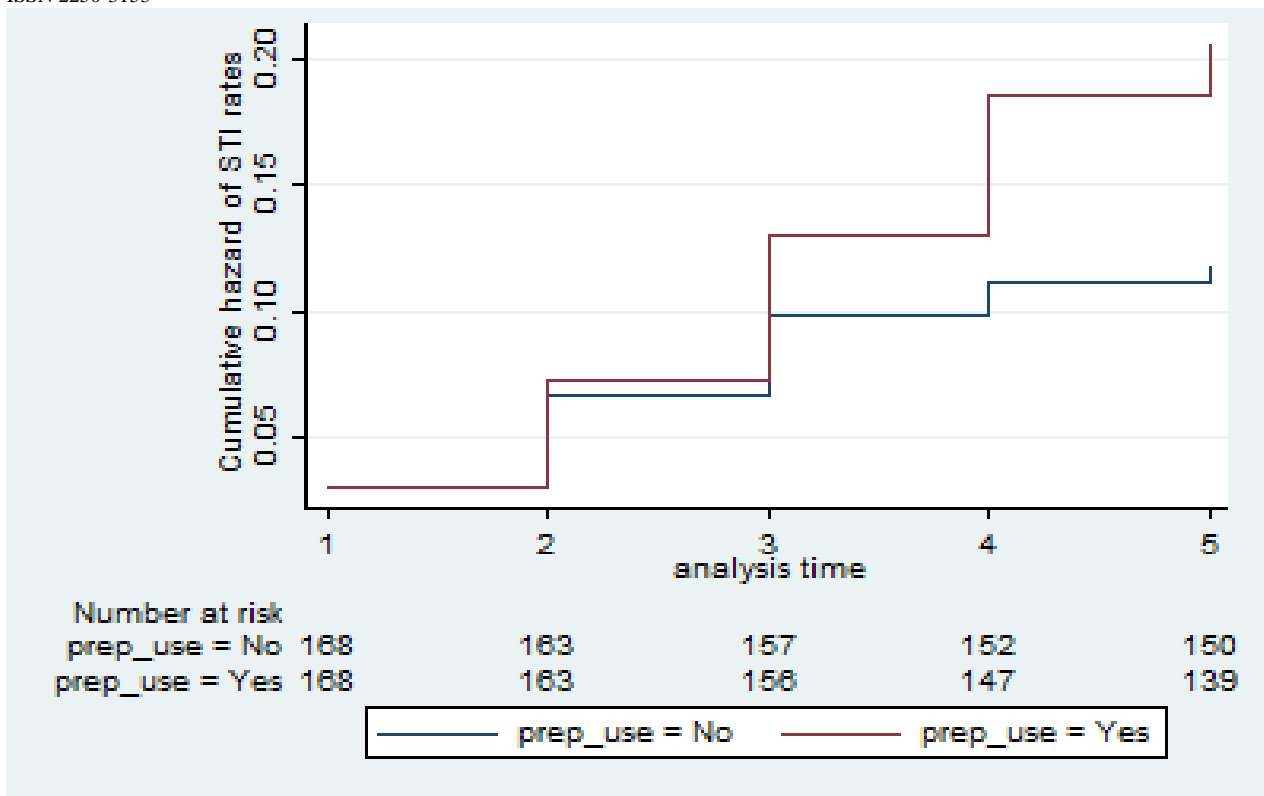


Figure 3: Cumulative hazard of contracting STI over time between the FSW who used PrEP and the FSW who did not use PrEP for HIV prevention in Nairobi.

DISCUSSION

Common Sexually Transmitted Infections affecting female Sex workers

According to this study, 52.1% of STIs affecting Female Sex Workers is as a result of Vaginitis which is caused by mixed microorganisms including; bacteria, yeast and trichomonas, but is predominantly caused by bacterial vaginosis (CDC, 2015), (Papp *et al.*, 2017b). Another common STIs seen in this study is cervicitis which can be caused by gonorrhoea, chlamydia or trichomonas (Katz *et al.*, 2012); and pelvic inflammatory disease (PID) which is mainly as a result of gonorrhoea and chlamydia infections. Meta-analysis and systemic reviews have suggested pooled prevalence for composite outcome of clamydia, gonorrhoea and early syphilis to be 23.9% (Ong *et al.*, 2019), which agrees with the findings of this study. A few participants were also diagnosed with syphilis and chancroid. These findings are consistent with WHO declaration of gonorrhoea as a global health concern. The findings of this study is also coherent with (Mayer *et al.*, 2014) findings in which 32.8% of bacterial STIs were diagnosed among participants using PrEP for HIV prevention. Studies have demonstrated pooled incidence rate of over 70 per 100 person years during PrEP follow up (Ong *et al.*, 2019) which compares with the finding of this study that revealed a pooled STI incidence rate of over 70 per 100 person years.

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 in another study, 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 possibly be explained by other factors other than behavior change.

Cumulative hazard of contracting STIs among the HIV oral PrEP users was very low at the first month but increased consistently over the studied period whereas the cumulative hazard of STI among the non-PrEP users was slightly higher than that of non-PrEP users at the beginning but remained low with very slight increase over time, similar to (Kojima *et al.*, 2016) meta-analysis in which the STI incidence rate ratio was over 25 times that of non-PrEP users, however, the STI hazard ratio between PrEP users and non-PrEP users was lower in this study. While (Liu *et al.*, 2016) has demonstrated an overall high STI incidences but did not increase over time among MSM using PrEP for HIV prevention, this study has 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 demonstrate high composite incidence rate (72.2. per 100-person time) and polled prevalence of STIs of 23.9%. These findings are however contrary to the findings of (Mattson *et al.*, 2008) which demonstrated insignificant difference in the rate of gonorrhoea, chlamydia, and trichomona infections in a randomized clinical trial between the circumcised and uncircumcised males participants.

In this study the hazard ratio of acquiring bacterial STI given that one is taking oral PrEP for HIV prevention is above one indicating that persons taking HIV oral PrEP are 1.7 times at higher risk of acquiring STIs than non-PrEP users, similar to (Hoorneborg *et al.*, 2019). The finding of this study on the association between HIV oral PrEP and incidences of STIs is insignificant and demonstrates that inconclusive inference can be made to support higher rate of STIs among PrEP users than non-PrEP users. This finding is contrary to the findings of (Montaño *et al.* 2017) which demonstrated up to 20 time higher rates of STIs among PrEP users than non-PrEP users, but the finding is in agreement with (Jenness *et al.*, 2017) demonstrated in a mathematical modelling that STI diagnosis would increase initially but fall within one year of PrEP use and is as well consistent with the findings of (Freeborn & Portillo, 2017).

Conclusions and recommendations

Vaginitis, cervicitis and pelvic inflammatory disease (PID) caused by gonorrhea, chlamydia or trichomonas, are the most predominant STIs identified among FSWs. This study has recorded high composite prevalence of STIs among FSWs in Nairobi County. The study has also demonstrated an increasing trend of bacterial STIs incidences and cumulative hazard rate among FSWs using oral PrEP for HIV prevention over the six months study period, whereas the STI incidence rate and cumulative hazard rate among the non- PrEP respondents has displayed a very slight increase with decrease in STI incidences as the study progresses over the same period. The STI hazard ratio between FSWs using HIV oral PrEP and non-PrEP users demonstrates that PrEP users are up to 1.7 times at risk of STI than non-PrEP users, but statistically insignificant (0.064, 95%CI). Therefore, this study does not have enough evidence to demonstrate that the use of HIV oral PrEP for HIV prevention among female sex workers increase risk of acquiring STIs.

STI prevention counselling should be emphasized during HIV PrEP initiation and during follow up; including advocating for combination prevention involving condom use alongside PrEP, and reducing the number of sexual acts per day to minimize STI exposure. Need to tailor STIs prevention intervention among HIV oral PrEP users and other non-PrEP using key populations according to their behavioural profile. Longitudinal cohort study that will run for at least one year to be conducted and diagnosis of sexually transmitted infections done using biological samples.

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