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EXPLORING THE PERFORMANCE AND IMPACT OF ORAL PrEP IN ADOLESCENT GIRLS AND YOUNG WOMEN IN MAKONDE DISTRICT, MASHONALAND WEST

BY

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Abstract

This study presents findings from a cross-sectional analytic study utilising a mixed-method approach to evaluate the performance and impact of Oral Pre-Exposure Prophylaxis (PrEP) among Adolescent Girls and Young Women (AGYW) in Makonde District, Mashonaland West. The objectives of the study were to analyse the initiation, retention, and adherence rates, and explore barriers to PrEP use among AGYW using the HIV prevention cascade. The study involved a review of 245 PrEP user records, in-depth interviews and focus group discussions with 81 current and former PrEP users, and discussions with 29 service providers serving as key informants. User records were selected using multi-stage sampling at public health facilities and, PrEP users and service providers were purposively sampled into the study to provide insights on the performance of oral PrEP in the district. The research revealed a low initiation rate of 47% (CI 41-52.9) among AGYW and a much lower initiation rate of 36.6% among 18-year-old adolescents. Multivariate analysis revealed a statistically significant association between retention on PrEP and the prescribing facility (Hazard ratio 0.3, $p< 0.05$, 95%CI 0.2-0.5). And age (>23years) among the AGYW was a good predictor of retention of Oral PrEP. There was no statistically significant association between adherence and sociodemographic characteristics ($p>0.05$).Thirty percent of users discontinued PrEP in the first month post-initiation and they were not followed up to ascertain if the period of risk had elapsed. Alarmingly, about 85% of users discontinued PrEP by the 6th month post-initiation, and 23.1% (-/+3.7sd) of AGYW defaulted before each subsequent visit. According to AGYW in the study, barriers to both initiation and retention of PrEP included negative health worker attitudes (n=17, 21%), fear of side effects (n=25, 30.9%), and inefficient service delivery (n=35, 43.2%). Healthcare providers (27.6%) also cited stigma, both historical and social, as a significant barrier to PrEP delivery. 58% of the study participants prefer integration of PrEP services with routine family clinics e.g. family planning services. More than 75% (n=62) of the former and current PrEP users admitted that they did not change their sexual behaviour after initiating PrEP. And in the period under study only one PrEP user seroconverted. However, the study highlighted a high HIV burden in Makonde district, with new HIV infections among AGYW four times higher than the cases reported in their male counterparts. These findings underscore the urgent need for targeted interventions to address the identified barriers and improve initiation and retention of PrEP among AGYW in the study area to effectively combat the HIV epidemic.

Key Terms: adolescent girls, young women, PrEP

Declaration Page

I declare that this dissertation is my original work except where sources have been cited and acknowledged. The work has never been submitted, nor will it ever be submitted to another university for the award of a degree

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Dedication

This dissertation is dedicated to my dear wife Ethel and our two beautiful children, Kupakwashe and Mufarowashe, who gave me a reason to persevere in my studies. I also dedicate this work to the Lord God Almighty for His unmatched grace that pulled me through when it seemed impossible.

List of Acronyms

AGYM	Adolescent Girls and Young Women
DPV	Dapivirine
DTG	Dolutegravir
ED-PrEP	Event Driven Pre-exposure Prophylaxis
FTC	Emtricitabine
HIV	Human Immune-deficiency Virus
MSM	Men who have Sex with Men
NNRTI	Non-nucleoside reverse-transcriptase inhibitor
NRTI	Nucleoside reverse-transcriptase inhibitor
PrEP	Pre-exposure prophylaxis
STI	Sexually Transmitted Infection
TAF	Tenofovir alafenamide
TDF	Tenofovir disoproxil fumarate
UNAIDS	The Jointed United Nations Programme on HIV/AIDS
WHO	World Health Organization
3TC	Lamivudine

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CHAPTER ONE: INTRODUCTION

1.1 Introduction

The use of oral pre-exposure prophylaxis (PrEP) in preventing HIV infections in different populations has been documented in various studies. However, limited attention has been given to adolescent girls and young women (AGYW), yet they are one of the populations with the highest risk of HIV infection in sub-Saharan Africa.

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral drugs by HIV-negative individuals to prevent HIV infection (WHO, 2020). In 2015, WHO recommended that daily oral pre-exposure prophylaxis (PrEP) be offered as an additional prevention choice for HIV-negative individuals at substantial risk of acquiring HIV as part of combination HIV prevention approaches. Individuals at substantial risk of acquiring HIV, include, but are not restricted to, men who have sex with men, serodiscordant couples (until the HIV-positive partner is receiving antiretroviral therapy and has achieved viral load suppression), sex workers, transgender women in most regions and adolescent girls and young women in high-incidence settings in southern and eastern Africa (WHO, 2017). WHO-recommended oral PrEP regimens are tenofovir disoproxil fumarate (TDF), TDF combined with emtricitabine (FTC), and TDF combined with lamivudine (3TC).

In sub-Saharan Africa, adolescent girls and young women (AGYW, defined as 15-24 years old) experience disproportionate rates of new HIV infections. Every week, 6,000 AGYW are newly infected with HIV (UNAIDS, 2021). This has led to a widespread call for the scale-up of biomedical interventions such as oral pre-exposure prophylaxis (PrEP) in this key population, to be used in addition to other existing HIV

prevention strategies such as condoms. Oral PrEP is a critical prevention method in the context of the numerous challenges still faced by women and girls in many settings in trying to protect themselves from HIV including economic dependence, gender-based violence, and unequal power dynamics. However, impact evaluations of PrEP focusing on adolescent girls and young women are currently limited.

In many settings data on oral PrEP is still being collected in demonstration projects and implementation programs so there is limited published evidence on its impact on this population overall. The Bill and Melinda Gates Foundation launched a new Data Use and Analysis Fund in the first quarter of 2023 which promises to make available unique sources of information, share lessons learned, and provide details about where this data can be accessed.

HIV infection is known to be an infrequent event among PrEP users because PrEP substantially reduces the risk of acquiring HIV (especially among those who adhere to their regimen) (Fonner, et al., 2016). Daily oral PrEP is almost 100% effective in adherent individuals (Rutstein, Smith, Dalal, Baggaley, & Cohen, 2020). In countries with high levels of oral PrEP uptake and high HIV testing and treatment rates, HIV diagnoses have declined, for example in the UK, HIV diagnosis declined by 35% between 2014 and 2018 and this was attributed to PrEP use. Such a decline occurred despite striking decreases in consistent condom use among MSM (O'Hallaron, Sun, & Nash, 2019).

Additional benefits have been documented, including reduced HIV anxiety and the ability to have sex free from fear (Keen, Hammoud, & Bourne, 2020). Increased pleasure and intimacy have been reported, as have feelings of empowerment and

control, which are especially important for women (Grant & Koester, 2016). The impact of PrEP on ending the HIV/AIDS epidemic can be significant and quite remarkable. Also, PrEP services provide an important opportunity to screen for other infectious diseases such as syphilis, hepatitis B, and hepatitis C virus infection, and provide linkages to care.

Individuals eligible for oral ED-PrEP can start oral PrEP by taking two doses 2–24 hours before potential exposure, regardless of whether they intend to use an oral daily or ED-PrEP dosing regimen, and continue to take one dose per day until two days after the day of the last potential sexual exposure. Event-driven PrEP can be started by taking two doses 2–24 hours before potential exposure and continuing to take one dose per day until two days after the day of the last potential sexual exposure. This is called the four-pill PrEP dosing strategy and comprises two PrEP pills taken 2–24 hours before sex; then, a third pill taken 24 hours after the first two pills, and a fourth pill taken 48 hours after the first two pills. WHO recommends event-driven PrEP only for cis-gender men who have sex with men (WHO, 2022), event-driven PrEP is not recommended for people in other risk groups or individuals with active hepatitis B infection (WHO, 2022).

All other individuals should start daily oral PrEP by taking one dose per day for seven days before potential exposure to HIV and can stop taking daily PrEP seven days after the last potential exposure. Daily PrEP is recommended for all people who are HIV-negative and at risk of HIV acquisition, regardless of gender, sexual orientation, or sexual behaviour. This PrEP dosing strategy consists of the use of one PrEP pill per day. It is also important to note that two efficacious non-oral products have been

developed: a monthly dapivirine (DPV) vaginal ring and a long-acting injectable (lasting 8 weeks) called cabetogravir (CAB-LA).

This research analysed the effectiveness of PrEP in reducing HIV incidence among AGYW, evaluated adherence to oral PrEP, and identified barriers and facilitators to its use among AGYW in real world settings. It also provided insights on broader issues such as sexual and reproductive health, gender dynamics, stigma, and access to healthcare services. Insights into the social, behavioural, and structural factors that influence PrEP uptake and implementation were also explored. The research will contribute to evidence-based strategies for HIV prevention, inform public health policies, and ultimately improve the health outcomes of this vulnerable population

1.2. Background to the Study

First conceptualised in 1985 by Dr. Robert Grant, pre-exposure prophylaxis (PrEP) has been the object of several studies since the landmark iPrEx Trial was released in November 2010. However, many of these studies have largely focused on Western men, leaving women, especially women in developing nations, virtually unexamined as the subject of these research studies. Nonetheless, with the progress of studies such as the ADAPT Study in Zimbabwe, the FACTS 001 Study in South Africa, and the TDF2 Study, young women, and girls are now beginning to see themselves represented in the medical research - and the findings of such studies so far have been particularly promising, especially in regards to reducing HIV incidence.

According to AVERT, an international HIV and AIDS charity, sub-Saharan Africa is one of the regions most affected by the HIV epidemic, with 1 in every 25 people living with HIV in 2019. The prevalence rate is particularly high among young women aged

15-24, where three in four new infections are among this demographic group. However, global efforts to reduce the HIV burden have led to a decrease in new infections among young women and adolescent girls by 25% from 2010 to 2019, and HIV-related deaths declined by 35% among the same group.

In the year 2020, about 25% of all new HIV infections in sub-Saharan Africa were amongst AGYW (aged 15–24), despite representing merely 10% of the population (UNAIDS, 2021). And in the 15–19years age group, six out of seven new HIV infections are acquired by adolescent girls (UNAIDS, 2021). In one study, among the 49% of the AGYW who were identified to have more than one risk factor for HIV infection, the highest risk factor for the 20–24-year age group was "irregular or no condom use" (Kharsany & Karim, 2016). This finding is important in the implementation of programs that will advocate for combined HIV prevention measures.

Several studies have shown that a substantial proportion of AGYW starting daily oral PrEP does not return for a medication refill 1 month after initiation, and most discontinue within the first 6 months (Irungu & Baeten, 2020). And also several qualitative studies have evaluated PrEP acceptability and motivations for PrEP persistence among AGYW within the context of clinical trials and demonstration studies (Pintye, et al., 2018), yet few data are available that explore discontinuation and persistence of daily oral PrEP use within programmatic settings (Irungu & Baeten, 2020).

Pill burden and difficulty concealing pill-taking have been identified as reasons for declining and discontinuing PrEP among the AGYW (Mugwanya K. K., et al., 2019).

In some studies, peer-to-peer models have been demonstrated to enhance initiation, continuation, and adherence to PrEP. PrEP has been identified as a sustainable solution that will provide AGYW with user control but uptake is low in this group (Mugwanya K. K., et al., 2019). Some studies have begun to unpack the broad spectrum of factors shaping AGYW's uptake and continuous engagement. Most of these studies have been concluded from AGYW experiences and opinions (Mugwanya K. K., et al., 2019)

Zimbabwe is one of the countries that accounted for nearly half of all the new HIV infections that occurred among AGYW globally in 2020 (UNAIDS, 2021). In order to curb new HIV infections, Zimbabwe included pre-exposure prophylaxis (PrEP) in its guidelines for Antiretroviral Therapy (ART) in 2016 as part of the combination HIV prevention. Through a phased approach, PrEP services were adopted with the first phase involving piloting in four districts (Chipinge, Mutare, Gweru, and Bulawayo) targeting adolescent girls and young women.

In Mashonaland West province, HIV prevalence is higher in adolescent girls and young women (4.16%) compared to their male counterparts (2.43%) (MOHCC, 2022). Makonde district, one of the seven districts in Mashonaland West province, has double HIV incidence in AGYW compared to its male counterparts (MOHCC, 2022). To reduce the number of new HIV infections among AGYW and other key populations, Pre-exposure prophylaxis was rolled out in Makonde district in 2020.

1.3 Statement of the Problem

Adolescent Girls and Young Women (AGYW) in Makonde District of Mashonaland West face a high burden of HIV infection. Despite the availability of Oral Pre-

Exposure Prophylaxis (PrEP) as a preventive measure, there is a lack of comprehensive understanding regarding its performance and impact on this specific demographic group. Therefore, this study aimed to explore the performance and impact of Oral PrEP among AGYW in Makonde District, focusing on factors such as initiation rates, adherence rates, retention, knowledge levels, barriers to access, and the overall effectiveness of PrEP in reducing HIV infection rates among AGYW in this district.

1.4.Research Objectives

1.4.1. Broad Objective

The purpose of this study was to evaluate the performance and impact of oral PrEP in adolescent girls and young women (AGYW) in Makonde district who were registered from the time of PrEP rollout in 2020 to 31 December 2022.

1.4.2. Specific Objectives

The specific objectives of the study were to:

1. Analyse oral PrEP initiation rates among adolescent girls and young women in Makonde district, Mashonaland West from 1 January 2020 to 31 December 2022.
2. Analyse oral PrEP adherence rates among adolescent girls and young women in Makonde district, Mashonaland West from 1 January 2020 to 31 December 2022.
3. Analyse oral PrEP retention rates among adolescent girls and young women in Makonde district, Mashonaland West from 1 January 2020 to 31 January 2022.

4. Explore the reasons for oral PrEP discontinuation among adolescent girls and young women in Makonde district who are at risk of HIV infection inorder to inform the rollout of other modalities of prevention.

1.5 Research Questions

1. How does the rate of initiation on oral PrEP among adolescent girls and young women in Makonde district vary?
2. Are there any worrying patterns of adherence on oral PrEP at each clinical visit among adolescent girls and young women in Makonde?
3. How does the rate of oral PrEP retention among adolescent girls and young women at high risk of contracting HIV in Makonde district vary, and what impact do socio-demographic factors have on the retention of oral PrEP?
4. Which innovative approaches can be used to address the reasons for oral PrEP discontinuation among adolescent girls and young women in Makonde district who are at risk of HIV infection?

1.6 Justification of the Study

The study set out to address the gap in knowledge regarding PrEP's performance and impact among adolescent girls and young women in real world settings. And to help develop models that can accommodate people alternating through periods of use and non-use, as well as switching between dosing regimens or modalities as they become available. PrEP use was explored in the context of the already existing mechanisms of preventing HIV among adolescent girls and young women; the differences and critical success factors for PrEP in practice. The broader question of whether new medical interventions are acceptable among the younger population was explored.

Retention and adherence to oral Pre-Exposure Prophylaxis (PrEP) among adolescent girls and young women were explored through the identification of the current best practices and key performance challenges. The study findings can help both academic researchers and policymakers in the field of public health to make informed decisions on how to improve and promote the use of oral PrEP in AGYW.

The study concluded by emphasising the importance of addressing factors to improve PrEP adherence in adolescent girls and young women. Adolescent girls, their families, researchers, and policymakers need to understand the current factors that support and hinder the girls' ability to maintain their health as well as possible prescriptions for change. This research provided insights on how new PrEP services could be tailored to be more acceptable. This can be achieved through giving health and social care professionals knowledge which could be used to better and more accurately advise young clients about how their adherence to PrEP could be supported.

1.7 Limitations of the Study

The researcher had limited financial resources to cater for travelling expenses and limited time which impacted the nature of the data presentation due to the deadline attached to the research. To overcome limitations, the researcher accompanied field teams with scheduled visits to the study sites and used effective data collection methods, time management during interviews, clear communication with study participants and concise data presentation.

1.8 Delimitation of the Study

Interviews were conducted with participants who were aged 18-24 years because the minimum legal age for consensual sex in Zimbabwe is 18 years, hence adolescents aged less than 18 years were not enrolled in the study.

1.9. Definition of terms

1.9.1. PrEP

Pre-exposure prophylaxis (PrEP) is a biomedical strategy for preventing HIV infection. It involves the use of antiretroviral medications by people who are HIV-negative to reduce their risk of HIV infection. The World Health Organization (WHO) recommends oral PrEP as part of a comprehensive prevention package for individuals at substantial risk of HIV infection. However, many key populations at risk of HIV infection, particularly adolescent girls and young women in sub-Saharan Africa, often face significant personal, structural, and health systems barriers to optimal PrEP use

Pre-exposure prophylaxis, or PrEP, is a newer medical advancement that provides a remarkable advancement in the arena of HIV prevention. PrEP utilises HIV medications that are typically used to treat HIV-positive individuals and use them in a preventative manner in people who do not have HIV. The medications work to prevent HIV from establishing a permanent infection inside the body.

1.9.2. Adolescent Girls and Young women

Adolescence is a transitional phase of growth and development between childhood and adulthood. The World Health Organization (WHO) defines an adolescent as any person between ages 10 and 19. This age range falls within the WHO definition of

young people, which refers to individuals between ages 10 and 24. In many societies, however, adolescence is narrowly equated with puberty and the cycle of physical changes culminating in reproductive maturity. In other societies, adolescence is understood in broader terms that encompass psychological, social, and moral terrain as well as the strictly physical aspects of maturation. In these societies, the term *adolescence* typically refers to the period between ages 12 and 20 and is roughly equivalent to the word teens.

1.10. Chapter Summary

In conclusion, the chapter presented an introduction to the whole study. It outlined the importance of this research and the expected study outcomes. This chapter also discussed the background of the study, statement of the problem, objectives, research questions, justification, and the delimitations of the study in terms of the demographic scope.

CHAPTER TWO: REVIEW OF RELATED LITERATURE

2.1. Introduction

This chapter looks at literature that has been published before on the topic of study and provides relevant background information required for contextualising the research questions and the interest in this study. Literature focusing on pre-exposure prophylaxis initiation, adherence and efficacy/effectiveness, impact on HIV incidence, challenges and outcomes of PrEP implementation in AGYW will be reviewed.

2.2. Conceptual framework

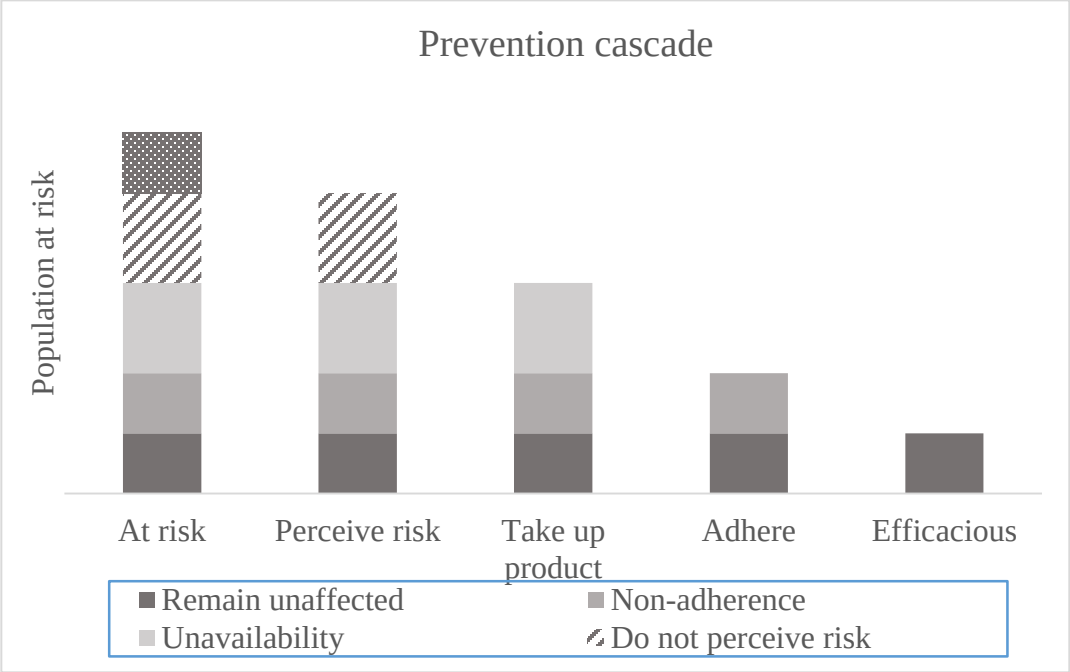

Figure 1: Conceptual HIV prevention cascade which can be applied to AGYW who are at risk of acquiring HIV (adapted from (Garnett, et al., 2016))

The first step in the prevention cascade is defining the population at risk of acquiring infection and if we could accurately identify those that would acquire the infection

without the intervention, then those lost at each step would potentially acquire infection if they do not use other preventive methods. And the population left after all the steps of the cascade would potentially remain uninfected. The highlighted conceptual framework demonstrates the rationale for initiating an intervention, however the overall effect might result from combined preventive interventions.

2.3. Efficacy and Effectiveness of Oral PrEP in AGYW

Efficacy is the capacity of an intervention to produce an effect or the ability of an intervention to produce a desired effect in expert hands and under ideal circumstances (Marchand, Stice, Rohde, & Becker, 2011). Clinical trials and program settings have demonstrated close to 95% efficacy in men who have sex with men (MSM) who adhere to oral daily or event-driven PrEP (Mayer, et al., 2020). In contrast, the efficacy of oral PrEP regimens containing tenofovir has varied widely across trials that enrolled women, with some studies reporting high efficacy and others reporting no efficacy (Holly, et al., 2018). Poor adherence and other factors, such as mode of transmission (sexual vs. parenteral), predominant HIV subtype, intensity of exposure, and percentage of stable serodiscordant couples have been strongly associated with a lack of efficacy (Holly, et al., 2018).

Effectiveness refers to the capability of producing a desired result and relates to how well a treatment works in practice, as opposed to efficacy, which measures how well it works in trials or laboratory studies. Oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) is a highly effective HIV prevention intervention. It is an innovative HIV prevention strategy that has high efficacy when used consistently around the time of HIV exposure.

Adherence to medication and retention in care are crucial contributors to the efficacy of pre-exposure prophylaxis (PrEP) for the prevention of HIV. The daily dose of oral PrEP has been shown in randomized controlled trials and open-label studies to be highly efficacious in preventing HIV acquisition if taken as prescribed (Beaten, Donell, & Ndase, 2012). Results from several studies have highlighted the importance of adherence to daily pill taking and they have shown reduced PrEP efficacy in the setting of low adherence to PrEP (Van Damme, Cornell, & Ahmed, 2012).

Evidence for oral PrEP efficacy in women at high risk of contracting HIV has been mixed and the reasons for the heterogeneity in efficacy for oral PrEP in women as compared with men are unclear, although blood antiretroviral medicine measurements have established differential adherence to daily pill-taking as a major factor (Marrazzo, et al., 2015). Efficacy trials that enrolled African women at risk of sexual acquisition of HIV found statistically significant PrEP efficacy for women (66% for TDF-FTC, 95% CI 28%–84%; 71% for TDF, 95% CI 37%–87%).

A study in Thailand also found significant efficacy in women (79%; 95% CI 17%–97%) (Choopanya, Martin, & Sunthara Samal, 2013). Pharmacological differences in vaginal versus rectal tissue concentration and the unique composition of the vaginal microbiome milieu have also emerged as additional potential explanations for the observed differences in efficacy between men and women (Cottrell, Yang, & Prince, 2016).

One study recommends the importance of ongoing research to identify optimal methods for PrEP delivery, such as integrated reproductive health which might be better suited for PrEP retention in high-risk populations (Bavinton & Grulich, 2021).

This alone necessitates the need to thoroughly examine the PrEP services offered to high-risk populations such as the AGYW. More research must be done to establish a suitable and preferred product for people at risk of HIV infection; this knowledge will aid efforts by product developers and trialists in developing products most likely to be acceptable and preferred by various populations worldwide.

2.4. PrEP Initiation and Inequalities

PrEP initiation rates have been increasing in Africa (Segal, 2021) and nine of the ten countries with the highest PrEP use per capita are located in Africa; however, the rate of uptake is still too slow to expect a significant population impact on the HIV epidemic. Inequalities within countries have also been noted to be emerging in PrEP access (Bavinton & Grulich, 2021), hence reducing inequalities is the primary focus of the UNAIDS global HIV strategy 2021–26 (UNAIDS, 2021).

Despite eastern and southern Africa accounting for approximately 43% of global HIV infections in 2019 (UNAIDS, 2020), major PrEP programs have been implemented in fewer than ten countries, with only South Africa having initiated more than 100000 PrEP users by the end of 2020 (Segal, 2021). In the same year, it was estimated that just less than 1 million people had initiated oral PrEP (Segal, 2021) far less than the 2020 UNAIDS target of 3 million (UNAIDS, 2017). In the year 2022, Zimbabwe had

initiated 53189 people on PrEP by September.

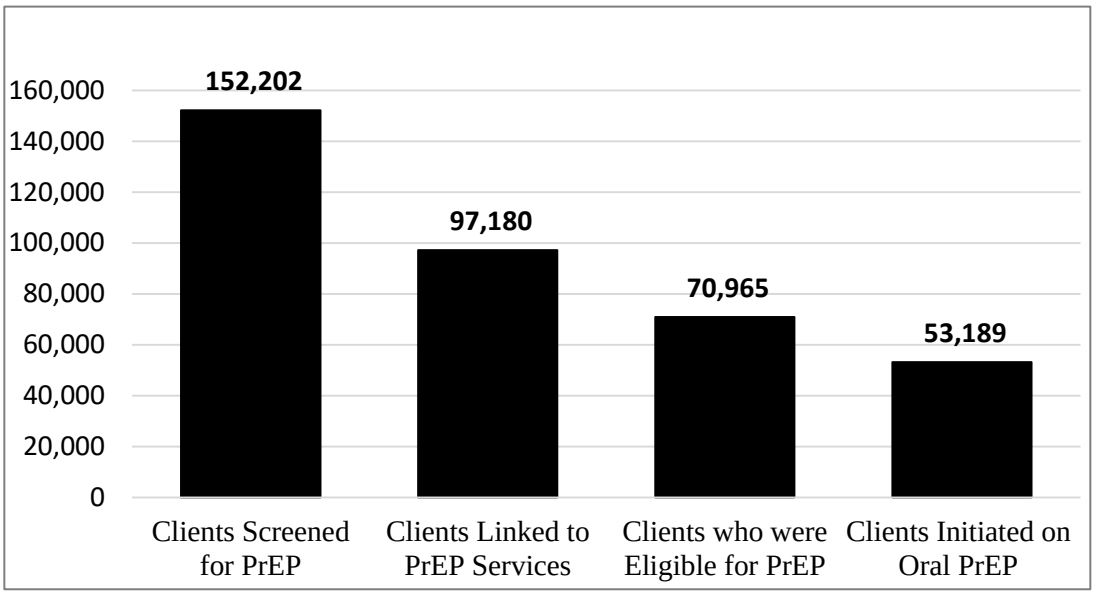

Figure 2: PrEP cascade cumulative figures (Jan-Sep 2022)

Inequalities in PrEP access exist among countries with divergent rates of PrEP uptake along racial and ethnic, socioeconomic, geographical, age, and self-identity lines. For example, in Western countries, uptake has typically been highest among gay men connected to urban gay communities and lower among minority ethnic groups, migrants, non-gay-identifying MSM, those with limited access to health care, and those living in peri-urban areas (Annequin, et al., 2020). Even within groups with access to health care, there is still a substantial gap between the estimated number suitable for or in need of PrEP and the number who have ever accessed it (Aung, et al., 2020).

2.5. Challenges and Barriers

Pre-exposure prophylaxis (PrEP) as an efficacious approach to preventing HIV acquisition among people at high risk of HIV infection can have a large effect on HIV

incidence if its uptake is sufficient (Sullivan & Sieger, 2018). Low uptake of oral PrEP has been attributed to barriers such as lack of partner support, need to conceal PrEP use from partners, lack of privacy from family members, and low empowerment on oral PrEP use in women, particularly in SSA (Beesham, et al., 2022). Several other challenges and barriers have been captured in studies on PrEP uptake and discontinuation. Among these barriers, low-risk perception and limited awareness have been reported repeatedly as barriers to oral PrEP uptake (Price, et al., 2018).

Among the studies that have consistently demonstrated a lack of awareness of PrEP among populations at risk of HIV acquisition as a barrier to use, limited knowledge about PrEP (i.e., if they have questions or concerns about it) has also been demonstrated to prevent PrEP initiation (Gomar, 2019). Lack of PrEP awareness has also been observed among people living with HIV, as reported by a survey in a Miami public hospital (Farthing, Rodriguez, & Armstrong, 2019). This has a huge impact because such people living with HIV would be unable to advise their partners about PrEP. In that same study, knowing about PrEP increased the likelihood of respondents encouraging their partners to use PrEP (Farthing, Rodriguez, & Armstrong, 2019).

Healthcare providers' knowledge and awareness are also crucial for successful implementation and can directly impact prescribing rates (Blumenthal, Jain, & Krakower, 2015). A disparity in awareness according to specialty was noted in one study where all infectious disease specialists surveyed had heard of PrEP, compared with around three-quarters of board-certified family medicine and internal medicine practitioners and half of obstetrics/gynecology and pediatric practitioners (Wood, et al., 2018). However, if PrEP is only available through specialist HIV clinics in

hospitals, the capacity to initiate new users will be hindered. PrEP programs should be nested within broader HIV prevention and health promotion efforts, which include HIV testing, treatment, sexual and reproductive health services, and potentially mental health and substance use services (Rivet & Bekker, Global PrEP roll-out recommendation for programmatic success, 2019).

Disparities in awareness and knowledge between different healthcare providers are important when considering the setting in which PrEP should be prescribed. Specific knowledge about PrEP medication, particularly how they work and the potential side effects, are critical aspects for the provision of PrEP by healthcare professionals (Hoffman, Guldry, & Collier, 2016). Reluctance to prescribe PrEP can be a result of provider misconceptions, such as concern that poor adherence may contribute to the development of resistance even though clinical evidence suggests that HIV drug resistance with PrEP use rarely occurs (Gibas, van den Berg, Powell, & Krakower, 2019).

Some individuals considered to be at risk for HIV perceive their own risk to be low. This can create another potential barrier to PrEP uptake (Kahle, Sharma, Sullivan, & Stephenson, 2018). This can also be compounded by insufficient ascertainment of HIV risk by healthcare providers (Zhang, Rhea, & Hurt, 2018). PrEP studies have demonstrated that partnership dynamics and accurate perception of HIV risk may facilitate consistent PrEP use among young women in South Africa, Zimbabwe, Kenya, and Tanzania (Hill, Maseko, & Chagomerana, 2020). The decision to take PrEP relies on acknowledging potential risk, and the gap between risk perceptions and

actual risk behaviours has been identified as a key contributor to people who are at risk but have low uptake of PrEP (Hammond, Vaccher, & Jin, 2019).

Perceived and/or experienced social stigma is a major barrier to PrEP use by at-risk individuals. The root cause may be the historical stigma surrounding HIV/AIDS (both the disease itself and being a member of a group considered at risk); for example, one might have concerns that by taking PrEP they would be mistakenly identified as HIV-positive. (Rael, Martinez, & Giguere, 2018). PrEP-related stigma at the healthcare provider level may compound the social stigma experienced by individuals. Healthcare providers may have concerns about the possibility of an increase in sexual behaviour by PrEP users due to the perception that HIV susceptibility is decreased and this may influence reluctance to prescribe PrEP (Golub, 2018).

Anticipation or experience of PrEP side effects and /or medication interactions may act as a barrier to PrEP use in AGYW. Several studies, in various demographic populations, have recorded concerns around short- and long-term safety of PrEP among individuals at risk (Kakalou, Lazarus, & Koutkias, 2019) Provider concerns around PrEP side effects and safety may also impact prescribing practices, exacerbating barriers to PrEP use.

Barriers that prevent uptake are not universal and can be population-specific, exacerbated by co-prevalent syndemic conditions such as poverty, inadequate education, and behavioural health issues (Chapman, Marrazzo, Amico, Mugavero, & Elopre, 2018). Improved education or training of individuals at risk and providers will be essential in overcoming a range of barriers to PrEP uptake. To raise awareness and uptake of PrEP among individuals at risk, delivery of brief educational sessions for

visitors to opportunistic infections/ sexual health clinics could be an effective approach (Chapman, Marrazzo, Amico, Mugavero, & Elopre, 2018)

Barriers and challenges in PrEP use (i.e. the factors that facilitate and impede uptake and adherence to PrEP among AGYW) can be assessed using the socioecological model. This model is useful in understanding the factors that influence health behaviour including HIV prevention (Dyson, Mobley, Harris, & Randolph, 2018).

The socio-ecological model has 5 levels

1. Individual factors i.e. knowledge, attitudes, and product attributes
2. Interpersonal factors accounting for the influence of social interactions on health decisions
3. Structural factors, for example, access to health services
4. Institutional factors including the provision of support tools and health provider attitude
5. Community factors, for example, community perceptions and social norms.

This model can also be used to evaluate the impact of PrEP use on normative behaviour among at-risk AGYW.

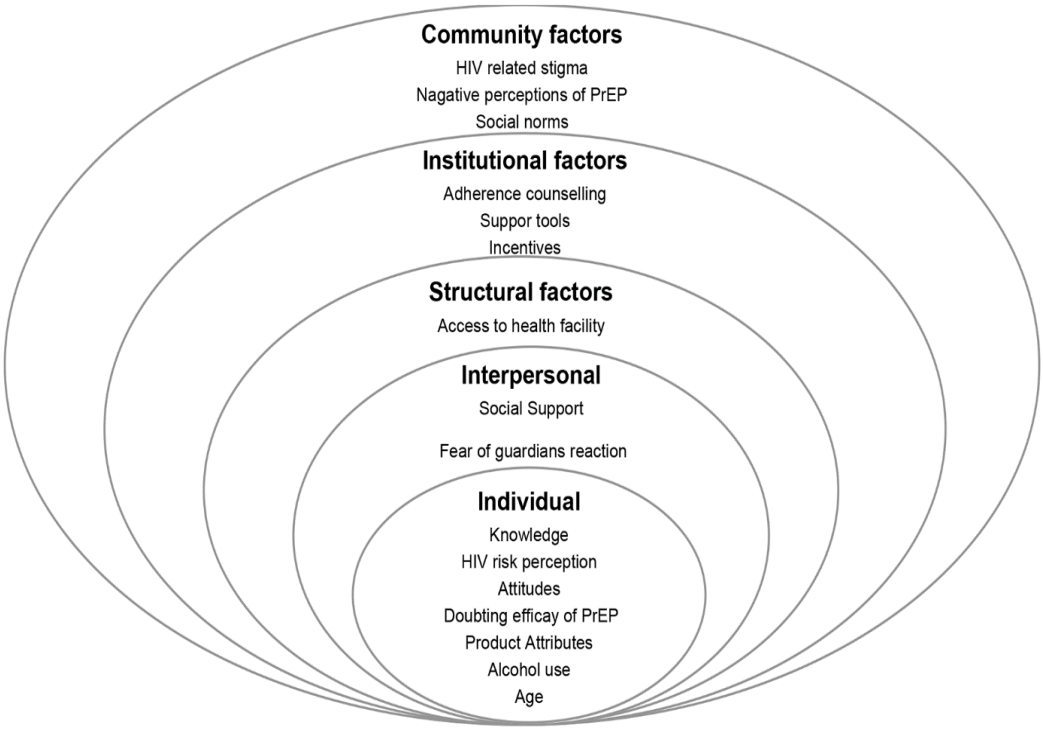

Figure 3: Potential barriers and challenges to PrEP uptake and adherence among AGYW at each level of the socio-ecological model (Adopted from Lancet, 2021).

The model takes into account barriers to daily oral PrEP adherence that have been demonstrated in other studies including psychosocial factors, intimate partner violence (IPV), lack of social support, stigma, and underestimation of HIV risk (Velloza, Khoza, & Scourgie, 2020). Gaps remain in knowledge about how AGYW aligns PrEP with HIV risk and optimal approaches to inform HIV risk perceptions and promote PrEP use.

2.6. Impact on HIV Incidence

The incidence rates of HIV among Adolescent girls and young women (AGYW) in sub-Saharan Africa are high and they range from 4 to 7 per 100 person-years in HIV prevention trials (UNAIDS, 2019). The HIV incidence rate among adolescent girls

and young women (AGYW) aged 15–24 years in sub-Saharan Africa is three times higher than adolescent boys and young men (Karim & Baxter, 2019). The disproportion in rates is attributed to several factors namely biological, social, and structural factors, including gender-based violence, gender inequities, socio-economic burdens, and HIV transmission networks involving age-disparate sexual partners (de Oliveira, et al., 2017)

A highly effective HIV prevention strategy such as daily oral pre-exposure prophylaxis (PrEP) is likely to have an impact when scaled up for AGYW in HIV endemic settings. To reduce the high HIV incidence among African AGYW, it is important to comprehend how to promote uptake and adherence to oral PrEP while in parallel developing and evaluating longer-acting and less adherence-dependent PrEP formulations.

HIV prevention trials in South African women demonstrated an HIV incidence of approximately 4% while another prevention trial of AGYW at risk of HIV demonstrated an incidence of 1% (ECHO Trial Consortium, 2019). In these studies, the breakthrough HIV infections were among women with low or no use of PrEP before HIV seroconversion. However there is a need to understand to what extent this low HIV incidence can be attributed to PrEP, additional research is required to determine whether PrEP use and adherence are aligned with periods of higher risk resulting in “prevention-effective adherence” (Haberer, et al., 2017).

Low HIV incidence demonstrated in studies can be attributed to the prevention services offered during the studies such as youth-friendly clinics, STI diagnosis and treatment, family planning counselling and services, peer support, healthcare provider

support, and counselling. Family planning clinics, youth-friendly clinics, and mobile clinics provide sexually active youth with sexual and reproductive health (SRH) services, however, there is a need for research to find out if AGYW will initiate and persist with PrEP in these settings (Celum, et al., 2022).

Oral tenofovir-based pre-exposure prophylaxis (PrEP) provides >90% protection against HIV infection when taken with high but not perfect adherence (Molinga, et al., 2017). Usually, infections identified in the first 1–3 months after PrEP initiation might be representing baseline infections, if they are not retrospectively assessed with more sensitive assays upon commencing PrEP (Celum, et al., 2022). Support for healthcare providers may be useful in the first few weeks after initiating PrEP to assess women's risk perception and PrEP motivations, challenges with PrEP use to mitigate early drop-off, and provision of adherence support and visit reminders to women at higher risk. These strategies may promote the continuation of longer-acting PrEP formulations when they are rolled out.

Efforts to continue to evaluate and understand factors associated with medication adherence and retention in PrEP care are needed (Herns, Pamwala, Pfeil, Sardinha, & Vito, 2023). Multiple clinical sites in the United States have begun to examine PrEP adherence and retention in real-world settings as opposed to clinical trials to identify potential areas of intervention to improve engagement in the continuum of PrEP care (Rusie, Orengo, & Burrell, 2018). Patient demographics have also been examined but there is a lack of significant difference in retention by age (Chan & Patel, 2016). While specific findings of factors associated with poor PrEP adherence have varied nearly

universally these studies show poor overall retention (Herns, Pamwala, Pfeil, Sardinha, & Vito, 2023).

HIV infection in PrEP users is poorly described because they have a lower viral load peak during primary HIV infection and often have fewer symptoms than individuals not exposed to PrEP. Also, PrEP prolongs the stages of seroconversion potentially complicating the diagnosis of primary HIV infection. Drug resistance is rare and occurs mostly when PrEP is initiated in undiagnosed patients who are at an extremely early stage of infection, in whom detection of HIV-RNA was not used to rule out HIV infection.

HIV seroconversions usually occur in users with poor adherence to PrEP (Laurent, et al., 2023). The prevalence of HIV seroconversion in PrEP users has been estimated at around 3%, with most PrEP 'failures' attributed to poor adherence (Ambrosioni, Petit, Liegeon, Laguna, & Miro, 2021). Studies in younger women who had access to PrEP demonstrated an associated lower-than-expected HIV incidence. In one such study, where PrEP and ART were offered to serodiscordant couples in Kenya and Uganda from 2012 to 2015, HIV incidence was 0.2%, representing a 96% reduction compared to matched historical controls without PrEP (Baeten, et al., 2016)

AGYW remains a critical population for HIV prevention and is disproportionately impacted by HIV across much of sub-Saharan Africa (UNAIDS, 2020). Population-based studies have shown greater reductions in incidence among men than women in the context of the scale-up of ART. Thus, primary prevention approaches, such as PrEP, may be important for reducing incidence among AGYW. Oral PrEP can lower

HIV incidence among AGYW as shown in several studies, including among women who are not in serodiscordant partnerships (Hayes, et al., 2019).

2.7 PrEP Discontinuation

PrEP discontinuation is an important challenge, as a high proportion of PrEP initiators cease taking PrEP within the first 3–6 months (Rutstein, Smith, Dalal, Baggaley, & Cohen, 2020). Very low continuation rates have been observed in some settings; studies in sub-Saharan Africa have seen more than half of PrEP initiators, and sometimes even more, discontinue PrEP by 6 months (Kinuthia, et al., 2020). Continuation rates and longer-term PrEP protection have been much higher in some populations in some settings than in others (Chidwick, et al., 2022)

PrEP is not a long-term intervention, and users can opt out if they perceive their risk of contracting HIV is low. However, discontinuing PrEP while the risk of infection is still present is likely to affect the impact of the intervention. Research that focuses on informing decisions to discontinue should be strengthened to address patterns of use that do not take into account periods of risk. Discontinuation of PrEP after proper risk assessment is done is probably the best way to address the challenge of risk perception.

2.8. Policy and Programmatic Considerations

PrEP implementation for AGYW requires more understanding and guidance to successfully implement PrEP programs. WHO recommends that PrEP programs consider the local context and individual risk when considering who might benefit from PrEP (Lachowsky, et al., 2019) Understanding real-world AGYW experiences

with and beliefs about daily oral PrEP use can inform programmatic PrEP implementation tailored to AGYW.

Zimbabwe developed a plan to scale up PrEP between 2018 and 2020, following PrEP's introduction in 2016 (MOHCC, 2018). Since then delivery of oral pre-exposure prophylaxis (PrEP) is primarily through HIV clinics in Zimbabwe. This poses a risk of missing an opportunity to reach adolescent girls and young women (AGYW) seeking other health services.

2.9. Summary

PrEP use has been targeting high-risk groups such as AGYW, however, studies have demonstrated poor performance of the intervention owing to various factors including poor adherence, lack of awareness, non-disclosure to spouses, and stigma (both use and historical) among other challenges. Most of the studies have focused on the implementation of the intervention in trials but the literature is insufficient on the evaluation of PrEP use in real world settings. Most of the studies have focused on MSM and some of the findings are not universally conclusive. AGYW constitute an important demographic group and the use of PrEP with good adherence in this group is likely to contribute immensely to epidemic control of AIDS.

CHAPTER THREE: METHODOLOGY

3.0 Introduction

This chapter outlines the research design and methodology employed in this study. The methodology of a study presents the theories of how the study has been carried out and how far the research design can enable the researchers to be able to come up with specific vital sound inferences (Perri & Bellamy, 2012). This further aids the conclusions that are likely to give answers to the research questions and determine how far the data obtained will match the expected outcome. An explanation of the necessary research steps, sampling and implementation of research procedures, data gathering, and analysis is presented.

Research methodology thus constitutes research methods and selection criteria of research strategies used in the context of the study. It constitutes tools for data collection and analysis. Practically they are the tools by researchers and are chosen based on criteria related to or even dictated by the major elements of the methodology in which they are embedded. They are tools used by researchers to gather empirical evidence. A description of the respondents who participated in the study is given and this as well includes a summary of how they were selected. A target population, sampling techniques, and ethical considerations for this study are also discussed. The last section outlines the validity and reliability of the employed method and contains some reflections on the research process.

3.1. Study Design

This section describes the research design chosen for this study. Study Design is a strategy chosen by a researcher before the data collection process to accomplish the research objectives. It is essential as it translates a problem into data that can be analysed to get accurate answers to research questions (Asenahabi, 2019). A research design is the plan, structure, and strategy of investigation conceived to obtain answers to research questions and to control variance (Malhotra, 2004). Therefore, a research design guides the research in the right direction, thus reducing inaccuracy, and eliminating bias and marginal errors.

The research employed an analytic cross-sectional design with a mixed-method approach, combining quantitative and qualitative data collection and analysis. This design was chosen because it allows for a comprehensive understanding of the impact of oral PrEP among AGYW in the Makonde district.

Quantitative data was collected from existing records at public health facilities in Makonde district for the period January 1, 2020, to December 31, 2022. These sources included PrEP registers, DHIS2, monthly return forms, and program reports at public health facilities. The data extracted encompassed sociodemographic characteristics, HIV status, PrEP initiation date, prescription details, adherence (measured by clinic visit status), retention (defined as having at least one follow-up visit within 90 days of the previous visit), and discontinuation (defined as no follow-up visit for more than 90 days or stopping PrEP by choice or provider recommendation)..

Qualitative information is described as soft data that is rich in description of human behaviour, conversations, and places and cannot be handled statistically (Bogdan &

Biklen, 1992). Qualitative research methods create openness. They encourage people to expand on their responses and open new topic areas not initially considered. This creates a thorough conception of the phenomenon which this research believes is a negotiated enterprise and complex process which can be understood using qualitative research methods.

This data was gathered through the following methods:

In-depth interviews: Conducted with current and former PrEP clients (AGYW) to explore their experiences and perspectives. Recruitment leveraged PrEP register data to identify and contact potential participants.

Focus group discussions: Facilitated discussions with groups of AGYW to explore shared experiences and group dynamics regarding PrEP use.

Key informant interviews: Conducted with healthcare providers working in Opportunistic Infection clinics to gain their perspectives on PrEP implementation and service delivery for AGYW.

3.2. Mixed Method Approach

The mixed method approach comprises a type of research methodology that involves conducting research, collecting data, and analysing findings. The mixed method approach is beneficial for a study because it provides the strengths of both qualitative and quantitative methods. For instance, the quantitative data that is analysed in a mixed method approach helps to explain the trends and patterns in the data, while qualitative data provides the depth of understanding and the underlying reasons behind the trends. Because of this, a mixed method approach does not just involve

collecting and analysing both types of data, but it also involves the use of both types of data in the same study to answer the research questions. This is distinct from conducting "qualitative research" or "quantitative research" where a study is designed specifically to use only one type of research methodology.

A study that employs the qualitative research methodology might use focus groups or interviews to collect data that is then analysed based on words, meanings, and interpretations. If the study warrants the use of quantitative research methodology, on the other hand, it might make use of surveys or experiments to collect data that is then analysed based on the mathematical analysis of numerical data. In short, both types of research in a mixed method approach can be employed to validate findings from each other - a strategy is known as "triangulation". Triangulation in mixed methods is the application and combination of several research methodologies in the study of the same phenomenon.

3.3. Study Area

The study was conducted in Makonde district, Zimbabwe, located in the Mashonaland West Province. Makonde district was chosen as the study area due to several factors:

High burden of HIV, adult prevalence of 10.5% (MOHCC, 2022). This makes PrEP a crucial intervention for preventing HIV transmission among AGYW.

AGYW population: 14% of the total population is aged 18-24 years (Zimstat, 2022). Hence a significant proportion of the population falls within the age group most at risk for HIV acquisition.

PrEP program availability: Makonde district has public healthcare facilities offering PrEP services, enabling the study to assess the program's impact on AGYW.

The population is served by 41 public healthcare facilities i.e. one provincial hospital, two mission hospitals, and 38 clinics that cater to these people. It is under the jurisdiction of Chief Magonde and has 19wards in total. The study's settings were selected public healthcare facilities in Makonde District which provide PrEP.

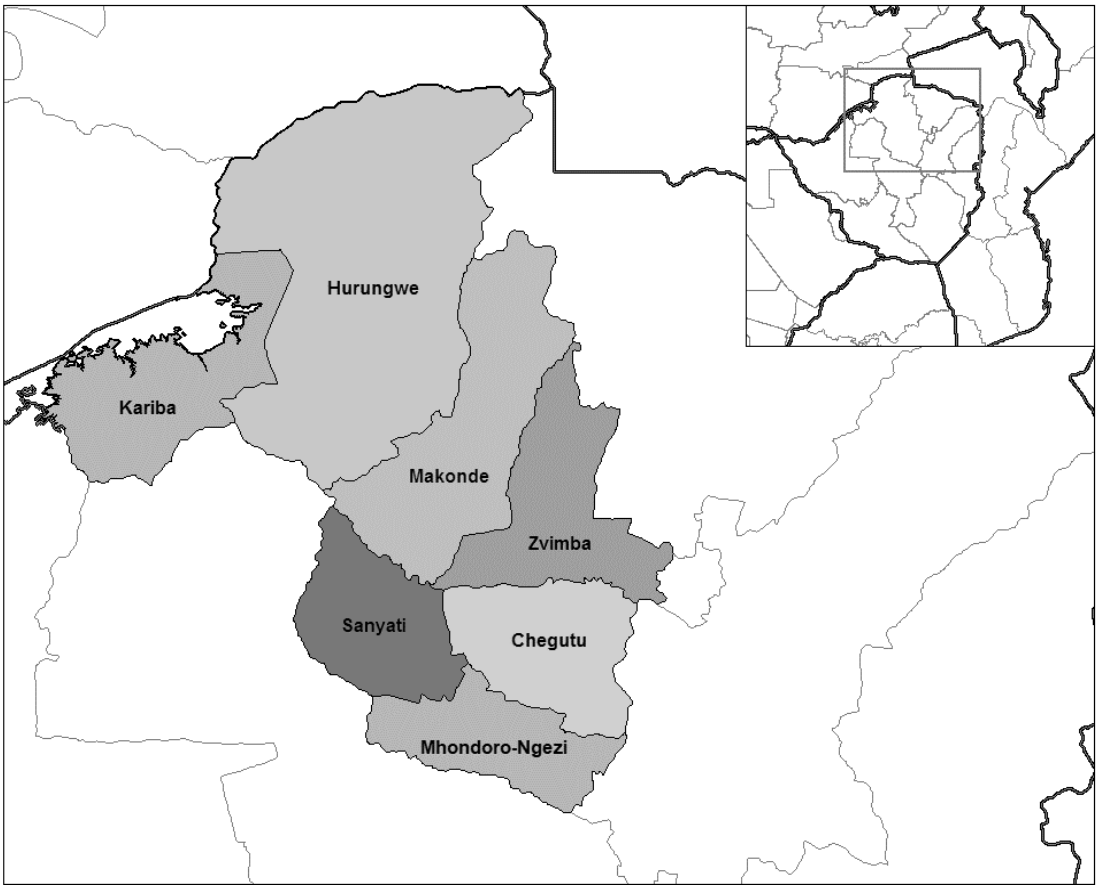

Figure 4: A map of Mashonaland West Province

3.4. Study Population

This section describes the target population and the inclusion/exclusion criteria for both the quantitative and qualitative components of the study.

3.5.1. Quantitative Data

Secondary data on PrEP users was obtained from existing records at public health facilities in Makonde district for the period January 1, 2020, to December 31, 2022. These sources included PrEP registers, DHIS2, monthly return forms, and program reports. The target population for the quantitative analysis included:

Inclusion criteria:

Cisgender women

HIV-negative

Aged 18-24 years

Initiated oral PrEP in Makonde district between January 1, 2020, and December 31, 2022

3.5.2. Qualitative Data

The qualitative component of the study involved data collection from two groups:

Adolescent girls and young women (AGYW):

Inclusion criteria:

Cisgender women

HIV-negative

Aged 18-24 years

Currently using or ever used oral PrEP in Makonde district

Healthcare providers:

Healthcare providers working in OI clinics on the day of data collection were purposively sampled to ensure the representation of different healthcare worker cadres (e.g., nurses, doctors, counsellors).

Rationale for Inclusion Criteria:

The inclusion criteria for both AGYW and healthcare providers were established to ensure the study population is relevant to the research objectives.

Focusing on cisgender women aligns with the study's focus on the impact of PrEP among this specific population group.

The age range of 18-24 years reflects the demographic most at risk for HIV acquisition in sub-Saharan Africa.

Including both current and former PrEP users in the qualitative data collection broadens the range of perspectives captured.

Exclusion Criteria:

The exclusion criterion for the AGYW focus group discussions aims to ensure participants have experience with the PrEP program within the Makonde district, facilitating a more focused discussion

3.6 Sample size

Using an oral PrEP retention rate of 6 months of 20% (Celum, et al., 2022) sample size of records to be reviewed was calculated using the Dobson formula at a 95% confidence interval and absolute error of 5%. Six months is a typical period for

evaluation of PrEP adherence and continuation in PrEP demonstration projects among African AGYW who have low-risk perception and dynamic partnerships (Celum, et al., 2022).

$\{(1.96)^2 \times (0.2)\ (0.8)\}/\ (0.05)^2 = 245$

Therefore, the sample size for quantitative data was 245.

In-depth interviews and focus group discussions with maximum variation saturation were done with 82 participants who were either former or current PrEP clients. 20 healthcare providers provided key information (Patton, 2002).

3.7. Sampling method

This section describes the sampling methods employed for both the quantitative and qualitative components of the study.

3.7.1. Quantitative Data

A multi-stage sampling approach was utilised to obtain quantitative data on PrEP users from public health facilities in the Makonde district.

Stage 1: Facilities were stratified by location (urban vs. rural) to ensure representation from both areas.

Stage 2: A calculated sample size of 245 was proportionally allocated to urban and rural facilities based on their client volume.

Stage 3: Within each selected facility, PrEP registers were used to identify AGYW who met the inclusion criteria (as outlined in section 3.5.1)

3.7.2. Qualitative Data

Purposive sampling was employed to recruit participants for the qualitative component of the study.

Adolescent girls and young women (AGYW): AGYW was purposively sampled to ensure the representation of diverse experiences and perspectives related to PrEP use. Data collection continued until maximum variation saturation was achieved, indicating a point where no new themes emerged from the interviews/focus groups.

Healthcare providers: Healthcare providers working in OI clinics on the day of data collection were purposively sampled to include representatives from different healthcare worker cadres (e.g., nurses, doctors, counsellors). This ensures a variety of viewpoints on PrEP implementation and service delivery for AGYW.

In both qualitative and quantitative research, the intent of sampling individuals is to choose individuals who are representative of a population so that the results can be generalised to a population. In this way, investigators first select their population and define it carefully. Then they choose a sample from this population.

Table 1: Data collection sites

Location	Facility
Urban	Chikonohono Clinic, Chinhoyi Provincial Hospital, Chinhoyi Clinic, Mzari Poly Clinic, Presbyterian Clinic, Makonde Christian Hospital
Peri-Urban	Alaska Clinic, Murereka Clinic, Portlet Clinic, Shackleton Clinic

Rural	Doma Clinic, Godzi Clinic, Kamonde Clinic, Kamuzingizi Council Clinic, Kanyanga Clinic, Long Valley Clinic, Manyamba Clinic, Matoranjera Clinic, Mutala Council Clinic, Nyamugomba Clinic, Obva Clinic, Umboe Clinic, Gandawasvika RDC Clinic, Sadoma Clinic

3.7.3 Multi-stage sampling

Multistage sampling is a sampling method that divides the population into groups (or clusters) for research as stated by (Raifman, Devost, Digitale, Chen, & Morris, 2022). It is a complex form of cluster sampling, sometimes also known as multistage cluster sampling. During this sampling method, significant clusters of the selected people are split into sub-groups at various stages to make it simpler for primary and secondary data collection. It is cost-effective and time-effective because this method helps cut down the population into smaller groups. This was helpful due to the time limit that the study was conducted.

Multistage sampling is particularly useful when the target population is large and geographically dispersed (Raifman, Devost, Digitale, Chen, & Morris, 2022). This is the case for the Makonde district. By dividing the sampling process into multiple stages, researchers can efficiently select samples from different geographic areas or subgroups, making the sampling process more manageable and cost-effective.

In primary data collection, multistage sampling can involve selecting clusters (such as neighbourhoods, schools, businesses, or health facilities) at the first stage, and then selecting specific units within those clusters at subsequent stages. This approach helps

researchers reach a diverse range of participants while maintaining a representative sample of the population.

In secondary data collection, multistage sampling may involve selecting data sources or databases at different stages, and then extracting samples from each source to create a composite sample for analysis. This method can help researchers integrate data from multiple sources to answer research questions or test hypotheses.

Overall, multistage sampling is a flexible and powerful sampling technique that can be applied to both primary and secondary data collection scenarios, providing researchers with a systematic way to obtain representative samples from complex populations.

3.7.4 Purposive Sampling

Purposive sampling (also known as judgement, selective, or subjective sampling) is a way of selecting a representative population in which the researcher relies on his or her judgement when choosing members of the population to participate in a study (Campbell, et al., 2020). The purpose of the research determines how the informants are selected.

Purposive sampling has its disadvantages. Firstly, purposive sampling is vulnerable to errors in judgement by the researcher. The very fact that it relies on the researcher's judgement puts it at the mercy of these judgments (Campbell, et al., 2020). Secondly, some scholars, especially those in business studies have argued that it is open to bias as the researcher may choose informants subjectively. Thirdly, it is not able to generalise research findings. These disadvantages are however subject to debate, and

the researcher does not think they weaken purposive sampling as a technique in general. The researcher felt that this was still the best sampling technique for a study such as this one. The concerns that these disadvantages raise can be catered for by avoiding overreliance on one informant.

3.7.5 Snowball Sampling

The other sampling procedure that this study used is snowballing. It was the view of this researcher that there is a thin line between purposive sampling and snowballing. The snowballing technique was used to select the rest of the respondents. Snowballing is useful when one is trying to reach populations that are hard to access (Raifman, Devost, Digitale, Chen, & Morris, 2022). Snowball or chain sampling is when the researcher locates one or two individuals and then asks them to name other likely informants and it is usually done to enable the identification of hard-to-find cases (Oppong, 2013).

In snowballing, the researcher initially contacts a few potential respondents and then asks them whether they know of anybody who has similar knowledge to the one that the researcher is looking for. It is also known as referral sampling as one element is approached at a time and then is asked to refer the researcher to the other elements of the population. During the research, the referral sampling was almost happening naturally. Some of the respondents that the researcher targeted naturally referred the researcher to other informants that they thought were more resourceful and knowledgeable.

3.8. Sources of Data

Two areas are considered when finding data which are the primary and secondary data sources.

3.8.1 Secondary Data

Secondary data refers to the data that has been collected for other purposes that have different dedications from those of the study (Orsini, et al., 2020). Thus, once the data is stored and archived it becomes secondary even though it was once primary for other purposes. It is data that has been already published and collected not only for the research in question but for other purposes. For this study, secondary data was retrieved from PrEP registers, DHIS2, and monthly report forms.

The advantage of using secondary data in the research study was that it was easy to have direct information from the source of monitoring information. This presents a direct link and also gives the researcher the field and the advantage of having a historical analysis and review of the data of a related area. It is time-saving and cost-efficient.

3.8.2 Primary data

Primary data refers to data collected originally from the source by the researcher for first-hand investigation from the basic area under survey (Tenny, Brannan, & Brannan, 2022).

Thus, this data was empirically gathered to enable and suit the study at hand to be analysed. The most advantageous reason for using primary data is that the statistics

can be adjusted and linked with the research objectives and answer the research questions in line with the focus of the study.

Primary sources provide first-hand testimony or evidence concerning a topic under investigation. Primary data expresses the direct views of those on the ground, thereby presenting the current information (Creswell & Creswell, 2018). In this study, the researcher used primary data that was collected by the researcher using semi-structured interviews, in-depth interviews, and focus group discussions from a varied number of respondents.

Using the primary data always presents the advantage of the researcher being able to adjust the data gathered to suit the situation under survey or study. With the use of primary data, the researcher will be exposed to the advantage of first-hand information that allows for the deduction of wanted and unwanted data from the findings. Using primary data brings about the clear opinions and reactions of the study participants. In addition, using primary data makes it an easy task for the researcher to analyse some of the unravelled expressions from the participants such as facial expressions during interviews and observations. The disadvantage of using primary data in this research is that it is time-consuming, for the study to be done correctly primary data collection requires the development and execution of a research plan

3.8.3 Study Instruments

These are the tools used by the researcher to collect information from participants. The choice of which tool to use depends on whether it can measure the variables in the research questions.

3.8.4 Data Collection Instruments

One key data collection tool employed in this research was oral interviewing. A series of interviews with people from different clinics in the communities were carried out using semi- and unstructured questionnaires that were administered directly by the researcher. Essentially, a flexible approach was employed during the interviews. The interview process was more interactive than the usual question-and-answer session.

3.8.5 Interviews

Interviews were conducted and recorded in English or Shona. Aside from the participant and interviewer, no one else was present. Preferences from clients about the interviewer's gender were respected. Interviews were conducted in person at the PrEP site or the client's preferred location. The interview guide was based on the Extended Health Belief Model that explores health behaviour constructs, including perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. The interview guides were used for clients who had accepted PrEP. Interviews lasted 15–60 minutes with the average being 30 minutes. Interviews served as a means to gather data by probing the perceptions, attitudes, beliefs, and feelings of the AGYW.

3.8.6 Semi-structured Interviews

An interview is a verbal interaction between two or more individuals but for a specific purpose (Kumar, 2011). It is more appropriate for complex situations as it allows the opportunity to prepare a respondent before asking sensitive questions and explaining complex ones. In this study, the researcher used semi-structured interviews. These are

interviews that offer a considerable amount of leeway to the researcher to probe the respondents along with maintaining a basic interview structure (Bhat, 2019). Semi-structured interviews were preferred because they allowed the researcher to be flexible to express the questions in the way that he judged to fit the situation.

An interview can be described as a communicative procedure where an investigator can deduce or extract the required information from the responsible person or informant. Thus, the nature and the results of the extracted information will be strongly influenced by the flexibility and nature of the environment in which the respondent or the informant was exposed and based on the previous experience. Therefore, based on the subjectivity of the interview, the information generated may be subjective information that will be shaped by the interviewer's experience.

A semi-structured questionnaire was used to collect data from PrEP users and healthcare providers. The questionnaire captured demographic characteristics, risk perception, experiences, opinions, challenges, and suggestions for improvement in the use of oral PrEP. The respondents had to supply their answers without being constrained by a fixed data set.

To keep the process manageable, each interview lasted for an average of 30 minutes. The atmosphere in these interviews was informal, resembling a conversation among acquaintances. The number of interviewees in each data collection station was determined by the availability of key informants who were known to be knowledgeable in the subject and who were willing to voluntarily participate in the research.

3.8.7 Focus Group Discussion

The researcher also held three focus group discussions. A focus group discussion involves gathering people from similar backgrounds or experiences together to discuss a specific topic of interest (Liamputtong, 2011). The data collection process adhered to ethical standards and quality assurance procedures. FGD discussions were important in weighing and balancing the information collected through interviews to produce generalisations that represent the use of PrEP among AGYW. The establishment of groups based on the inclusivity of all AGYW criteria is always prone to the effects of excluding critical information

3.8.8 Data extraction tool

This also is a systematic review, data extraction is the process of capturing key characteristics of studies in structured and standardised form based on information in journal articles and reports. It is a necessary precursor to assessing the risk of bias in individual studies and synthesising their findings. Data extraction is the process of obtaining raw data from a source and replicating that data somewhere else. The raw data can come from various sources, such as a database, Excel spreadsheet, web scraping, or others.

Data collection took place from 1 January 2024 to 15 March 2024, secondary data extraction from PrEP registers was done the same day with interviews for PrEP users and healthcare providers at each facility. A data extraction tool (appendix 5) was used to collect information from PrEP registers and the collected information included demographic characteristics, pattern of PrEP use, STI/HIV status, risk profile, and adverse events during PrEP use. Program reports, monthly return forms, and DHIS2

were used to obtain district HIV statistics and verification of data obtained in PrEP registers.

3.9 Pilot study

A pilot study is a small-scale preliminary investigation conducted to test the feasibility, refine research methods, and identify any potential challenges before the main study (Hassan, Schattner, & Mazza, 2006). It is a process of testing the feasibility (in terms of time, resources, and participant willingness) of the main study.

A pilot study was conducted at Karoi District Hospital to:

Evaluate the interview guide: Assess the clarity, flow, and appropriateness of the interview guide for PrEP users.

Refine data collection procedures: Test recruitment strategies, interview duration, and note-taking procedures.

Identify potential challenges: Anticipate any logistical or ethical issues that might arise during the main study. Twelve participants aged 18-24 years took part in the pilot study as per recommendation (Hassan, Schattner, & Mazza, 2006).

3.10 Recording Data

Data was collected through a combination of methods. In some instances, data was gathered while recording using a voice recorder and some conversations could not be recorded due to various reasons. The data gathered was documented by way of taking notes as the respondents communicated their stories and the researcher observed activities on the ground. It was important to seek consent to the taking of notes. Due

to surveillance and violence arising from the difficult political conditions in the country, people are quite sceptical of anyone intending to record conversations.

3.11 Measures to ensure the reliability and validity of the questionnaire

Reliability of a questionnaire refers to the dependability, confirmability, or consistency of a questionnaire to produce the same results when administered to the same respondents under similar conditions (Erlingsson & Brysiewicz, 2012). Reliability should be consistent and dependable across multiple sources of evidence. Reliability refers to the ability for findings to be repeated and come out with the same results. For example, if a study were to be redone, using the same methods and the same participants, it should correlate and the data can be deemed reliable.

Validity refers to how credible or believable the research is and it refers to the trustworthiness of the findings. In other words, it is the degree to which the results are truthful. Validity measures the research method and how relevant and effective it is to bring out the desired results.

Measures taken to enhance the validity of this study included:

Triangulation: Utilising multiple data collection methods (interviews, focus groups, and document review) strengthens the validity of the findings by providing a more comprehensive understanding of the phenomenon under investigation.

Member Checking: Sharing preliminary findings with participants to get their feedback on the accuracy and completeness of the interpretations was considered.

Evaluating the validity and reliability of research findings is important especially if the results of the research are to be used to influence policy makers.

3.12 Data analysis and organisation

The study used STATA software for quantitative data analysis and Epi Info7 software for qualitative data analysis. Quantitative data analysis involved cleaning, coding, validating, and summarising the data using descriptive and inferential statistics. Cox hazards ratio regression was used to identify the predictors of long-term (> 6 months) PrEP retention. Multiple logistic regression was used to determine the statistical significance of adherence to oral PrEP and sociodemographic characteristics.

Qualitative data analysis involves transcribing, translating, coding, categorising, and interpreting the data using thematic analysis. The study then triangulated observations to compare and integrate the findings. The data for this study was analysed using thematic analysis. Thematic analysis is a method of analysing qualitative data, which is usually applied to a set of texts, such as interview transcripts. The researcher closely examined the data to identify common themes or topics, ideas, and patterns of meaning that come up repeatedly.

Braun & Clarke (2012) describe it as a way of identifying what is common to the way a topic is talked or written about, and of making sense of those commonalities. They go on to emphasise that the patterns of meaning that thematic analysis allows the researcher to identify must be important concerning the particular topic and research question being explored. So, while many themes may be deduced from a collection of interview texts, the researcher focused on those who responded to the research questions.

In this study, the researcher coded the responses before entering the data into Microsoft Excel followed by entering the data into Epi Info7 which was used for data analysis. Nominal data in the questionnaire included sex, marital status, and risk profile, while ordinal data included age and level of education. Descriptive statistics like percentages and frequencies were used to analyse nominal and ordinal variables.

The frequency of each response was expressed as a percentage for clarity. Tables and bar graphs were used for data presentation.

3.13 Data Dissemination

Findings were disseminated to various stakeholders, including the Provincial Medical Director, program managers/officers, healthcare providers, researchers, and partners supporting HIV prevention programs. Formats and channels for dissemination used included meeting presentations and reports.

3.14 Ethical Consideration

The researcher ensured that participants were fully and accurately informed about the reasons, aims, and purpose of the study. In addition, the researcher ensured the respondents were not coerced to participate, that is, participation was voluntary. Permission for the study was sought from the Africa University Research Ethics Committee (AUREC) and the Provincial Medical Director (Mashonaland West). Informed consent was sought from the participants and confidentiality was maintained by not mentioning names of participants.

See Appendix 7 for the AUREC ethical clearance letter and Appendix 6 for the PMD approval letter. The ethical principles that were applied by the researcher in this study

include respect for persons, justice, beneficence, and non-maleficence. More details are discussed below.

3.15.1 Respect for persons

Participants in a research study should agree to take part in the study voluntarily, without fear, undue encouragement, or dishonesty. Informed consent protects the interests of participants. It ensures participants are offered enough information about a study before consenting to participate. All the participants in this study were independent persons who could sensibly make their own decisions. This is because all of them were adults of normal mental capacity. The researcher explained to all potential participants that participation was voluntary and those who chose not to take part in the study would not be punished. The researcher also explained the study details to all the study participants. Those who consented to participate in the study were requested to sign an informed consent form

3.15.2 Justice

Justice in research involves choosing participants based on the requirements of the study, and not on a particular group's vulnerability. Justice promotes the following principles of equity, access, participation, and harmony for culturally diverse populations, those currently most at risk for acts of social injustice. All the potential participants at the selected healthcare facilities had an equal opportunity to participate in the study through random sampling of the target population.

3.15.3 Beneficence and non-maleficence

Beneficence is the promotion of the good of the study participants by the researchers. Human research must yield benefits for participants or other people in society. In this study, healthcare facility managers were expected to use the findings from the study to reduce barriers to PrEP care, which would reduce the number of people getting infected with HIV in society. Non-maleficence specifies that researchers must lessen unnecessary harm in studies that involve human beings.

3.15.4 Confidentiality and privacy

Confidentiality in research guarantees data provided by participants is kept in strict confidence while privacy ensures that participants have control over what they disclose to researchers. The researcher protected the privacy and confidentiality of all participants by concealing their identities on data capturing tools. Informants were also assured that their names were not going to be used to avoid implicating any individuals or exposing them to public scrutiny, thereby protecting those who participated in the research. After completing the data analysis process, the data were kept on a password-protected computer while the recorded responses were kept in a locked steel cabinet that only the researcher had access to. The data would be kept for five years, after which it would be permanently deleted from the computer and the hardcopy responses would be destroyed through shredding.

3.16 Summary

This chapter has outlined the research design and the research methods that were used in the study. It discussed in detail these research methods and gave reasons why the

researcher chose them. This is a study that is both quantitative and qualitative with two sampling methods, that is, purposive sampling and snowball sampling were used to select informants.

The study used a cross-sectional analytic approach with primary data obtained through interviews using semi-structured questionnaires and secondary data obtained from reviews of medical records. The study was conducted in Makonde District in Mashonaland West. Eighty-one former and current PrEP users were purposively sampled for the study, selected from twenty-six healthcare facilities in the district between 1 January 2024 and 6 March 2024. PrEP monitoring information was accessed for two hundred and forty-five users registered from 1 January 2020 to 31 December 2022. Stata and Epi Info 7 were used for analysing the data. The next chapter will concentrate on the results of the study.

CHAPTER FOUR: DATA PRESENTATION, ANALYSIS AND INTERPRETATION

4.1. Introduction

This chapter contains a presentation of the study results, a discussion of the results, and an interpretation of the findings. The results are presented starting with the demographic characteristics of participants involved in the study, followed by thematic presentation of findings from the interviews. Statistical analysis methods used include Cox hazard proportions regression to determine the predictors of long-term retention on PrEP and multiple logistic regression to determine the association between adherence rate and sociodemographic characteristics.

4.2. Data Presentation

Baseline demographic characteristic of PrEP service providers, Makonde District, Mashonaland West, 2024

Table 2: Age of service providers

Variable	Obs	Mean	Std. Dev.	Min	Max
Age	29	34.55172	5.852876	26	48

The mean age for the service providers was 34.5 years, with the youngest 26 years and the eldest 48 years old.

Table 3: Role of service providers

Role	Frequency	Percent	Cumulative
Counsellor	6	20.69	20.69
Nurse	23	79.31	100.00
Total	29	100.00	

79.3% of the service providers interviewed were nurses.

Table 4: Service providers' years of experience

Variable	Obs	Mean	Std. Dev.	Min	Max
experience	29	7.517241	4.755603	1	19

The average number of years of experience for service providers was 7.5 years. With the longest-serving member in the OI department having worked for 19 years in a public health facility.

Baseline demographic characteristic of PrEP users, Makonde District, Mashonaland West, 2024

Table 5: Age of current and former PrEP users

Variable	Obs	Mean	Std. Dev.	Min	Max
Age	81	21.77778	1.86415	18	24

A total of 81 PrEP users were interviewed in focus group discussions and in-depth interviews, and their mean age was 21.8 years.

Table 6: Duration of PrEP use

Variable	Obs	Mean	Std. Dev.	Min	Max
Duration of use	81	2.604938	1.472065	1	6

The PrEP users (both current and former) interviewed had a mean period of PrEP use of 2.6 months. The lowest period of PrEP use was 1 month.

Baseline demographic characteristics of PrEP users registered from 1 January 2020 to 31 December 2022, Makonde District, Mashonaland West.

Table 7: Age of Oral PrEP users registered from January 2020 to December 2022

Variable	Obs	Mean	Std. Dev.	Min	Max
age	245	21.04898	2.019792	18	24

245 individual records for AGYW were reviewed; their mean age was 21.0 years.

Table 8: Distribution of PrEP users according to facilities

facility	Freq.	Percent	Cum.
Clinic	196	80.00	80.00
Hospital	49	20.00	100.00
Total	245	100.00	

80% of the AGYW whose records were accessed were from a clinic setting and 20% were recipients of care from a hospital opportunistic infection clinic/department.

Table 9: Marital status of PrEP users

Marital Status	Freq.	Percent	Cum.
Married	22	8.98	8.98
Not married	223	91.02	100.00
Total	245	100.00	

91.0% of the AGYW who were sampled in the study were not married (divorced, widowed, or in a relationship).

Table 10: Client profile for PrEP users

Risk profile	Freq.	Percent	Cum.
Serodiscordant	49	20.00	20.00
Commercial sex worker	47	19.18	39.18
General population	149	60.82	100.00
Total	245	100.00	

60.8% of AGYW included in the study were classified as the general population, in terms of client risk assessment profile. There is a possibility of not volunteering information by AGYW since some profiles are perceived as immoral, however, all were assessed and identified to have high risk of contracting HIV. In this instance, the assessment would include the primary complaint that an individual would present with at the clinic or hospital e.g. STI infection.

PrEP users responses

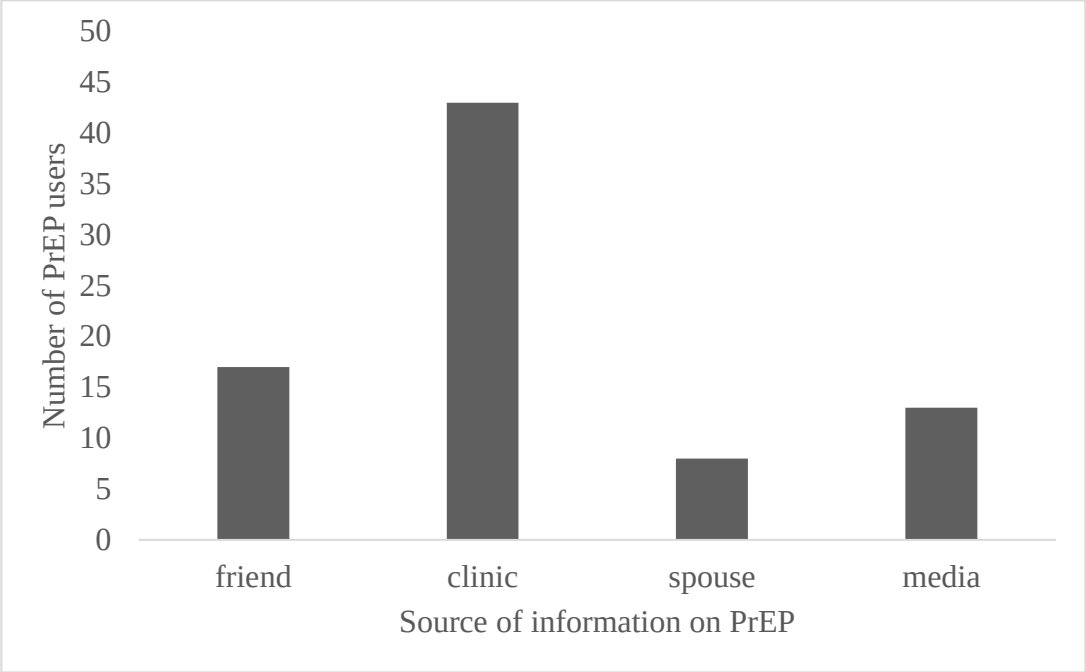

Figure 5: Response to question on the source of information on PrEP

53.1% (n= 43) of PrEP users interviewed had received information about PrEP when they visited the local clinic or health facility. And less than 10% (n=8) had been advised by their spouses about the possibility of using PrEP. All of the users who had received information on oral PrEP after visiting a public health facility had either gone for HIV testing, ANC booking, STI treatment, or postnatal care visits. Media was cited to have played a role in the decision to consider PrEP by 16.0% (n=13) of the interviewees.

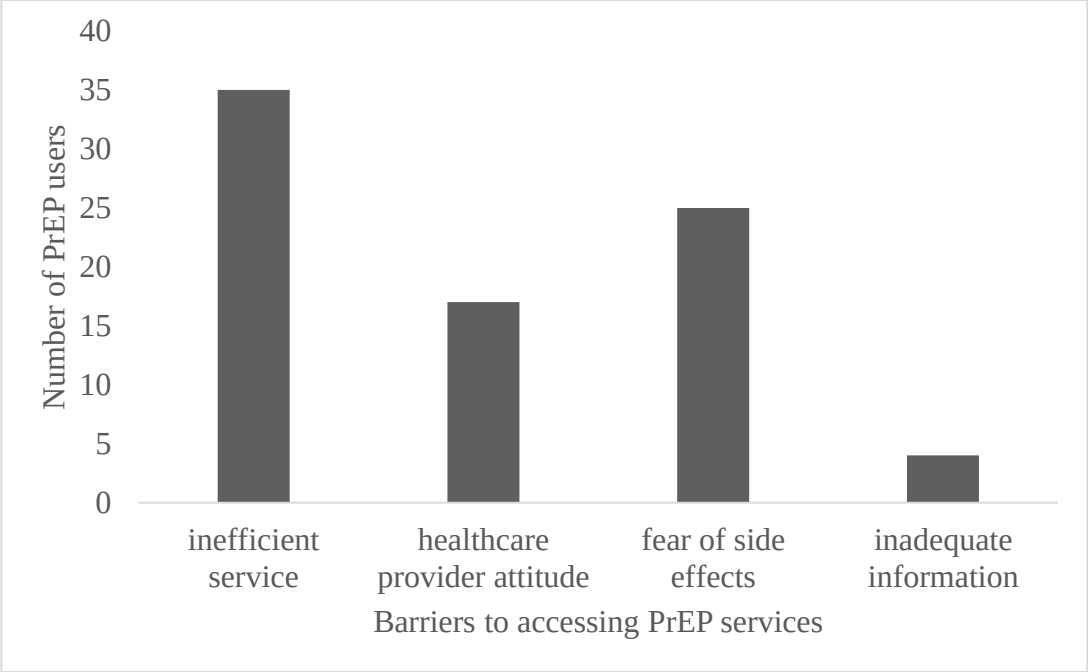

Figure 6: Response to the question on barriers to accessing PrEP services

43.2% (n=35) of current and former PrEP users think that the main barrier to accessing PrEP at public health facilities is inefficient service. According to the respondents, public health facilities have long waiting hours, long queues, and staff shortages that can hinder clients from accessing PrEP services. In this instance, the client is not critically ill hence they can decide to walk away if they are not served on time. Only 4.9% (n=4) feel they would benefit from more information on PrEP to improve the use of the prevention method. 30.9% (n=25) fear side effects and gave this as a reason for discontinuing oral PrEP. However, there has never been a report of adverse events from PrEP in Makonde and the interviewees admitted that they have never encountered anyone who developed side effects from PrEP.

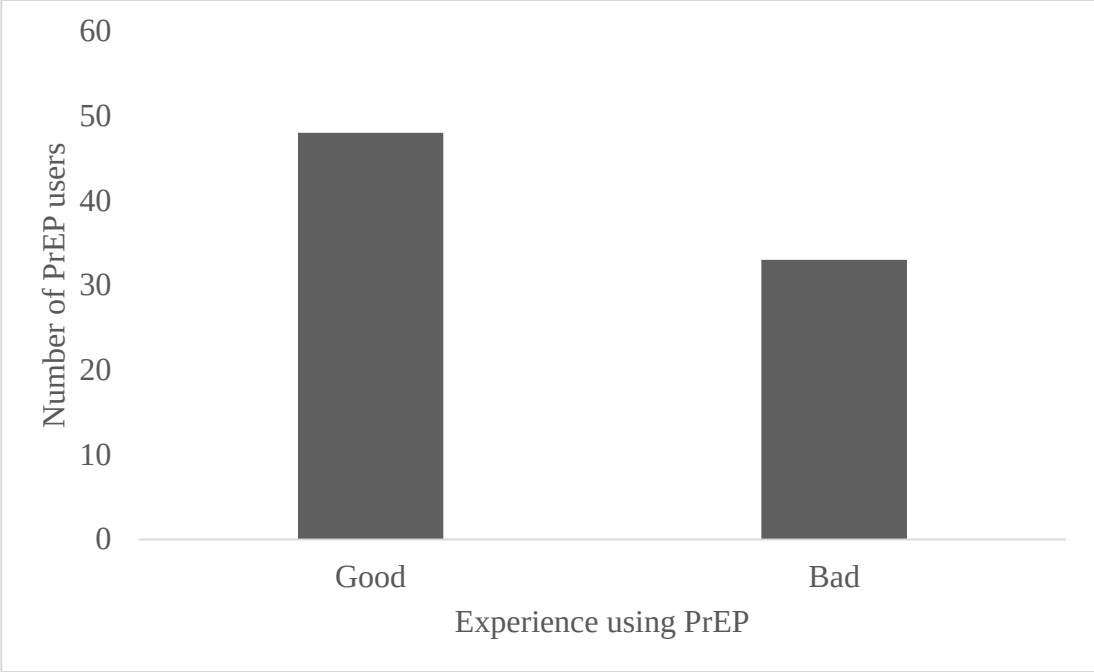

Figure 7: Response to question on experience using PrEP

59.3% (n=48) of the participants admitted to having had a good experience in using oral PrEP i.e. besides the inefficient service at public health facilities, they did not experience side effects and they had no challenges in following the dosing regimen. The other 40.7% (n=33) had a bad experience using oral PrEP i.e. besides service challenges at public health facilities, they had challenges in adhering to the dosing regimen and they had to change their place of residence soon after starting PrEP making it difficult to get PrEP refills in time. Some cited fear of side effects as the cause of the unpleasant experience while taking oral PrEP.

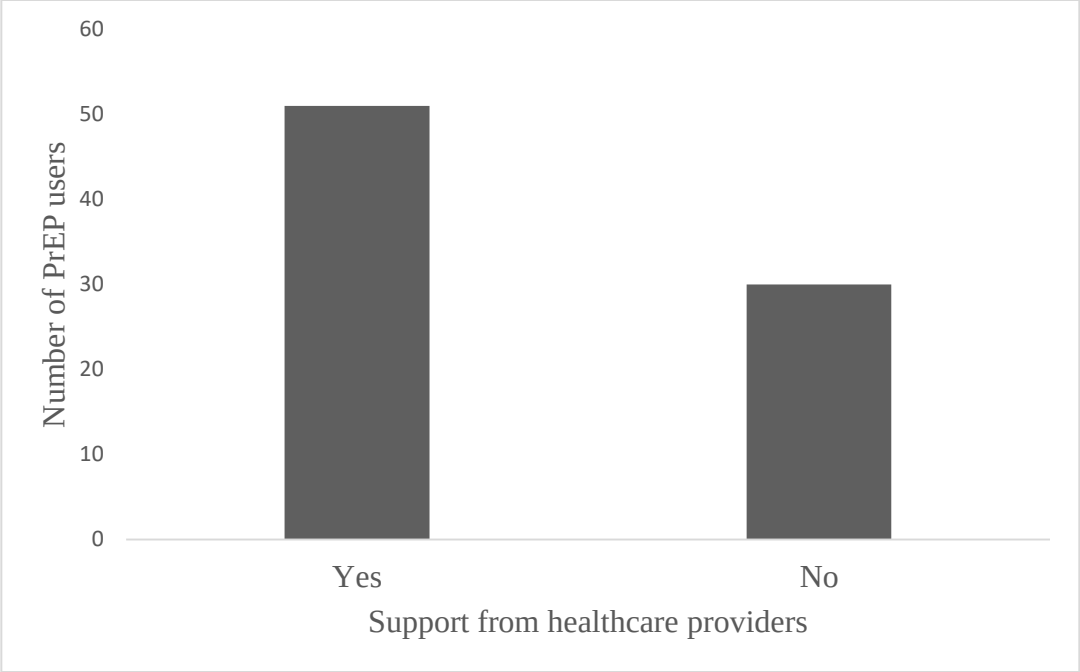

Figure 8: Response to question on availability of support from service providers

64.2% (n=52) of the participants admitted to getting support from healthcare providers before and after starting oral PrEP. Support was given through counselling, with sessions focusing on the benefits of oral PrEP and also dispelling some of the misconceptions propelled in the use of oral PrEP e.g. PrEP prevents other STIs. 35.8% (n=29) of the respondents felt that the healthcare providers did not do enough to provide the necessary support before initiation and during the period of oral PrEP use. The support that the participants expected included making sure that they did not have to wait for long to get the chance to be served since the same healthcare providers would have persuaded them to consider oral PrEP.

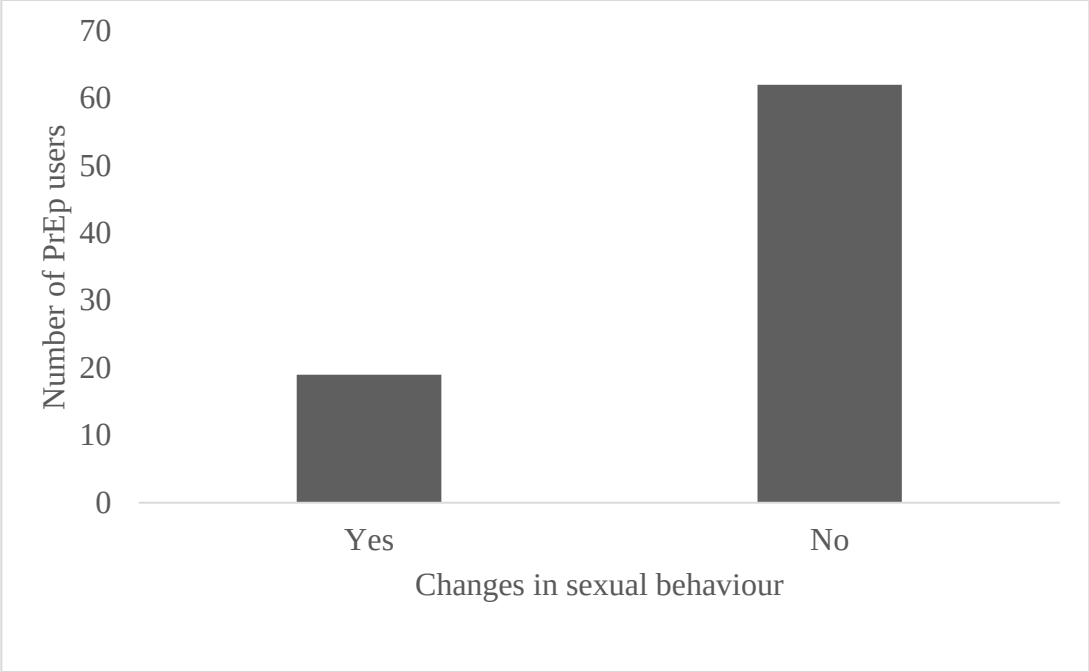

Figure 9: response to the question on changes in sexual behaviour after PrEP initiation

76.5% (n=62) of the participants did not change their sexual behaviour; they admitted to having maintained their risky sexual behaviour (especially commercial sex workers) because they felt safe being on oral PrEP. 23.5% (n=19) of the participants admitted to having changed their sexual behaviour after they had been treated for an STI and started on oral PrEP; this increased their awareness of the risk of contracting HIV.

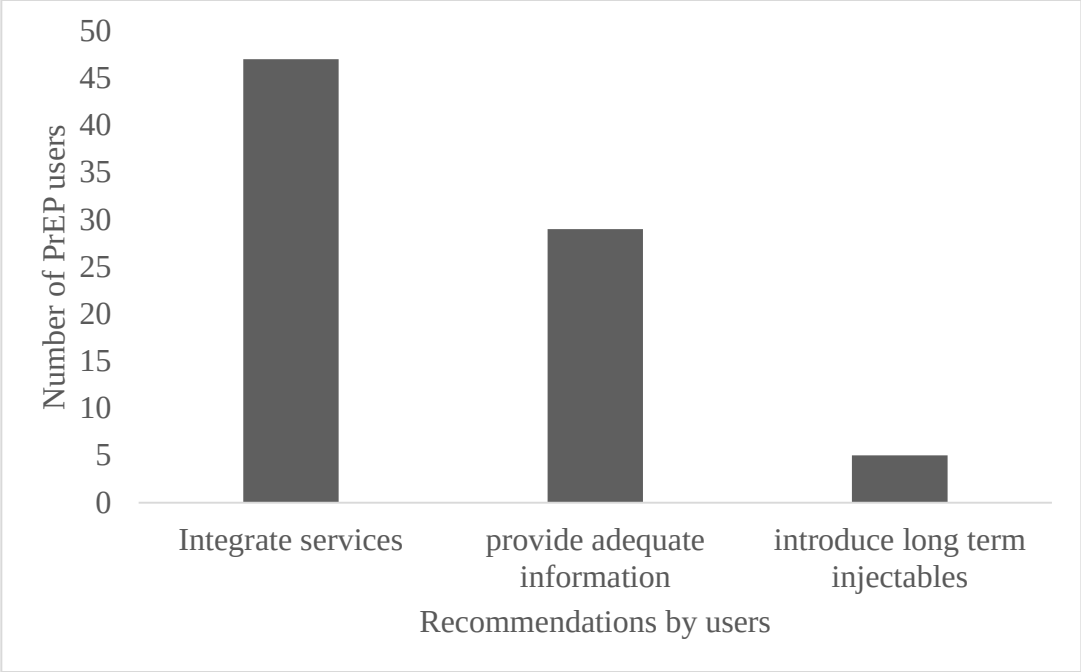

Figure 10: Responses to the question on recommendations to improve PrEP services delivery

58% (n=47) of the participants want PrEP services to be integrated into routine service delivery. PrEP services are normally offered in opportunistic infection/HIV clinics and this has been associated with stigma according to the interviewees. OI clinics are known to be a preserve for HIV-positive clients only, and participants feel that getting served by these clinics is admitting that they are HIV "patients in waiting". Another issue that emanated from the discussion was that AGYW would prefer long-term injectables over oral daily PrEP. This would help reduce the number of clinical visits that one should make to the public health facility. Each visit includes getting a repeat HIV, STI screen, counselling, and long waiting hours; participants think that the integration of services and the introduction of a long-term injectable can help solve some of these challenges.

Service Provider responses

Table 11: Initiatives to improve uptake of Oral PrEP

Initiatives to improve uptake of oral Prep	Frequency	Percent	Cum. Percent
Counselling of eligible clients	8	27.6%	27.6%
Integration of services	1	3.5%	31.0%
None	15	51.7%	82.8%
Partner involvement	5	17.2%	100%
Total	29	100%	100%

51.7% (n=15) of the service providers interviewed did not see the need to institute any measures to improve the performance of oral PrEP in Makonde district. However, they admitted that they had challenges with retaining AGYW on oral PrEP. Only 3.5% (n=1) of service providers cited the need to have PrEP services integrated with routine services.

Table 12: Specific clients facing challenges in accessing PrEP

Specific populations facing difficulties in using oral Prep	Frequency	Percent	Cum. Percent
Commercial sex workers	4	13.8%	13.8%
Married women	5	17.2%	31.0%
Serodiscordant couples	8	27.6%	58.6%
Young unmarried girls (?clarity on actual relationship arrangements)	12	41.4%	100%
Total	29	100%	100%

41.4% of the service providers admitted having challenges retaining young unmarried girls on oral PrEP. These AGYW were in relationships that could not be ascertained if they were transactional arrangements or multiple-partner sexual relationships. Commercial sex workers were reported to have fewer challenges in using PrEP according to service providers.

Table 13: Facilitators to discontinuation of oral PrEP

Have you observed any factors that contribute to client disengagement?	Frequency	Percent	Cum. Percent
Change in risk profile	6	20.7%	20.7%
Fear of side effects	6	20.7%	41.4%
Migration	7	24.1%	65.5%
Stigma	8	27.6%	93.1%
HIV testing frequency	2	6.9%	100%
Total	29	100%	100%

27.6% of the interviewed service providers highlighted stigma (social and historical) as the main cause of PrEP discontinuation. Historical stigma is closely related to stereotyping people who take ARVs as being promiscuous, given the background of how HIV was viewed in the late 90s up to the early 2000s. 6.9% of the participants cited that the frequency of HIV testing when one is on PrEP is unpleasantly frequent: getting pricked each time when one came for a resupply was a deterrent to users. 20.7% of the service providers reported that a change in risk profile was a factor in PrEP discontinuation, especially among the unmarried group.

Table 14: Additional resources required to improve retention of oral PrEP

Are there any additional resources or support that would be beneficial to retaining AGYW on prep	Frequency	Percent	Cum. Percent
Community engagement	4	13.8%	13.8%
Job aids	6	20.7%	34.5%
None	19	65.5%	100%
Total	29	100%	100%

65.5% of the service providers interviewed thought that there was no need to provide extra resources or support to ensure the success of the PrEP program. While 13.8% of the service providers highlighted the need for community engagement and awareness of PrEP. 6 service providers requested job aids to assist in explaining and improving the quality of information disseminated to PrEP users.

PrEP initiation

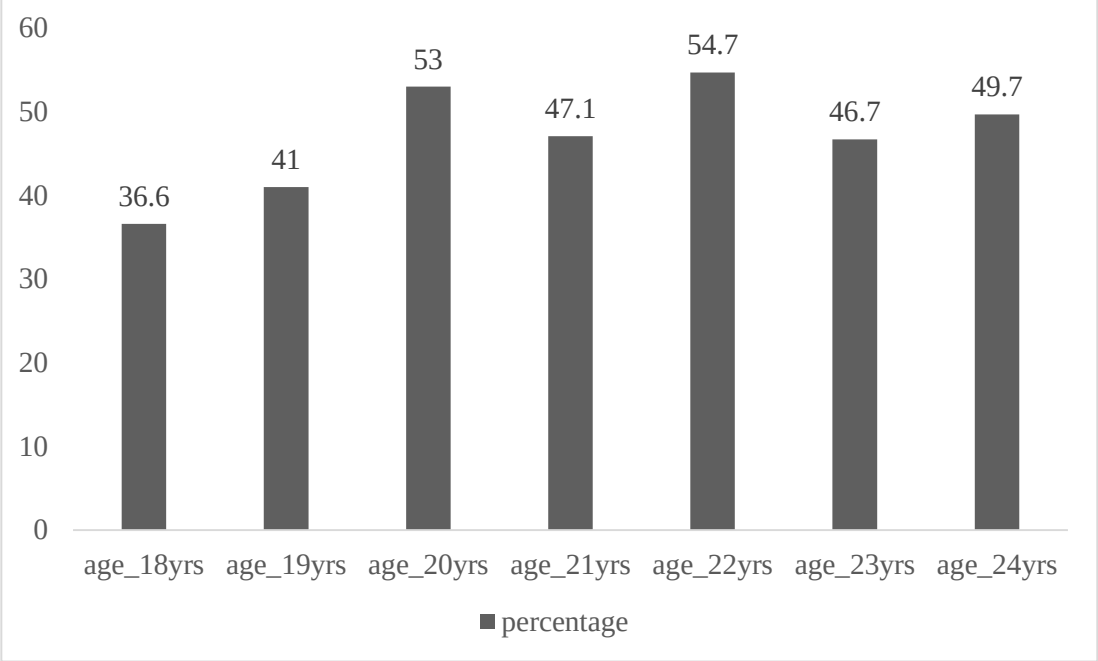

Figure 11: Average initiation rate according to age in AGYW, Makonde District, Mashonaland West, 2020-2022

18-year-old recipients of care had the lowest PrEP initiation rate in the 18-24 years age group. The average PrEP initiation rate for AGYW in Makonde district was 47.0% [95% Conf. Interval 41.0 - 52.9]. Makonde district was second to Hurungwe district for the lowest PrEP initiation rate in AGYW.

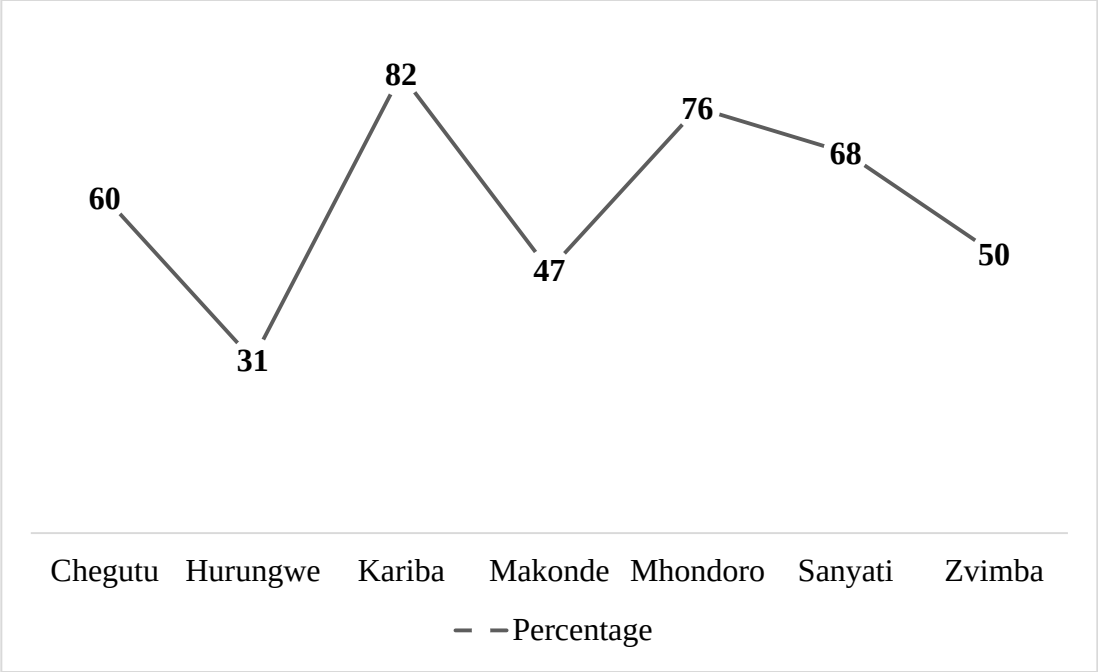

Figure 12: Average PrEP initiation rate according to district, Mashonaland West 2020-2022

In Mashonaland West, only 2 districts had less than 50% oral PrEP initiation rates in AGYW, namely Makonde district and Hurungwe district.

PrEP retention

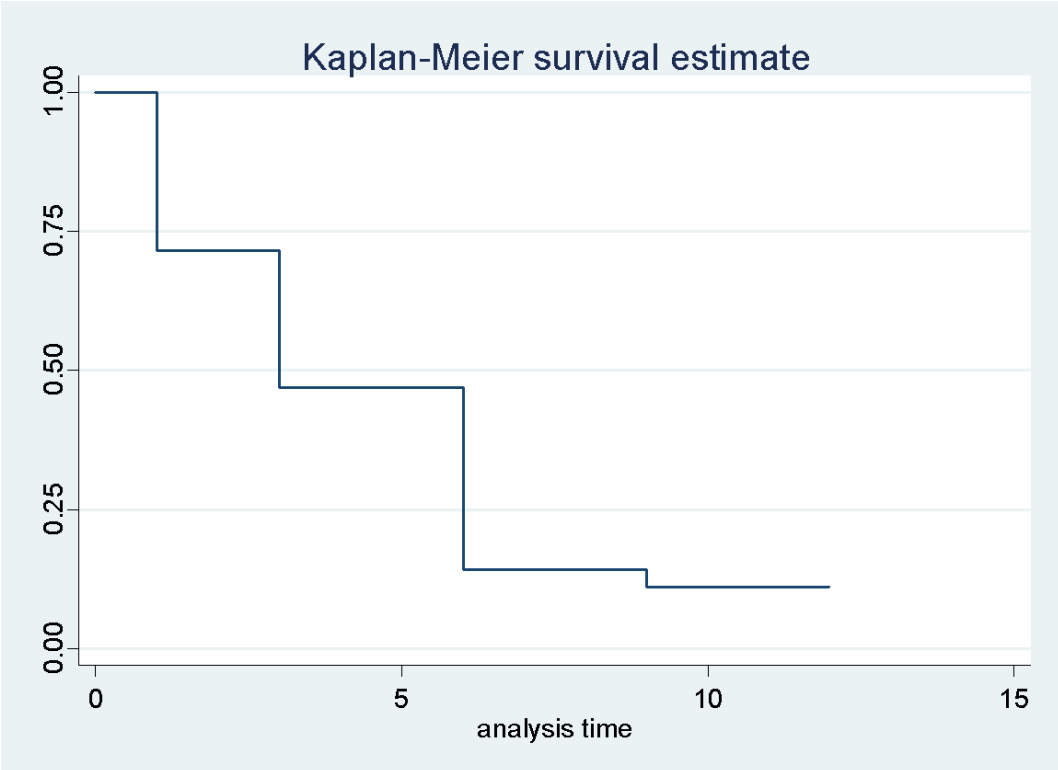

Figure 13: Retention rate at each clinical visit (1, 3, 6, 9, and 12 months)

1 month after oral PrEP initiation, ~ 30% of AGYW had discontinued and by the 6th month, over 80% had discontinued. Between the 3rd month and the 6th month after PrEP initiation, over 30% of the remaining users had discontinued oral PrEP. This observation is important especially if the reason for discontinuing is not linked to a period of low risk. PrEP is not expected to be a long-term intervention for an individual who has low risk perception, however, all the individuals in this study were classified to be at high risk of contracting HIV. To explore this observation further, we can look at the outcome for those who had discontinued at each clinical visit:

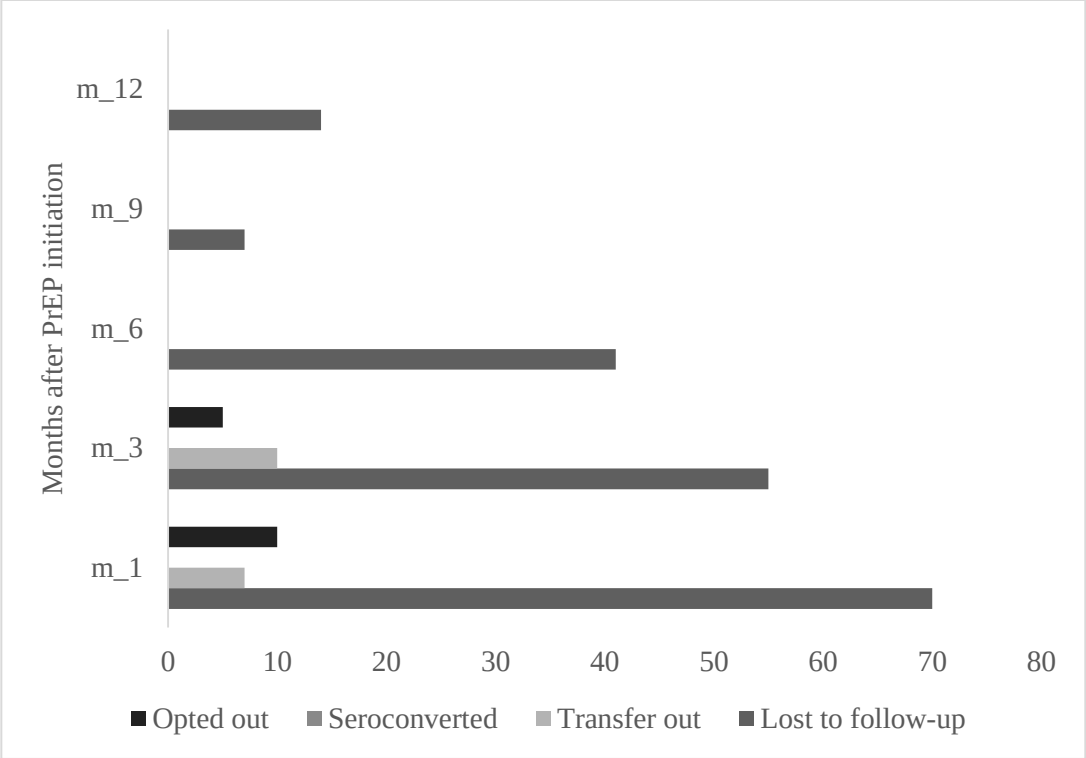

Figure 14: Outcomes for AGYW who had discontinued oral PrEP

At each clinical visit, an average of 78.6% of those who had discontinued were not followed up i.e. there was no communication made to ascertain the reason(s) for discontinuing oral PrEP. Losing PrEP clients with no proper discharge plan or outcome is likely to affect the impact of the intervention. In the first month, 90% of those who had discontinued were not followed up.

Association between retention rate and sociodemographic characteristics

Stata software was used to analyse retention after cleaning and coding the data. Cox regression was used to determine the sociodemographic predictors of long-term (> 6 months) retention on PrEP.

Retention by facility

Table 15: Cox hazard proportional regression to determine association between long term (> 6months) retention of PrEP and type of facility

Facility	Time at risk	Incidence rate	Number of subject	Survival time 25%	50%	75%
Hospital	81	.5802469	47	1	1	3
Clinic	1045	.1636364	198	3	6	6
total	1126	.1936057	245	1	3	6

Users enrolled at a clinic had an average time of use of PrEP of 6 months whereas those initiated at a hospital had an average time of use of 1 month. The incidence rate of 0.58 for the hospital suggests that AGYW receiving oral PrEP at the hospital had a higher hazard or risk of discontinuation compared to those initiated at a clinic. This indicates that there are factors or characteristics specific to the hospital setting that are associated with a higher likelihood of discontinuing oral PrEP. These factors could include issues related to access to care, quality of services, patient support, or other clinic-specific variables influencing retention.

The incidence rate of 0.16 for the hospital indicates that individuals receiving oral PrEP at the clinic had a lower hazard or risk of discontinuation compared to those initiated at the hospital. This suggests that the clinic setting had factors or characteristics that promote better retention of oral PrEP compared to the hospital. These factors could include better access to care or other clinic-specific variables that contribute to improved retention rates.

In summary, the results suggest that there are differences in retention rates on oral PrEP between the clinic and hospital settings, with the hospital having a higher risk of discontinuation compared to the clinic.

Retention by marital status

Table 16: Cox hazard proportional regression determine association between long term retention of PrEP and marital status

Marital status	Time at risk	Incidence rate	Number of subject	Survival time 25%	50%	75%
Married	98	.2040816	22	1	3	6
Single	1028	.192607	223	1	3	6
total	1126	.1936057	245	1	3	6

Married clients (Incidence rate of 0.20):

The incidence rate of 0.20 for married clients suggests that individuals who were married and receiving oral PrEP had a slightly higher hazard or risk of discontinuation compared to single clients. This indicates that being married was associated with a slightly increased likelihood of discontinuing oral PrEP. Factors such as relationship dynamics, support systems, communication within the marriage, or other variables related to marital status can potentially influence retention rates.

Single clients (Incidence rate of 0.19):

The incidence rate of 0.19 for single clients indicates that individuals who were single and receiving oral PrEP had a slightly lower hazard or risk of discontinuation compared to married clients. This suggests that being single may be associated with a slightly lower likelihood of discontinuing oral PrEP compared to being married. Factors such as independence, self-efficacy, social support outside of a marital

relationship, or other variables related to single status can potentially contribute to better retention rates.

In summary, the results suggest that there may be a small difference in retention rates on oral PrEP between married and single clients, with married clients having a slightly higher risk of discontinuation compared to single clients.

Retention by risk profile

Table 17: Cox hazard proportional ratio determine association between long term retention of PrEP and risk profile

Risk profile	Time at risk	Incidence rate	Number of subject	Survival time 25%	50%	75%
Serodiscordant couple	195	.2358974	49	1	3	6
Commercial Sex worker	222	.1846847	47	1	3	6
General population	709	.1847673	149	1	3	6
total	1126	.1936057	245	1	3	6

Serodiscordant individuals (Incidence rate of 0.24):

The incidence rate of 0.24 for serodiscordant individuals suggests that this group had the highest hazard or risk of discontinuation of oral PrEP compared to commercial sex workers and the general population. This may indicate that individuals in serodiscordant relationships face specific challenges or factors that increase the likelihood of discontinuing oral PrEP. Factors such as relationship dynamics, stigma, disclosure issues, or other factors related to being in a serodiscordant relationship can influence retention rates.

Commercial sex workers (Incidence rate of 0.18):

The incidence rate of 0.18 for commercial sex workers indicates a lower hazard or risk of discontinuation of oral PrEP compared to serodiscordant individuals, but is similar to the general population. This suggests that commercial sex workers had intermediate retention rates on oral PrEP. Factors such as access to healthcare services, stigma, social support, or occupational factors may impact retention in this group.

General population (Incidence rate of 0.18):

The incidence rate of 0.18 for the general population suggests that this group had a similar hazard or risk of discontinuation of oral PrEP as commercial sex workers. This indicates that individuals in the general population and commercial sex workers had comparable retention rates on oral PrEP. Factors such as access to healthcare, awareness of PrEP, social support, or other population-specific variables may influence retention in these groups.

In summary, the results suggest that there were differences in retention rates on oral PrEP among different risk profiles in AGYW, with serodiscordant individuals having the highest risk of discontinuation, followed by commercial sex workers and the general population.

Table 18: Cox hazard proportional ratio determine association between long term retention of PrEP and multiple sociodemographic variables

Variable	Haz. Ratio	Std. Err	z	P>|z|	[95% Conf.	Interval]
Facility	.3159036	0.770039	-4.73	0.000	.195915	.5093795
Marital status	.9331664	.2279792	-0.28	0.777	.5781021	1.506308
Education level						
1	1.041954	.2464308	0.17	0.862	.6554389	1.656398
2	.91892498	.42227463	-0.18	0.854	.3728003	2.263912
Risk profile						
1	.9240246	.2021327	-0.36	0.718	.6018401	1.418685
2	.9192498	.1613976	-0.48	0.632	.6516037	1.296832
Age						
19	1.259749	.406093	0.72	0.471	.6728487	2.358579
20	1.079972	.2699715	0.31	0.158	.6616511	1.762771
21	1.251448	.3106076	0.90	0.366	.7693883	2.03554
22	.8823519	.2103195	-0.53	0.600	.5530283	1.407785
23	.3852648	.1234	-2.98	0.003	.2056459	.7217695
24	1	(omitted)				

The p- p-values for the association between retention and facility, and age> 23 years are less than 0.05. Their hazard ratios lie within the 95% confidence interval hence the associations are significant. Therefore there is a statistically significant association between the type of facility and retention of oral PrEP, and also a statistically significant association between age and retention of oral PrEP.

PrEP Adherence

PrEP adherence was analysed using the clinical visit status. Recipients of care were classified as follows:

1. Defaulted PrEP - if they returned for their refill after 2 weeks of the scheduled visit
2. Active on PrEP - if they returned early, on time, or less than 2 weeks after their scheduled visit.

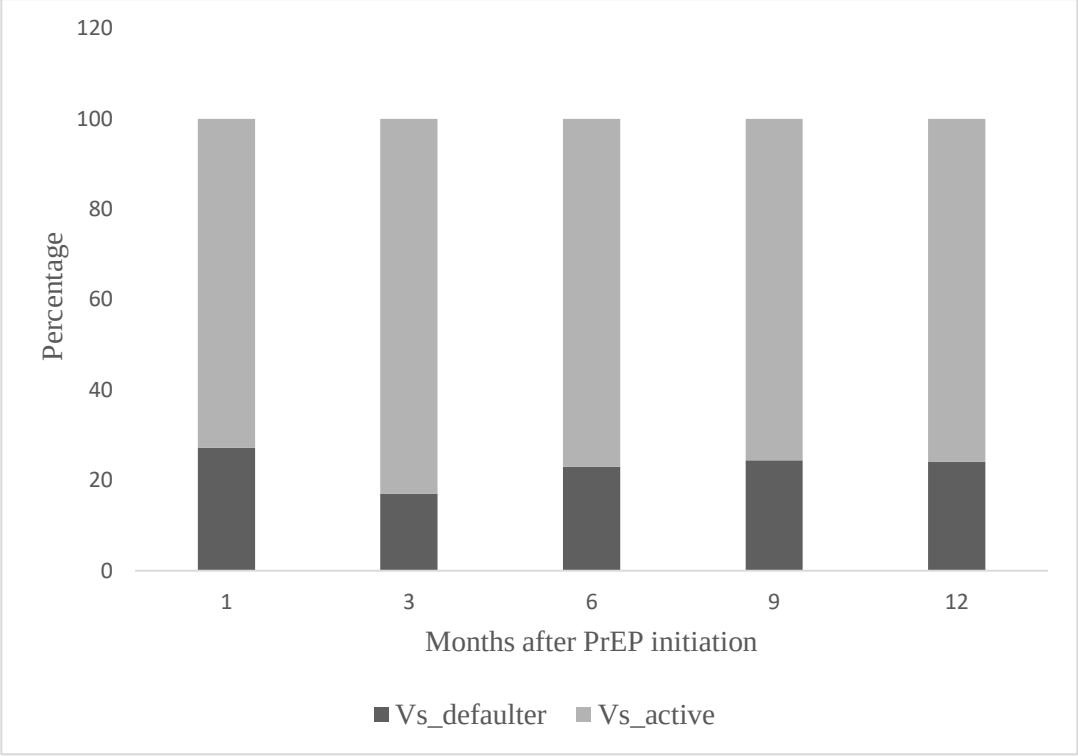

Figure 15: Proportion of defaulters at each clinical visits by retained AGYW

The average percentage of defaulters was 23.1% +/- 3.72 SD at each clinical visit. This is a significant number considering that impact from use of PrEP relies on adherence.

Association between adherence rate and other variables.

Logistic regression

Table 19: Association of adherence rate and sociodemographic characteristic

Variable	Odds Ratio	95%	C.I.	Coefficient	S. E.	Z-Statistic	P-Value
Age	0.9	0.7	1.2	-0.1	0.1	-0.5	0.6
Marital Status	0.7	0.2	2.6	-0.3	0.7	-0.5	0.6
Risk profile	0.8	0.5	1.2	-0.3	0.2	-1.1	0.3
Facility	1.3	0.4	4.6	0.3	0.6	0.4	0.7

There was no statistical significance on the associations between defaulting and other variables such as age, marital status, or risk profile at the first visit post PrEP initiation and also with subsequent visits.

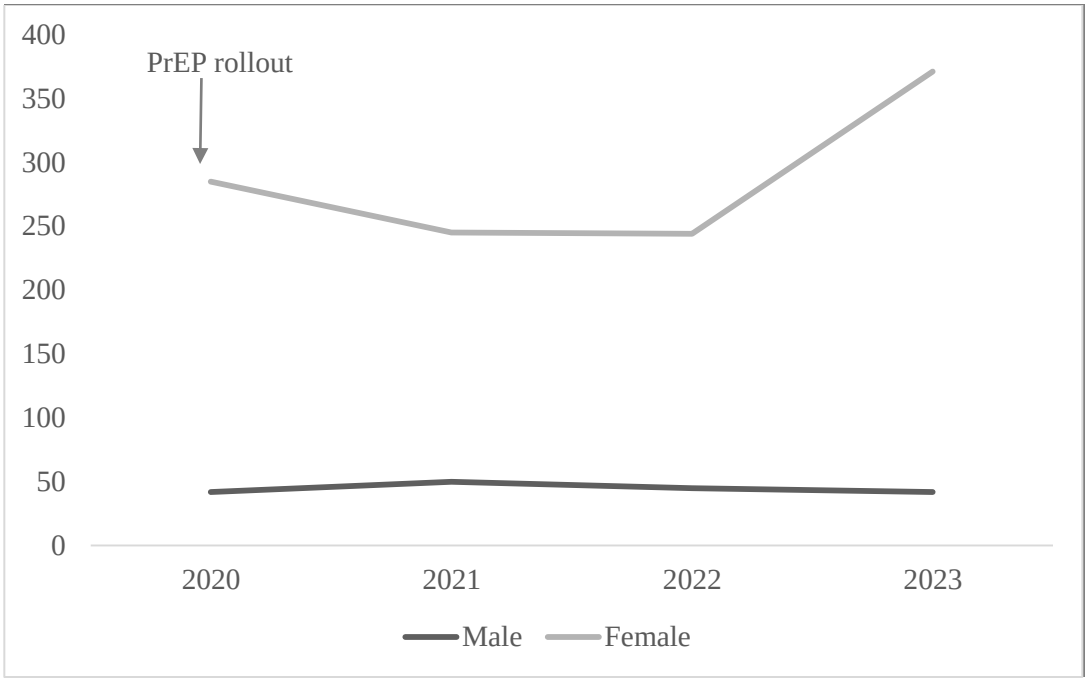

Figure 16: New HIV infections in AGYW compared to their male counterparts

AGYW remain disproportionately affected by HIV compared to their male counterparts. The number of new HIV infections is 3-4 times higher in AGYW compared to their male counterparts. The slight decrease in new cases from 2020-21 can be attributed to several factors including reduced access to testing services during the COVID-19 pandemic. AGYW had almost double the number of new HIV infections in 2023 compared to 2022. During the period January 2020-December 2022, only one PrEP user was documented to have seroconverted, and it was established that she was not taking PrEP consistently.

4.3. Discussion and Interpretation

This study provided an opportunity to evaluate the performance and impact of oral PrEP among AGYW. It is one of the few studies that have provided scrutiny into the programmatic implementation of PrEP in this susceptible age group.

The average PrEP initiation rate among AGYW in Makonde district was 47%, the lowest rate (36.6%) was recorded in eligible clients aged 18 years. PrEP users who were interviewed reported inefficient service (43.2%), healthcare provider attitude (21%), fear of side effects (30.9%), and inadequate information (4.9%) as barriers to PrEP initiation and retention. At the facility, factors such as quality of service and healthcare provider attitude contributed significantly to retaining clients on PrEP.

The crucial role of information in the continuum of PrEP initiation, adherence, and retention was highlighted by 28% of the service providers interviewed. 53.1% of the AGYW reported that they had received information about PrEP after they had visited the clinic or hospital for treatment of some illness (e.g. STI). Information on PrEP is usually available at public health institutions. However, the role of the community in disseminating information cannot be understated, including the role of media, 16% of the interviewed PrEP users acknowledged the role of media in influencing their decisions on PrEP.

30.9% of former and current PrEP users admitted that they feared developing side effects after using oral PrEP. The fear of side effects was reported by PrEP users as a contributor to bad experience, each dose was potentially linked to the development of an adverse event. Of the 40.7% of the PrEP users who reported having a bad

experience using PrEP, the fear of side effects among other factors that include type of facility and healthcare provider attitude contributed to the experience.

Integration of PrEP services into routine health services was highlighted by 58% of the PrEP users interviewed. However, a significant proportion of health service providers (51.7%) who were interviewed did not think there was a need for any improvements in the current PrEP service delivery model. This is despite 43.2% of PrEP users citing inefficient service delivery at public health facilities which can also be attributed to a lack of integrated services. This was further affirmed by the statistically significant association between the type of facility and retention in care. Clinics provided better service because of low patient volumes and shorter waiting periods. At hospitals, integration of services would translate to less stigma and better service because opportunistic infection clinics are usually busy and are a preserve for HIV patients.

Among several reasons cited by healthcare workers for discontinuing PrEP, there was the change in risk profile (20.7%), stigma (27.6%), and migration (24.1%). Some of the PrEP users are migrants, especially in small-scale mining areas resulting in the discontinuation of PrEP. In the period January 2020 to December 2022, 30% of PrEP users discontinued in the first month, and another 30% discontinued PrEP between the third and the sixth month after PrEP initiation. About 90% of users who discontinued PrEP before the 1st clinical visit were not followed up and this can be the cause of losing over 80% of PrEP users, 6 months post-PrEP initiation. Following up on patients can help retain some of them if the cause for discontinuation can be resolved by counselling and providing more information.

There was no statistically significant association between adherence and sociodemographic characteristics. One user who seroconverted was confirmed to have inconsistently taken PrEP. If taken consistently during the period of risk, PrEP has been demonstrated to be effective in reducing the risk of HIV infection.

4.4. Chapter Summary

This chapter presented the findings from the study conducted in Makonde District on the performance and impact of oral Pre-Exposure Prophylaxis (PrEP) among Adolescent Girls and Young Women (AGYW) with several key findings including:

Barriers to PrEP uptake: Fear of side effects, negative health worker attitudes, migration, inefficient service delivery, and lack of adequate information.

Statistical significance of facility and retention on PrEP: An analysis revealed a statistically significant association between the facility where PrEP services were provided and retention rates among AGYW, indicating disparities in service quality and accessibility.

Low Initiation Rate: The study reported a low initiation rate of 47% among AGYW in Makonde District, highlighting the need for targeted interventions to increase PrEP uptake and improve adherence in this population.

CHAPTER FIVE: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1. Introduction

Adolescent Girls and Young Women (AGYW) in Makonde District encounter numerous challenges in accessing and utilising oral Pre-Exposure Prophylaxis (PrEP) for HIV prevention. This chapter provides a summary of the comparison of the findings in this study that influence the effective implementation of PrEP among AGYW in the district and findings from previous studies, the statistical significance of the association between facility type and retention on PrEP, as well as the low PrEP initiation rate observed. And explores areas for future research.

5.2. Discussion

Oral PrEP as a preventive strategy can lower the burden of HIV if uptake and adherence are adequate. However, low PrEP initiation rates demonstrated in this study can negatively affect the effectiveness of PrEP in reducing the number of new HIV infections. In a study to evaluate the feasibility of integrated implementation of PrEP and family planning services, only 26% of eligible clients aged < 24 years were initiated on oral PrEP (Mugwanya K. K., et al., 2019). Low initiation rates have also been reported by other studies (Siegler, et al., 2018).On the contrary, several other studies have demonstrated good uptake of oral PrEP. These different findings provide insight into the dynamics associated with the use of PrEP in different contexts.

In a study to assess barriers to PrEP, fear of side effects was reported by less than 5% of women who did not initiate PrEP (Golub, 2018). Fear of side effects among PrEP users has also been documented in several other studies but was reported to be less frequent (Keen, Hammoud, & Bourne, 2020). The observation of fear of side effects in this study is not new, contrary to previous studies which have reported fear of side effects as insignificant, findings from the study in Makonde show that the fear of side effects is a barrier among AGYW. A plausible explanation might be the level of awareness and adequacy of information given to the AGYW in Makonde district.

There have been suggestions to integrate PrEP services within broader HIV prevention and health promotion efforts, which include HIV testing, treatment, sexual and reproductive health services, and potentially mental health and substance use services (Rivet & Bekker, 2019). Integration of PrEP services into routine health delivery is likely to improve initiation, retention, and adherence among PrEP users. The benefits of offering a service that is not only available through specialised clinics are numerous and include accessibility of the service, reduced stigma, and improved quality of service. In Kenya and many other African settings, there has been advocacy to incorporate PrEP services with routine family clinic services (Mugwanya K. K., et al., 2019). Hence the recommendation by PrEP users in Makonde district to integrate services has been an important discussion point for a while and now requires advocacy.

A lack of changes in sexual behaviour has been demonstrated in another study where healthcare providers raised concerns about the possibility of an increase in sexual behaviour by PrEP users due to the perception that HIV susceptibility is decreased

(Golub, 2018). PrEP users have been reported to exhibit liberty in the way they perceive their risk. Information that is disseminated to users on commencing PrEP has a role to play in the modelling of behaviour, as well as emphasising the concept of combined HIV prevention methods. Availing adequate information on science-based interventions is pivotal in several public health programs that have recorded success (Frieden, 2014).

Spousal or partner consent has a huge influence on PrEP use. The Partners PrEP demonstration study in Kenya and Uganda reported that individuals who experience intimate partner violence had three times higher odds of stopping their PrEP use than individuals without these experiences (Cabral et al., 2018) and also had an increased risk of low PrEP adherence (Roberts et al., 2016). With PrEP users admitting that partner involvement will help improve PrEP uptake, adherence, and retention, it shows that spouses or partners have a role in the decision to start or continue PrEP. In one study, 41% of women with partners of unknown HIV status who declined PrEP frequently reported needing to consult their partners (Willie, Keene, Kershaw, & Stockman, 2021)

Several qualitative studies have documented potential barriers to PrEP uptake including stigma, institutional factors, health worker attitude, and economic factors (Auerbach, Kinsky, Brown, & Charles, 2015). However, in this study, some of the PrEP users and service providers reported that migration, especially in small-scale mining areas, was a cause for discontinuing PrEP. Previous studies have not identified migration as a significant cause for discontinuing PrEP. This goes on to show that there is a growing need to contextualise PrEP service delivery (Chidwick, et al., 2022).

In one study, 40% of women initiated on PrEP were reported to have continued beyond 1 month (Gombe, et al., 2018).In Makonde, 69% of AGYW continued beyond the first month and this is higher than retention rates reported from other programs targeting young women within sub-Saharan Africa (Gombe, et al., 2018). Predictors of PrEP retention such as age and marital status have been considered to have substantial influence in previous studies, with multivariate analysis demonstrating the influence of these on PrEP uptake too. In Makonde district, retention was demonstrated to have a statistically significant association with the type of facility. This finding is important when addressing the challenges affecting long-term retention of PrEP for AGYW who are at risk of HIV infection. Among the most frequently reported reasons for discontinuation is low perceived risk of acquiring HIV.

5.3. Conclusions

Efforts to improve the impact and performance of oral PrEP among AGYW in Makonde District must address the identified barriers, analyse facility-specific factors influencing retention, and target interventions to enhance initiation rates. By overcoming these challenges, we can enhance the effectiveness of PrEP as a critical HIV prevention tool for this vulnerable population.

5.4. Recommendations

1. Education and Awareness Campaigns

Develop and implement comprehensive education and awareness campaigns targeting AGYW, community members, and healthcare providers to increase knowledge about

PrEP, and its benefits, and dispel myths about side effects. Utilise various communication channels, including social media, community events, and peer-led initiatives to reach a wider audience.

2. Healthcare Provider Training and Support

Provide ongoing training for healthcare providers on PrEP guidelines, counselling techniques, and addressing stigma to ensure they are equipped to offer quality services to AGYW. Foster a supportive environment within healthcare facilities to encourage AGYW to seek PrEP services without fear of judgement or discrimination.

3. Improving Service Delivery

Streamline service delivery processes to reduce waiting times, ensure consistent availability of PrEP medication, and enhance the counselling and support services offered to AGYW. Implement systems to track and manage PrEP supplies efficiently to prevent stock-outs and interruptions in treatment.

4. Community Engagement and Peer Support

Engage community leaders, youth groups, and local organisations to promote PrEP awareness and facilitate access to services within the community. Establish peer support programs where AGYW who are already on PrEP can provide guidance, encouragement, and share their experiences with those considering or newly initiated on PrEP.

5. Facility-level Interventions

Conduct a thorough assessment of different healthcare facilities providing PrEP services to identify factors influencing retention rates and implement targeted interventions to address disparities. Establish quality improvement initiatives within facilities to enhance the overall PrEP service delivery, including monitoring and evaluation mechanisms to track progress.

6. Data-driven Decision Making

Continuously collect and analyse data on PrEP uptake, adherence, and retention rates among AGYW to inform programmatic decisions and identify areas for improvement. Use data to assess the impact of implemented interventions and adjust strategies as needed to optimise PrEP outcomes in the region.

By implementing these recommendations in a coordinated and sustainable manner, stakeholders can work towards overcoming barriers, improving retention rates, and increasing the initiation of oral PrEP among Adolescent Girls and Young Women in Makonde District, ultimately enhancing HIV prevention efforts and promoting the well-being of this vulnerable population.

5.5 Implications

The study underscores the importance of addressing barriers such as fear of side effects, improving healthcare provider attitudes and service delivery, enhancing information dissemination, and analysing facility-specific factors to enhance PrEP outcomes among AGYW. The findings emphasise the urgency of implementing tailored interventions, community engagement strategies, and healthcare system

improvements to promote PrEP uptake and retention, ultimately contributing to more effective HIV prevention efforts for AGYW in Makonde District.

5.6. Suggestions for Further Research

There is a need for research focusing on the patterns of use of PrEP in line with periods of risk for HIV infection among AGYW. Part of the aspects of the study should include how AGYW perceives their risky period. Another area of study will include analysing the impact of facility-specific factors on retention and adherence in other age groups.

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Appendix 1.

Consent Form (English)

Informed consent form

My name is Munashe Chimene, a final year (Master of Public Health) student from Africa University. I am carrying out a study titled Exploring the Performance and Impact of Oral PrEP in Adolescent Girls and Young Women in Makonde District, Mashonaland West province. Please participate in this interview/focus group discussion.

Purpose of the study:

The purpose of the study is to explore the performance and impact of oral PrEP in adolescent girls and young women (AGYW) in Makonde District during the period 1 January 2020 to 31 December 2022. You were selected for the study because you are eligible for this study.

Procedures and duration

The interview or discussion is expected to take about 30 minutes

Benefits and/or compensation

The research will help improve the delivery and implementation of combined HIV preventive strategies amongst adolescent girls and young women in settings where uptake, adherence, and continuation of PrEP remain low despite higher incidence.

Confidentiality

Information obtained in the study will not be disclosed together with the identity of participants. The identity of participants will remain confidential unless permission is sought to do so. Names and other identifications will not be asked for in the questionnaire.

Voluntary participation

Participation in this study is voluntary. If a participant decides not to participate in this study, their decision will not affect their future relationship with Africa University or the Ministry Of Health and Child Care. If you choose to participate, you are free to withdraw your consent and discontinue participation without penalty.

Offer to answer questions

Before you are interviewed, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

Authorization

If you have decided to participate in this study please sign this form in the space provided below as an indication that you have read and understood the information provided above and have agreed to participate.

---------- ----------

Name of Research Participant (please print) Date

Signature of Research Participant or legally authorised representative.

If you have any questions concerning this study or consent form beyond those answered by the researcher including questions about the research, your rights as a research participant, or if you feel that you have been mistreated and would like to talk to someone other than the researcher, please feel free to contact the Africa University Research Ethics Committee on telephone (020) 60075 or 60026 extension 2156 email aurec@africau.edu

Name of Researcher: Munashe Chimene

Appendix 2.

Consent Form (Shona)

Chibvumirano chakatsanangudzwa

Ndinonzi Munashe Chimene, ndiri mugore rekupedzisira reMaster of Public Health neAfrica University. Ndiri kuita tsvakurudzo yakanzi: *Exploring the Performance and Impact of Oral Prep in Adolescent Girls and Young Women in Makonde District, Mashonaland West province* (Mhenenguro yakanangana nekushandiswa kweOral PrEP kuvasikana vachangosamhuka nemadzimai echidiki mudunhu reMakonde, Mashonaland West). Ndinokumbirisawo kuti mundibatsire mutsvakurudzo ino nekupindura mibvunzo/nekupinda muungano nevamwe tichitaura.

Chinangwa chetsvakurudzo

Chinangwa chetsvakurudzo ino ndechekupenengura kushanda kwe Oral PrEP uye zvipingaidzo zviripo takanangana nevasikana vachangosamhuka nemadzimai echidiki mudunhu reMakonde kubva musi wa1 January 2020 kusvika musi wa31 December 2022. Wakasarudzwa kupinda mutsvarukurudzo iyi nekuti wakaonekwa wakakodzera nekuda kwezera rako.

Matanho nenguva

Kana mabvuma kupinda mutsvaguridzo, munotarisirwa kupindura mibvunzo yese ichabvunzwa. Zvinotarisirwa kuti hamutori nguva inodarika maminutes makumi matatu chete kupindura mibvunzo muungano ino.

Zvakakoshera tsvakurudzo iyi

Tsvakurudzo iyi ichabatsira pakususukidzwa nekusimudzirwa kwemabasa akanangana nematanho ekudzivirira kuparadzirwa kweHIV kuvasikana vachangosamhuka nemadzimai echidiki, kunyanya munzimbo umo vanotora mapiritsi okudzivirira kuparirira kweHIV (PrEP) nenguva iri kure uye vasingasimbirirani nazvo.

Pauviri (Confidentiality)

Uchapupu huchawanikwa hauzobudiswa kune wechitatu, ndezvevaviri mutsvakurudzi nemupinduri. Hakuna zita kana zvimwe zvine chekuita nemupinduri zvichabudiswa kune vamwe. Kana paine zvine chekuita nemipunduri zvichabuda, zvinobuda chete ndokunge atendera. Nechinangwa chekudzivirira kuzivikanwa kwevapinduri, mazita avo nezvimwe zvingangoite kuti vazivikanwe hazvidiwi.

Chido chako

Kupinda muchirongwa chino hakumanikidzirwi asi zvinobva muchido chako iwe mupinduri. Kana mupinduri akasarudza kusapinda mutsvagurudzo iyi, izvi hazvikanganisi ukama hwake neAfrica University kana Bazi Rezveutano

Nekuchengetwa kwevana (Ministry of Health and Child Care) pane remangwana. Kana ukasarudzo kubuda mutsvakurudzo, Hapana charango chaunotemerwa.

Kana uine mibvunzo …

Usati watanga kupindura mibvunzo, bvunza zvaunoda kunzwisisa. Tora nguva yako uchifunga nezvazvo.

Mvumo

Kana wabvuma kupinda muhurongwa hwetsvakurudzo ino, ndokumbira usaine fomu rino panzvimbo yakasiyiwa pazasi semucherechedzo wekuti waverenga ukanzwisisa uye unobvuma kubata basa retsvakurudzo iyi.

---------- ----------

Zita rako mupinduri (Ita zvekunyora) Dheti

Siginecha kana runyoro rwemupinduri kana uyo anotenderwa kumumiririra zviri pamutemo.

Kana uine mibvunzo kana zvimwe zvaungada kunzwisisa pamusoro petsvakurudzo ino zvisina kupindurwa nemutsvakurudzi zvinosanganisira kodzero dzako nezvimwe zvinobata zvine chekuita netsvakurudzo, kana kusabatwa zvakanaka, sununguka kufonera veAfrica University Research Ethics Committee panhamba dzinoto (020) 60075 or 60026 extension 2156, uye kuvanyorera tsambambozha (email) pa aurec@africau.edu

Zita Remutsvakurudzi: Munashe Chimene

Appendix 3.

PrEP user Interview/Focus Group Discussion Guide

1. Welcome and introductions:

- Will start by welcoming the participants and thanking them for their participation.
- Introducing myself and my role in the study.
- Briefly explain the purpose of the focus group discussion/interview.

2. Purpose of the study:

- Explain that the study aims to explore the performance and impact of Oral Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Makonde District, Mashonaland West.
- Emphasise that their insights and experiences are valuable for improving PrEP implementation and ensuring its effectiveness.

3. Confidentiality and anonymity:

- Assure participants that their identities and responses will be kept confidential.
- Explain the steps taken to ensure anonymity, such as assigning pseudonyms or using participant codes.
- Seek consent to participate in the study

4. Ground rules:

- Set ground rules for the discussion, including respect for others' opinions, active listening, and allowing everyone to participate.

- Encourage participants to share their personal experiences and perspectives openly and honestly.

Discussion Questions:

1. Knowledge and awareness of PrEP:

   a. What is your understanding of Oral PrEP?

   b. How did you hear about PrEP before using it?

2. Perceptions and attitudes toward PrEP:

   a. What are your perceptions and attitudes toward using PrEP as a prevention method?

   b. Are there any concerns or misconceptions you have about PrEP?

3. Access and availability of PrEP:

   a. Besides you, has anyone you know ever accessed PrEP in Makonde District?

   b. What are the barriers and facilitators to accessing PrEP in this district?

4. Experiences and challenges with PrEP use:

   a. What has been your experience with using PrEP?

   b. What challenges or difficulties have you faced while using PrEP?

5. Knowledge and support from healthcare providers:

   a. Have you received information or support from healthcare providers regarding PrEP?

   b. How knowledgeable and supportive are healthcare providers in Makonde District about PrEP?

6. Impact of PrEP on AGYW:

a. In your opinion, what impact has PrEP had on the lives of AGYW in Makonde District?

b. Have you observed any changes in sexual behaviour or risk perception among AGYW who use PrEP?

7. Community perceptions and social norms:

a. How is PrEP perceived in your community?

b. Are there any social norms or cultural factors that may influence AGYW's decision to use PrEP?

8. Recommendations for improving PrEP implementation:

a. Based on your experiences and insights, what recommendations do you have for improving PrEP implementation in Makonde District?

Conclusion:

1. Summary of key points:

Summarise the main points discussed during the focus group discussion.

2. Final thoughts:

- Provide participants with an opportunity to add any final comments or thoughts they may have.

3. Appreciation and closure:

- Thank the participants for their valuable contributions and time.
- Reiterate the importance of their insights in shaping effective PrEP programs and policies.

Appendix 4

PrEP Services Provider Interview Guide

Introduction:

Thank the participant for their time and willingness to participate in the interview. Explain the purpose of the interview, which is to gather information about their experiences, challenges, and perspectives regarding PrEP (Pre-Exposure Prophylaxis) services in Makonde District. Assure them that their responses will remain confidential and will only be used for research purposes.

1. Background and Experience:

a. Can you briefly describe your role and responsibilities as a healthcare worker providing PrEP services in Makonde District?

b. How long have you been involved in delivering PrEP services?

c. Have you received any training specific to PrEP implementation? If yes, please provide details about the training.

2. PrEP Implementation:

a. How would you describe the current implementation of PrEP services in Makonde District?

b. Can you discuss any challenges or barriers you have encountered in providing PrEP services?

c. Are there any specific populations or communities that face difficulties in accessing or utilizing PrEP? If yes, please elaborate.

d. What strategies or initiatives have been implemented to promote PrEP awareness and uptake in the district?

3. Service Delivery and Support:

a. How are PrEP services integrated into the existing healthcare system in Makonde District?

b. Can you discuss the availability and accessibility of PrEP services in terms of clinics, healthcare facilities, and community-based settings?

c. What counselling and support services are provided to individuals seeking PrEP?

d. Are there any challenges in ensuring a consistent supply of PrEP medications? If yes, please explain.

4. Client Engagement and Retention:

a. How do you identify individuals who may benefit from PrEP?

b. What strategies are employed to engage and retain clients in PrEP services?

c. Have you observed any factors that contribute to client disengagement or discontinuation of PrEP? If yes, please provide examples.

d. Are there any efforts to involve community members or organisations in promoting PrEP awareness and adherence? If yes, please describe them.

5. Monitoring and Evaluation:

a. How is the effectiveness of PrEP services monitored and evaluated in Makonde District?

b. Are there any data collection and reporting systems in place to track PrEP uptake and adherence?

c. How do you assess the impact of PrEP services on reducing HIV transmission in the district?

d. Are there any challenges or limitations in monitoring and evaluating PrEP services? If yes, please elaborate.

6. Future Improvements:

a. In your opinion, what improvements can be made to enhance PrEP services in Makonde District?

b. Are there any additional resources or support that would be beneficial for healthcare workers providing PrEP services?

c. Do you have any suggestions for addressing the challenges or barriers faced in PrEP implementation?

d. Are there any lessons learned or best practices from your experience that could be shared with other healthcare workers or districts?

Conclusion:

Thank the participant for their valuable insights and contribution to the interview. Encourage them to share any additional information or concerns they may have regarding PrEP services in Makonde District

Appendix 5

Data Extraction Tool

1. Demographic Characteristics

Age:

Marital status:

Patient ID:

Risk profile:

2. PrEP Details

Start Date: The date when the patient started PrEP.

Subsequent visits and status of visit:

End Date: Date when the patient stopped PrEP (last date of refill> 90 days).

Prescribing Facility: Name.

Adherence: (clinical visit status).

3. Monitoring Information

HIV Testing: Dates and results of HIV testing during the PrEP period.

STI Testing: Dates and results of STI testing during the PrEP period.

Side Effects: Any reported side effects experienced by the patient.

Other Notes: Any additional relevant information or notes related to the patient's PrEP monitoring.

Appendix 6

Approval letter from the PMD

Telephone: 23211-6

Telegraphic Address:
"PROVMED" Chinhoyi
Fax: 23218

E-mail: pmdmashwest@gmail.com

ZIMBABWE

MINISTRY OF HEALTH AND CHILD CARE

PROVINCIAL MEDICAL DIRECTOR
(Mashonaland West Province)
P.O Box 139
Chinhoyi
Zimbabwe

14 November 2023

Dear Dr Chimene

RE: Request to conduct a study on the performance and impact of oral PrEP in adolescent girls and young women in Makonde District, Mashonaland West.

Permission to conduct the study and use of PrEP monitoring tools in Makonde district is granted.

The study will be conducted from 1 December 2023 to 31 March 2023.

The study is important for the province.

Yours sincerely,

MINISTRY OF HEALTH & CHILD CARE
PROVINCIAL MEDICAL DIRECTOR
MASHONALAND WEST PROVINCE
14 NOV 2023
P.O. BOX 139, CHINHOYI
ZIMBABWE TEL: 067-23218

Dr. C. Dhege

Provincial Medical Director Mashonaland West Province

Appendix 7: AUREC approval letter

Investing in Africa's future

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC)

P.O. Box 1320 Mutare, Zimbabwe, Off Nyanga Road, Old Mutare-Tel (+263-20) 60075/60026/61611 Fax: (+263 20) 61785 Website: www.africau.edu

Ref: AU3044/24 5 January, 2024

MUNASHE CHIMENE
C/O Africa University
Box 1320
MUTARE

RE: EXPLORING THE PERFORMANCE AND IMPACT OF ORAL PrEP IN ADOLESCENT GIRLS AND YOUNG WOMEN IN MAKONDE DISTRICT, MASHONALAND WEST

Thank you for the above-titled proposal that you submitted to the Africa University Research Ethics Committee for review. Please be advised that AUREC has reviewed and approved your application to conduct the above research.

The approval is based on the following.

a) Research proposal

- **APPROVAL NUMBER** AUREC 3044/24
  This number should be used on all correspondences, consent forms, and appropriate documents.
- **AUREC MEETING DATE** NA
- **APPROVAL DATE** January 5, 2024
- **EXPIRATION DATE** January 5, 2025
- **TYPE OF MEETING**: Expedited
  After the expiration date, this research may only continue upon renewal. A progress report on a standard AUREC form should be submitted a month before the expiration date for renewal purposes.
- **SERIOUS ADVERSE EVENTS** All serious problems concerning subject safety must be reported to AUREC within 3 working days on the standard AUREC form.
- **MODIFICATIONS** Prior AUREC approval is required before implementing any changes in the proposal (including changes in the consent documents)
- **TERMINATION OF STUDY** Upon termination of the study a report has to be submitted to AUREC.

AFRICA UNIVERSITY
RESEARCH ETHICS COMMITTEE (AUREC)
APPROVED
P.O. BOX 1320, MUTARE, ZIMBABWE

Yours Faithfully