Retention in HIV care among female sex workers on antiretroviral treatment in Lusaka, Zambia: A retrospective cohort study

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May 30, 2020
KEY WORDS

Adherence

Antiretroviral Therapy

Key Populations

Lost-to-follow-up

HIV/AIDS

Retention

Lusaka

Zambia
DECLARATION

I declare that “Retention in HIV care among female sex workers on antiretroviral treatment in Lusaka, Zambia: A retrospective cohort study” is my own work and that it has not been submitted for any degree or examination in any other university and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

Name: Clement Mudala Bwalya

Signature: 

Date: May 30, 2020
DEDICATION

I dedicate this thesis in memory of my late mother, sister and father. To my late mother and father, they valued education as a stepping-stone to success.

To my wife and my three daughters, this one is for your patience and sacrifice while I dedicated my time to study. I love you all
ACKNOWLEDGEMENTS

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Also, I would like to extend my gratitude to FHI 360 under USAID Open Doors project for their valuable support to allow me to use data to conduct this study.

Further, I would like to thank my family for their support and encouragement in completing this thesis. To my wife, Alice Lungu Bwalya, and our daughter Mwelwa, Chengelo, and Chichetekelo, thank you for your sacrifice and love during the completion of the thesis.
# LIST OF ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbr</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>ART</td>
<td>Antiretroviral Therapy</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>CD4</td>
<td>Cluster of Differentiation 4</td>
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<td>CSO</td>
<td>Central Statistics Office</td>
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<td>FSW</td>
<td>Female Sex Worker</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>KP</td>
<td>Key Population</td>
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<td>LTFU</td>
<td>Lost-To-Follow-Up</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>ODP</td>
<td>Open Doors Project</td>
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<td>PLHIV</td>
<td>People living with HIV</td>
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<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
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<tr>
<td>SOPH</td>
<td>School of Public Health</td>
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<tr>
<td>UWC</td>
<td>The University of the Western Cape</td>
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<tr>
<td>UNAIDS</td>
<td>United Nations Program on HIV/AIDS</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Developement</td>
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<td>WHO</td>
<td>World Health Organization</td>
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ABSTRACT

Background: HIV/AIDS remains a major public health issue that is affecting all population groups and communities in Zambia. Among the most affected groups are key populations (KPs) such as female sex workers. KPs are considered at high risk of contracting HIV but have limited access to HIV services and retention in care due to internalized stigma, discrimination, criminalization, and negative attitudes towards HIV treatment. Under the USAID Open Doors project in Zambia, KPs access comprehensive HIV prevention, care and treatment services. The test and treat strategy is implemented by the project in support of the UNAIDS 90-90-90 targets by 2020 to diagnose 90% of people living with HIV, put 90% of them on treatment, and for 90% of them to have suppressed viral load.

Aim: This study aimed to determine retention in care among female sex workers (FSWs) in the first six months after ART initiation using the HIV care cascade.

Methodology: A retrospective cohort study was conducted of all new HIV positive female sex workers (FSWs) initiated on ART between October 2018 and June 2019 (9 months period) based on the electronic records. Data were extracted from SmartCare, an electronic health record system used by the ART clinic. Microsoft Excel and Epi-Info 7 software were used for data entry and analysis. Kaplan–Meier survival analysis was conducted to examine differences in retention rates.

Results: A total of 205 FSWs were initiated on ART, out of which 180 were active on ART (36 youths and 144 adults) and 25 were lost to follow-up (four youths and 21 adults) during the 9 months study period. Of the 180 FSWs active on ART, 36 were FSWs aged 18 – 24 years (youths) representing 90% retained in care while 144 were FSWs aged 25 – 42 years (adults) with 87% being retained on ART treatment. Retention in ART care was not significantly different in the survival curves between the age groups of FSW youths and FSW adults during the study period (p-value = 0.637). Retention in ART care was not statistically significant for education (p-value = 0.481), marital status (p-value = 0.545), and occupation (p-value = 0.169).

Conclusion: Retention in ART care among FSWs was 88%. However, there were no significant differences by age group identified in this study. While this study shows 88% retention rate among FSWs, it will be used as a baseline in meeting the UNAIDS 90-90-90 goals.
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CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

Globally, 37.9 million people were living with HIV in 2018 with 23.3 million people accessing antiretroviral therapy (UNAIDS, 2019). Of those that were living with HIV, 79% knew their status, 62% were accessing treatment and 53% were virally suppressed (UNAIDS, 2019). Further, there were 1.9 million new infections among adults in the world (aged 15 years and above) with 45% accounted for by key populations (sex workers, men who have sex with men, transgender people, people who inject drugs, and prisoners) and their sexual partners. Among the new HIV infections, 9% were sex workers (UNAIDS, 2018).

The key populations (KPs) and their sexual partners accounted for 54% of new HIV infections globally, 25% of new HIV infections were in Eastern and Southern Africa (UNAIDS, 2019). In Eastern and Southern Africa, there were 20.6 million people living with HIV and 13.8 million (67%) on antiretroviral therapy (UNAIDS, 2019). Among the KPs, the risk of acquiring HIV compared to the general population is 21 times higher for sex workers (UNAIDS, 2019).

According to the Zambian Demographic and Health Survey 2018, 11.1% of persons aged 15 – 59 years are infected with HIV with women having higher HIV prevalence of 14.2% compared to 7.5% among men (Zambia Statistics Agency, Ministry of Health Zambia, and ICF, 2019). HIV epidemic is geographically diverse and varies across provinces. Specifically, HIV prevalence is 12.4% in the Central Province, 15.4% in the Copperbelt Province, 15.1% in the Lusaka Province, 12.4% in the Southern Province, and 6.1% in the North-Western Province (Zambia Statistics Agency, Ministry of Health Zambia, and ICF, 2019). Data on HIV prevalence among KPs is unknown and scarce (AVERT, 2020), but, an Integrated Biologic and Behavioral Surveillance (IBBS) study among female sex workers (FSWs) found that HIV prevalence ranged between 46% - 73% in five districts (FHI 360, 2015). While this information on HIV prevalence exist, sex work and same sex relationships are illegal in Zambia. Strides have been made to recognize KPs (such as FSWs) through the Zambia National HIV and AIDS Strategic Framework 2017-2021 (NASF 2017-2021).

As part of the strides to accelerate HIV epidemic control, the UNAIDS 90-90-90 provided targets as follows: 90% of persons living with HIV knowing their HIV status, 90% of persons who test positive for HIV start on treatment, and 90% of those on treatment to achieve viral load suppression to undetectable levels (UNAIDS, 2014). Further, UNAIDS has advocated for leaving no one behind through the Sustainable Development Goals (SDGs). In particular,
SDGs 3 encourage universal health coverage for all, and SDG 10 reducing inequality especially among KPs to avert high HIV prevalence (UNAIDS, 2020). In 2017, Zambia introduced the “test and treat” strategy in support of the UNAIDS 90-90-90 and recommended for all HIV infected individuals to be put on treatment and care immediately regardless of CD4 cell count (WHO, 2016). Therefore, HIV positive persons no longer wait for their CD4 count to drop to a certain level before starting treatment. Further, the strategy supports universal routine HIV testing, counselling and treatment in all public and private health facilities in Zambia. Since the implementation of the “test and treat” strategy, Zambia has seen a significant increase in the people starting HIV treatment from 23,000 in the first quarter of 2016 to 45,000 in the final quarter of 2017 (UNAIDS, 2019).

1.2 PROBLEM STATEMENT
Retention is a critical determinant of adherence as patients must be actively attending and participating in an ART programme to receive their medications and to have their HIV clinical indicators monitored. However, limited data exists on the retention of HIV care and treatment among HIV positive FSWs in sub-Saharan Africa (Lancaster et al., 2016). A study by Koirala et al. (2017) found that KPs (including FSWs) living with HIV are less likely to be retained in HIV care due to internalized stigma due to sex work and sexual orientation, discrimination, legal environment and criminalization, and negative attitudes towards HIV treatment. Further, Smart (2011) adds that adherence to treatment and retention in care are critical components of HIV treatment and management. Among KPs living with HIV poor adherence can result in negative health outcomes and treatment-resistant strains of the virus (Palella et al., 2003; Jensen-Fangel et al., 2004; and Bangsberg, Moss, & Deeks, 2004). Furthermore, UNAIDS (2019) recognized that the most affected population group are FSWs that remain vulnerable to HIV in contrast to other adult populations. Therefore, it is important for FSWs to test for HIV, prevent HIV transmission and suppress the virus through adherence to treatment and retention in care.

1.3 PURPOSE OF THE STUDY
To date, limited or no studies have been done regarding retention in HIV treatment programs in Zambia among FSWs. The purpose of this prospective cohort study was to provide critical information on the current levels of retention in care, adherence to treatment, and loss to follow-up among FSWs on antiretroviral therapy. There is no local data that exist on the number of FSWs that are on treatment in Zambia. Little is known about HIV prevalence and factors that influence adherence to treatment and retention in care among FSWs in Zambia. The study will
benefit programme managers and policy makers in Zambia to inform the scaling up and strengthening of ART programmes in resource constrained settings targeting FSWs. In addition, the findings will be used to advocate for FSW rights to access freely HIV and ART services.

1.4 THESIS OUTLINE

This thesis is structured in six chapters beginning with an introduction to the study in chapter one above providing an overview of HIV and treatment coverage globally, sub-Saharan Africa, and Zambia in particular. In addition, the introductory chapter describes challenges of ART retention and looks at the purpose of the study. Chapter two looks at literature review focusing on the definition and overview of retention in HIV care, and individual and interpersonal factors affecting KPs retention in HIV care. Chapter three focuses on the study methodology including the study design, study population and sampling, data collection processes, data management and data analysis, as well as the validity and reliability. Conclusion of chapter 3 looks at ethical considerations for the study. Chapter four outlines study results comparing retention rates among youth and adult female sex workers and factors affecting retention such as age, education, occupation, and marital status. Chapter five highlights discussions based on the results in chapter four. Finally, the thesis is completed in chapter six with conclusions to the study and recommendations.
CHAPTER 2: LITERATURE REVIEW

2.1 DEFINITION OF RETENTION IN HIV CARE

Stricker et al. (2013:466) defined retention in care as “a client’s continued engagement in health services and captures the whole ‘continuum of HIV care’: from enrolment in care to discharge/death of the client, and adherence to treatment as the extent a client follows a prescribed medication or treatment regimen”. Retention in care' implies regular engagement with medical care, once entered into the system (Geng et al., 2010; Roscoe and Hachey, 2019). The World Health Organization (2012) defined ‘Retention in HIV care’ as engagement in care, when an eligible HIV positive person is linked to treatment, put on ART and retained in care services.

2.2 OVERVIEW OF RETENTION IN HIV CARE

Retention in care remains a major challenge in many African countries affected by HIV including Zambia. The risk of non-retention in care and adherence to treatment may result in increased sickness and death (MoH, 2014). According to Layer et al. (2014), severe illness at the time of HIV diagnosis prompts linkage to care. There are several benefits of retention in HIV care for both individuals and communities such as improved clinical outcomes, reduced transmission of HIV, lower healthcare costs and increased access to ART (Zulliger et al., 2015).

Adherence and retention are interconnected as they focus on reducing new HIV infections and improve health outcomes. According to Stricker et al. (2013) the best health outcomes are attained when a client adheres to HIV treatment and is retained in care. This can be achieved when the drugs are available to the client. Laibon et al. (2016) argued that non-adherence to ART treatment has the potential for an increased HIV burden, new HIV infections, and a strain on the country’s health targets. Adherence to treatment is about a person’s conduct in taking ART medication while retention is about a person remaining in an HIV treatment program (Holtzman, Brady and Yehia, 2015).

Stricker et al. (2013) noted that 226,307 clients in sub-Saharan Africa were retained in care at varying rates depending on the treatment duration as follows: 86.1% at 6 months; 80.2 % at 12 months; 70.0 % at 24 months; and 64.6 % at 36 months. Graham et al. (2013) recorded that among 58 participants who were followed on ART, 40% of MSM had less than 95% adherence, versus 28.6% of heterosexual men and 11.5% of women. A study by WHO (2012) in Malawi compared retention in care between patients on pre-ART and ART at these intervals one month
(pre-ART 25% versus ART 99%), two months (pre-ART 18% versus ART 97%), three months (pre-ART 11% versus ART 95%) and six months (pre-ART 4% versus ART 90%).

A study by Lancaster et al. (2016) noted that among the HIV positive FSWs, ART initiation ranged from 19% in Kenya to 48% in Rwanda. While among the 268 HIV positive FSWs in the Dominican Republic in treatment for 6 months, 92% attended HIV care while 37% reported missed visits (Zulliger et al., 2015). In Burkina Faso, among FSWs initiated on ART in the first six months 80% achieved adherence of 95% measured by pill count (Lancaster et al., 2016). This was different in Rwanda where 30% FSWs missed taking their pills after ART initiation (Lancaster et al., 2016).

According to Januraga et al. (2018), KPs that had graduated from high school and beyond were more likely to start ART than those without high school education. A study by Januraga et al. (2018), found that among 831 KPs enrolled, 703 were linked to HIV care and only 606 who were linked to care started ART, with 457 being retained in care, while 294 had viral suppression. Similarly, Vuylsteke et al. (2015) observed these retention rates 75% at 6 months, 68% at 12 months, 55% at 24 months, and 47% at 36 months among sex workers attributed to attrition due to lost to follow-up.

Retention in HIV care remains a challenge among KPs who are disproportionately affected by HIV and confront stigma and other barriers to health services such as attitudes, and disrespectful and abusive treatment by health care providers (Zulliger et al., 2015; Layer et al., 2014).

2.3 INDIVIDUAL FACTORS AFFECTING FSW IN CARE

According to Koirala et al. (2017), KPs that are living with HIV are less likely to be retained in HIV care due to internalized stigma, discrimination, criminalization, and negative attitudes towards HIV treatment. FSWs failure to be retained in HIV care is because of high mobility, limited information about HIV/AIDS services, misconceptions about HIV negative results, drug abuse, fear of HIV positive results and stigma (Wanyenze et al., 2017; Lancaster et al., 2016). FSWs are vulnerable to loss to follow-up (LTFU) due to this population’s low willingness to self-identify as FSWs (Su et al., 2016). A study in Rwanda and Swaziland among FSWs attributed lack of adherence to treatment due to hunger (Lancaster et al., 2016). Similar observations were made among young KPs such as poverty as barriers to HIV care and treatment (Lall et al., 2015).

Further, self-stigma related to sex work and alcohol abuse have been attributed to affect retention in HIV care among FSWs (Zulliger et al., 2015). Among female and male sex
workers, factors affecting retention as a result of LTFU were limited education, mobility, and lack of adherence to counselling (Vuylsteke et al., 2015).

Kamacooko et al. (2020) survival curve for the time to LTFU after ART initiation during the 12 months follow-up period was 90%. Kamacooko et al. (2020) used the age at ART initiation, marital status, highest level of education attained, current job, and behavioural characteristics in determining factors affecting LTFU. In addition, Kamacooko et al. (2020) used the Kaplan-Meier technique to estimate time to LTFU after ART initiation, and multivariable cox proportional hazards model for predictors of LTFU. Similarly, Lilian et al. (2020) used Kaplan Meier survival analysis and multivariate logistic regression to assess LTFU at six months comparing those initiated on the same day in ART and those initiated later on ART. Those that were initiated on the same day 30.1% were LTFU while 22.4% were LTFU among those initiated on ART after 1-7 days (Lilian et al., 2020). Furthermore, Lilian et al. (2020) observed that increase in age reduced LTFU (adjusted odds ratio = 0.97, p = 0.001).

A study conducted by Lall et al. (2015) among HIV-positive youth and adolescents KPs found that age influenced adherence to ART. While Januraga et al. (2018) noted that older patients were less likely to be lost to follow-up than younger patients. However, Lancaster et al. (2016) observed that there was little to no association between age and adherence to ART.

Filimão et al. (2019) used Kaplan Meier estimates to assess adherence to ART pick-up, and cox proportional hazards model to determine factors associated with non-adherence. According to Filimão et al. (2019), the likelihood of being non-adherent to ART pick-up was 50% after initiation at 166 days. Further, Filimão et al. (2019) observed that being widowed was associated with higher adherence to ART pick-up than other marital status (p = 0.01).

Adeniyi et al. (2018) concluded that marital status was an independent predictor of adherence. Similar conclusion was made by Bam et al., (2015) who found that about 83% of the married people adhered to ART compared to other marital status (divorced, separated, unmarried). The observation made by Adeniyi et al. (2018) and Bam et al. (2015) are not supported by Shigdel et al. (2014) who believes that there is no significant association between marital status and adherence to ART.

In their study, Nachega et al. (2014) observed that HIV-infected individuals who were employed were more likely to adhere to ART than the unemployed ones. This is different from the conclusion made by others who observed that those who were unemployed had high adherence levels than the employed (Okoronkwo et al., 2013; Saha et al., 2014).

According to Eyassu et al. (2016), ART adherence increased with someone’s level of education. Eyassu et al. (2016), concluded that non adherence was associated with lack of
education attributed to level of understanding and knowledge of the patients. However, Adeniyi et al. (2018) and Bam et al. (2015) observed that high level attainment of education was associated with low adherence to ART among FSWs.

2.4 INTERPERSONAL FACTORS AFFECTING KP RETENTION CARE

2.4.1 Health system factors

Ndori-Mharadze et al. (2018) pointed out that HIV positive FSWs are at greater risk of poor linkage to treatment and retention in care due to stigma and discrimination experienced within healthcare settings. Further, KP stigma, discrimination, criminalization, poor nutrition, food insecurity, marginalization and mobility may contribute to poorer retention in care (Charurat et al., 2015; Ibiloye et al., 2018; Lyons et al., 2017). Lillie et al. (2018) observed limited drug supply (one month) given to KPs as a barrier to retention, as well as rigid appointment schedules and the long waiting time at the clinics. Nakanwagi et al. (2016) observed some of the barriers to linkage in care among FSWs as negative attitudes of health care providers (HCPs), perceived stigma, discrimination and rigid treatment policies.

2.4.2 Societal factors

Wanyenze et al. (2017) identified societal factors affecting retention in care as community stigma related to sex work, fear of being identified as HIV positive among fellow sex workers, community members and HCPs. Furthermore, other factors observed were privacy at the facility, misconceptions (ARVs kill fast, weaken and disrupt work), limited access to PrEP, inappropriate operating hours, lack of support and skills among HCPs to handle post-violence, existing legal environment that impede same sex relations among consenting adults, and stigma and discrimination (Laibon et al., 2016; Nakanwagi et al., 2016; Wanyenze et al., 2017). KPs attributed missing HIV medication to long distance to the health facility, and limited supply of the drugs (Laibon et al., 2016). Sex work and same sex relations are criminalized in many countries including Zambia (Laibon et al., 2016). Arrests by the law enforcement agencies exacerbated retention in care (Wanyenze et al., 2017).
CHAPTER 3: METHODOLOGY

3.1 AIM
This study aimed to determine retention in care among female sex workers (FSWs) in the first six months after ART initiation using the HIV cascade.

3.2 OBJECTIVES
• To describe baseline sociodemographic and clinical characteristics of FSWs on ART.
• To determine the retention rate among HIV positive FSWs on ART at 1, 3 and 6 months.
• To determine factors associated with retention in care among HIV positive FSWs on ART.

3.3 STUDY DESIGN
A retrospective cohort study design was conducted by reviewing electronic records of FSWs initiated on ART at the USAID Open Doors Wellness Centre in Lusaka, Zambia between October 2018 and June 2019. The reasons for this study design were to provide a baseline statistic and evaluate retention in care among FSWs in the first six months after ART initiation using the HIV cascade.

3.4 STUDY SETTING
The study was conducted at the USAID Open Doors Wellness Centre in Lusaka District of the Lusaka Province of Zambia. Lusaka is the capital city of Zambia and the most urbanized area in the country. According to the Central Statistics Office (2016), Lusaka had a population of 2,777,439. Lusaka has the second highest HIV prevalence of 15.1% in Zambia (Zambia Statistics Agency, Ministry of Health Zambia, and ICF, 2019). Lusaka District has seven constituencies: Chawama, Kabwata, Kanyama, Lusaka Central, Mandevu, Matero, and Munali (Lusaka City Council, 2019). All seven constituencies are covered by the USAID Open Doors project in Lusaka District.

The USAID Open Doors project operates eight wellness centres in these provinces and districts as follows: Central (Kabwe and Kapiri Mposhi), Copperbelt (Kitwe and Chililabombwe), Lusaka (Lusaka and Chirundu), North-Western (Solwezi) and Southern (Livingstone) provinces. The USAID Open Doors Wellness Centres are funded by the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) through U.S. Agency for International Development (USAID). The project is implemented by FHI 360 and through a local partner, Zambia Health Education and Communications Trust (ZHECT). The project supports increased access to and use of comprehensive HIV prevention, care and treatment among KPs facing the greatest infection risks, and yet they have the least access to HIV services because
their behaviour is often stigmatized, and even criminalized. Further, the project works with Community Resource Partners (CRPs) who are members of the key population to inform the design of tailored interventions which respond to their individual needs and KP community. This is in line with the UNAIDS principle of “Nothing for us without us”.

Specifically, the project targets female sex workers (FSW), men who have sex with men (MSM), and transgender (TG) people. Lusaka site has the highest population of KPs among the eight project sites (including a population size estimate of FSW at about 3,100).

The USAID Open Doors Wellness Centre in Lusaka is managed by health care providers (Clinicians, and Nurses) and supported by counsellors, KPs trained as peer educators and counsellors, and data entry staff. The Lusaka Open Doors wellness centre provides the following package of services: HIV testing and counselling (including self-testing); peer education and sensitization offered through KPs; condom and lubricants promotion and distribution; STI screening and treatment; reduce stigma and discrimination (health care provider training and sexual diversity training); access to other health/social services such as VMMC, cervical cancer, FP; gender based and intimate partner violence screening and support; referral to continuum of care for KPLHIV: SWs, MSM and TGs; alcohol and mental health harm reduction services; pre (PrEP) and post exposure prophylaxis (PEP); and strengthening linkages from communities to facilities.

In Lusaka, Ngombe Clinic is the main referral site for the Open Doors Wellness Centre that refers its clients for ART services. Ngombe Clinic staff support KPs with HIV and ART services.

3.5 POPULATION AND SAMPLING

All eligible adult female sex workers (FSWs) aged 18 years and older that tested HIV positive, enrolled and initiated on ART between October 2018 and December 2018 and followed up until June 2019 at the USAID Open Doors Wellness Centre and/or the Ngombe Clinic ART referral centre were registered in the study. The study used all-inclusive sampling because of size of the population and to give all FSWs an opportunity to be in the study (Babbie, 2008). Therefore, all eligible FSWs were included.

Inclusion: All New HIV positive FSWs that were aged 18 years and above and started treatment during the study period.

Exclusion: Known HIV positive FSWs regardless of age and ART initiation. In addition, new HIV positive FSWs aged below 18 years old and those without ART/SmartCare numbers. The study sample excluded FSWs who started ART before October 2018 and after December 2018.
The project electronic database had 205 FSWs that were eligible based on the set criteria for the study period of between October 2018 and December 2018 and followed up until June 2019.

3.6 DATA COLLECTION

3.6.1 Data collection procedure
The study used data collection tool as shown in appendix 1 to extract routine patient records that are kept by the project wellness centre in the electronic ART register via an excel export template. Further, the study collected clinical data from SmartCare, an electronic health record system used by the ART referral partner Ngombe Clinic. Each FSW has been assigned one ART number that is recorded both in the ART register and SmartCare. The ART number was used to correlate and complete data using a standardized data collection template for all FSWs using specific variables of interest. As part of ensuring confidentiality, no names or addresses were included in the extracted data from Microsoft excel. The study collected socio-demographic data from the project ART register while clinical characteristics were obtained from SmartCare.

The study collected the following: socio-demographic data (age, sex, gender, occupation, marital status, education level, ART start date); and clinical characteristics (CD4 count, WHO clinical stage, TB treatment, co-trimoxazole, ART start date, ART regimen at start date, ART regimen at last visit, date of LTFU, date of appointment kept - for those not LTFU, adherence level - drug refill visits, last pharmacy ART refill visit date - to determine time to discontinuation on ART, patient transferred out, and patient died).

3.6.2 Data collection tools
A data extraction form was used to collect data from both electronic ART register at the project wellness centre and SmartCare at the ART referral centre, Ngombe Clinic. A data extraction tool (see Appendix 1) was used for data collection.

Definition of Outcome Variables
o Retention in the ART program was defined as a visit to the clinic for at least one of the following services at least once in the past 3 months: clinical visit, laboratory monitoring and drug refill (pharmacy).

o Non-retention in the ART program was defined as patients who did not come to the clinic during the last 3 months and were not transferred out and/or have died.

o Loss to follow-up (LTFU) was defined as patients who missed clinical appointments and/or lost contact with the wellness centre or the ART referral facility for at least 3 consecutive
months, did not return, and are not known to have died. Loss to follow-up rates were calculated by dividing the number of individuals who were lost to follow-up for a given month by the number of appointments for that month.

### 3.7 DATA ANALYSIS

Microsoft Excel was used for data entry for this study for all FSWs that were initiated on ART treatment at the USAID Open Doors wellness centre and followed up for a period of 6 months. In addition, Microsoft Excel was used to depict descriptive statistics (frequencies and graphs). Descriptive statistics were used to characterize FSW characteristics: age, gender, length on ART, and retention in care at 6 months.

Also, data analysis was done using the Epi-Info 7 software. The retention rate was estimated using survival analysis methods. The Kaplan-Meier survival analysis with log-rank test was used to compare the survival curves between youths (18 - 24) and adult (25 - 42) female sex workers at 1, 3, and 6 months retention rates. No finite population corrections were applied when estimating the retention rates. Kaplan-Meier curves were constructed using these conventions:

- FSWs retained in the program were censored at their date of last clinical visit, laboratory monitoring, or drug refill, whichever is the latest (“last visit date”).
- FSWs who were transferred out were censored at the date of transfer.
- Deaths were considered as discontinued (event) at date of death (or last visit date if death date is unavailable or if death date > 3 months from the last visit date).

FSWs who did not come to the clinic during the last 3 months and were not transferred out and did not die were considered as discontinued from the ART program. As discontinuation time the last date of any of the 3 services (clinical visit, laboratory visit or pharmacy visit) was applied.

FSWs who did not receive an ART drug refill during the last 3 months, and were not transferred out, were considered as discontinued from ART. The date of last ART refill, if not within the last 3 months, was considered the date of ART discontinuation.

In addition to estimation of the retention rates, predictors of overall retention in care were examined. Predictors of retention in the program were assessed using a Cox regression method (Cox-proportional hazards model) at the wellness centre to analyze difference in retention between youths (18 - 24) and adult (25 - 42) female sex workers. Possible predictors of retention, individual risk factors were assessed in the analysis including the demographic characteristics.
3.8 VALIDITY AND RELIABILITY

3.8.1 Validity
Because Inclusive sampling was used for the study. All FSWs had an equal chance of being selected from the electronic database based on the inclusion and exclusion criteria. Also, selection bias was minimized as all FSWs aged 18 years old and above who started ART at the wellness centre were included in the study. A standardized tool for data collection (see Appendix 1) was piloted to reduce measurement error. In addition, the study researcher engaged with the data entry clerks and their supervisors at the wellness centre and the ART referral facility that capture the data into the electronic database and monitor the ART FSW data for accuracy and completeness to reduce measurement bias.

3.8.2 Reliability
Reliability in this study was enhanced by the processes noted above and measurement of variables of interest for all FSWs on ART from the electronic database and verified using existing patient files at both the USAID Open Doors wellness centre and the ART linkage facility Ngombe Clinic in Lusaka. Bruce, Pope & Stanistreet (2009) noted that reliability is the same as repeatability. Therefore, reliability was measured by the ability to produce same results at different occasions. Reliability is the degree to which a test is free from measurement errors, reflects consistency and replicability over time. The USAID Open Doors wellness centre receives support from the project staff from FHI 360 who conduct regular data quality assurance (DQA) checks and validation to determine the reliability of the data from the routine clinical data sources. The DQAs involve reviewing the database for missing and duplicate values, accuracy and consistency of data such as age, and completeness of data entry. Further, extensive consultations were done with providers to assess the data collection tool developed to ascertain whether it captures all the study variables. Moreover, the data was extracted from the electronic database using the inclusion/exclusion criteria by the study researcher. This was to ensure uniformity and consistency of the extracted data from the electronic database ART register and SmartCare. Further, data quality checks were done by reviewing and matching between the two data sources for each FSW.

3.9 GENERALIZABILITY OF STUDY
The study findings were generalized to FSWs aged 18 years and above that attended services at the USAID Open Doors Wellness Centre and/or the Ngombe Clinic ART referral centre that have been registered in the study.
3.10 ETHICS STATEMENTS

The study was approved by the University of the Western Cape Biomedical Research Ethics Committee (see Appendix 2) and Zambian ERES Converge ethics committee (see Appendix 3). In addition, FHI 360 management (USAID Open Doors Project) gave permission for project data usage (see Appendix 4).

This cohort study involved key populations a vulnerable group who are HIV positive that have been initiated on ART through the USAID Open Doors project. There was minimal risk as it did not involve direct contact with human subjects. The most significant risk to the FSW clients was the potential for loss of privacy and confidentiality when having their electronic medical record reviewed through the study. Based on the sensitivity of the data, no patient names were required nor used in the review. All patient data was entered and stored in a computer file that was password protected with access limited to the researcher. This was to protect subjects’ privacy and confidentiality. All data was stripped of identifiers before being entered into the database.

There was no direct contact with human subjects nor real-time effect on their care (National Research Council, 2014). Therefore, no consent was required as routine anonymized data was used for this study. The benefit to the cohort and ART program managers is the valuable information on retention that will inform and strengthen ART treatment programs for FSWs.

In addition, findings of the study will be shared through presentations to project staff and stakeholders. Approval will be sought to disseminate the results from FHI 360, including publication and presentations at local and international conferences of the results.
CHAPTER 4: RESULTS

This chapter presents the outcomes of the current study. These are presented and interpreted based on the objectives of the study. The study data was extracted from 205 records of female sex workers (FSWs) initiated on ART at the USAID Open Doors Wellness Centre in Lusaka, Zambia between October 2018 and December 2018, and followed up until June 2019. All the 205 FSWs were HIV-infected and linked to ART, aged 18 years and above. The results are presented in four sections; the first section has the details of the socio-demographic characteristics of the FSWs. In the second section, details of the clinical characteristics of the participants are highlighted. In section three, retention in care is presented among FSWs based on their socio-demographic characteristics. In section four, retention in care is compared between youth and adult FSWs.

4.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

Table 1 provides a description of the socio-demographic characteristics of the participants in the study. In the current study, 205 FSWs were included based on a criterion of being HIV positive and having started ART treatment. The majority (80%) of the participants were aged 25-42 years, with 20% aged 18-24 years. The median age of the participants was 30 years, and the interquartile range was 8 years. About 95% of the FSWs had formal education. A total of 196 (91.2%) of FSWs considered themselves as unemployed, with 8.3% in some form of employment (formal or informal), and only one was a student. Considering the marital status, the majority (63.9%) of the FSWs were never married, 22.4% were separated, 8.3% were divorced, 1% widowed and 4.4% were married.

Table 1: Socio-demographic characteristics of female sex workers (N=205)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Type</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>18 – 24 years</td>
<td>40</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>25 – 42 years</td>
<td>165</td>
<td>80%</td>
</tr>
<tr>
<td>Education</td>
<td>None</td>
<td>10</td>
<td>4.9%</td>
</tr>
<tr>
<td></td>
<td>Primary</td>
<td>46</td>
<td>22.4%</td>
</tr>
<tr>
<td></td>
<td>Junior Secondary</td>
<td>95</td>
<td>46.3%</td>
</tr>
<tr>
<td></td>
<td>Senior Secondary</td>
<td>52</td>
<td>25.4%</td>
</tr>
<tr>
<td></td>
<td>Post-Secondary</td>
<td>2</td>
<td>1.0%</td>
</tr>
<tr>
<td>Occupation</td>
<td>Formal Employed</td>
<td>2</td>
<td>1.0%</td>
</tr>
</tbody>
</table>
4.2 CLINICAL CHARACTERISTICS OF STUDY PARTICIPANTS

Figure 1 describes the various ART treatments used by the participants. The majority (67%) of the FSWs were on EFV+3TC+TDF 600 mg ART combination, followed by Tenofovir, lamivudine and efavirenz fixed-dose combination (FDC) tablet (22%), TDF+3TC+DTG FDC had 6% of FSWs, while TDF+3TC+DTG was the least used (5%). Out of 205 FSWs initiated of ART, 88% remained active on treatment throughout the follow-up period, while 12% were lost to follow up (Figure 2). There were no transfers to other facilities or deaths recorded during the study duration.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Type</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informal Employed</td>
<td>15</td>
<td>15</td>
<td>7.3%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>187</td>
<td>187</td>
<td>91.2%</td>
</tr>
<tr>
<td>Student</td>
<td>1</td>
<td>1</td>
<td>0.5%</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single (Never Married)</td>
<td>131</td>
<td>131</td>
<td>63.9%</td>
</tr>
<tr>
<td>Married</td>
<td>9</td>
<td>9</td>
<td>4.4%</td>
</tr>
<tr>
<td>Separated</td>
<td>46</td>
<td>46</td>
<td>22.4%</td>
</tr>
<tr>
<td>Divorced</td>
<td>17</td>
<td>17</td>
<td>8.3%</td>
</tr>
<tr>
<td>Widowed</td>
<td>2</td>
<td>2</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

Figure 2: ART treatment combination for FSWs in care
4.3  RETENTION IN CARE BY SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

Table 2 shows the bivariate analysis of possible socio-demographic characteristics associated with treatment status. Out of the 205 FSWs, 180 were active on ART during the study period while 25 were considered as lost to follow-up. Of the 180 FSWs active on ART, 36 were youths aged 18 – 24 years, and 144 were adults aged 25 – 42 years. Among 25 FSWs classified as LTFU, 4 were youths and 21 were adults. When compared between those retained in care and LTFU among the age groups, 90% of the youths were active on ART while 87% of the adults remained on treatment during the study period. This difference was however not statistically significant (p-value = 0.637). Similarly, education was not significantly associated with ART treatment (p-value = 0.481). Retention on ART was highest among 17 FSWs that responded to be employed (formal and informal) and one student, while those that were unemployed at 87%. The difference was not statistically significant (p = 0.169). Marital status did not significantly influence retention (p-value = 0.545); however, nine married and two widowed FSWs were all retained, compared to those who never been married (88%), separated (89%), and divorced (76%).
Table 4: Retention rates by socio-demographic characteristics of female sex workers

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Active on ART (%)</th>
<th>LTFU (%)</th>
<th>Odds Ratio (95% CI)</th>
<th>P-values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 – 24 years</td>
<td>36 (90%)</td>
<td>4 (10%)</td>
<td>1.312 (0.424 - 4.061)</td>
<td>0.637</td>
</tr>
<tr>
<td>25 – 42 years</td>
<td>144 (87%)</td>
<td>21 (13%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>9 (90%)</td>
<td>1 (10%)</td>
<td>1.192 (0.730 - 1.947)</td>
<td>0.481</td>
</tr>
<tr>
<td>Primary</td>
<td>37 (80%)</td>
<td>9 (20%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Junior Secondary</td>
<td>87 (92%)</td>
<td>8 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior Secondary</td>
<td>45 (87%)</td>
<td>7 (13%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Secondary</td>
<td>2 (100%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formal Employed</td>
<td>2 (100%)</td>
<td>0 (0%)</td>
<td>0.191 (0.018 - 2.027)</td>
<td>0.169</td>
</tr>
<tr>
<td>Informal Employed</td>
<td>15 (100%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>162 (87%)</td>
<td>25 (13%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>1 (100%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single (Never Married)</td>
<td>115 (88%)</td>
<td>16 (12%)</td>
<td>0.920 (0.704 - 1.203)</td>
<td>0.545</td>
</tr>
<tr>
<td>Married</td>
<td>9 (100%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separated</td>
<td>41 (89%)</td>
<td>5 (11%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>13 (76%)</td>
<td>4 (24%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>2 (100%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.4 RETENTION IN CARE BY FSW AGE GROUP

Figure 3 shows the probability of being retained in care among FSWs is similar between the youths (18 – 24 years) and adults (25 – 42 years) in the first 3 – 4 months. Also, there was no statistically significant difference in retention in care between the FSWs aged 18 – 24 years and 25 – 42 years. Based on the survival analysis, the probability of being retained in care was higher among FSW youths than adults beyond the 3 - 4 months during the study period. However, the log rank test showed that there was no statistically significant difference in the survival curves between the FSW youths and FSW adults during the 9 months study period (p-value = 0.637). Furthermore, the likelihood of being retained in care among adult FSWs at 6
months was significantly less compared to youth FSWs (HR = 0.78; 95% CI = 0.27-2.26) see Table 3.

Figure 5: Kaplan-Meier survival analysis for retention in care

As shown in Table 3, being FSW adult reduces the hazard by a factor of 4%. The hazard ratio HR = 1.021, with a 95% confidence interval of 0.926 to 1.125. Also, there was no statistically significant difference in hazard rates of retention in care between youths and adults (p = 0.958).

Table 6: Cox proportional hazards regression model by KP group and age

<table>
<thead>
<tr>
<th>KP Group</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
<th>Coefficient</th>
<th>S. E.</th>
<th>Z-Statistic</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>KP Group</td>
<td>0.9619</td>
<td>0.2207 - 4.1917</td>
<td>-0.0389</td>
<td>0.7510</td>
<td>-0.0517</td>
<td>0.9587</td>
</tr>
<tr>
<td>Age</td>
<td>1.0213</td>
<td>0.9264 - 1.1258</td>
<td>0.0210</td>
<td>0.0497</td>
<td>0.4231</td>
<td>0.6722</td>
</tr>
</tbody>
</table>
CHAPTER 5: DISCUSSION

This study focuses on treatment outcomes among FSWs initiated on ART under the USAID Open Doors project in Zambia. The findings from the study show that ART provision offered to key populations in a programme targeted for them may lead to higher ART retention rates at six months. The study was a retrospective cohort study design conducted by reviewing 205 electronic records of FSWs initiated on ART at the USAID Open Doors Wellness Centre in Lusaka, Zambia between October 2018 and June 2019. According to Setia (2016), retrospective cohort study allows data to be collected from records of events that have already occurred in the past and facilitates collection of outcomes of various variables at baseline and at follow-up. Further, a retrospective cohort requires less time and resources to complete, and has potential to reduce selection bias (Setia, 2016).

The study found that among the 205 HIV positive FSWs that were linked to care due to the test and treat strategy, 180 were active on ART during the study period while 25 were considered as lost to follow-up. Further, the study found that among the 205 FSWs, 88% were retained in care, 12% were LTFU, and there were no deaths or transfer out. This can be attributed to the USAID Open Doors project innovations of using key populations and training providers in offering KP friendly services to ensure test and treat strategy is implemented in its programs like other FHI 360 LINKAGES projects (FHI 360, 2020). The test and treat strategy are implemented by the USAID Open Doors project in support of the UNAIDS 90-90-90 targets by 2020 to diagnose 90% of people living with HIV, put 90% of them on treatment, and for 90% of them to have suppressed viral load.

Similarly, studies with high retention rates within 6-months such as the study in Malawi showed ART retention on at 1, 2, 3 and 6 months was 99%, 97%, 95% and 90% respectively (WHO, 2012). While Zulliger et al. (2015) observed among the 268 HIV positive FSWs in the Dominican Republic in treatment for 6 months, 92% attended HIV care while 37% reported missed visits. Stricker et al. (2013) noted that 86.1% retention at 6 months among 226,307 clients in sub-Saharan Africa.

Demographic factors considered in the findings of age, education, occupation and marital status varied across literature reviews.

Age

Among the 180 FSWs (36 youths and 144 adults) retained in care in this study, 25 were considered as lost to follow-up (four youths and 21 adults). Among the youths aged 18 – 24 years, 90% were retained in HIV care while 87% of the adults aged 25 – 42 years were retained.
on ART treatment. The difference was not statistically significant with a p-value of 0.637, at 95% CI. Likewise, a study by Okoronkwo et al. (2013) reported that there was no significant difference in nonadherence by age groups. While Lall et al. (2015) concluded that age was an important factor that impacted on adherence and retention in care among HIV positive KPs when compared between youths and adults. This is different from this study that found that there was no significant difference in retention between the two age groups.

Education

This study found that lack of formal education did not influence retention on ART (p-value of 0.481 at 95% CI). Among those without formal education, 90% were retained in care during the study period compared to those with any form of education at 88%. Bam et al., (2015) reached a similar conclusion that increase in education was not related to better adherence, as they noted that lower educational level showed better adherence. This contradicts Okoronkwo et al. (2013) who identified education as a predicting factor and concluded that those with some form of education (primary, secondary, tertiary) were more likely to be adherent than those without education. Similar observations were made by Meloni et al. (2016) who suggested that patients with lower education levels may have problems in understanding the instructions at ART clinics lowering their adherence. Further, Vuylsteke et al. (2015) observed that limited education affected retention in care resulting in LTFU. However, this study did not make similar conclusions.

Occupation

This study had a 100% retention rate among FSWs that responded to be employed (formal or informal) while those that were unemployed were at 87% (The difference was not statistically significant with the p = 0.169). Similar conclusion was reached by Nachega et al. (2014) who suggested that employed respondents were more likely to adhere than the unemployed. This is inconsistent with Okoronkwo et al. (2013) who showed that the unemployed were more likely to adhere than the employed. Furthermore, Nachega et al. (2014) observed that employment promotes adherence to ART. Also, Meloni et al. (2016) described the unemployed to have high attrition rate than the employed. This can be attributed to financial issues affecting patients to regularly access health services (Nguyen et al., 2013). In addition, a study in Rwanda and Swaziland among FSWs attributed lack of adherence to treatment to poverty (Lancaster et al., 2016; Lall et al., 2015).

Marital Status

Being married and widowed in this study showed retention rate of 100%. This is comparable to Bam et al. (2015) who noted that retention was higher in married patients than other marital
status categories. Furthermore, this is supported by Meloni et al., (2016) who found that being single was linked to lost to follow up.
CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

Achieving HIV epidemic control requires targeting drivers of new infections such as female sex workers (FSW), men who have sex with men (MSM), and transgender people. While sex work and same sex relations are criminalized in Zambia, it is important that we address the national and international HIV goals of leaving no one behind on the fast track to controlling the HIV epidemic by 2020 and ending the threat of HIV and AIDS as a public health issue by 2030. In Zambia, FSWs (known as key populations) are often unable or unwilling to access HIV services because of stigma and discrimination. This is reflective in the retention rates observed in this study of meeting the 95-95-95 targets. The WHO recommended guidelines of “test and treat” will facilitate the attainment of 95-95-95 targets that countries like Zambia aim to reach to effectively provide KPs with ART services. This study has shown that tailored programs for KPs are vital in eliminating HIV/AIDS particularly with a high adherence and retention rate at six months among FSWs.

Further, there is need to decriminalize sex work and same sex relations to meet the UNAIDS cascade of 90-90-90 by 2020. We can speculate that the mobility of key populations affect retention in care, adherence to treatment, and loss to follow-up. However, more studies are needed to validate why KPs beyond FSWs decide to stop taking their drugs or are considered LTFU. Therefore, every KP on treatment and retained in care offers a positive view in scaling up treatment as prevention.

Lastly, this study will provide a baseline for ART retention among FSWs in Zambia. Currently, there is no baseline that support ART outcomes among KPs in Zambia.
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Wanyenze, R., Musinguzi, G., Kiguli, J., Nwah, F., Mujisha, G., Musinguzi, J., Arinaitwe, J. and Matovu, J. (2017). “When they know that you are a sex worker, you will be the last person to be treated”: Perceptions and experiences of female sex workers in accessing HIV services in Uganda. BMC International Health and Human Rights, 17(1).


APPENDICES

APPENDIX 1: DATA COLLECTION TOOL

<table>
<thead>
<tr>
<th>Questions</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. KP type</td>
<td>FSW ____</td>
</tr>
<tr>
<td>2. Gender</td>
<td>F ____</td>
</tr>
<tr>
<td>3. Age</td>
<td>____</td>
</tr>
<tr>
<td>4. Marital status</td>
<td>Single (never married)</td>
</tr>
<tr>
<td></td>
<td>Married ___</td>
</tr>
<tr>
<td></td>
<td>Widowed ___</td>
</tr>
<tr>
<td></td>
<td>Separated ___</td>
</tr>
<tr>
<td></td>
<td>Divorced ___</td>
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<tr>
<td>5. Education (highest level attained)</td>
<td>None ____</td>
</tr>
<tr>
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<td>Primary ___</td>
</tr>
<tr>
<td></td>
<td>Junior Secondary ___</td>
</tr>
<tr>
<td></td>
<td>Senior Secondary ___</td>
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<td>Post-Secondary ___</td>
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<td>Informal employment ____</td>
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<td></td>
<td>Unemployed ____</td>
</tr>
<tr>
<td></td>
<td>Student ____</td>
</tr>
<tr>
<td>7. Date tested HIV positive</td>
<td><strong><strong>/</strong></strong>/_______</td>
</tr>
<tr>
<td>8. ART treatment start date</td>
<td><strong><strong>/</strong></strong>/_______</td>
</tr>
<tr>
<td>9. Type of ART regimen</td>
<td>First Line ____</td>
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<td>Second Line ____</td>
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<td>10. WHO staging</td>
<td>Stage 1 ____ Stage 2 ____</td>
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<td>11. Baseline CD4 count</td>
<td>____ cells/mm</td>
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<td></td>
<td>____ Missing</td>
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<tr>
<td>12. KP on co-trimoxazole at baseline</td>
<td>Yes ____ No ____ N/A ____</td>
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<td>Questions</td>
<td>Responses</td>
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<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------</td>
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<tr>
<td>13. KP on TB treatment at ART start</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>14. Pharmacy last drug refill date</td>
<td><strong><strong>/</strong></strong>/_______</td>
</tr>
<tr>
<td>15. KP active on ART</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>16. KP retained in care at 1 month</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>17. KP retained in care at 3 months</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>18. KP retained in care at 6 months</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>19. KP inactive due to loss to follow-up</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>20. When was the KP declared lost to follow-up</td>
<td><strong><strong>/</strong></strong>/_______</td>
</tr>
<tr>
<td>21. KP inactive due to transfer out</td>
<td>Yes ____ No ____</td>
</tr>
<tr>
<td>22. When was the KP transferred out</td>
<td><strong><strong>/</strong></strong>/_______</td>
</tr>
<tr>
<td>23. KP inactive due to death</td>
<td>Yes ____ No ____</td>
</tr>
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</table>
APPENDIX 2: UWC ETHICS COMMITTEE APPROVAL

21 November 2019

Mr CM Bwalya
School of Public Health
Faculty of Community Health Sciences

Ethics Reference Number: BM19/9/10

Project Title: Retention in HIV care among key populations on antiretroviral treatment in Lusaka, Zambia: A prospective cohort study.

Approval Period: 19 November 2019 – 19 November 2020

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

NHREC REGISTRATION NUMBER 130416-050
24\textsuperscript{th} February, 2020

Ref. No. 2019-Dec-013

The Principal Investigators,
Mr. Clement M. Bwalya,
P. O. Box 320303,
LUSAKA.

Dear Mr. Bwalya,

RE: RETENTION IN HIV CARE AMONG KEY POPULATIONS ON ANTIRETROVIRAL TREATMENT IN LUSAKA, ZAMBIA: A PROSPECTIVE COHORT STUDY.

Reference is made to your protocol submission dated 11\textsuperscript{th} February, 2020. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Ordinary Review</th>
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<tbody>
<tr>
<td>Approval and Expiry Date</td>
<td>Approval Date: 24\textsuperscript{th} February, 2020</td>
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<tr>
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<td>Expiry Date: 23\textsuperscript{rd} February, 2021</td>
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<td>Protocol Version and Date</td>
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<td>23\textsuperscript{rd} February, 2021</td>
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<td>Information Sheet,</td>
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<td>Consent Forms and Dates</td>
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<tr>
<td>Consent form ID and Date</td>
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<td>23\textsuperscript{rd} February, 2021</td>
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<tr>
<td>Recruitment Materials</td>
<td>Nil</td>
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<td>23\textsuperscript{rd} February, 2021</td>
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<td>Other Study Documents</td>
<td>Data Collection Sheet.</td>
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<td>23\textsuperscript{rd} February, 2021</td>
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<tr>
<td>Number of participants approved</td>
<td></td>
</tr>
<tr>
<td>for study</td>
<td>23\textsuperscript{rd} February, 2021</td>
</tr>
</tbody>
</table>
Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- A reprint of this letter shall be done at a fee.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,

ERES CONVERGE IRB

Dr. Jason Mwanza
CHAIRPERSON
APPENDIX 4: FHI 360 PROJECT DATA USAGE PERMISSION LETTER

August 28, 2019

Clement Mudala Bwalya
Deputy Chief of Party, USAID Open Doors Project
FHI 360 Zambia
Plot 2374, ZNFU complex, Showgrounds
Lusaka, Zambia

Dear Mr. Bwalya,

RE: APPROVAL TO USE PROJECT DATA FOR RESEARCH

I refer to your letter dated August 27, 2019 in which you were requesting to use project data for your research as part of your academic requirements.

I wish to inform you that permission has been granted to you with the understanding that ethical issues are considered, and that the results of your study will contribute to informing the USAID Open Doors project programming.

Sincerely,

Joseph Kamanga
FHI Country Representative/Chief of Party - USAID Open Doors Project