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SALIENT BELIEFS, PREFERENCES AND INTENTION TO USE HIV PRE-EXPOSURE PROPHYLAXIS AMONG PREGNANT AND BREASTFEEDING WOMEN IN ZAMBIA



UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

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A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfillment of the requirements for the degree

of

Doctor of Philosophy in Public Health

(HIV and Women's Reproductive Health)

May, 2024

JOHANNESBURG, SOUTH AFRICA

Declaration

I, Twaambo Euphemia Hamoonga, declare that this thesis is my own original work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any degree or examination at any other University or institution.

Signed:  Date: 20th May 2024

Dedication

This is dedicated to my late parents (Ebby Hamoonga and Swebbie Maimbo). Had PrEP been discovered in the 1980s, the story would have been different. This achievement would have put a smile on your faces.

Conference Proceedings

1. Oral: Preferences for PrEP service delivery among pregnant and breastfeeding women in Zambia: A discrete choice experiment. 2nd International Pediatrics HIV/AIDS Symposium in Africa: Zimbabwe; 12th – 14th December 2023.

2. Poster: Hamoonga TE, Mutale W, Hill LM, Igumbor J, Chi BH (2022). "PrEP protects us" Behavioural, normative and control beliefs influencing pre-exposure prophylaxis uptake among pregnant and breastfeeding women in Zambia. International Conference on HIV and Pediatrics: Montreal, Canada: 27th – 28th July 2022.

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2. Oral: Salient beliefs and intention to use PrEP among HIV-negative pregnant and breastfeeding women in Zambia at the Global Health Scholars Symposium (Virtual presentation, 11th November 2022).

Original papers

1. **Hamoonga T E.,** Mutale W., Hill L. M., Igumbor J., Chi B. "PrEP Protects Us": Behavioural, Normative and Control beliefs influencing PrEP uptake among Pregnant and Breastfeeding women in Zambia. Frontiers in Reproductive Health, 2023. **5**.

2. **Hamoonga T. E.,** Mutale W., Hill L. M., Igumbor J., Chi B. Salient beliefs and intention to use pre-exposure prophylaxis among pregnant and breastfeeding women in Zambia: Application of the Theory of Planned Behaviour. Glob Public Health, 2023. **18**(1): p. 2184483.

3. **Hamoonga T. E.,** Mutale W., Bosomprah S., Igumbor J., Chi B. Preferences for PrEP service delivery among pregnant and breastfeeding women in Zambia: A discrete choice experiment (Under review: Frontiers in Reproductive Health)

Other publications within the PhD period

1. Chi B. H., Saidi F, Graybill L A., Phanga T., Mollan K., Amico, K. R, Freeborn K., Rosenberg N., Hill L., **Hamoonga T**., Richardson B., Kalua T., Phiri S., Mutale W. A patient-centered, combination intervention to support adherence to HIV pre-exposure prophylaxis during pregnancy and breastfeeding: a randomized pilot study in Malawi. JAIDS Journal of Acquired Immune Deficiency Syndromes. September 28, 2023.

2. Ajeigbe O, Arage G, Besong M, Chacha W, **Hamoonga TE**, Desai R, Doegah P, et al. Culturally relevant COVID-19 vaccine acceptance strategies in sub-Saharan Africa. The Lancet Global Health. 2022;10(8): e1090-e1.

3. Namukoko, H., Likwa, R.N., **Hamoonga, T.E.** *et al.* Unmet need for family planning among married women in Zambia: Lessons from the 2018 Demographic and Health Survey. *BMC Women's Health* **22,** 137 (2022).

4. Mungandi K, Likwa RN, **Hamoonga TE**, Banda J, Zyambo C. Predictors of alcohol consumption among adolescents and young adults in Lusaka, Zambia. Afri Health Sci. 2022;22(4). 704-715.

5. **Hamoonga TE,** Olowski P and Musonda, P (2019). Vaginal douching in Zambia: a risk or benefit to the fight against cervical cancer: a retrospective cohort study. BMC Women's Health. (19:135).

Awards

1. Center for International Reproductive Health Training, University of Michigan: Seed grant to conduct a study aimed at exploring male partners' knowledge and beliefs about PrEP use for HIV prevention by pregnant women in Lusaka, Zambia (May 2024- ongoing).

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3. Virology Education: Scholarship to attend the 2022 International Conference on HIV and Pediatrics in Montreal, Canada, as a presenter of a paper (27^{th} -28^{th} July, 2022).

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Abstract

Pregnant and breastfeeding women living in sub-Saharan Africa are at substantial risk for HIV infection, and maternal seroconversion may affect the quality of life for the mother, and is a risk for vertical transmission of HIV. Despite the adoption of PrEP into national guidelines for HIV prevention, its uptake in antenatal and postnatal settings in Zambia remains low. We used an exploratory sequential mixed methods design to explore facilitators and barriers to uptake of PrEP among pregnant and breastfeeding women (18 years or older) not living with HIV in Zambia. We purposively recruited 24 women for the qualitative component and conveniently selected 389 women for the quantitative component of the study at Chipata Level 1 Hospital in Lusaka. For qualitative data, Nvivo was used for data management and data was analysed using thematic analysis. Quantitative data was analysed using chi-square test, pearson correlation coefficient (r) and logistic regression analysis using Stata v.16.

Findings from our qualitative study showed that women had positive attitudes and favourable intentions to use PrEP. Most women felt that people who are important to them, especially their male partners, would not support PrEP use during pregnancy and breastfeeding. The anticipated disapproval from partners made women believe that PrEP use would not entirely be under their control, with some reporting that they would not use PrEP if their partners disapproved. Women also cited rude health care provider attitude as a potential barrier to uptake. Some women preferred receiving PrEP from a health facility for fear of stigma in the community while others preferred community-based delivery as an avenue for creating PrEP awareness. This paper was published in Frontiers in Reproductive Health.

In our second paper, we determined intention to use PrEP during pregnancy and breastfeeding and also identified salient beliefs associated with it. Participants had positive attitude and favourable intention to use PrEP during pregnancy and breastfeeding (mean = 6.65, SD = 0.71 and mean = 6.01, SD = 1.36), respectively. They felt that people who are important to them would approve of their use of PrEP (mean = 6.09, SD = 1.51) and also believed that they would be able to use PrEP if they desired (mean = 6.52, SD = 1.09). All salient beliefs positively and significantly predicted intention to use PrEP during pregnancy and breastfeeding: attitude ($\beta = 0.24$, $p<0.01$); subjective norms ($\beta = 0.55$, $p<0.01$); and perceived behavioural control ($\beta = 0.22$, $p < 0.01$). This paper was published in Global Public Health.

The third paper discusses findings from a discrete choice experiment (DCE) on preferences for PrEP service delivery among pregnant and breastfeeding women. In this study, waiting time, travel time, health care provider attitude and amount of PrEP supply at each refill were important considerations likely to influence PrEP use during pregnancy and breastfeeding (all $p<0.01$). Women expressed strong preference for 3-month's supply of PrEP compared to other attribute levels ($\beta= 1.69$, $p<0.01$). They were willing to wait for 5 hours at the facility, walk for more than an hour to a facility dispensing PrEP, encounter a health care provider with a negative attitude as long as they received PrEP enough for 3 months. This paper is under review in Frontiers in Reproductive Health.

The overall contribution of this PhD research to the body of knowledge on HIV prevention strategies is the ability to identify beliefs about PrEP and how each salient belief influences intention to use PrEP during pregnancy and breastfeeding. It is also one of the first to estimate the

benefit (value or satisfaction) that women derive from different attributes of PrEP service delivery for pregnant and breastfeeding populations interested in using PrEP. This information could provide guidance on specific beliefs and service delivery attributes of PrEP that women prefer the most and therefore need to be prioritized if PrEP uptake is to improve in antenatal and postnatal settings.

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I'm grateful to my supervisors, Professor Benjamin Chi, Professor Wilbroad Mutale and Professor Jude Igumbor for the unwavering support and mentorship throughout my PhD journey. I also extend my gratitude to Prof. Carla Chibwesha, Prof. Lauren Hill, Prof. Samuel Bosomprah and Dr. Oludije Arije for their immeasurable contribution towards this work.

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I am sincerely grateful to my husband, Avitol and daughters Tirzah, Janelle and Atarah, for being the greatest cheer leaders throughout this journey. Thank you for your constant encouragement and for believing in me. You are the reason why I never gave up!

Above all, I am grateful to the Lord, God, for giving me strength to carry on and for His faithfulness throughout this journey.

Structure of the thesis

This thesis comprises three parts: Part 1 comprising Chapter 1 and Chapter 2; Part 2 which consists three empirical chapters- Chapters 3, 4 and 5; Part 3 comprises the general discussion and conclusion as Chapter 6. This PhD is by publication, having two published papers and the third one under peer review.

Part 1: General Introduction

Chapter 1: Background of the study and literature review
Chapter 2: Methodology

Part 2: Empirical Chapters

Chapter 3: *"PrEP protects us":* Behavioural, normative, and control beliefs influencing pre-exposure prophylaxis uptake among pregnant and breastfeeding women in Zambia (published).

Chapter 4: Salient beliefs and Intention to use Pre-exposure prophylaxis (PrEP) among HIV-negative pregnant and breastfeeding women in Zambia: Application of the Theory of Planned Behaviour (published).

Chapter 5: Preferences for pre-exposure prophylaxis delivery among HIV-negative pregnant and breastfeeding women in Zambia: Evidence from a discrete choice experiment (under review).

Part 3: General discussion and Conclusion

Chapter 6: General Discussion
Chapter 7: Conclusion and Recommendations

Author contributions

I was responsible for conceptualizing and developing the protocol for this study. This included conducting literature review, identifying research gaps, proposing study objectives, and writing the methodology. I sought ethics clearance from institutional review boards at the University of Zambia and the University of the Witwatersrand, and got necessary approvals from the National Health Research Authority in Zambia. I was in charge of overseeing implementation of the study, including all field work activities. I analysed the data, conducted model diagnostic tests and interpreted results. I wrote the first drafts of all the manuscripts, submitted manuscripts to peer reviewed journals and collated suggested corrections and edits upon receiving comments from reviewers.

Supervisors/Co-authors

Provided guidance during study conceptualization and protocol development. Professor Samuel Bosomprah and Dr. Oludije Arije assisted with data analysis for the discrete choice experiment paper. All supervisors and co-authors reviewed, edited and approved the final versions of the manuscripts before submitting to peer-reviewed journals.

Collaborations

Throughout this PhD, I received support and mentorship from the following collaborators listed below.

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List of Abbreviations

AIDS:	Acquired human immune deficiency syndrome
ANC:	Antenatal care
AOR:	Adjusted odds ratio
OR:	Odds ratio
DCE:	Discrete choice experiment
HIV:	Human immunodeficiency virus
HR:	Hazards ratio
IDIs:	In-depth interviews
KIIs:	Key informant interviews
MTCT:	Mother-to-child transmission
NGT:	Nominal group technique
PMTCT:	Prevention of mother to child transmission
PNC:	Postnatal care
PrEP:	Pre-exposure prophylaxis
TPB:	Theory of planned behaviour
UNAIDS:	Joint United Nations Programme on HIV and AIDS
WHO:	World Health Organization
ZDHS:	Zambia Demographic and Health Survey

PART 1:

INTRODUCTION

LITERATURE REVIEW

METHODOLOGY

1.0. Chapter 1: Introduction and background

1.1. HIV prevalence globally

Despite advances in the scientific understanding of the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) and its prevention and treatment, HIV remains an ongoing threat to population health worldwide. Although the world has committed to ending AIDS by 2030, rates of new infections and deaths are not falling rapidly enough to meet that target (1). According to the 2022 UNAIDS report, approximately 4000 people—including 1100 young people (aged 15 to 24 years)—become infected with HIV every day. In 2021, 650 000 [500 000–860 000] people died of AIDS-related causes—one every minute. People in low- and middle-income countries constitute the vast majority of people living with HIV. In 2021 alone, approximately 20.6 million (53%) of people living with HIV were from eastern and southern Africa (2). The impact of COVID 19 has also made continued progress against HIV, including the need for more urgent action, more difficult (3).

In almost all countries where HIV affects many groups, young women aged 15–24 years (who are also likely to be pregnant), are three to five times more likely than their male counterparts to have HIV (1). Reports indicate that progress against HIV remains fragile and acutely inadequate among priority populations such as children and adolescent girls and young women in sub-Saharan Africa, where women and girls accounted for 63% of all new HIV infections in 2021 (3). In this region, adolescent girls and young women (aged 15 to 24 years) are three times more likely to acquire HIV than adolescent boys and young men of the same age group; one adolescent girl or young women (15 – 24 years old) becomes infected with HIV every three minutes (Figure 2) (2).

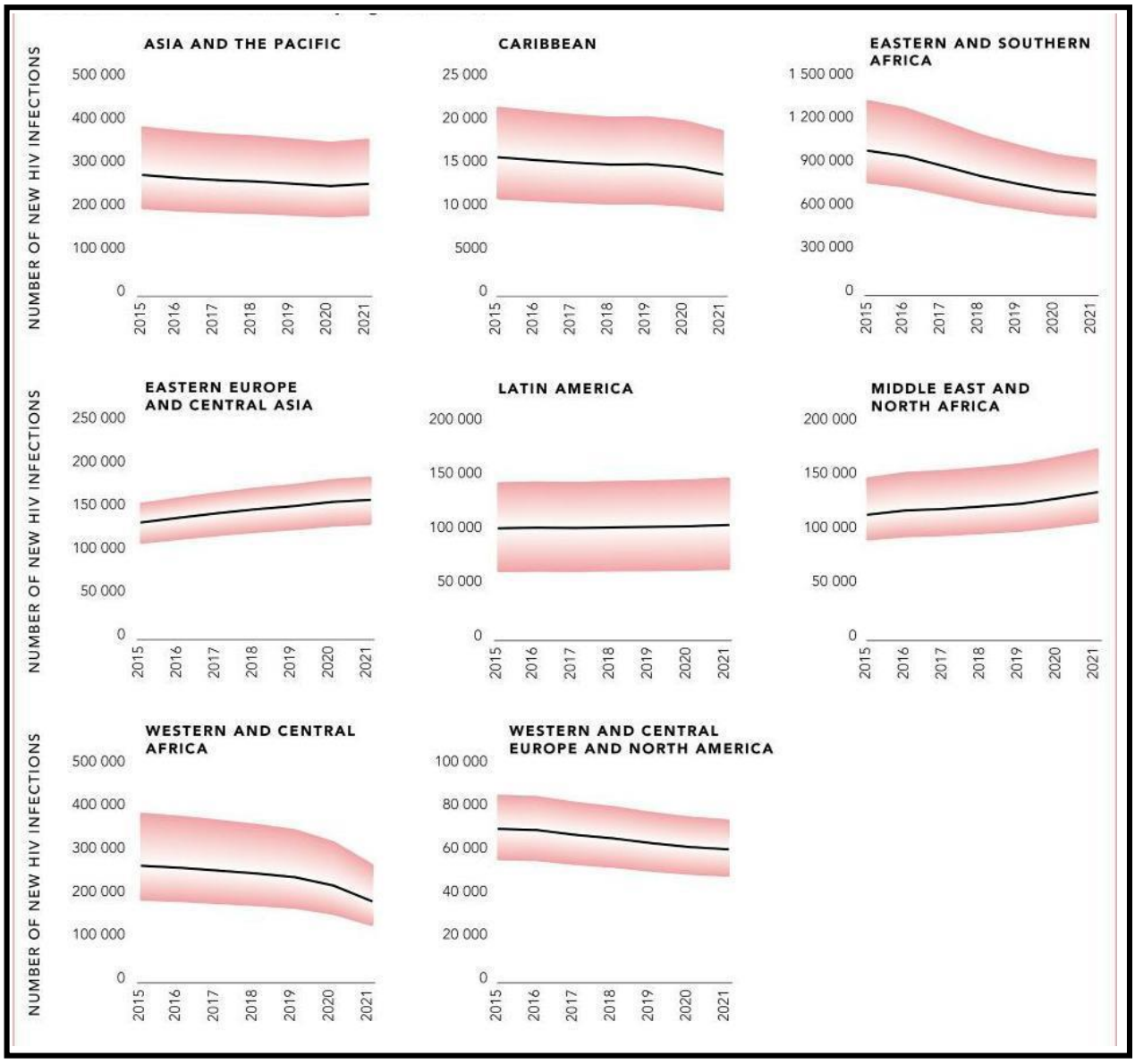


Figure 1. New HIV infections, by region, 2015–2021. Source: UNAIDS epidemiological estimates, 2022 (4)

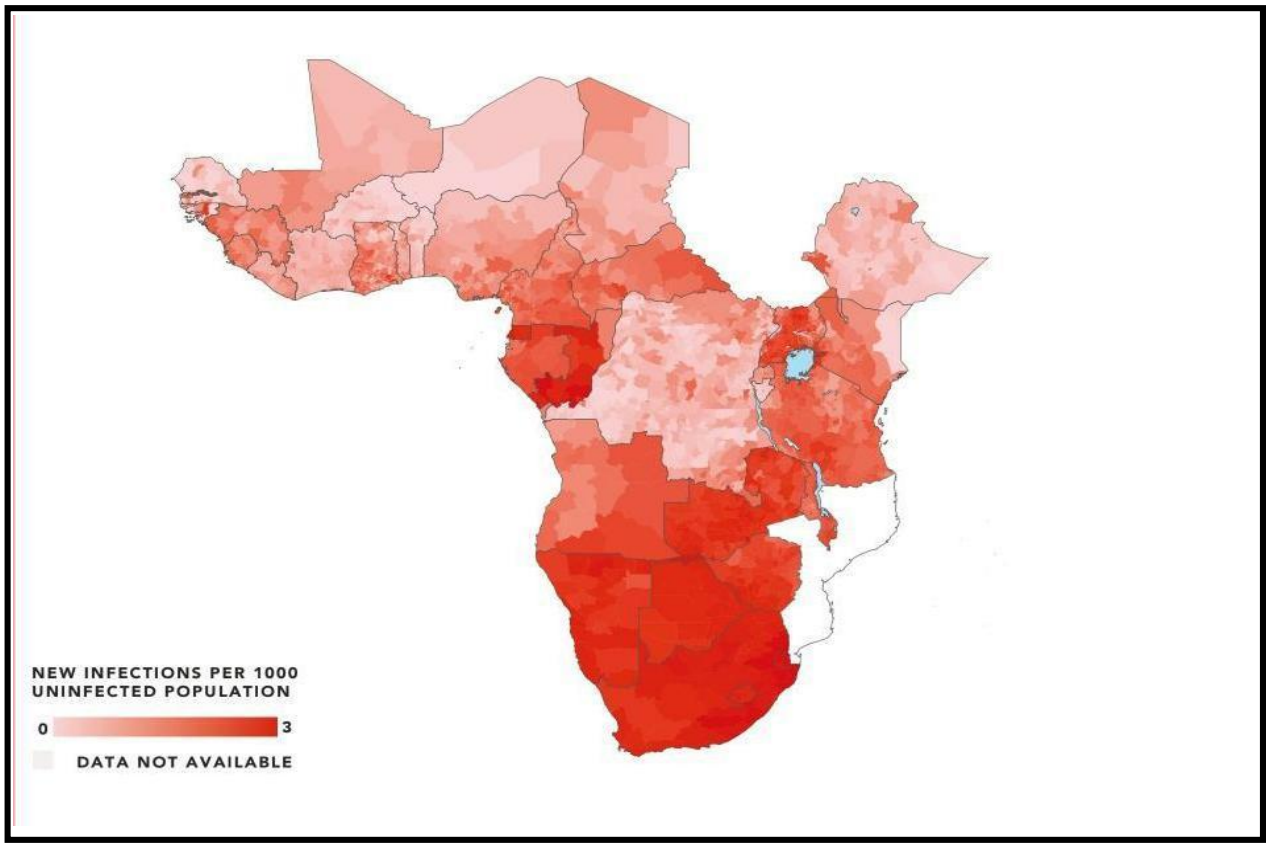


Figure 2. HIV incidence among adolescent girls and young women (aged 15–24 years), subnational levels, sub-Saharan Africa, 2021. Source: UNAIDS epidemiological estimates, 2022 (4).

1.1.1. Zambia's HIV/AIDS profile

According to the 2022 UNAIDS report, there were about 38 000 (32 000 – 44 000) new HIV infections in the country in 2021. About 22 000 of these infection occurred among women (aged 15+ years) while 3 800 were among children (aged 0 – 14 years). The country also recorded 19 000 AIDS-related deaths across all age groups; 9 300 among women (15+ years) and 2 400 among children below the age of 15 years. In 2021, 97% of pregnant women living with HIV were accessing antiretroviral medicines, and the rate of vertical transmission including during breastfeeding stood at 7.6%, a decline from 16.7% in 2015. 31.9% early infant diagnosis (5).

1.1.2. Risk of HIV-infection during pregnancy and breastfeeding

Pregnant and breastfeeding women in sub-Saharan Africa are disproportionately affected by the HIV epidemic. In Kenya, for instance, of 2,135 mothers who had tested HIV-1 seronegative antenatally and accepted HIV-1 re-testing at 6 weeks postpartum, 53 (2.6%) were HIV-1 seropositive yielding an estimated HIV-1 incidence of 6.8 (95% CI: 5.1-8.8) per 100 woman-years) (6). In another study in Kenyan discordant couples, results showed that the HIV transmission probability was 1.05 per 1,000 sex acts during non-pregnant intervals, 2.19 in early pregnancy, 2.97 in late pregnancy, and 4.18 in postpartum women (7).

A systematic review and meta-analysis that was conducted to estimate maternal HIV incidence during pregnancy/postpartum reported high HIV incidence during pregnancy/postpartum (3.8/100 person-years). HIV incidence rate was relatively higher during pregnancy compared to the postpartum period, i.e. 4.7/100 person years vs. 2.9/100 person-years, respectively. The same study also found significantly higher HIV incidence in African than non-African countries (i.e. 3.6% vs. 0.3%, respectively) (8). Similarly, a recent systematic review and meta-analysis conducted in sub-Saharan Africa by Graybill and others also reported high HIV incidence during pregnancy and breastfeeding (3.6/100 person-years) (9). HIV incidence rates reported during pregnancy and postpartum in sub-Saharan Africa are comparable to those reported in randomized trials among key populations such as discordant couples and sex workers in Kenya and Uganda (10, 11). Further, these incidence rates are consistent with the World Health Organization (WHO) definition of populations at substantial risk of HIV infection (12), thereby suggesting that pregnancy and postpartum are periods of considerable susceptibility to HIV infection.

1.1.3. Risk factors for maternal seroconversion

Factors contributing towards the high risk for HIV infection during pregnancy and breastfeeding are multifaceted, including biological, physiological and immunologic alterations in pregnant and postpartum populations (7, 13-17). Evidence shows that pregnancy is associated with a general maternal immune suppression that assures tolerance of the semiallogeneic fetus, and that during pregnancy, the adaptive immune responses are weakened, thereby resulting in reduced viral clearance (18). A study in Uganda attributed the high risk of HIV infection to biologic factors such as hormonal changes during pregnancy, including increased concentrations of progesterone, that potentially alter local immune responses and the genital tract mucosa (19).

The risk of HIV acquisition during pregnancy has also been attributed in part to social and behavioral factors (20). Higher frequency of unprotected sexual activity among pregnant women contributed to a 2-fold risk of HIV infection during pregnancy in a prospective study of 1085 serodiscordant couples with HIV-susceptible female partners in Kenya (21). In a study conducted among HIV-uninfected pregnant/breastfeeding women in South Africa, participants reported non-use of condoms mainly due to the belief that contact with sperm is good for the development and growth of the baby (22). Similarly, participants in Kenya believed that sperm was good for the baby's growth and hardening of the fontanelle (23). Post-partum abstinence, sometimes lasting about 3 months, was also viewed as increasing the women's risk for HIV infection owing to their partners' tendency to have other sexual partners during this period. Other risk factors that emerged included lack of control over sex decisions and condom use in pregnancy, and low perceived risk (e.g. beliefs that their partner has the same HIV-negative sero-status) (22).

Low levels of HIV testing among male partners compounded by low partner HIV status disclosure have also been reported as potential contributing factors to the increased risk of maternal HIV acquisition (24). In one study, HIV acquisition during pregnancy and postpartum occurred in undiagnosed chronic serodiscordant relationships, in which women had increased mucosal susceptibility due to vaginal infections (14).

1.1.4. Maternal HIV seroconversion and risk of mother-to-child transmission

Women who acquire HIV during pregnancy and breastfeeding significantly contribute to the pediatric burden of HIV globally (25). Although WHO advises that in locations with a high rate of HIV incidence, women who initially test negative for HIV should be retested later in pregnancy and during breastfeeding (26), repeat testing is not often performed, and therefore women who seroconvert during pregnancy go undiagnosed and therefore untreated (27). The implication is an increased risk of HIV mother-to-child transmission (MTCT) due to the high HIV viral load during incidental infection (28). Findings from a mathematical model in South Africa showed that 34% of vertical HIV transmission was a result of mothers seroconverting after their first antenatal visit (29).

A systematic review and meta-analysis showed that the risk of mother-to-child transmission in African cohorts was significantly higher among women with incident compared to those with chronic HIV infection. The study reported a 3-fold increased risk of MTCT in the postpartum period and a 2-fold increased risk in pregnancy/postpartum periods combined (8). In 2018, about 140 000 women in the 21 sub-Saharan African focus countries acquired HIV infection while pregnant or breastfeeding. During the same period, about 130 000 (87 000 - 210 000) children

acquired HIV in utero, at birth or while breastfeeding (25). According to the 2019 UNAIDS estimates, the mother-to-child transmission rate at the end of breastfeeding was 11.8% [9.8–15.2%] in the focus countries in Africa. In southern Africa, 17 000 of the 53 000 new infections in children were the result of women being infected during pregnancy or breastfeeding (25).

1.1.5. PrEP as a biomedical intervention for HIV prevention

Biomedical interventions such as pre-exposure prophylaxis (PrEP) have the potential to reduce the risk of maternal sero-conversion and consequently contribute towards the elimination of HIV mother-to-child-transmission. PrEP is the use of anti-retroviral drugs (ARVs) by HIV-uninfected people prior to exposure to block the acquisition of HIV (12). PrEP with daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) has been proven to be effective for prevention of HIV acquisition among serodiscordant couples (10, 30). Based on this evidence from several clinical trials, WHO in 2013 published the first consolidated guidelines on the use of antiretroviral (ARV) drugs for HIV treatment and prevention across all age groups and populations (31).

The 2013 WHO guidelines were later revised in 2015, to support the provision of daily oral pre-exposure prophylaxis (PrEP) as a prevention choice for people at substantial risk of HIV infection (HIV incidence greater than 3 per 100 person-years in the absence of PrEP) as part of combination prevention approaches (12). The recommendations were premised on evidence from clinical trials conducted among HIV positive women that showed that TDF-FTC is safe during pregnancy (32) with extremely low levels of drug acquired via breastfeeding among infants (33). This essentially meant that HIV-uninfected pregnant and breastfeeding women at substantial risk of HIV infection

could be offered PrEP, depending on individual behaviour and the characteristics of sexual partners (12).

The global health sector strategies on HIV aimed at ending AIDS as a public health threat by 2030 also acknowledges the importance of PrEP in addressing the HIV epidemic. The Strategy calls for a renewed focus on primary prevention, including new prevention approaches such as PrEP (34). Some of the programmatic coverage indicators and targets aim at increasing uptake of PrEP among pregnant and breastfeeding women. Increased uptake of PrEP in antenatal and postnatal settings will not only contribute towards reducing the number of people newly infected with HIV per year to 335,000 or 0.025 per 1000 uninfected population per year, but may also contribute significantly towards reducing the number of children 0-14 years of age newly infected with HIV per year to 15,000 as per the global targets on HIV (Sustainable Development Goal 3.3.1) (34).

The need for combination strategies for HIV prevention is also highlighted in the 2021-2026 global strategic plan, where it is targeted that more than 95% of people at risk of HIV use combination prevention (3). Indeed, attaining the global plan to eliminate HIV infections in children calls for combination strategies including pre-exposure prophylaxis for pregnant and breastfeeding women whose elevated risk of seroconversion is associated with an appreciable risk of MTCT. In 2021, 144 countries reported that they had adopted the WHO recommendations on oral PrEP in national guidelines (Figure 3). In the same year, Zambia was among other countries that recorded more than 5 140 people receiving PrEP (Figure 4).

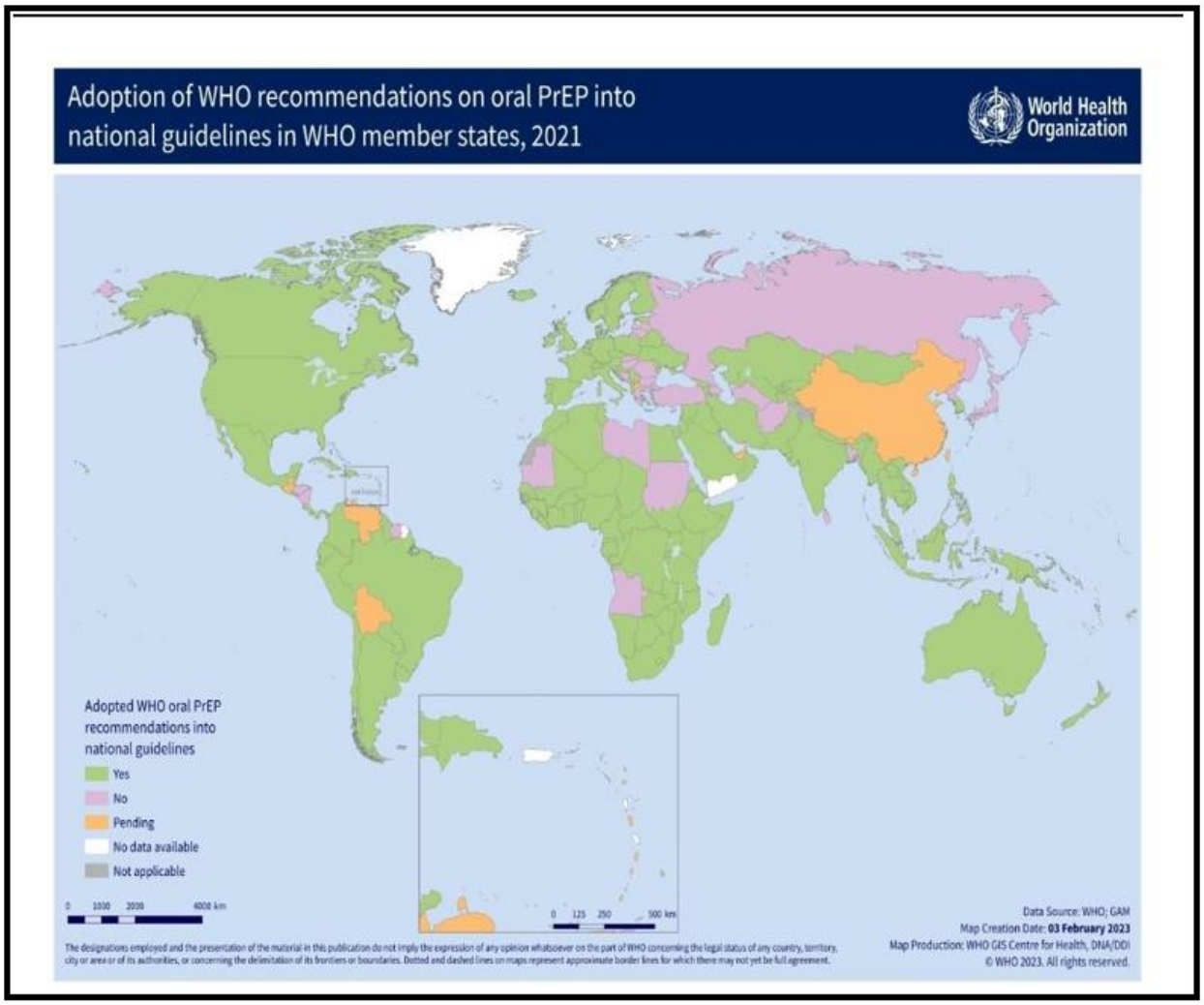


Figure 3. Adoption of WHO recommendations on oral PrEP into national guidelines in WHO member states, 2021. Source: AIDSinfo, Global data on HIV epidemiology and response (4)

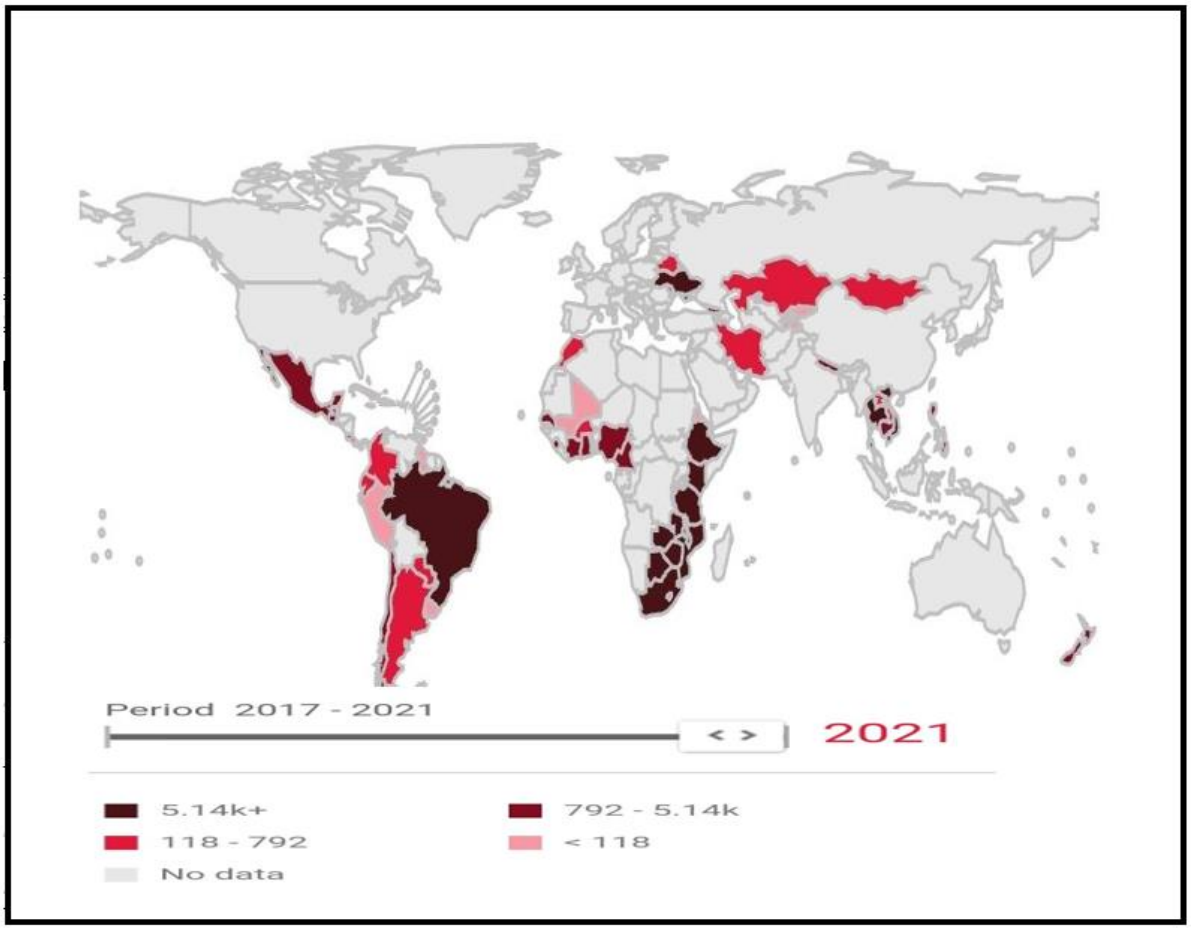


Figure 4. People receiving PrEP. Source: AIDSinfo, Global data on HIV epidemiology and response (4)

1.2. Problem statement and study justification

1.2.1. Problem statement

Zambia has a generalized HIV epidemic, with the current prevalence standing at 11.1% among adults (15-49 years) (35). According to the 2022 UNAIDS report, there were about 38 000 (32 000 – 44 000) new HIV infections in the country in 2021. About 22 000 of these infections occurred among women (aged 15+ years) while 3 800 were among children (aged 0 – 14 years) (5). The

prevalence among young men and women (15-24) which stands at 3.8% is equally higher among young women (5.6%) than young men (1.8%) (35). The HIV prevalence rate among pregnant women is estimated at 10% which is just slightly below the national prevalence. Unfortunately, only about 67% of women (15-49 years) in 2018 knew that HIV could be transmitted from mother to child (35), thereby presenting a challenge for HIV prevention during a time when the risk of vertical transmission is high. With respect to mortality, Zambia recorded 19 000 AIDS-related deaths across all age groups; 9 300 among women (15+ years) and 2 400 among children below the age of 15 years (5). Promoting uptake of PrEP, especially among pregnant and breastfeeding women could contribute towards the reduction of the HIV incidence rate, and thereby result in a downward trend in HIV/AIDS-related morbidity and mortality.

Although Zambia has more than 95% of pregnant women living with HIV on antiretroviral medicine, the rate of vertical transmission of HIV at the end of breastfeeding remains considerably high, about 7.6% in 2021, a decline from 16.7% in 2015 (5). Previous HIV prevention programmes have emphasized abstinence, condom use and being faithful to one sexual partner. However, evidence from the recent Zambia Demographic and Health Survey shows low uptake of condoms among women. For instance, among women who had sex with a non-regular partner, only 35% used a condom during last sex with a non-regular partner (25), thereby signaling an urgent need for a paradigm shift in programme implementation for HIV prevention in antenatal and postnatal settings in Zambia. Unlike barrier methods such as condoms, PrEP can be taken discreetly, may not require negotiation with partners and allows for couples to fulfill their pregnancy intentions while maintaining a negative HIV status (36).

1.2.2. Study justification

In 2016, Zambia introduced PrEP for the first time in its consolidated guidelines for treatment and prevention of HIV infection, which supported PrEP for serodiscordant couples and high-risk persons (37). The guidelines were expanded in 2018 (38), and in 2019 the Zambia Ending AIDS national HIV prevention campaign was implemented, focusing on public education and demand creation. This saw the national roll-out of PrEP and service delivery supported at 728 facilities by the end of 2019. By September 2019, a total of 26 953 clients had initiated PrEP (39). As of 2021, there were approximately 147 397 people who were receiving PrEP in Zambia (4). In 2020, in line with WHO guidelines, the Zambian Ministry of Health extended provision of PrEP to pregnant and breastfeeding women at substantial risk of HIV infection (40).

Despite pregnant and breastfeeding women expressing interest in PrEP, uptake of services in this population still remains low. In a study conducted among women accessing family planning services in Lusaka, only 1% of the 644 enrollees who were offered oral PrEP accepted it. The proportion of study visits at which PrEP was requested was also low at 0.57% (41). There is limited understanding of factors contributing to the low uptake of PrEP among pregnant and breastfeeding women in Zambia. The WHO recommends operational research in diverse settings to generate demand for prevention services (including PrEP) and to identify and engage people at substantial risk for HIV (12). In order to inform PrEP programming in antenatal and postnatal settings in Zambia, there is need to explore and determine context-specific facilitators and barrier to uptake of PrEP among end-users. Understanding beliefs, intentions, preferences and several other considerations that go in decision making either for or against PrEP is important for developing successful scale-up implementation programs.

1.3. Literature review

According to Nunn and others, the PrEP continuum of care should include: (1) identifying individuals at highest risk for contracting HIV, (2) increasing HIV risk awareness among those individuals, (3) enhancing PrEP awareness, (4) facilitating PrEP access, (5) linking to PrEP care, (6) prescribing PrEP, (7) initiating PrEP, (8) adhering to PrEP, and (9) retaining individuals in PrEP care (42). In settings where PrEP is a new intervention, such as in antenatal and postnatal settings, the starting point in ensuring successful implementation is exploring the 'awareness' (steps 1, 2 and 3) and 'uptake' (steps 4, 5, 6 and 7) components of the PrEP cascade as these have the potential to impact both adherence and retention in care among pregnant and breastfeeding women who initiate PrEP for HIV prevention.

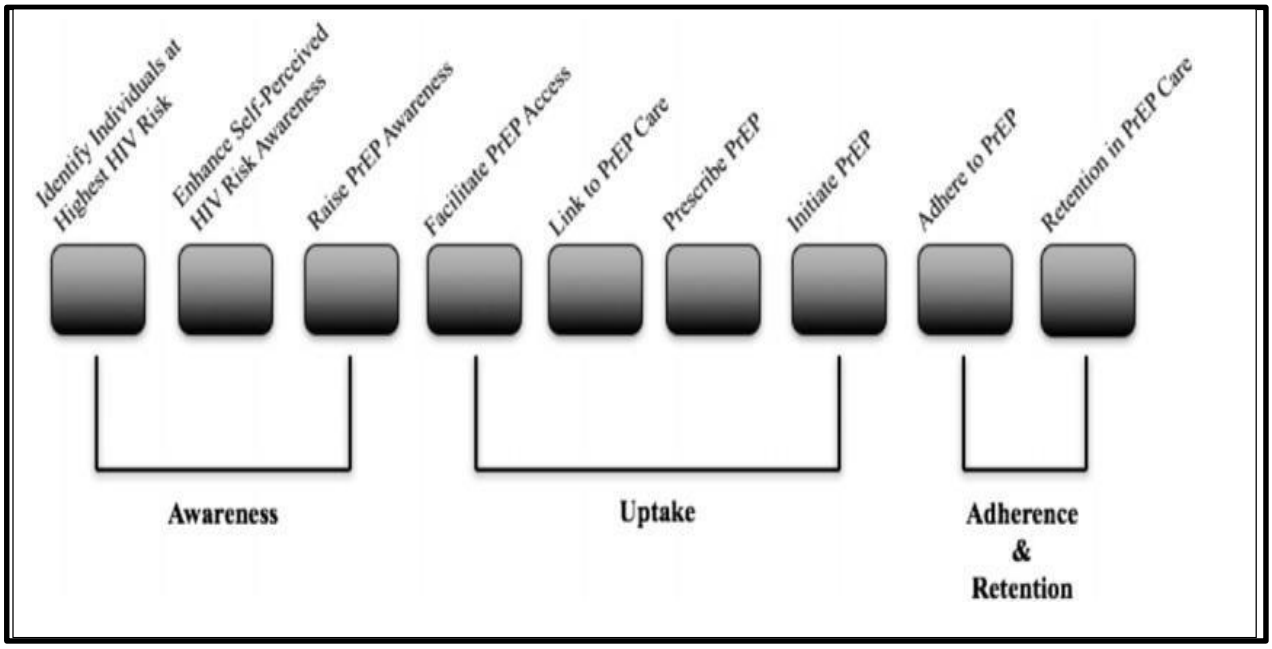


Figure 5. Continuum of care. Source: Nunn et al. (42)

1.3.1. HIV risk perception among pregnant and breastfeeding women

How pregnant and breastfeeding women perceive their own risk for HIV acquisition may influence their attitude towards PrEP use for HIV prevention. Intrapersonal as well as interpersonal socio-cultural factors, including beliefs about HIV risk and those surrounding the use of PrEP, have the potential to facilitate or hinder uptake of PrEP services. Studies that have evaluated risk perception among pregnant and breastfeeding women have reported mixed findings, although the majority of the studies have reported high perceived risk in this population (22, 43-46). This risk perception is mainly rooted in cultural practices about sex during pregnancy and postpartum.

In a study conducted in Kenya, almost all participants perceived pregnancy as a time of potentially high HIV risk primarily due to changes in sexual behavior within relationships. Several participants who reported feeling "less intimate" or "less free" to have sexual intercourse with their male partners while pregnant felt that the infrequent sexual intercourse within their primary partnership drove male partners to engage in sexual relationships with other people who could be HIV-infected (43). In another study in Kenya and South Africa, participants described their potential HIV exposure as due to their partners' multiple concurrent partnerships, unknown HIV status, and low condom use (either to avoid hostile condom negotiations or to please long-term partners) (44).

In South Africa, women perceived their risk for HIV infection to increase during the postpartum period largely because of postpartum abstinence that ensues when women move to their mothers' homes after delivery (22). A study in Malawi found that most pregnant and breastfeeding women

considered themselves at risk owing to the cultural beliefs that sex should cease between the 6th and 8th months of pregnancy and should only resume 6 months after delivery. Pregnant and breastfeeding women in this study expressed fear of HIV infection if their spouses found other partners during this period of abstinence (45).

Conversely, more than half of postpartum women in a study conducted in Zambia perceived themselves to be at either no risk (31%) or low risk (20%) for HIV infection. About 20% and 26% perceived themselves to be a moderate and high risk, respectively. Surprisingly, 52% of women who reported that they were at no or low risk for HIV infection were in fact HIV-positive (46). These results highlight the need for risk reduction education targeting women with seronegative test results to incorporate messages aimed at enhancing women's ability to correctly assess their own risk for HIV acquisition during pregnancy and postpartum.

1.3.2. Attitude towards PrEP use among pregnant and breastfeeding women

In most African societies, pregnancy is perceived as a test of fertility and identity. In addition to pregnancy being viewed as a rite of passage from childhood to womanhood, it is also regarded as a duty for married women to have children (47). Having children is viewed as a way to keep the marriage and prevention of polygamy in the marriage (48). In fact, failure to have children is viewed as a threat to the viability of the relationship among couples (36). Owing to this, most women tend to be skeptical and cautious about anything that they think could negatively affect the development and growth of their baby. At the same time, women are motivated to address health issues during pregnancy in order to protect their infants. The perception of increased risk and the

desire to have HIV-uninfected babies present an opportunity to promote PrEP use for prevention of HIV infection for both mother and baby.

Studies that have measured hypothetical willingness to use PrEP have shown high acceptability, with concerns about HIV acquisition during pregnancy and further transmission of the virus to the child being major motivations for interest in PrEP use (22, 49). Among women who initiated PrEP during pregnancy in Kenya, the reported underlying motivations included the desire to fulfil pregnancy intentions within serodiscordant partnerships without fear or worry of HIV transmission. PrEP was seen as an important back-up strategy to ensure infants would be born HIV-uninfected. The belief that taking PrEP would support the HIV-positive partner to adhere to ART was also a facilitator of PrEP use among pregnant women (36).

In a study conducted in South Africa, PrEP was seen as providing a feeling of safety with condom-less sex by several women who reported multiple sexual partners during pregnancy and postpartum. Women reported continued PrEP use even during periods of postpartum abstinence which ranged from weeks to months. The major motivation for initiating and wanting to continue taking PrEP was the desire to remain HIV uninfected and have an HIV-free infant. PrEP helped the women feel protected or safe when they had sex with their partners who they thought were risky partners, or when navigating condom use was difficult (50). Similar motivations for PrEP use were reported in Kenya, where women expressed positive attitudes about PrEP because they viewed it as an HIV prevention option for themselves and their infants during pregnancy, when they desired sex less frequently, which could lead their partners to have outside partnerships (43). In another study, pregnant women whose partners had not been tested for HIV or whose serostatus

remained unknown had 1.6-times odds of PrEP retention compared to their counterparts whose partners had been tested (aOR= 1.60; 95% CI= 1.02-2.52) after adjusting for covariates (51).

Despite the positive attitude towards PrEP expressed in most studies, some women did not see the need to take PrEP during pregnancy and postpartum because they felt their risk for acquiring HIV infection was low. A quantitative study showed that pregnant women who had HIV-negative partners or low risk perception were less likely to continue on PrEP (52). The idea of having to take a daily medication for an extended period of time, compounded by the possibility of forgetting to take a pill every day discouraged some pregnant women from wanting to take PrEP (53).

Concerns about side effects and safety, and potential impact on the baby were also cited as barriers to PrEP use in other studies. In a study conducted in Malawi, for example, many women who were uninterested in PrEP perceived maternal and fetal health risks associated with taking PrEP (53). The perception that PrEP was used for prevention and not necessarily for treatment made some women question whether experiencing side effects of PrEP was worth it during pregnancy. For others, discerning pregnancy symptoms from PrEP side effects caused confusion and distress as they feared their symptoms could be signs of potential danger to their infant from PrEP use, including pregnancy loss (36).

Low PrEP awareness was also cited in several studies as having the potential to negatively impact PrEP uptake in antenatal and postnatal settings. Participants in a study conducted in South Africa and Kenya reported that PrEP awareness was very low in the communities where participants

resided, with most of the participants primarily hearing about PrEP for the first time at the clinic where the study took place, while seeking contraception or treatment for an existing STI (44).

Pill-related factors such as a dislike for taking tablets, difficulties with committing to daily pill taking and challenges taking PrEP in addition to other tablets were also reported. This was specifically a challenge for several women in a PrEP study who reported taking other tablets such as vitamins for pregnancy and analgesics post-delivery. Although pregnant and breastfeeding women in this study reported ensuring that they remembered to take PrEP for the first 7 days to achieve adequate levels of protection before having condomless sex, some reported that they frequently forgot to take their daily PrEP when not planning to have condomless sex (54).

1.3.3. Subjective norms about PrEP use during pregnancy and breastfeeding

Studies conducted among pregnant and postpartum women have reported how the broader social networks of women could support or discourage PrEP use. Referents range from partners, family members, friends and community members. Women who feared or had experienced community stigmatization reported concerns about disclosing PrEP use, for fear of being assumed to be living with HIV. In Malawi, some participants' fear of being labeled HIV-positive extended beyond their partners to other family and community members, noting a lack of familiarity with the concept of using HIV antiretroviral drugs for primary prevention (53). Other women reported being questioned about their HIV status when disclosing their PrEP use (50). Participants in another study felt that community-level stigma against people living with HIV would lead women to avoid PrEP access points, if offered within traditional HIV service facilities, since collecting drugs can be associated with being HIV infected (43).

In Kenya, many pregnant and postpartum women perceived that male partners would react negatively, including becoming physically violent, if they discovered that women used PrEP. Pregnant and postpartum women feared that male partners unfamiliar with PrEP would confuse PrEP for HIV treatment since the "same drugs" are used for both prevention and treatment. Participants reported that If male partners suspected their pregnant partners were HIV-infected, this could create problems within the relationship and family (43).

Pregnant and postpartum women reported that lack of PrEP awareness among the community at large would have implications for whether pregnant women decide to openly use PrEP. High internalized and anticipated PrEP stigma among pregnant women in South Africa was associated with lower PrEP care initiation at first antenatal care visit (aOR internalized stigma = 0.06; 95% CI = 0.03-0.11 and aOR anticipated stigma = 0.55; 95% CI = 0.31–1.00) compared to women with low reported stigma, after controlling for covariates (51). PrEP stigma was also reported among pregnant and postpartum women in other studies (54, 55).

Fear of (and actual) accusation of infidelity (by partners) and promiscuity (by family) were reported as barriers to PrEP use among adolescents and young girls in another study (44). Community-level stigma against HIV and potential for conflating PrEP with antiretroviral therapy (ART) was viewed as necessitating the discreet use of PrEP. Participants identified clinicians as potential facilitators of PrEP use who could explain PrEP to male partners on behalf of pregnant women (43).

While disclosure of PrEP use was reported in some studies as a source of experiencing PrEP-related stigma, other women who disclosed their PrEP use reported that such disclosure made adherence to

PrEP considerably easier, as it eliminated several barriers to adherence such as hiding pills (55). Similar findings were reported in another study where pregnant and postpartum women cited encouragement from their primary partner, a friend or relative regarding their decision to start or continue taking PrEP as an important driver of consistent PrEP use. Most of the women reported that their partners played a critical role in reminding them to take PrEP. According to these women, disclosing their use of PrEP, and educating others in their lives about the benefits of taking PrEP helped them to overcome PrEP stigma (50).

1.3.4. Control beliefs about PrEP use during pregnancy and breastfeeding

Although pregnant and breastfeeding women demonstrated positive attitudes toward PrEP use for HIV prevention, most of them believed that getting approval from partners, family members, and friends was important. In a study conducted in Kenya, nearly all women reported that male partners play a central role in medical decisions during pregnancy and would need to be involved in choices about taking PrEP. It was further reported that women from poor neighborhoods were more likely to defer to husbands' wishes when considering PrEP use during pregnancy given their greater socio-economic dependency on their male partners. Mothers-in-law were described as a potential barrier to pregnant women's use of PrEP because of concerns that using PrEP in pregnancy would terminate the pregnancy (56). Unstable social structure characteristics (i.e., financial hardship) and inadequate peer and partner support, including parental rejection were reported as barriers to PrEP uptake and continuation among pregnant adolescent girls and young women (AGYW) in a study conducted in South Africa (57).

While some participants in Kenya believed that decisions made during pregnancy are supposed to be family decisions, mainly owing to the Kenyan culture where a baby is viewed as belonging to the wider family and community after childbirth (56), some women felt that disclosing PrEP use would negatively impact their ability to initiate and adhere to PrEP. The ease or difficulty associated with taking PrEP during pregnancy and breastfeeding was often discussed in relation to anticipate approval or disapproval from people considered important in the women's lives. At the center of these discussions was HIV-related stigma. Pregnant and breastfeeding women in Kenya reported that the only way they could take PrEP was if they could hide it from others. Participants believed that if PrEP could be accessed discreetly and PrEP use could be "hidden" or "secret," it would prevent community stigma among users (43).

Although concealing PrEP use during pregnancy was considered as an option, women highlighted some challenges of doing so. Participants thought that concealing PrEP drugs from male partners would be challenging during pregnancy because the other drugs that they received during ANC such as antimalarials, hematinics, vitamin supplements, were known to male partners, and therefore discreet use of PrEP would require additional measures in such scenarios. Some participants who described clinicians as a "second God," someone you could "listen to" and "trust" believed that attending ANC with their partners could facilitate PrEP use, as clinicians could seize the opportunity to clarify PrEP's indication for HIV prevention. Participants perceived that clinician-initiated PrEP counseling would be more effective than women discussing PrEP with male partners alone (43).

1.3.5. Preferences for PrEP service delivery

Taking into account client preferences may increase uptake of PrEP in a given target population. Understanding the service-delivery attributes of PrEP would enable program managers and implementers to provide patient-centered care which is likely to yield positive results. Stated-preference methods such as discrete choice experiments (DCEs) have, in the recent past, been used in health care settings to identify and evaluate the relative importance of aspects of decision making related to health outcomes and health care services. Stated-preference methods use surveys/questions to elicit subjects' preferences for hypothetical options in an experimental framework (58).

From one study that looked at access/service delivery factors influencing willingness to use PrEP in a general population, preferred attributes were: convenient location of place that dispenses PrEP, such as clinics and pharmacies; waiting time; flexibility to have PrEP delivered by another person to the individual; the requirement for routine blood tests every few months (59). In another study conducted among female sex workers in Malawi, dispensing location was the most important factor while clinic waiting time was the least important factor (β or relative utility=0.54; 95% CI: 0.50, 0.58 and β=0.22; 95% CI: 0.16, 0.26), respectively. Respondents preferred to receive PrEP at family planning clinics compared to STI clinics and ART clinics (60).

Waiting time is an attribute of service delivery likely to influence uptake of services. Participants who preferred health facilities for PrEP pick-ups were concerned about the waiting time at such facilities, which they felt was too long. Participants preferred locations that could provide PrEP without having to keep clients waiting (59). Participants revealed that they preferred quick access to

PrEP without having to spend long hours in queues waiting to receive PrEP. Instances when facilities are busy and they are required to wait for a long time was seen as a barrier to using PrEP (61).

Travel time to the facility dispensing PrEP can present challenges to PrEP users who may require transport money in order to access services. In a study conducted among pregnant and postpartum women in South Africa, reported barriers to postpartum PrEP access included transport, logistical, financial and access related barriers to consistent clinic attendance. Postpartum PrEP use was specifically challenging for women since they needed to make special facility visits just to receive PrEP, and therefore increased the burden of PrEP use associated with transportation costs and waiting times (54).

In a study conducted among pregnant AGYW in South Africa, participants reported that high-quality study provider-client relationships facilitated PrEP use and continuation (57). In another study, some of the participants were concerned about the attitude of health workers when they are seeking services. This was viewed as a major barrier because they thought if the health workers are rude to the clients, they might not find it conducive to collect PrEP. Some, especially younger participants, feared that if those dispensing the medication are known to them, they might talk about them in the community to the extent of reporting them to their parents (61).

There is limited literature on preferences of pregnant and breastfeeding women with respect to amount of PrEP drugs supplied at each refill. The few studies that have used DCEs to explore preferences for PrEP delivery have focused on key populations such as men who have sex with men and female sex workers. To the best of our knowledge, this is the first study to quantify

preferences for PrEP service delivery in antenatal and postnatal settings using a discrete choice experiment. In a discrete choice experiment that was conducted among female sex workers in Malawi, respondents preferred picking up PrEP every 2 months or every three months compared to monthly. Women preferred picking up PrEP every 2 months (mean level utility = 0.10; SD = 0.20) to monthly (mean level utility = 0.02; SD = 0.11) or every 3 months (mean level utility = − 0.12; SD = 0.03) (60).

1.3.6. Gaps in the literature

From literature review, it can be noted that most of the studies on PrEP use during pregnancy and breastfeeding were conducted either in South Africa or Kenya, with only one study from Zambia that explored hypothetical attitude towards PrEP. Although other studies have explored facilitators and barriers to PrEP use during pregnancy and postpartum, their context could be different from the Zambian context. Notably, South Africa and Kenya have had numerous PrEP demonstration projects since the first WHO guidelines on PrEP, and therefore are at different stages of PrEP implementation relative to Zambia. Insights from Zambia could be valuable in informing PrEP implementation in this regard. As per WHO recommendation, there is need to generate knowledge about PrEP use in diverse settings because what works in one context may not work as perfectly in another.

Further, most of the studies have explored beliefs about PrEP in the target population have been qualitative in nature and may not have estimated quantitatively the effect of these beliefs on potential and/or actual uptake of PrEP. This is the first study in Zambia to quantifying the contribution of individual beliefs on intention to use PrEP in antenatal and postnatal settings. This information is

essential because it gives program implementers an idea of which beliefs to target for optimum uptake of PrEP.

Finally, no study has used a discrete choice experiment to evaluate preferences for PrEP service delivery in antenatal and postnatal settings. Patient-centered approaches inherent in differentiated service delivery would benefit from the knowledge of the utility that pregnant and breastfeeding women derive from different attributes of PrEP service delivery. This knowledge is even more critical in resource constrained settings like Zambia where it may not be possible to address all service delivery related barriers to PrEP uptake. Program implementers could prioritise addressing the preferred attributes in order to improve demand and uptake of PrEP observed among pregnant and breastfeeding women in Zambia. Therefore, the current study specifically fills the knowledge gap on salient beliefs that pregnant and breastfeeding women in Zambia have about PrEP; demonstrates the effect of each of the beliefs on intention to use PrEP and finally quantifies the utility that women derive from different attributes of PrEP service delivery. The study also highlights the benefit that women who choose to use PrEP during pregnancy and breastfeeding would derive from different ways of delivering PrEP.

1.4. Theoretical framework

This study was guided by the Theory of Planned Behaviour (TPB) (62) and the Access to care framework (63). The two frameworks were useful in demonstrating the relationship between and among various explanatory variables and how the variables influenced PrEP initiation intention. The TPB was used to explore individual level factors (also referred to as 'demand-side factors') influencing women's intention to use PrEP while the Access framework provided useful insights on

health system factors (also referred to as 'supply-side factors'), specifically focusing on how service delivery could influence uptake of PrEP for HIV prevention during pregnancy and breastfeeding. A summary of each of the two frameworks is given below.

1.4.1. Theory of Planned Behaviour

The Theory of Planned Behaviour is a theory that explains how socio-cognitive factors influence one's behavior in various situations. It is an extension of the Theory of Reasoned Action (TRA). The TPB was made necessary owing to the main limitation of the TRA in explaining behaviours for which individuals do not have complete volitional control. The theory of planned behavior incorporates some of the central concepts in the social and behavior sciences and provides a conceptual framework that is useful in aiding our understanding of the complexities of human social behavior such as PrEP uptake. Central to the TPB is an individual's intention to perform the behavior. In this case, intention is seen as a product of various motivational factors relevant to the behavior in question (62).

According to this theory, if people evaluate the suggested behaviour as positive (attitude) and if they think their significant others want them to perform the behaviour (subjective norm), and if they feel they can enact the given behaviour successfully (perceived behavioural control), this results in a higher intention (motivation) to perform the behavior in question and they are more likely to do so (62). Attitudes toward the behavior, subjective norms with respect to the behavior, and perceived control over the behavior have been found to predict behavioral intentions in several health-related studies with a high degree of accuracy (64-68). In turn, these intentions, in combination with perceived behavioral control, can account for a considerable proportion of variance in behavior. Accordingly, higher intentions should translate to higher odds of performing the behavior (62).

1.4.1.1. Attitude as a construct of the Theory of Planned Behaviour

Attitudes develop reasonably from the beliefs that people hold about the object of the attitude (in this case, PrEP). Individuals are likely to favor behaviors that they believe have largely desirable consequences. Similarly, they tend to form unfavorable attitudes toward behaviors that they associate with mostly undesirable consequences. As shown in the equation below, the strength of each salient belief (b) is combined in a multiplicative fashion with the subjective evaluation (e) of the beliefs attribute, and the resulting products are summed over the (n) salient beliefs. A person's attitude (A) is directly proportional to this summative belief index (62).

$$A = \sum_{n=1}^{n} (b_i e_i)$$

1.4.1.2. Subjective norms as a construct of the Theory of Planned Behaviour

Subjective norms are seen as a product of normative beliefs and the motivation to comply with the referent person in question. Normative beliefs are concerned with the likelihood that important referent individuals or groups approve or disapprove of performing a given behavior (e.g. PrEP uptake). The strength of each normative belief (n) is multiplied by the person's motivation to comply (m) with the referent in question. The subjective norm (SN) is directly proportional to the sum of the resulting products across the (n) salient referents as shown below (62):

$$SN = \sum_{n=1}^{n} (n_i m_i)$$

1.4.1.3. Perceived behavioural control as a construct of the Theory of Planned Behaviour

Perceived behavioral control refers to people's perception of the ease or difficulty of performing the behavior of interest. It refers to people's confidence in their own ability to perform a given behavior. The more resources and opportunities individuals believe they possess, and the fewer obstacles or impediments they anticipate, the greater should be their perceived control over the behavior. Specifically, each control belief (c) is multiplied by the perceived power (p) of the particular control factor to facilitate or inhibit performance of the behavior. The resulting products are summed across the (n) salient control beliefs to produce the perception of behavioral control (PBC) as depicted in the equation below (62).

$$PBC = \sum_{n=1}^{n} (c_i p_i)$$

In summary, personal evaluation of a behavior (attitude), socially expected mode of conduct (subjective norm), and self-efficacy with respect to the behavior (perceived behavioral control) are very important concepts in social and behavioral research. The application of the TPB in the context of PrEP has the potential to provide a lot of information that could be extremely useful in our efforts to understand PrEP uptake during periods of elevated risk of HIV infection. An exploration of the beliefs that women have about using PrEP during pregnancy and breastfeeding provides a gateway to understanding the unique underlying factors that would induce some women to use PrEP and prompt other women not to use PrEP for HIV prevention. Indeed, this information could be useful in guiding program implementation and interventions that could be effective in improving uptake of PrEP in antenatal and postnatal settings in Zambia and sub-Saharan Africa at large.

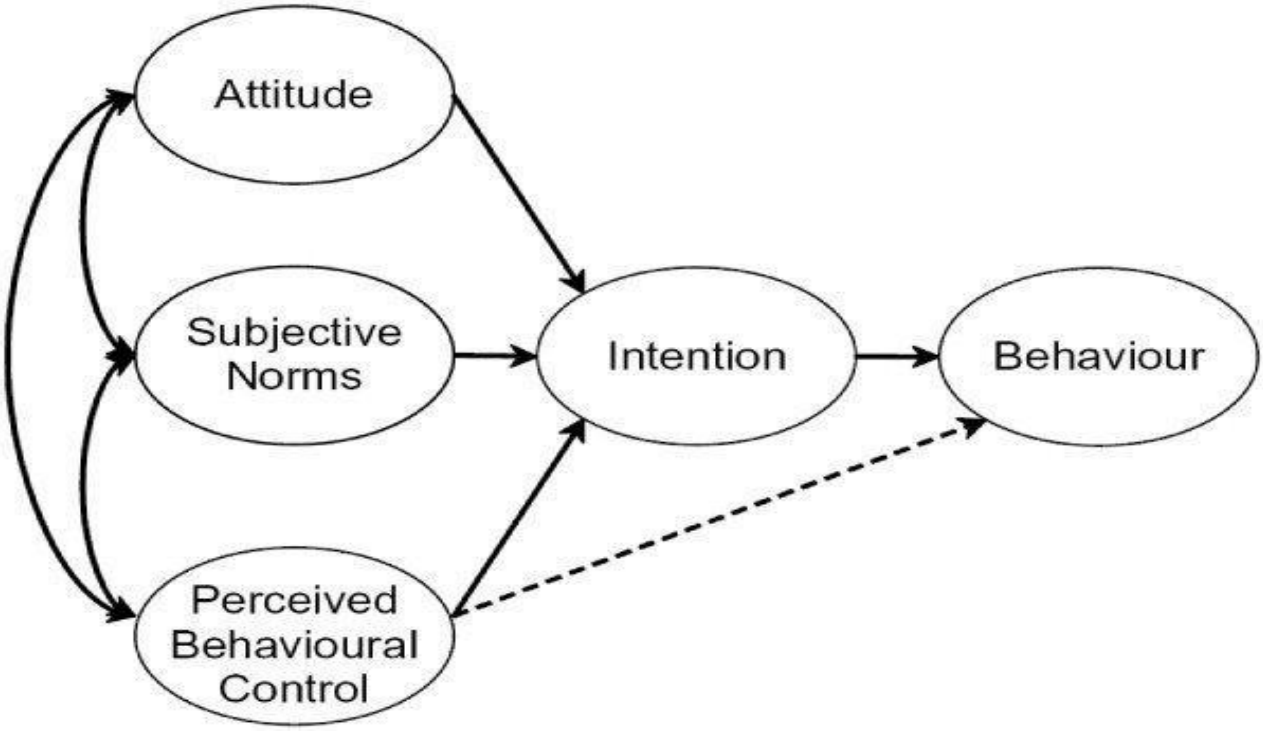


Figure 6. Theory of Planned Behaviour conceptual framework (62)

1.4.2. Access to health care framework

The study adopted the Access to care framework (63) in order to identify health systems factors (supply-side factors) that could influence PrEP uptake among pregnant and breastfeeding women who may be interested in using PrEP for HIV prevention. The framework considers both demand-side and supply-side factors in explaining access to health care services. However, only the supply-side factors were adopted for the purposes of the current study, since the demand-side factors were being explored using the Theory of Planned Behaviour. The five key areas adopted from the framework are described below.

1.4.2.1. Approachability

Approachability relates to the understanding that individuals who have health needs are capable of actually identifying that the health service required exists, can be reached, and that it can have an impact on their health. Several elements about health care service delivery such as transparency, information regarding available treatments and services and outreach activities have the potential to contribute towards making the services more or less approachable. Additionally, a crucial aspect to this notion of approachability of services is the ability to perceive need for care among populations. This is determined, in part, by factors such as health literacy, knowledge about health and beliefs related to health and sickness (63). Under this domain of access to health care, the current study explored PrEP knowledge and awareness among study participants and determined HIV risk perception as a potential determinants of PrEP uptake.

1.4.2.2. Acceptability

The concept of acceptability considers the role of culture and social factors in influencing people's acceptance of the aspects of the service in question (PrEP use). Examples of such cultural and social factors include the sex or social group of providers, the beliefs associated to systems of medicine, and people's judgement of appropriateness to seek care. For example, a society forbidding casual physical contact between unmarried men and women would reduce acceptability of care and acceptability to seek care for women if health service providers are mostly men. Because different groups may judge appropriateness and quality differently, one challenge that arises is that of ensuring that health care services are designed in such a way that the needs of different cultural, socioeconomically disadvantaged and vulnerable populations are met (63). Based on this

understanding, the current study explored the influence that the gender of health care providers dispensing PrEP would have on uptake of PrEP among pregnant and breastfeeding women.

1.4.2.3. Availability and accommodation

The concept of availability and accommodation refers to the fact that health services (either the physical space or those working in health care roles) can be reached both physically and in a timely manner. Availability constitutes the physical existence of health resources with sufficient capacity to produce services (existence of productive facilities). It also relates to modes of provision of services. Ability to reach health care relates to the notion of personal mobility and availability of transportation, occupational flexibility, and knowledge about health services that would enable one person to physically reach service providers. Inability of individuals to be absent from work to consult medical providers would be an example of this (63). Based on this understanding of access to health care, the current study determined preferences for PrEP service delivery with respect to the location for PrEP pickup as well as amount of PrEP supply at each refill.

1.4.2.4. Affordability

According to the access to health care framework, affordability reflects the economic capacity for individuals to spend resources and time in order to use appropriate health care services. In this sense, affordability is viewed as a product of prices of services and related expenses in addition to the opportunity costs that are associated with loss of income. Economic studies of utilization model people's demand for health care services using variables such as travel time and the opportunity costs linked to it, patient's income, price of care, and perceived quality of care (63). The current study employed this notion of affordability to determine pregnant and breastfeeding women's

preferences for PrEP service delivery with respect to waiting time at, and travel time to the facility dispensing PrEP.

1.4.2.5. Appropriateness

Appropriateness denotes the fit between services and clients' needs, its timeliness, the amount of care spent in assessing health problems and determining the correct treatment and the technical and interpersonal quality of the services provided. Adequacy relates to the appropriateness (what services are provided) and quality (the way in which they are provided) of health services. Opportunity to utilise only services of poor quality in this sense is seen as restriction of access to health care. The rationale here is that one should not have access to health care based on geographical and organisational availability and affordability alone, but that access encompasses the possibility to choose acceptable and effective services, largely because this generates different health outcomes or satisfaction towards services (63). In this current study, the notion of appropriateness was used to determine preferences for PrEP service delivery with respect to health care provider attitude.

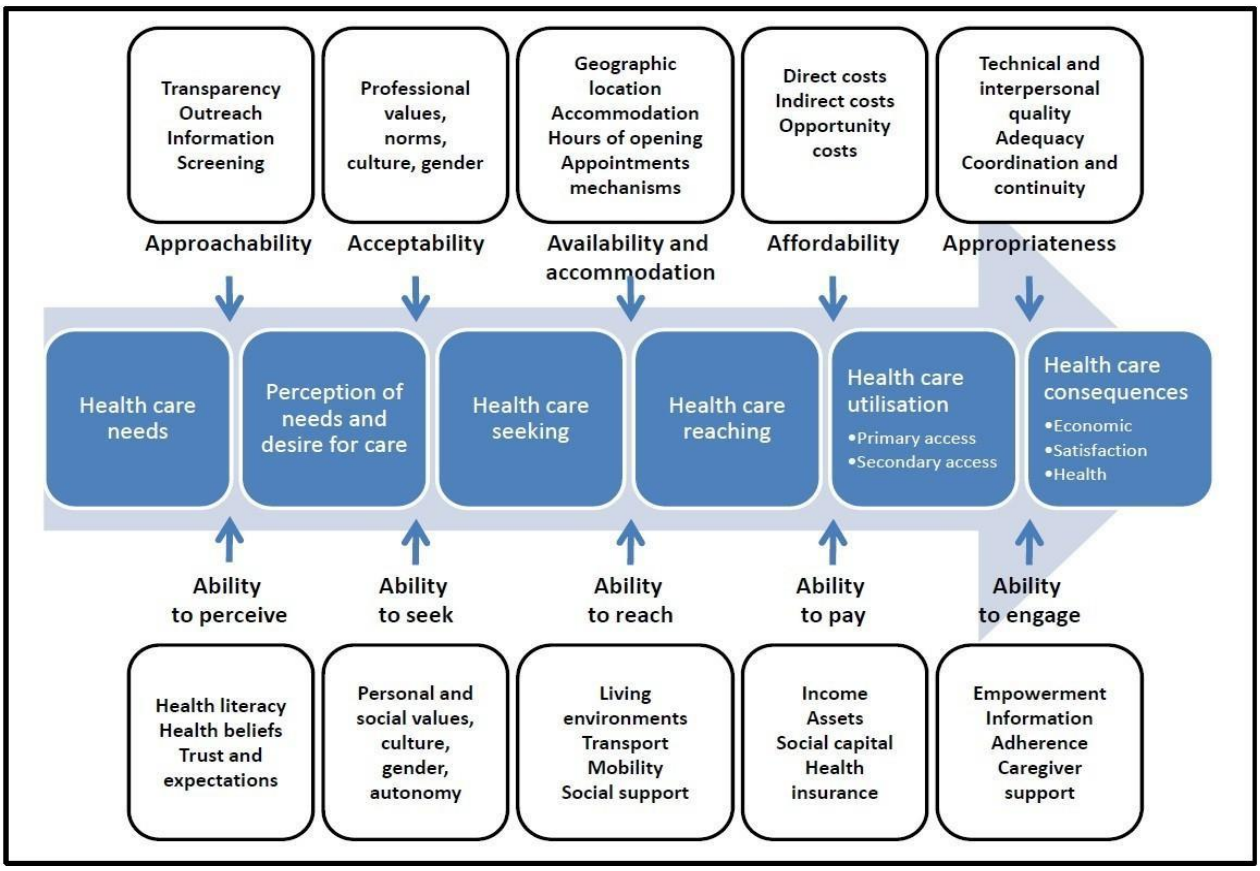


Figure 7. Patient-centred access to health care: conceptualizing access at the interface of health systems and populations (63)

1.5. Conceptual framework

Health care services utilization such as PrEP use is a product of the interrelationship between demand-side and supply-side factors. In the context of the current study, while pregnant and breastfeeding women may have positive attitudes as well as favourable subjective norms and perceived behavioural control about using PrEP, supply-side factors such as travel time, waiting time, location, attitude of health care providers and amount of supply at each refill may influence the women's decision whether or not to effect the health behavior of interest (PrEP uptake). In like manner, addressing the supply-side factors alone may not be enough to result in the desired health

behavior. In order to comprehensively determine factors associated with the low uptake of PrEP in antenatal and postnatal settings, the current study merged the TPB together with supply-side factors of the Access framework as illustrated in Figure 3 below.

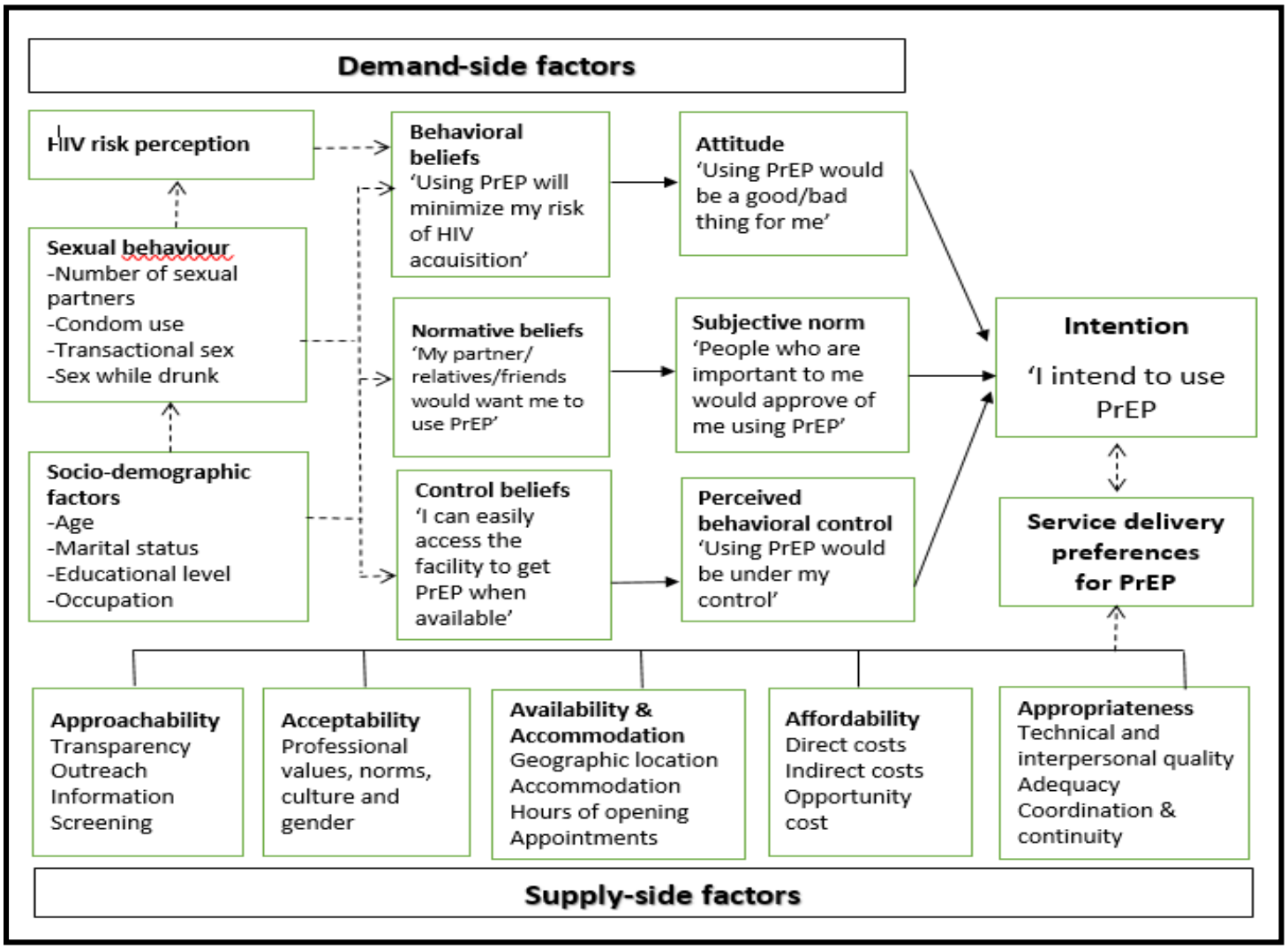


Figure 8. Conceptual framework. Adapted from the Access framework (Levesque et al., 2013) and the Theory of Planned Behaviour (Azjen, 1991)

1.6. Research question and objectives

1.6.1. Research question

What are the demand-side factors and supply-side factors that are likely to influence uptake of PrEP among women during pregnancy and breastfeeding?

1.6.2. Overall aim

To explore and describe demand-side and supply-side factors likely to influence uptake of PrEP among women during pregnancy and breastfeeding.

1.6.3. Specific objectives

1. To explore salient beliefs about PrEP use among HIV-negative pregnant and breastfeeding women in Lusaka.
2. To determine the association between salient beliefs and intention to use PrEP among HIV-negative pregnant and breastfeeding women in Lusaka.
3. To explore service delivery attributes of PrEP likely to influence its uptake among HIV-negative pregnant and breastfeeding women in Lusaka.
4. To estimate the relative importance of different attributes of PrEP service delivery among HIV-negative pregnant and breastfeeding women in Lusaka.
5. To estimate the benefit that HIV-negative pregnant and breastfeeding women derive from PrEP service delivery in antenatal settings in Lusaka.

Chapter 2: Methodology

This Chapter presents the design of the overall study, study site, participants, data collection, analysis and ethical considerations.

2.1. Study design and setting

The study employed mixed methods, combining elements of qualitative and quantitative research approaches to expand the breadth and depth of understanding and corroboration (69). The study adopted an exploratory sequential mixed methods design, specifically using the survey-development variant. Using this design, a formative study was conducted in the first part, and findings informed the development of a structured questionnaire that takes into account the local context of the study population. The questionnaire was then used to collect quantitative data aimed at testing and generalizing the initial qualitative findings to the larger sample of pregnant and breastfeeding women not living with HIV (70). The exploratory sequential mixed methods design is illustrated in Figure 5. The methodology for the current study will be presented in two phases; the qualitative component followed by the quantitative component.

This study was conducted at Chipata Level 1 hospital, a government facility that is located in one of the peri-urban areas of Lusaka. The site was purposively selected based on the volume of pregnant women seen at the facility. This Hospital serves a population of over 100,000, averaging 400-450 new antenatal patients attending ANC clinic each month with an additional 900-1000 return ANC visits. Based on facility records, the HIV prevalence among pregnant women attended to at this health facility is approximately 16%.

2.2. Study participants and sampling

Study eligibility was restricted to HIV-negative pregnant and breastfeeding women aged 18 years or older seeking antenatal or postnatal care services at the Maternal and Child Care clinic within the hospital. Study participants were recruited using purposive sampling for the qualitative component and convenience sampling for the quantitative component as probabilistic sampling techniques could have obstructed the flow of service owing to the high volume of patients seen at the facility. A health care provider at the MCH clinic identified women that were HIV-negative and referred them to the study team responsible for recruiting participants. Women who met the eligibility criteria were recruited in the study.

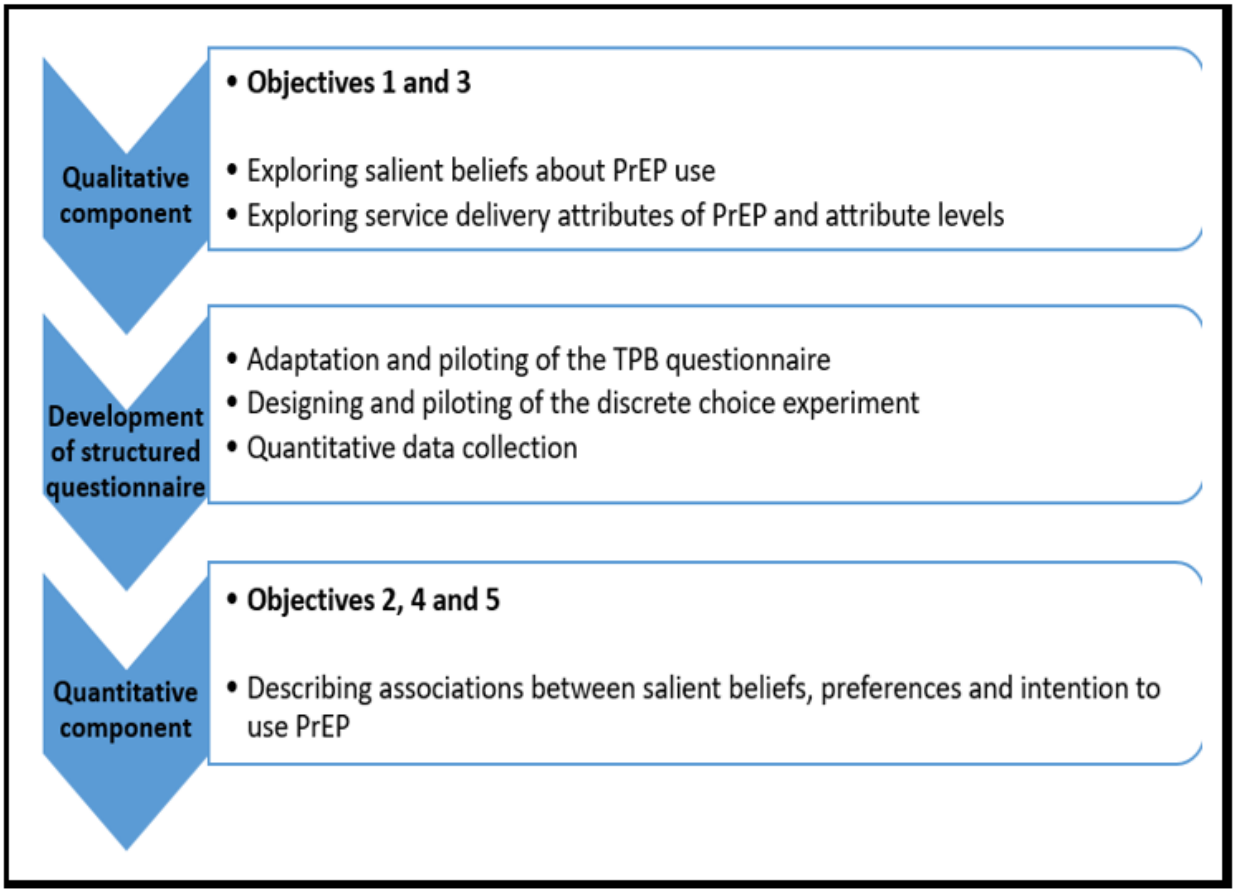


Figure 9. Exploratory sequential mixed methods design

2.3. Qualitative component of the study

The aim of the qualitative component of this study was to inform the TPB questionnaire and the discrete choice experiment. This component answered the first and third objectives of the current study: Objective 1 - To explore the salient beliefs about PrEP use (attitude, subjective norm and perceived behavioural control) influencing uptake of PrEP; Objective 3- To identify service delivery attributes (venue, travel time to facility, waiting time, frequency of HIV testing) of PrEP among HIV-negative pregnant and breastfeeding women in Lusaka.

2.3.1. Data collection

In-depth interviews (IDIs) using a semi-structured interview (SSI) guide (see appendix 5) were conducted with 24 participants in order to collect information on salient beliefs about PrEP use for HIV prevention during pregnancy and breastfeeding. IDIs were also used to explore initial attributes and attribute levels for PrEP service delivery. The SSI guide was pretested with pregnant and breastfeeding women prior to data collection. A nominal group technique (NGT), an alternative to focus group discussions (71), was used to arrive at the final list of attributes and attribute levels for the discrete choice experiment. Interviews for both the IDIs and the nominal group were conducted in either English, Nyanja or Bemba, depending on the respondents' preferences. Nyanja and Bemba are the local languages commonly spoken in the study area.

Trained research assistants explained the purpose of the study and sought informed consent from study participants prior to conducting both the in-depth interviews and the discussions. Permission to audio-record the interviews was obtained from individual participants. For both in-depth interviews and the nominal group, participants were given unique identification numbers which

were used in place of actual participants' names. Flexibility was employed throughout the data collection process, allowing for adjustments to the interview guide in the process of exploring new insights that emerged during the interviews.

2.3.2. Data analysis

Audio-recorded interviews were transcribed verbatim, translated to English and uploaded into Nvivo for data management and analysis. Data were coded using both deductive and inductive approaches and were analysed thematically. The nominal group technique was used to identify attributes and attribute levels for the discrete choice experiment. Participants for the NGT were purposively selected from the initial group of women who participated in the IDIs. In the first step, the purpose of the investigation was explained to the NGT participants. This was followed by a display of all service delivery attributes that were identified from the IDIs. These were written on a flip chart which was displayed in front of the participants. Subsequently, participants were given a sheet of paper on which they quietly and independently wrote five attributes that would motivate them to use PrEP, based only on the list that was written on the flip chart. This was followed by a random round-robin recording of each participant's selected attributes on another flipchart. After all responses had been collected and reviewed by the group, each group member was asked to select their top five attributes which they wrote on their plain papers and subsequently ranked from most to least important. Scores for each attribute were aggregated to select the top five with the highest scores. The same procedure was repeated in order to select the top three attribute levels for each of the top five attributes.

2.4. Quantitative component of the study

This component of the current study was conducted with the aim of answering the second, fourth and fifth objectives: To predict intention to use PrEP; To estimate the relative importance of different attributes of PrEP service delivery; To estimate the total benefit that HIV-negative pregnant and breastfeeding women derive from PrEP service delivery in antenatal settings, respectively.

2.4.1. Study design

A cross-sectional study was conducted to investigate intention to use PrEP, while a discrete choice experiment (DCE) was used to determine women's preferences for PrEP service delivery. These two parts were combined into a single participant encounter. The DCE was designed using Stata v.16. Five attributes and two to three attribute levels were used (described in Chapter 5) and these were selected based on findings from the NGT and also based on similar studies (59, 72, 73).

2.4.2. Sample size calculation

The calculated sample size for the quantitative component of this study was arrived at using the formula: $n = \frac{1000c}{ta}$, where n is number of respondents, t is number of tasks per respondent (twelve)- the number generally used in health applications to prevent response inefficiency over time (74), a is the number of alternatives (two) and c is the largest product of number of levels of any two attributes (3×3=9), which allows comparison of all two-way interactions (75). The calculated minimum sample size required for the study was 375. This was adjusted upwards (final sample size = 392) using the 2013/2014 Zambia Demographic and Health Survey (ZDHS) response rate for urban women (95.8%, that is 0.958) (35, 76), to account for non-response,

including attrition due to incomplete interviews. The final sample size comprised 389 women as three questionnaires were incomplete.

2.4.3. Data collection

The structured questionnaire used for the survey was developed using findings from the formative (qualitative) component of this study. The final questionnaire was translated into Nyanja and Bemba and back translated to English for validation. The questionnaire was pre-tested to evaluate feasibility, clarity of questions and to estimate the amount of time required to complete the survey. Trained research assistants administered the questionnaire using paper-based forms. The questionnaire will have three parts. The first part of the questionnaire collected data on socio-demographics, sexual behaviour, perceived risk for HIV infection, and PrEP-related knowledge.

The second part of the questionnaire collected information on the TPB constructs (attitudes, subjective norms, perceived behavioural control and intention to use PrEP). Data to assess intention to use PrEP was collected using the Theory of Planned Behaviour questionnaire which was adapted to PrEP and to the Zambian context, using information from the qualitative study. All response formats for the TPB constructs were on a 7-point self-reporting scale, ranging from 1 (strongly disagree) to 7 (strongly agree).

The third part of the questionnaire (DCE) collected data on preferences for PrEP service delivery. Stata v.16 was used to generate and combine choice sets. The full factorial design produced about 243 combinations given 5 attributes and 3 attribute levels (3^5). Because it is not possible to present 243 choice sets to an individual, a fractional factorial design was used to generate 12 tasks with

two alternatives per task, that were presented to women in the final DCE. For each choice set presented, participants had to choose only one alternative which they evaluated as having a better combination of preferred attributes. Study personnel explained the different attributes and attribute levels to each participant. Further, pictorial descriptions of attribute levels were also included in order to aid comprehension.

2.4.4. Data analysis: Socio-demographic and behavioral characteristics

Data on socio-demographics, sexual behavioral characteristics, risk perception and PrEP knowledge were analyzed using descriptive statistics. Proportions and chi-square tests were used to summarize categorical variables while means and standard deviations were used for continuous variables with a normal distribution. For skewed data, the median and interquartile range were used. Continuous data such as number of sexual partners in the past 30 days, number of lifetime sexual partners and age were categorized based on similar studies that explored these variables. Pearson Chi Square test was used to explore baseline differences among study participants.

2.4.5. Data analysis: Intention to use PrEP

The primary outcome was intention to use PrEP, which was measured on a continuous scale. Mean scores and the associated standard deviations were used to determine women's attitudes, subjective norms, perceived behavioural control and intention to use PrEP. Since multiple items were used to measure each of the four constructs of the TPB, the Cronbach's alpha was used to determine internal consistency of items (77). Pearson's product-moment correlation coefficient (r) was used to examine bivariate linear relationships between intention to use PrEP and the measured

constructs of the TPB. Multiple linear regression analysis was used to explain intention to use PrEP given the salient beliefs while adjusting for potential confounders.

2.4.6. Data analysis: Preferences for PrEP service delivery

The primary outcome was marginal utility of the attributes used in designing the DCE, which represent the women's preferences for PrEP delivery. Descriptive statistics were used to generate graphs representing the frequencies for each attribute. Mixed logit regression analysis was used to estimate the marginal utility associated with each of the attributes included in the study, which also represents the strength of each attribute in determining a woman's likelihood to take PrEP. Willingness to wait (WTW) was used to determine the relative utility derived from each attribute against waiting time, similar to a 'willingness to pay' analysis (78).

2.5. Ethical considerations

2.5.1. Ethical approval

Ethical clearance obtained from the University of Zambia Biomedical Research Ethics Committee (UNZABREC), the Human Research Ethics Committee (HREC) at the University of the Witwatersrand, and the University of North Carolina at Chapel Hill. Approval was obtained from the National Health Research Authority (NHRA) in Zambia and permission to conduct the study at Chipata Level 1 hospital was received from Lusaka District Medical Office.

2.5.2. Informed consent

Information sheets and consent forms were translated into Nyanja and Bemba. Study participants provided written consent prior to participating in the different parts of the study. Study personnel

read the information sheet together with the participants in the language of the potential participant's choice (English, Nyanja or Bemba) and answered any questions raised by participants. In addition, contact details for the principal investigator (PI) were provided on the information sheet, in case the participants needed to contact the PI. Risks and benefits associated with participating in the study explained to participants. Prospective participants were informed that their participation was entirely on voluntary basis and that declining to participate would not affect their ability to receive care at the facility. Discussions were held in a private place to ensure confidentiality.

2.5.3. Confidentiality

To ensure confidentiality, the study team used unique identifiers (identity numbers) for each participant on the data entry forms. A form linking the identity numbers to the participants' names was kept separately from the data collection forms and was only made available to members of the study team. No study participant was identified in any report or publication arising from this study.

2.5.4. Potential risks and benefits to study participants

There were no benefits associated with participating in this study at the individual level. However, it is hoped that findings from the study may inform local strategies to promote patient-centered delivery of PrEP services in the context of HIV prevention in antenatal and postnatal settings. In terms of risk, it was anticipated that some participants could feel uncomfortable to discuss matters pertaining to their sexual behaviour. Participants were at liberty to skip or refuse to answer any questions they may not have wanted to answer. In addition, participants were free to end the

interview at any time. Ensuring that all interviews were conducted in a private place was an additional measure to minimize the potential risks.

2.5.5. Distress protocol

In the event that a participant showed signs of distress or felt uncomfortable (e.g. crying, getting upset) during the interview, steps outlined in the distress protocol were followed (see Appendix 7). In brief, the interviewers were to suggest to the respondents that they take a break and/or have a drink of water; ask them how they were feeling, listen with empathy and offer support; if the participant chose to continue, interviewers were to explain that they could take a break from the interview at any time. Also signpost participants for further support external to the study.

2.5.6. Reimbursement/Compensation

There was no direct cost associated with participating in this study since women were recruited during their routine antenatal/postnatal care visit. An indirect cost (opportunity cost) with respect to time spent responding to questions during the interview was anticipated. To compensate for this, an amount of K50.00 as transport reimbursement, a drink and biscuit were given to each participant at the end of the interview.

2.5.7. Data storage and dissemination of findings

All data collected during this study were backed up on an external hard drive which was secured under lock and key. Data will be kept for a period of 5 years after which it will be deleted and overwritten. Study findings will be disseminated through appropriate local channels, including the

Schools of Public Health at both the University of Zambia and the University of the Witwatersrand (South Africa), the Ministry of Health, and also to a broader audience of the scientific community at the Zambia Health Research Conference. Findings will also be shared at the faculty interim seminar at Wits University, as well as international public health research conferences such as the HIV Research for Prevention Conference, International Workshop on HIV and Pediatrics, and International Paediatric HIV Symposium in Africa, among others. Findings will also be published in credible peer-reviewed journals. Privacy and confidentiality of participants will be maintained in all results dissemination and publication activities.

PART 2

EMPIRICAL CHAPTERS

CHAPTER 3: Salient beliefs about PrEP use during pregnancy and breastfeeding

Chapter 3 presents a publication that focuses on salient beliefs about PrEP use during pregnancy and breastfeeding. This is a qualitative paper that explored behavioural beliefs, normative beliefs and control beliefs that pregnant and breastfeeding women hold about using PrEP for HIV prevention. The paper also used qualitative enquiry to understand supply-side factors that could influence PrEP use during pregnancy and breastfeeding.

3.0. Chapter Three: *"PrEP protects us":* Behavioural, normative, and control beliefs influencing pre-exposure prophylaxis uptake among pregnant and breastfeeding women in Zambia

Authors: Twaambo E. Hamoonga, Wilbroad Mutale, Lauren M. Hill, Jude Igumbor, Benjamin H. Chi

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Abstract

Background

Although pre-exposure prophylaxis (PrEP) is recommended for pregnant and breastfeeding women at elevated HIV risk, uptake has been low in Zambia.

Methods

In in-depth interviews, we explored beliefs about PrEP among 24 HIV-negative pregnant and breastfeeding Zambian women. Thematic analysis was used to identify behavioural, normative and control beliefs likely to influence PrEP uptake.

Results

Most women viewed PrEP as a good method of protecting themselves and their babies from HIV infection. Partners were cited as key referents in decision making about PrEP use. Many women felt that PrEP use was not entirely in their control. Most reported that they would not use PrEP if their partners did not approve. Health care providers with negative attitudes, travel time of more than an hour to clinics, and extended waiting times were cited as barriers to PrEP uptake.

Conclusion

HIV-negative pregnant and breastfeeding women had a positive attitude towards PrEP but barriers to uptake are multifaceted**.**

Key words

PrEP, beliefs, pregnant, breastfeeding, Theory of Panned Behaviour, intention, Zambia, sub-Saharan Africa

Introduction

In sub-Saharan Africa, pregnancy and breastfeeding are periods of increased risk for HIV acquisition. In two meta-analyses, HIV incidence during these periods were at or above the World Health Organization's threshold for high risk (3.0 infections per 100 person-years) (8, 9). The risk of HIV acquisition during pregnancy has been attributed in part to health facility-related factors (e.g., inadequate education about HIV prevention among antenatal care (ANC) attendees (79, 80)), social and behavioral factors (e.g., low condom utilization (20, 22, 45, 81)) and low rates of HIV status disclosure to sexual partners (24, 36). Biological, physiological and immunologic alterations also contribute to the elevated HIV risk observed in pregnant and postpartum populations (7, 13-17).

Biomedical interventions such as pre-exposure prophylaxis (PrEP) have the potential to reduce the risk of maternal HIV acquisition (26) and may play an important role in the elimination of HIV mother-to-child-transmission. The World Health Organization (WHO) endorses the use of PrEP during pregnancy and breastfeeding for HIV-negative women who are at higher risk of HIV acquisition, depending on individual behaviour and the characteristics of sexual partners (26). This recommendation is based on PrEP's efficacy and its safety track record across numerous studies in pregnancy (82). While many national programs have introduced PrEP for pregnant and breastfeeding populations (83), there is need to identify and engage people at risk for HIV and further improve demand for PrEP (12, 84).

The Zambia Ministry of Health first introduced PrEP as a key strategy for HIV prevention in 2016 (39). In line with WHO recommendations, the country's 2020 HIV treatment and prevention

guidelines extended the provision of PrEP to HIV-negative pregnant and breastfeeding women at substantial risk for HIV acquisition (40). However, to date, uptake of these services in antenatal and postnatal populations has been limited, with some studies reporting rates as low as 1% (41), despite the high rate of mother-to-child transmission (25). The increasing burden of new infant HIV infections can be traced to incident maternal HIV during pregnancy and breastfeeding (85) which may go undiagnosed and therefore untreated. Taking PrEP during pregnancy and breastfeeding has the potential to reduce the risk of maternal seroconversion and onward mother-to-child transmission of HIV. However, factors that may influence uptake of PrEP in this population largely remain unknown.

To better understand facilitators and barriers to PrEP uptake in antenatal settings, we conducted a qualitative study guided by the Theory of Planned Behaviour (TPB) framework. We applied the TPB to understand behavioural, normative and control beliefs that pregnant and breastfeeding women have about PrEP. The TPB assumes that individuals act rationally, according to their attitudes, subjective norms, and perceived behavioral control. According to this theory, in order to predict whether a person intends to engage in a health behaviour, it is important to know whether the person is in favour of doing it (attitude), how much the person feels social pressure to do it (subjective norm), and whether the person feels in control of the behaviour in question (perceived behavioural control) (62). Strategies that are able to modify these three factors can raise a woman's intention to take PrEP and, by doing so, increase the likelihood that she actually takes up the intervention (86).

Materials and methods

Study design and population

In this qualitative study, we recruited HIV-negative pregnant and breastfeeding women from Chipata Level 1 Hospital in Lusaka, Zambia. This government health facility has a catchment population of over 100,000 and an antenatal clinic that attends to about 400-450 new ANC attendees each month. The HIV prevalence among pregnant women attended to at this health facility is approximately 16%, similar to the national prevalence for women (35). Purposive sampling was used to recruit study participants from the Maternal and Child Health clinic, where they were receiving either antenatal or postnatal care services. Pregnant and breastfeeding women aged 18 years or older and with a documented HIV-negative result in their antenatal record, were eligible. We enrolled 24 participants between November 2020 and March 2021. The sample size was determined using the principle of theoretical saturation, the point where additional interviews did not add any new insights on beliefs that women held about PrEP (87).

Data collection

We used a semi-structured questionnaire which had two components: the first part which was structured was used to collect data on socio-demographic characteristics of study participants (i.e. age, educational attainment, employment status and marital status), risky sexual behaviour as well as knowledge about PrEP. The second part which took the form of an interview guide was developed based on the Theory of Planned Behaviour questionnaire (62). The Theory of Planned Behaviour questionnaire has been used in several studies focusing on health-related behaviour to predict both intention and actual behaviour (64-67, 88, 89). The interview guide focused on behavioural beliefs (beliefs about advantages and disadvantages of taking PrEP), normative beliefs (beliefs about how other people expect pregnant and breastfeeding women to behave with respect

to whether or not to take PrEP), and control beliefs (how much control pregnant and breastfeeding women have over taking PrEP) (86). Women in our study were asked what they believed were the advantages and disadvantages of taking PrEP during pregnancy and breastfeeding; who they believed would approve or disapprove of their decision to take PrEP; and what they believed were potential facilitators and barriers to PrEP use. The interview guide also included questions aimed at exploring preferences for PrEP delivery in the target population.

The interview guide was piloted to ensure that questions were appropriately phrased and understood. Minor revisions were made based on this feedback and the revised guide was translated into two local languages (Nyanja and Bemba). SSIs were conducted by trained research assistants fluent in English, Nyanja, and Bemba. Prior to enrollment, interviewers described the study and emphasized the voluntary nature of participation. Written informed consent was obtained prior to any study activities. At the beginning of the interview, study staff described PrEP as medicine that HIV-negative people who feel that they might be at risk of acquiring HIV could take to prevent new infections. The following description was read to participants: "PrEP is the use of anti-retroviral drugs by HIV-uninfected people to protect them from getting infected with HIV. Daily oral PrEP is effective in preventing HIV infection when taken consistently." Interviews were conducted in English and local languages (Nyanja, and Bemba), based on the participant's preference. All interviews were audio-recorded, and later transcribed and translated to English.

Data analysis

Thematic analysis (90, 91), was used to identify beliefs and preferences that may influence PrEP uptake in antenatal and postnatal settings. Two study team members developed independent codebooks; differences were resolved through consensus and consolidated into a final version.

Prior to data coding, we engaged in an iterative process of reading transcripts, which was accompanied by memoing, to identify common and unique content from the transcripts. This process was followed by categorizing content from each transcript under the sub-themes that were identified and later the broad themes (Theory of Planned Behavior constructs) based on the final codebook that was developed. Codes relating to advantages and disadvantages of using PrEP were categorized under attitude towards PrEP while codes relating to people who would approve or disapprove of the women's decision to use PrEP were categorized under subjective norm. Control beliefs comprised codes relating to presence of factors that would make it easy or difficult for women to use PrEP during pregnancy or breastfeeding. We also had several codes representing preferences for PrEP delivery during pregnancy and breastfeeding. Data were summarized using a framework matrix. The main themes and sub-themes are presented in Table 1. We used NVIVO v.12 (QSR International, Burlington, MA, USA) for data management and analysis.

Ethical approval

The study received approval from the University of Zambia Biomedical Research Ethics Committee (Lusaka, Zambia) and the Human Research Ethics Committee at the University of the Witwatersrand (Johannesburg, South Africa). Additional approvals were obtained from the Zambia National Health Research Authority and the Lusaka District Medical Office prior to study activation.

Results

We conducted in-depth interviews with 24 HIV-negative pregnant and breastfeeding women. Baseline characteristics of study participants are presented in Table 1. Fifty percent of the women

were aged below 24 years (IQR: 22-30 years) and the majority were married and living with their partners (18 of 24). Few women perceived themselves to be at high risk for HIV infection, the majority knew their partner's HIV status.

Beliefs about PrEP

Most women (14 of 24) did not know about PrEP prior to the interview. Among the few that reported having knowledge about PrEP, some mistook PrEP for post-exposure prophylaxis while others described PrEP as treatment for sexually transmitted diseases. Beliefs that women held about PrEP were categorized into three broad themes based on the Theory of Planned Behaviour framework: (1) behavioural beliefs; (2) normative beliefs, and (3) control beliefs. We also asked specific questions about service delivery preferences for PrEP. Because these are related to control beliefs, these perspectives were included in that latter section. Table 2 is a summary of the broad and sub-themes from the interviews.

Table 1. Respondent characteristics: HIV-negative pregnant and breastfeeding women (N=24)

Characteristic	n (%)
Age in years, median (IQR)	24 (22 – 30)
Length of interview in minutes, median (range)	14 (8 – 43)
Marital status	
Never been married before	5 (21)
Married (living with partner)	18 (75)
Married (not living with partner)	1 (4)
Educational attainment	
Primary	7 (29)
Secondary	17 (71)
Employment	
Not working	17 (71)
Working for wages	1 (4)
Self employed	6 (25)
Maternal status	
Pregnant	13 (54)
Breastfeeding	11 (46)
Condom use in the last 30 days	
Never	18 (75)
Sometimes	6 (25)
Transactional sex in the last 30 days	
Yes	2 (8)
No	22 (92)
Partner HIV status	
Known	21 (88)
Unknown	3 (12)
Perceived HIV risk	
No risk	3 (13)
Low risk	13 (54)
Moderate risk	6 (25)
High risk	2 (8)
PrEP awareness before interview	
Yes	10 (42)
No	14 (58)

Table 2. Main themes and sub-themes from the study

Behavioral beliefs	**Advantages of taking PrEP** ● Protects pregnant/breastfeeding woman from contracting HIV ● Protects the baby from contracting HIV	*"I would want to protect myself, and my baby as well, so that we do not contract HIV…. as you know…you can't just be trusting him just because you live with him... it's important to just drink the medicine so that you protect yourself." (Participant 007).*
	Disadvantages of taking PrEP ● Concerns about side effects to the woman ● Concerns about side effects to the baby ● Pill burden ● Stigma/labelling from family, friends and community members	*"I think I can be scared of taking this medication in the sense that I can be taking it [PrEP] without being sick and yet experiencing side effects like weight gain and so on. This can discourage me from taking this medication…" (Married, pregnant).*
Normative beliefs	**People who would approve or disapprove** ● Partner ● Other family members	*"My grandmother can disapprove, even my parents, like my mother… she would say no, you should just be using protection [condoms], things like that (Single, pregnant).*
	What other people would think ● Stigma associated with HIV status ● Promiscuity	*"…my husband can disapprove. He can think that I can be sleeping around since I know that I won't get sick because of taking PrEP. This would make it difficult for me to take PrEP." (Married, breastfeeding).*

Behavioural Beliefs about PrEP

Participants were asked what they thought were the advantages and disadvantages of taking oral PrEP every day during pregnancy and breastfeeding. The women expressed both positive and negative views. After learning about PrEP from the interviewer, participants felt that PrEP was good for them and their babies as it had the potential to protect them from acquiring HIV.

"What I feel is the advantage of taking PrEP is that, PrEP protects us. It is good in the sense that one cannot easily be infected with HIV/AIDS. For example, my husband can have sex with another woman who may be HIV positive but when he sleeps with me, I may not be infected because PrEP will protect me from getting sick. So I feel oral PREP is good." (Married, breastfeeding).

In addition, lack of trust for the partner was seen as a motivating factor to initiate PrEP during pregnancy and breastfeeding as a way of ensuring that they remained HIV-negative. According to some participants, trusting anyone, including one's own husband was a difficult thing to do. They argued that it was impossible for a woman to know all the whereabouts of her partner, adding that men would engage in multiple sexual relationships and in some instances, they would not even disclose to their spouses that they are on antiretroviral therapy. Women were of the view that, in such circumstances, PrEP could protect them from HIV infection if they had an unfaithful partner or had sex with someone who was HIV positive.

"… it is so hard to trust someone these days. It is also hard to trust your own husband. This world is cruel, you can find that your husband is on ARVs [HIV treatment] and you do not know about it. So it is better for me to be taking PrEP in order to protect myself from contracting HIV/AIDS… taking PrEP can protect me from contracting HIV/AIDS." (Married, pregnant).

Despite the positive impressions about PrEP in general, some women raised concerns about its use during pregnancy or breastfeeding. Fear of side effects, pill burden, and forgetfulness were some

of the major issues that were seen as disadvantages of taking PrEP during pregnancy and breastfeeding. Women reported that they were given several other medications during pregnancy (e.g., iron supplements) and that adding more medications could be burdensome. They also reported that they did not want to deal with the side effects of PrEP.

> *"I think I can be scared of taking this medication in the sense that I can be taking it [PrEP] without being sick and yet experiencing side effects like weight gain and so on. This can discourage me from taking this medication because I wouldn't want to experience side effects when I know that I am not sick." (Married, pregnant).*

> *"I think I have some reservations because I fear that my baby can be born prematurely because of taking PrEP." (Single, pregnant)*

Other women did not view PrEP negatively in itself. The disadvantage they reported was linked to how others might view women who take PrEP when they are not sick [HIV-negative]

> *I have not seen any disadvantage of taking PrEP. The only problem is with people who may end up laughing at you that you are taking medication yet you are not sick. This can discourage someone from taking PrEP (Participant 02).*

Normative beliefs about PrEP use

We asked women to tell us about who they thought would approve and/or disapprove of their decision to take PrEP during pregnancy. Community and family members, especially male partners, were often cited. Stigma and being labeled to be on ART seemed to be a major concern

that would hinder uptake of PrEP by pregnant and breastfeeding women.

> *"There is too much stigmatization in the community. If I tell my friend that I am taking this medication, she will go round telling people that I am sick [HIV positive] and that is why am taking the medication when in the actual sense, I am protecting myself. This is what happens in our communities, we are used. The community does not support in any way." (Married, breastfeeding).*

Women also felt that people in their communities did not know much about PrEP, and that most community members would mistake PrEP for HIV treatment. The alleged lack of knowledge and stigma were seen as factors that would lead to pregnant and breastfeeding women being labeled as being HIV-positive once seen taking PrEP.

> *"Sometimes you can decide to share with your friends about the medicine you are drinking [PrEP], they can think that you are taking ARVs [HIV treatment] and not PrEP, as you know knowledge levels are different among people in the community. There are people who are educated and those that are not educated and wouldn't understand how PrEP works. They would say that PrEP is just the same as ARVs [HIV treatment] and that the difference is just the colour [of the pills]." (Married, pregnant).*

Other participants viewed PrEP as something that would promote promiscuity among women. They argued that the mere knowledge that PrEP would protect one from contracting HIV would

make women engage in risky behaviour including having multiple sexual partners.

> *"I think people can take advantage of the fact that PrEP protects them from contracting HIV/AIDS. They can start misbehaving because they know that they will not get sick. This is the disadvantage I can think of." (Married, breastfeeding).*

Control beliefs about PrEP use

Pregnant and breastfeeding women were asked to describe circumstances that would make it easy and those that would make it difficult for them to take PrEP. For most women, whether or not to take PrEP would depend on approval from family members, including their male partners. In most cases, approval and support from their partners was seen as an important consideration when deciding to take PrEP. Women viewed the lack of support or approval from family members as a possible barrier to taking PrEP during pregnancy and breastfeeding.

> *"I think my husband can make it difficult for me to take this PrEP. It can be difficult in that I do not take any pills. He may ask why I am taking PrEP because he knows I do not take any pills and he also knows that I use the injection as my contraceptive…he would wonder why I am taking this medication. He may also seek advice from his family and friends who could end up misleading him by making him believe that I am taking ARVs [HIV treatment]and not PrEP." (Married, breastfeeding).*

Some of the women stated that they would not take PrEP if their partners did not first approve.

"…my husband can disapprove. He can think that I can be sleeping around since I know that I won't get sick because of taking PrEP. I will need to explain to him the benefits of taking PrEP and if he is to understand then I can go ahead…but I would not drink it if he were to disapprove." (Married, pregnant).

Although all acknowledged the important role of the partner, some women felt that they would still go ahead and take PrEP even without the support of their spouses. The final decision as to whether or not to take PrEP during pregnancy and breastfeeding was entirely up to them.

"I think my husband can disapprove…. I can listen to him but that does not mean that I have to follow everything that he tells me to do. If at all I have decided to take the medication on my own, then he will have no right to stop me from taking it." (Married, pregnant).

Daily dosing was also reported as a potential barrier to PrEP uptake. Women likened the idea of taking PrEP to taking oral contraceptives. They argued that there was no guarantee that they would remember to take PrEP on a daily basis when they were already having challenges taking oral contraceptives consistently during non-pregnant intervals. Some women were of the view that perhaps taking PrEP in form of injections would make it easier for them to use PrEP.

"I think the issue of taking it [PrEP] daily is a problem because I can forget. It would be better if at all the medication was in form of an injection for 3 or 5 months. Taking tablets on a daily basis is dangerous because a person can forget to take it

sometimes. We sometimes forget to take family planning pills, what would make us not to forget to take PrEP?" (Married, breastfeeding).

A few women made reference to structural factors when asked about barriers to PrEP use. Despite reporting that long distances and lack of transport money to the facility would make it difficult for them to take PrEP, most of the women felt that this would not stop them from using PrEP.

"The distance does not matter as long as you know the importance of taking this medication. I can give an example of the people who are on ARVs [HIV treatment], they move for long distances in order for them to access ARVs. They even keep transport money or look for transport money in order for them to collect their medication. (Married, pregnant).

Preferences for PrEP delivery

Women were asked about health systems-related factors that could make it easy or difficult for them to use PrEP during pregnancy and breastfeeding. They described the attitude of health care providers as having the potential to either promote or hinder uptake of PrEP during pregnancy and breastfeeding. Women felt that health care providers needed to be polite, kind, patient, good-hearted and maintain confidentiality. They reported that a good attitude would encourage women to use PrEP. A bad attitude, on the other hand, could lead to discouragement for starting and maintaining PrEP.

"Some nurses are rude and when they are talking, you are able to tell that they are

rude. They should be kind to us because sometimes, you can get upset and some of us are emotional. They should be good and polite to us, because if they continue being rude, people can be discouraged from taking PrEP because it is like we are forcing them to do what they do not want to do." (Married, breastfeeding).

Women were asked whether the gender of the health care provider dispensing PrEP mattered when it came to influencing uptake of PrEP during pregnancy and breastfeeding. For most women, gender did not seem to be an issue with respect to PrEP uptake. However, among those who had a preference for a specific gender, choices were based on different factors, including attitude and ability to relate to their experiences; some felt that female health care providers were more understanding compared to males.

"They should be female because I am not comfortable with male health care providers..., I would feel shy when talking to a male health care provider. I can easily answer any question that a female nurse will ask me, but for a male nurse, I may not be free to answer accordingly." (Married, breastfeeding).

We asked women whether waiting time at the health facility would be a source of concern when it came to using PrEP during pregnancy and breastfeeding. The majority of them reported that they would not want to be in the queue for a long time. The amount of time that women would be willing to wait at the facility in order to get PrEP ranged from 5 minutes to about 4 hours. Most viewed waiting time as being dependent on how early one arrived at the facility and how many people they found already waiting in the queue. They also reported that waiting at the facility was

something that they were used to doing and that it was normal practice to do so.

> *"Queues will always be there; it all depends on how fast the queue is moving. If one does not want to spend too much time in the queue, then they have to come [to the facility] early." (Married, pregnant).*

Women preferred a health facility close to where they lived as this would make it easier for them to get to the facility to access PrEP. The amount of time they were willing to spend en route to the facility dispensing PrEP ranged from 15 minutes to 2 hours. Although women preferred a facility that was closer to their homes, they reported that even if the facility was far, they would still make an effort to overcome this barrier in order to get PrEP. All women reported that they wanted to get PrEP from a health facility, either a clinic or hospital. When asked whether they would want PrEP to be delivered to their homes, women had differing views. Home delivery of PrEP would address the challenges associated with transportation to and from the health facility. It would also provide a positive opportunity for other community members to learn about PrEP.

> *"I think it would be good if they delivered the medicine at my home. Home is actually better because other people can also get to learn about PrEP." (Married, breastfeeding).*

For other women, getting PrEP from the clinic was viewed negatively, as it would lead to discrimination and stigma. They expressed concern that queueing up for PrEP at the facility would make other people think that the women were actually on ART. For some women, getting PrEP

from other facilities where people did not know them was seen as a better option.

> *"If we collect from the clinic, isn't it that we are supposed to be in a queue and other people who see us may think that we are sick or that we are getting ARVs [ART]? It is even better to collect from a clinic where people do not know you. People have a tendency of concluding." (Married, breastfeeding).*

Summary of findings

In summary, we find that HIV-negative pregnant and breastfeeding women have positive attitudes towards PrEP use as a way of protecting themselves and their babies from HIV infection. Partners were cited as key referents when it comes to decision making on health-related matters and that their approval was critical if women were to use PrEP during pregnancy and breastfeeding. Women also believed that location for PrEP pick-up, attitude of health care providers, waiting time and distance to the facility may influence their decision to take PrEP during pregnancy and breastfeeding. These findings are mapped to the Theory of Planned Behavior conceptual model in Figure 10.

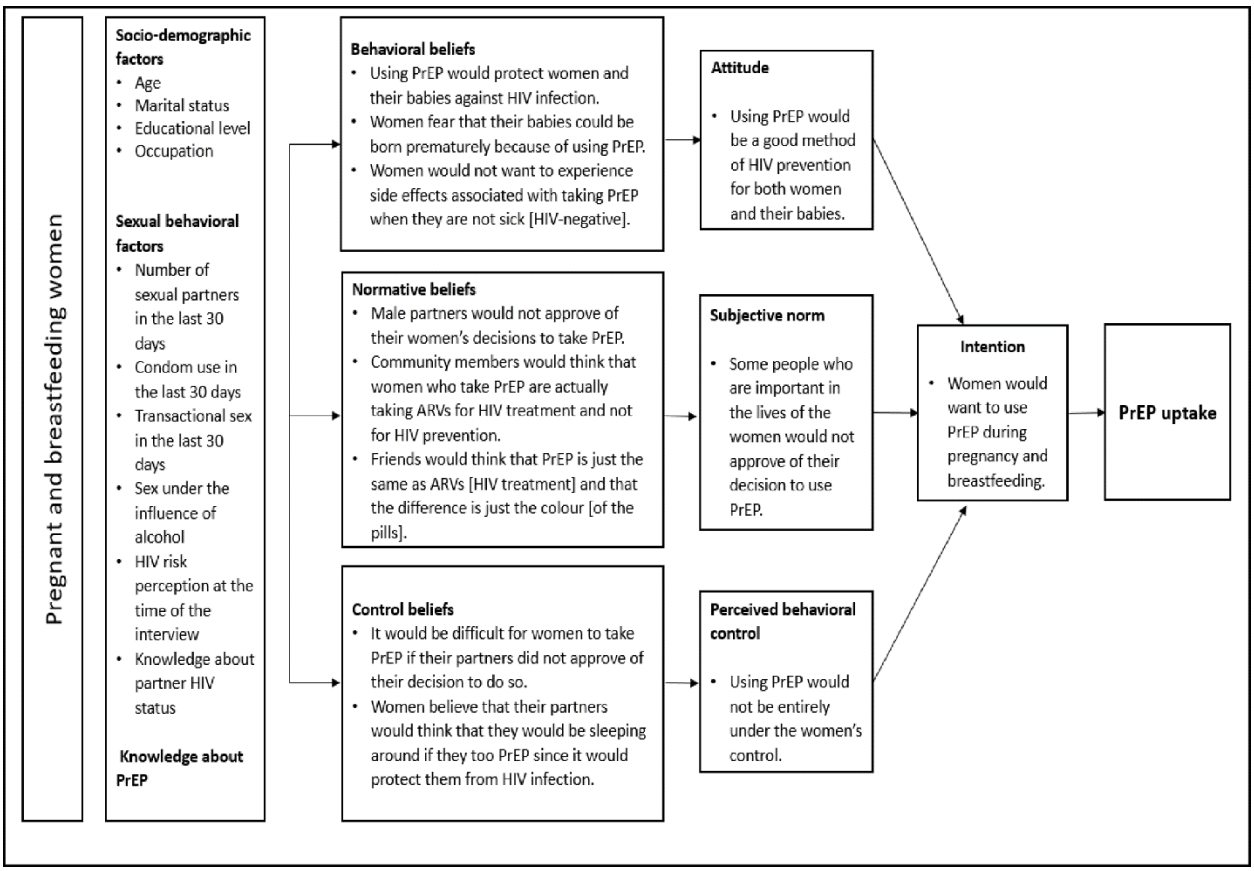


Figure 10. Mapping of findings onto the Theory of Planned Behaviour Conceptual Framework

Discussion

Women's perceptions about PrEP, particularly as they relate to the health of their children, have the potential to promote or hinder uptake during pregnancy and breastfeeding (92). Several of our key findings, particularly on women's behavioural beliefs and knowledge about PrEP echo results from other qualitative studies (22, 93), including one conducted by team members in Zambia and Malawi in 2017-2018 (94). Interestingly, despite the time that elapsed, many of the concerns remain the same, suggesting that more work is needed in outreach and education among prospective PrEP users.

Although women generally viewed PrEP as a good method to protect themselves and their infants from HIV infection, some participants expressed concerns that the availability of PrEP would encourage other women to engage in risky sexual behaviour. Health care providers in Kenya reported that PrEP users were sometimes confused, even frustrated, with their insistence on using condoms in addition to PrEP (93). Similar fears around the potential for PrEP to reduce condom use were reported in Eswatini (95). Davey et al. also noted that the perceptions that PrEP would lead to more risk or more condom-less sex was a potential barrier to uptake and adherence (92).

Stigma and misinformation are often cited as barriers to PrEP use (96). From our results, women feared that, if they took PrEP, people would label them as being HIV-positive and not being truthful about their HIV status. They attributed this to inadequate knowledge about PrEP in their communities. In a similar study conducted in Uganda, South Africa and Zimbabwe, participants mentioned that they would refrain from taking PrEP because of its association with antiretroviral drugs and HIV-related stigma. This was a key barrier to uptake as participants linked taking daily tablets to people living with HIV (61). HIV-related stigma is common in Zambia (97, 98) and could negatively impact PrEP uptake, adherence, and retention in care at a time when women need it the most to ensure that their infants and themselves stay HIV-negative. Deliberate efforts aimed at developing community-based education programs with a focus on demystifying PrEP may have a significant impact on PrEP uptake among HIV-negative pregnant and breastfeeding women.

The level of male partner support may influence women's decision to take PrEP during pregnancy and breastfeeding. Evidence suggests that men are generally viewed as head of house and ultimate decision makers who are actively involved in health-related decision-making during pregnancy

and breastfeeding (99, 100). Our study found that women had divergent views about who would approve of their decision to take PrEP during pregnancy and breastfeeding. The key referents, however, were mostly women's partners. Similar findings have been reported in similar settings. In a study that contextualized male roles and participation in PMTCT programs in Malawi and Zambia, for instance, both men and women reported that they had to consult and seek approval from their partners on decisions that related to their health (99). Other studies also reported that men were the primary advisors and key decision-makers on health-related decisions during pregnancy and breastfeeding (94, 101, 102).

From our findings, male partners may, to a greater extent, determine actual uptake of PrEP by women during pregnancy and breastfeeding. Similar findings were reported elsewhere (102). Such gender-based power differentials, specifically the lack of autonomy among women to make decisions concerning their health may present a barrier to PrEP uptake during pregnancy and breastfeeding. Male involvement in promoting PrEP uptake among pregnant and breastfeeding women could increase the use of PrEP in this target population. In some circumstances, such engagement may be challenging and this should be recognized. Programs should offer these women additional support for HIV prevention, whether through PrEP or other proven modalities.

Participants in our study expressed concern about the gender of health care providers. Interestingly, however, gender was rarely discussed in isolation, but rather with reference to the attitude of health care providers. Women who preferred to be attended to by male health care providers viewed female health care providers negatively. This finding is supported by prior research where respondents complained about the poor attitude of health care providers, especially

female nurses being disrespectful, rude and using abusive words (100). Participants in our study reported that health care providers who had a bad attitude would make it difficult for women to use PrEP during pregnancy and breastfeeding. Some women felt that they would not use PrEP if the health care providers dispensing PrEP were rude to them. Our findings on the impact of health care provider attitude on PrEP uptake are consistent with other studies (61).

Distance and waiting time are structural factors that may have a negative impact on PrEP uptake and retention in care. Women in our study reported that having a health facility nearer to where they lived would make it easier for them to take PrEP. A study in Uganda also found that walking time to the clinic of thirty minutes or greater was associated with decreased odds of uptake of PrEP (103). Although distance was cited as a barrier in our current study, it is possible that its effect on PrEP uptake could be indirect as women may have taken into consideration the transport-related costs of remaining in PrEP care if they decided to initiate PrEP in the future. Waiting time in the queue was also cited as a potential barrier to PrEP uptake. Women did not want to wait for a long time at the facility in order to collect PrEP. Similar to our findings, a study conducted in Botswana, Tanzania and Uganda reported that lost wages due to waiting time was a barrier to adherence among individuals on antiretroviral therapy (104). These findings are corroborated by those from a recent study conducted by our team (89).

Strengths and limitations

The main strength of this study is our use of an established theoretical framework to determine potential barriers and facilitators to PrEP use in pregnant and breastfeeding women. The perspectives shared are specific to this population, providing important insights during an important period in women's lives. At the same time, we also recognize some limitations. First,

this study focused on individual-level cognitions and did not explore other unconscious influences that could potentially account for variances in PrEP uptake behavior. However, evidence suggests that interventions resulting in large changes in intention are likely to also change behavior (105). Second, our results are a mix of beliefs held by women who were and those who were not knowledgeable about PrEP prior to study participation. Responses of the latter could be prone to social desirability bias.

Third, we enrolled only pregnant and breastfeeding women in our study. While this was viewed as a strength overall, we acknowledge our limited ability to compare these responses to those of other women outside of this window. Further, it is possible that some participants' responses may not have specifically focused on PrEP use during pregnancy and breastfeeding intervals, owing to their limited awareness about PrEP prior to the interviews and lack of experience using PrEP. Nevertheless, their perspectives still offer useful insights on beliefs likely to influence PrEP uptake in antenatal and postnatal settings.

Exploring and documenting the lived experiences of women who have used PrEP during pregnancy and breastfeeding could enhance our understanding of facilitators and barriers to PrEP uptake and onward adherence and retention in care in this population. This represents a gap for further research. Fourth, the study was based at a single facility and, therefore, our results may not be generalized to the larger antenatal and postnatal populations in Zambia—or in the sub-Saharan African region. As with all qualitative studies, we instead focus on the depth of participant beliefs and preferences to inform future PrEP implementation in antenatal settings. Fifth, PrEP was not readily accessible at the study site at the time this study was implemented. The hypothetical nature of PrEP in the study only provided partial understanding of facilitators and barriers to PrEP uptake as the views of women interviewed may differ from those of women who have experience taking

PrEP during pregnancy and breastfeeding. Nevertheless, the positive attitude towards PrEP use among participants was reassuring and provides an avenue to promote uptake of PrEP during pregnancy and breastfeeding.

Conclusion

Our study suggests that HIV-negative pregnant and breastfeeding women have positive attitudes towards PrEP but barriers to PrEP uptake are multifaceted. To ensure that PrEP implementation in antenatal settings is successful, there is need to address the inadequate knowledge about PrEP among pregnant and breastfeeding women—and the broader community as well. Interventions that promote male involvement in female-initiated methods for HIV prevention may result in improved knowledge and a more supportive attitude among men towards women who wish to use PrEP during pregnancy and breastfeeding. Addressing contextual barriers—including distance, waiting time at the facility, and health care provider attitude—could have a significant impact on PrEP uptake. Above all, exploring the lived experiences of pregnant and breastfeeding women who have used PrEP before would be critical to the design of effective PrEP implementation strategies in this population in need.

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CHAPTER 4

Beliefs associated with intention to use PrEP

Chapter 4 is a publication on pregnant and breastfeeding women's attitude, subjective norms, perceived behavioural control and intention to use PrEP. The paper uses a quantitative approach to determine the association between salient beliefs and intention to use PrEP. Further, multivariable linear regression is used in order to determine the relative contribution of individual beliefs on intention to use PrEP while controlling for potential confounders.

Chapter Four: Salient beliefs and intention to use pre-exposure prophylaxis among pregnant and breastfeeding women in Zambia: Application of the Theory of Planned Behaviour.

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Abstract

Primary HIV prevention is a priority for pregnant and breastfeeding women in sub-Saharan Africa; however, such services should be designed to optimise uptake and continuation. Between September and December 2021, we enrolled 389 women who were not living with HIV into a cross-sectional study from antenatal/postnatal settings at Chipata Level 1 Hospital. We used the Theory of Planned Behaviour to study the relationship between salient beliefs and intention to use pre-exposure prophylaxis (PrEP) among eligible pregnant and breastfeeding women. On a seven-point scale, participants had positive attitudes towards PrEP (mean = 6.65, SD = 0.71), anticipated approval of PrEP use from significant others (mean = 6.09, SD = 1.51), felt confident that they could take PrEP if they desired (mean = 6.52, SD = 1.09) and had favourable intentions to use PrEP (mean = 6.01, SD = 1.36). Attitude, subjective norms, and perceived behavioural control significantly predicted intention to use PrEP respectively ($\beta = 0.24$; $\beta = 0.55$; $\beta = 0.22$, all $p < 0.01$). Social cognitive interventions are needed to promote social norms supportive of PrEP use during pregnancy and breastfeeding

Key words

PrEP initiation intention, pregnant, breastfeeding, beliefs, sub-Saharan Africa

Introduction

Pregnant and breastfeeding women in sub-Saharan Africa remain at high risk for HIV infection (8, 9). In 2018 alone, an estimated 140,000 women in sub-Saharan Africa acquired HIV infection while pregnant or breastfeeding (25). Biological, physiological and immunologic alterations that pregnant women experience further contribute to the elevated HIV risk observed during this period (13-17). This population is also of particular interest because incident maternal HIV infection during pregnancy poses an increased risk for mother-to-child transmission (MTCT) (8, 24). Mothers who are acutely infected with HIV are twice as likely to transmit HIV to their children compared to their counterparts with chronic infection (106). In Zambia, maternal seroconversion during late pregnancy and breastfeeding contributes significantly to the paediatric HIV burden (85), accounting for about 13% of child infections (3). Unfortunately, for most pregnant and breastfeeding women, HIV prevention has emphasised condom use, counselling, and education (107, 108). Until recently, access to biomedical interventions has been limited.

PrEP is effective in preventing HIV infection to pregnant and breastfeeding women and could thus contribute towards the prevention of mother-to-child HIV transmission (PMTCT). In accordance with the World Health Organization guidelines recommending offering PrEP to at-risk populations (26), the 2020 Zambia HIV prevention guidelines extended the provision of PrEP to pregnant and breastfeeding women at risk for HIV infection (40). Despite these recommendations and several health benefits of PrEP at the individual and population level, both knowledge and uptake of PrEP among pregnant and breastfeeding women still remain low (94). Unfortunately, there is paucity of knowledge about factors likely to influence uptake in the target population.

Qualitative studies that have explored reasons for low uptake of PrEP among young African women indicated the need for social support from their partners and significant others, and reported fear of their partners' reactions about product use (109). Women also reported concealing use of PrEP and even hiding it for fear of being mistaken to be HIV positive (110). PrEP studies conducted among pregnant and breastfeeding women in sub-Saharan Africa have mainly been integrated within demonstration projects and have been qualitative in nature, with recent studies focusing on how best to integrate PrEP in antenatal settings. Most were conducted in Kenya and South Africa (50, 52, 111), and none of them have determined salient beliefs and their relative importance in influencing pregnant and breast-feeding women's intention to use PrEP. This research gap is even more evident in Zambia where there is limited literature on facilitators and barriers to PrEP uptake in antenatal settings. Determining modifiable antecedents of PrEP uptake, such as beliefs about PrEP and how these influence pregnant and breastfeeding women's intentions to use it may provide useful information that could inform interventions aimed at improving demand for PrEP in the target population.

Overcoming the social and structural barriers to universal access to combination HIV prevention services such as PrEP, requires an understanding of modifiable social cognitive antecedents of the target health behaviour (in this case, PrEP uptake). The Theory of Planned Behaviour (TPB) is a useful framework in understanding such relationships. According to this theory, behaviour is seen as a product of positive, pro-behaviour intentions. These intentions are in turn determined by attitudes toward using PrEP, subjective norms surrounding PrEP use, and perceived behavioural control (the perceived ease or difficulty of taking PrEP) (62). Intention can be used as a proximal determinant of behaviour (Francis et al.,2004). In the context of low PrEP uptake, understanding

beliefs influencing intention could provide useful information on target behaviours that could influence actual PrEP uptake.

The TPB has been used in several health related studies to predict both intention and actual behaviour such as cervical cancer screening (88), HIV testing (64), human papillomavirus vaccine uptake (65), condom use (66, 67), and PMTCT (68). We applied the TPB to determine salient beliefs (attitude, subjective norms, perceived behavioural control) and their association with intention to use PrEP among pregnant and breastfeeding women not living with HIV in Zambia.

Methodology

Study design and setting

We conducted a cross-sectional quantitative study to determine women's attitudes, subjective norms, and perceived behavioural control, and how these theorised constructs influence intention to use PrEP during pregnancy and breastfeeding. This study was conducted at the maternal and child health clinic in Chipata Level 1 Hospital (Lusaka, Zambia). The site was purposively selected based on the volume of pregnant women seen at the facility. Each month, it averages 400–450 new antenatal patients and 900–1000 return antenatal visits.

Study population and procedures.

We recruited study participants using convenience sampling. We recruited pregnant and breast-feeding women aged 18 years or older with a documented HIV-negative result in their antenatal record. This study was part of a larger discrete choice experiment (DCE) whose aim was to deter-

mine preferences for PrEP delivery among pregnant and breastfeeding women not living with HIV and its sample size (n = 392) was based on those analyses. In this study, we did not offer PrEP to participants as part of the study procedures. However, it was available at the health facility where the study was conducted. Women who reported that they would like to use PrEP for HIV prevention were referred to the maternal and child health clinic within the hospital to discuss their interest to use PrEP with the health care providers.

Study personnel described the study and obtained written informed consent from eligible participants. The questionnaire was translated to Nyanja and Bemba (local languages commonly spoken in the study area) and then back translated to English for validation. It was further pre-tested to evaluate feasibility and clarity of questions. The questionnaire was administered to the women using face-to-face interviews in a private place within the hospital premises.

Measurement

The first part of the questionnaire included questions on the women's sociodemographic and obstetric characteristics, PrEP-related knowledge, engagement in risky sexual behaviour as well as HIV risk perception. The second part of the questionnaire collected information pertaining to the women's beliefs about PrEP use during pregnancy and breastfeeding. To do this, we selected an existing 37-item survey based on the TPB (86) and used it to guide the phrasing of questions for our questionnaire. Since the TPB questionnaire has not been validated in the Zambian context, we conducted a separate elicitation study (n = 24) in order to inform the development of PrEP-specific questions that would comprehensively capture beliefs likely to influence pregnant and breastfeeding women's intention to use PrEP, in Zambia. In this formative work, we asked women

questions about the most frequently perceived advantages and disadvantages of taking PrEP; the most important people or groups of people who would approve or disapprove of using PrEP; and the perceived barriers or facilitating factors which could make it easier or more difficult to use PrEP during pregnancy and breastfeeding. This information was used to develop items that we used in the current study to measure attitudes towards PrEP, subjective norms about PrEP and perceived behavioural control of PrEP, respectively. This process was informed by the TPB framework. We used the Chronbach's alpha as a measure of internal consistency reliability to select the final items that were used to measure each of the TPB constructs.

The dependent variable, intention to use PrEP, was measured using a 3-item scale which was: 'I intend to take PrEP during pregnancy and breastfeeding'; 'I expect to take PrEP during pregnancy and breastfeeding'; 'I want to take PrEP during pregnancy and breastfeeding'(α= 0.80). Participants responded to each item on a 7-point Likert scale with responses ranging from strongly dis-agree (1) to strongly agree (7). A composite score for intention was obtained by getting the mean of the three items. The independent variables were attitudes towards PrEP, subjective norms about PrEP and perceived behavioural control of PrEP use. The scale measuring attitudes towards PrEP included four items: 'Overall, I think that taking daily oral PrEP would be: harmful (1) to beneficial (7)'; 'Overall, I think that taking daily oral PrEP would be not helpful (1) to helpful (7)'; 'Overall, I think that taking daily oral PrEP would be bad (1) to good (7)'; 'Overall, I think that taking daily oral PrEP would be wrong (1) to right (7)' (α= 0.78). A composite score for attitude towards PrEP was obtained by calculating the mean of the four items.

The subjective norms were measured with the following item: 'It would be expected of me to take daily oral PrEP during pregnancy and breastfeeding'. The perceived behavioural control scale was measured with the following single item: 'I am confident that I could take daily oral PrEP during pregnancy/breastfeeding if I wanted to'. Responses for both subjective norms and perceived behavioural control ranged from strongly disagree (1) to strongly agree (7). For all of the measures (attitudes, subjective norms, perceived behavioural control and intention), higher scores indicate more favourable attitudinal beliefs, greater perceived normative influence, greater perceived efficacy/controllability and more favourable intentions towards PrEP use.

Data analysis

We used descriptive statistics (frequencies and proportions) to describe background characteristics (socio-demographics, sexual behaviour and knowledge about PrEP) of study participants. Means and standard deviations were used to summarise the TPB constructs. Pearson Product Moment Correlation (r) was used to determine the correlation between intention to use PrEP and the three TPB predictor variables. We used simple linear regression to obtain unadjusted estimates for the association between intention to use PrEP and each of the TPB predictor variables, stratified by maternal status. Next, we used multivariable linear regression analysis using robust standard errors to obtain adjusted estimates of the association between intention to use PrEP and the predictor variables, including maternal status (pregnant or breastfeeding), while adjusting for other significant background characteristics (age, education, marital status and employment status). Associations were considered statistically significant at $p< 0.05$ at the 95% level of significance. We used the r-squared values from the stata output to determine the variance in intention to use PrEP explained by the models. We also assessed multi-collinearity in the final model using the

variance inflation factor (VIF). VIFs greater than 10 were suggestive of presence of multi-collinearity. All analyses were conducted using Stata v.16 (StataCorp LLC, Lakeway Drive College Station, Texas 77845, USA).

Ethics approval

The study received approval from the University of Zambia Biomedical Research Ethics Committee (Lusaka, Zambia) and the Human Research Ethics Committee at the University of the Witwatersrand (Johannesburg, South Africa). Additional approvals were obtained from the Zambia National Health Research Authority and the Lusaka District Medical Office prior to study activation. All participants provided written informed consent prior to initiating study activities.

Results

Between September and December 2021, we administered a structured questionnaire to 389 pregnant and breastfeeding women not living with HIV who were receiving care at the study facility. Table 3 shows that participants had a median age of 26 years (IQR: 22–30) and the majority were married and cohabiting with a partner (84.1%). More than half of the participants (58.1%)had acquired secondary education and about one-third (33.4%) had acquired primary education. Very few women had acquired tertiary education (2.8%) and the majority were unemployed (69.2%). More than three quarters (86.9%) of the women never used condoms with their regular sexual partner in the 30 days preceding the survey, and a cumulative one-third of women perceived themselves to be at either moderate risk (20.6%) or high risk (12.6%) of HIV infection. The majority (63.7%) were not aware of PrEP prior to the survey. Among those who

knew that PrEP protects against HIV infection, the majority (65.3%) cited health facility staff as their source of information.

Table 3. Characteristics of study participants (n=389)

Characteristic	**Total n (%)**
Age in years, median (IQR)	26 (22 - 30)
Age group (years)	
15-24	161 (41.4)
25-34	181 (46.5)
35+	47 (12.1)
Marital status	
Not married	44 (11.3)
Married (cohabiting with partner)	327 (84.1)
Married (not cohabiting with partner)	18 (4.6)
Education	
No formal education	22 (5.7)
Primary	130 (33.4)
Secondary	226 (58.1)
Tertiary	11 (2.8)
Employment status	
Not working	269 (69.2)
Employed for wages	27 (6.9)
Self employed	93 (23.9)
Maternal status	
Pregnant	172 (44.2%)
Breastfeeding	217 (55.8%)
Lifetime sexual partners	
1 partner	119 (30.6)
2-3 partners	179 (46.0)
>4 partners	91 (23.4)

Condom use (past 30 days)	
Never	338 (86.9)
Sometimes	36 (9.2)
Always	15 (3.9)
Partner HIV status	
Known	318 (81.8)
Unknown	71 (18.2)
HIV risk perception	
No risk	158 (40.6)
Low risk	102 (26.2)
Moderate risk	80 (20.6)
High risk	49 (12.6)
PrEP awareness prior to interview	
Yes	141 (36.2)
No	248 (63.7)
Source of information about PrEP	
Health facility staff	64 (65.3)
Mass media	8 (8.2)
Family member	13 (13.3)
Friends	9 (9.2)
Other	4 (4.1)

Results from Table 4 show that participants in our study had favourable intentions towards PrEP use (mean = 6.01, std. dev. = 1.36) and positive overall evaluation of taking PrEP (mean =6.65, std. dev. = 0.71). Participants also responded to items on social norms for PrEP and perceived behavioural control about PrEP use with high levels of agreement (mean = 6.09, std. dev. = 1.51 and mean = 6.52, std. dev. = 1.09), respectively. Results in Table 4 also show that all the three

predictor variables were positively correlated with intention to use PrEP: attitude (r = 0.37, p< 0.001); subjective norms (r = 0.74, p< 0.001); perceived behavioural control (r = 0.48, p< 0.001).

Table 4. Self-reported intention, attitude, subjective norms and perceived behavioural control regarding PrEP use and Pearson correlations among the Theory of Planned Behaviour constructs

TPB Construct	Min - Max	Mean [a] (Std. Dev.)	Mean [b] (Std. Dev)	Mean [c] (Std. Dev)	PrEP Intention	PrEP Attitude	PrEP Subjective norms	PrEP Perceived behavioural control
PrEP Intention	1 - 7	6.01 (1.36)	5.72 (1.51)	6.24 (1.18)	r=1	r=0.37 P<0.01	r=0.74 P<0.01	r=0.48 P<0.01
PrEP Attitude	1 - 7	6.65 (0.71)	6.59 (0.78)	6.69 (0.65)	–	r=1	r=0.28 P=<0.01	r=0.41 P<0.01
PrEP Subjective norms	1 - 7	6.09 (1.51)	5.81 (1.75)	6.31 (1.25)	–	–	r=1	r=0.42 P<0.01
PrEP Perceived behavioural control	1 - 7	6.52 (1.09)	6.44 (1.14)	6.58 (1.05)	–	–	–	r=1

[a] Mean scores and standard deviation among both pregnant and breastfeeding women
[b] Mean scores and standard deviation among pregnant women
[c] Mean scores and standard deviation among breastfeeding women

In simple linear regression, stratified by maternal status, intention to use PrEP was statistically significantly associated with all the three constructs of the TPB both among pregnant and breast-feeding women, separately (all p< 0.01). However, coefficients for the association between PrEP intention and attitude (β= 0.83, p< 0.01) as well as subjective norms (β= 0.72, p< 0.01) were higher among breastfeeding compared to pregnant women (β= 0.55, p< 0.01 and β= 0.61, p< 0.01) (Table 5). Among both pregnant and breastfeeding women combined (Table 5), intention to use PrEP was statistically significantly associated with: attitude (β= 0.70, p< 0.01); subjective norms (β= 0.67, p< 0.01); perceived behavioural control (β= 0.60, p< 0.01); and maternal status (β=0.52, p< 0.01).

Women who had more positive attitudes, those who held more positive subjective norms and those who felt more confident in their ability to take PrEP during pregnancy and breast-feeding also reported higher levels of PrEP intention. Breastfeeding women reported higher levels of PrEP intention compared to their pregnant counterparts. Subjective norms explained 55% of the variance in intention to use PrEP while perceived behavioural control explained 23% of the variance in intention to use PrEP. Attitude explained 13% while maternal status explained 4% of the variance in intention to use PrEP during pregnancy and breastfeeding.

Table 5. Unadjusted estimates for intention to use PrEP stratified by maternal status

	Unadjusted estimates among pregnant women				Unadjusted estimates among breastfeeding women			
Predictor variable	β (95% CI)	Std. Error	t	p-value	β (95% CI)	Std. Error	t	p-value
Attitude	0.55 (0.26 – 0.83)	0.14	3.82	<0.01	0.83 (0.61 – 1.04)	0.11	7.56	<0.01
Subjective norms	0.61 (0.52 – 0.70)	0.05	13.16	<0.01	0.72 (0.64 – 0.80)	0.04	17.34	<0.01
Perceived behavioural control	0.68 (0.51 – 0.86)	0.88	7.80	<0.01	0.51 (0.37 – 0.64)	0.07	7.36	<0.01

In the second model (Table 6), we adjusted for all the theoretical constructs of the TPB. In this model, all the TPB predictor variables were positively associated with intention to use PrEP: attitude (β= 0.24, p= 0.03); subjective norms (β= 0.57, p< 0.001); perceived behavioural control (β= 0.21, p= 0.01). This model explained 60% of the variance in intention to use PrEP (p< 0.01). In the third and final model, we adjusted for all the TPB constructs, maternal status and sociodemographic characteristics of participants. All the predictor variables were positively associated with intention to use PrEP: attitude (β= 0.24, p= 0.03); subjective norms (β= 0.55, p< 0.01); perceived behavioural control (β= 0.22, p< 0.01); breastfeeding (β= 0.24, p= 0.01).

Participants who scored higher on the attitude, subjective norms and perceived behavioural control scales, as well as breastfeeding women, reported greater intention to use PrEP both in the unadjusted and adjusted models. Subjective norms had the strongest association with intention to use PrEP. The final model explained 61% of the variance in intention to use PrEP among pregnant and breastfeeding women. There was no evidence of multi-collinearity in the final model as defined a priori (i.e. variance inflation factors less than 10 for all the variables included).

Table 6. Unadjusted and adjusted estimates for intention to use PrEP among HIV-negative pregnant and breastfeeding women

	Model 1				**Model 2**				**Model 3**			
	Unadjusted estimates				**Adjusted estimates [a]**				**Adjusted estimates [b]**			
Predictor variable	**β (95% CI)**	**Robust Std. Error**	**t**	**p-value**	**β (95% CI)**	**Robust Std. Error**	**t**	**p-value**	**β (95% CI)**	**Robust Std. Error**	**t**	**p-value**
Attitude	0.70 (0.52 – 0.88)	0.09	7.77	<0.01	0.24 (0.03 – 0.45)	0.11	2.23	0.03	0.24 (0.02 – 0.45)	0.11	2.15	0.03
Subjective norms	0.67 (0.60 – 0.73)	0.03	21.63	<0.01	0.57 (0.47 – 0.68)	0.05	10.76	<0.01	0.55 (0.45 – 0.66)	0.05	10.44	<0.01
Perceived behavioural control	0.60 (0.49 – 0.71)	0.06	10.86	<0.01	0.21 (0.06 – 0.36)	0.08	2.75	<0.01	0.21 (0.06 – 0.36)	0.08	2.82	<0.01
Breastfeeding	0.52 (0.25 – 0.79)	0.14	3.81	<0.01					0.24 (0.06 – 0.42)	0.09	2.57	0.01
R-squared					**0.60**				**0.61**			

[a] Model 2 adjusted for the Theory of Planned Behaviour constructs only (attitude, subjective norms and perceived behavioural control)

[b] Model 3 adjusted for the Theory of Planned Behaviour constructs and maternal status, alongside key characteristics of study participants (i.e., age, marital status, education, employment status, HIV risk perception)

Discussion

In this study, we showed that PrEP attitudes, subjective norms, and perceived behavioural control were associated with PrEP use intentions among PrEP-naïve pregnant and breastfeeding women. Further, we demonstrated that pregnant and breastfeeding women not living with HIV have positive attitudes towards PrEP. Women in our study believed that people who are important to them would support their decision to use PrEP during pregnancy and breastfeeding. They also believed that they could easily take PrEP if they desired. Our study demonstrates that women who held favourable beliefs about the benefits of PrEP (attitude) had higher intention to use it during pregnancy and breastfeeding. A similar positive association on intention was observed among women who anticipated PrEP approval from others (subjective norms) and those who were confident that they could take PrEP during pregnancy and breastfeeding if they desired (perceived behavioural control).

One-third of women in our study perceived themselves to be at moderate to high risk of HIV infection, but the majority never used a condom with their regular sexual partners during pregnancy and breastfeeding. This is despite the generally high HIV prevalence–across multiple populations–reported in the catchment area of the study site. In a population characterised by low education and employment, women may face challenges in negotiating safer sex practices with their male partners. This is exacerbated by the gender and power imbalances within relationships already inherent in such societies that tend to operate in a synergistic manner to further elevate these women's vulnerability to HIV infection (112). Designing interventions aimed at sensitising women on risk factors for HIV infection could empower them with knowledge to help them better assess their own HIV risk and hopefully enable them to appreciate the importance of taking PrEP in order to protect themselves and their infants against HIV infection.

The majority of women in our study who knew about PrEP cited health facility staff as their source of information. Women and the broader community members who rarely seek healthcare from health facilities may never get to know about PrEP. This could be even worse for men, who tend to avoid health facilities because health services are considered to be for the sick, weak and generally female and children spaces (99). Therefore, concentrating PrEP education at health care facilities, especially Maternal and Child Health clinics, may further lower the prospects of men ever getting to know about the benefits of PrEP to the family and the community at large. Without this knowledge, men would be less likely to support their female partners who choose to initiate PrEP during pregnancy and breastfeeding. The more community members know about PrEP, the more they are likely to have positive attitudes towards PrEP– and the more they are likely to support women who choose to use PrEP during pregnancy and breastfeeding.

Compared to pregnant women in our study, those who were breastfeeding showed more positive attitudes, subjective norms and control beliefs about PrEP use. They also reported higher PrEP intention. In qualitative studies, pregnant women generally raised persistent concerns about infant safety with antiretroviral exposure (36, 113). Furthermore, pregnant women could have been more skeptical about product use compared to their breast feeding counterparts due to the value placed in a woman's ability to bear children, especially in our context, where most often than not, failure to have a child is viewed as a threat to the stability of the relation-ship (36). PrEP messaging should therefore emphasise the importance of initiating PrEP early on in order to stay HIV-negative throughout the maternal period when the risk for sero-conversion and onward MTCT is highest.

Our finding of a positive association between women's positive attitude towards PrEP and the intention to use PrEP corroborates results of previous studies. For example, African American women who had positive perceptions and attitudes towards PrEP showed willingness to use PrEP (114, 115). Similar observations on the association between attitudes and intention were observed among women who inject drugs (116). In the United States, women's perceptions of the beneficial outcomes of PrEP were associated with intention to use PrEP in the next three months (117). It is imperative that PrEP messaging focuses on factors that may influence PrEP attitudes such as increasing PrEP knowledge and awareness on the benefits of PrEP in HIV prevention, as well as accurate HIV risk assessment in the target population (118). Behavioural interventions that target these factors could lead to positive attitudes which could translate to improved demand and actual uptake of PrEP by pregnant and breastfeeding women (62).

Women's broader social contexts may influence their decision to take PrEP and adhere to it. Young and McDaid argue that these social and cultural factors significantly influence women's perception and decisions regarding their use of HIV prevention methods including PrEP (119). In our study, we found that women who anticipated positive peer norms or less disapproval from people who are important to them were more likely to intend to use PrEP during pregnancy and breastfeeding. Our findings corroborate those from similar studies conducted among women, that found an association between receiving encouragement and support from loved ones and other women on PrEP and intention to use PrEP (114, 117, 120-123). Together, these findings reiterate the need for interventions that advocate for the adoption of social norms that promote PrEP uptake by emphasising PrEP benefits for pregnant and breastfeeding women.

Since male partners are key decision makers in health-related decisions during pregnancy and breastfeeding (99, 101, 102), it is important that male partners are engaged in female-controlled HIV

prevention initiatives such as PrEP. This is even more critical for populations such as our study population where the majority of women are unemployed and may be dependent financially on their male partners. A lack of this anticipated approval from significant others may negatively influence pregnant and breastfeeding women's intention to use PrEP and ultimately uptake (114). PrEP education messages that target broader communities, including couple-based approaches could improve community members' understanding about PrEP. This could address potential barriers to PrEP uptake, such as PrEP stigma, posed by negative social norms about PrEP (121).

Women in our study felt confident that they could take PrEP if they desired. This is contrary to the socio-culturally acceptable norm where women have to consult and seek approval from their partners on decisions that relate to their health, which is commonplace in Zambia (99). This also contrasts the common belief that women have limited control over their sexual and reproductive health choices and practices (124, 125). It is possible that women in our study felt confident about their ability to take PrEP because they believed that people who are important to them would approve of their decision to use PrEP during pregnancy and breastfeeding. This confidence could also be based on the premise that PrEP provides women an increased sense of empowerment in directing their own sexual health (122), including control when they cannot control their partner's behaviour or where barrier protection fails (126).

Our findings further show a positive association between perceived control beliefs and intention to use PrEP. Women who felt confident about their ability to take PrEP had high intention to use it. These results corroborate findings from similar studies conducted among women (116, 122). In light of our findings, the importance of empowering women so that they can have more control over their own health cannot be over-emphasised. Women in power-imbalanced relationships tend to depend on their male partners

because men usually tend to bring more financial assets (i.e. money, status) to the relationship. As the economic inequity between men and women increases, and favours men, women will be more likely to experience adverse health outcomes (112). Hence, empowering women economically may give them some level of control over PrEP-related decisions including its uptake.

Our study makes a significant contribution to the body of knowledge on salient beliefs that may influence intention to use PrEP in a population that is disproportionately affected by HIV. To the best of our knowledge, this is the first study to investigate psycho-social correlates of PrEP and how these correlates influence intention to use PrEP among pregnant and breastfeeding women not living with HIV in Zambia. However, we do note some limitations. First, because of limited PrEP availability in antenatal settings, we were only able to determine beliefs associated with intention (as opposed to actual PrEP uptake). According to the belief disparity hypothesis, people hold more positive beliefs about hypothetical behaviours compared to when the behaviour is enacted in real life (127). Therefore, it is possible that participants' perceptions of PrEP could change when given an opportunity to take it. Second, very few women knew about PrEP prior to their participation in this study. Their responses were mainly dependent on the description of PrEP provided by interviewers and could also have been influenced by social desirability.

Third, we did not identify factors associated with the observed positive attitude towards PrEP use during pregnancy and breastfeeding. However, findings from a related qualitative study suggested that pregnant and breastfeeding women's attitudes toward PrEP were influenced by the belief that it has the potential to protect them and their infants from contracting HIV. PrEP was viewed as a way of protecting themselves in the event that their partner was cheating or secretly on ART (128). Fourth, the cross-sectional nature of the data limits our ability to make causal conclusions on the association between the theorised TPB beliefs

and intention to use PrEP since both exposures and outcome were measured at the same time. Despite these limitations, intention has been proven in several studies as a reliable antecedent to actual behaviour. Therefore, our findings are still valid and informative regarding beliefs that may influence uptake of PrEP in antenatal settings.

Conclusion

Consistent with the Theory of Planned Behaviour, our findings show that women's attitudes, subjective norms and perceived behavioural control are important correlates of intention to use PrEP during pregnancy and breastfeeding. Our findings suggest that social cognitive interventions aimed at generating demand for PrEP among pregnant and breastfeeding women should promote positive attitudes, subjective norms and control beliefs about PrEP use. Future studies should investigate how attitudes, subjective norms, perceived behavioural control, and intentions influence actual PrEP uptake in antenatal and postnatal settings.

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Disclosure statement

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Data availability statement

The data that support the findings of this study are available from the corresponding author, [TEH], upon reasonable request.

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Chapter 5:

Preferences for PrEP service delivery in antenatal and postnatal settings

5.0. Chapter Five: Preferences for pre-exposure prophylaxis delivery among HIV-negative pregnant and breastfeeding women in Zambia: Evidence from a discrete choice experiment

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Abstract

Introduction: Pregnant and breastfeeding women at substantial risk for HIV infection in sub-Saharan Africa can benefit from biomedical interventions such as pre-exposure prophylaxis (PrEP). We estimated the benefit that pregnant and breastfeeding women may derive from PrEP service delivery in order to guide PrEP roll-out in the target population in Zambia.

Methods: Between September and December 2021, we conducted a discrete choice experiment (DCE) among a convenient sample of 389 pregnant and breastfeeding women not living with HIV in Lusaka, Zambia. Women aged 18 years or older, with a documented negative HIV result in their antenatal card responded to a structured questionnaire containing 12 choice sets on service delivery attributes of PrEP: waiting time at the facility, travel time to the facility dispensing PrEP, location for PrEP pick-up, health care provider attitude and PrEP supply at each refill. Mixed logit regression analysis was used to determine the participant's willingness to trade off one attribute of PrEP for the other at a 5% significance level. Willingness to wait (WTW) was used to determine the relative utility derived from each attribute against waiting time.

Results: Waiting time at the facility, travel time to the facility, health care provider attitude and amount of PrEP supply at each refill were important attributes of PrEP service delivery (all $p<0.01$). Participants preferred less waiting time at the facility ($\beta= -0.27$, $p<0.01$). Women demonstrated a strong preference for a 3-months' supply of PrEP ($\beta= 1.69$, $p<0.01$). They were willing to wait for 5 hours at the facility, walk for more than an hour to a facility dispensing PrEP, encounter a health care provider with a negative attitude in order to receive PrEP enough for 3 months.

Conclusion: Patient-centered approaches can help to inform the design and implementation of PrEP services among pregnant and breastfeeding women. In this study, we found that a reduction in clinic visits—including through multi-month dispensing of PrEP—could improve uptake of services in antenatal and postnatal settings.

Key words: PrEP, HIV/AIDS, discrete choice experiment, pregnant, breastfeeding, Zambia, preferences

Introduction

Pregnant and breastfeeding women are disproportionately affected by HIV in sub-Saharan Africa (9), and HIV infection during pregnancy has implications for both maternal and child health (8, 24). In order to end the AIDS epidemic by 2030, the adoption of safe and effective HIV prevention methods, such as PrEP, are urgently needed (129). In South Africa, for instance, a study showed that offering PrEP to pregnant and breastfeeding women could significantly reduce new HIV infections in the country by 2.5% - 7.2% between 2020 and 2030 (130). Another modeling study found that the introduction of PrEP, in combination with other modalities, could reduce HIV incidence by as much as 45% among pregnant and breastfeeding women (131). As a female-controlled HIV prevention technology, PrEP provides additional protection when women fail to negotiate condom use with their partners (132). PrEP provision in antenatal settings, can also lead to reduced mother-to-child transmission of HIV—from in utero through breastfeeding (133).

PrEP was first introduced in Zambia in 2016 as a component of HIV prevention services in line with the World Health Organization guidelines at the time. National campaigns have been implemented in the years that followed—including Zambia Ending AIDS (39) with a goal of educating the public about PrEP and generating new demand for the intervention. In 2020, the Zambian Ministry of Health specifically recommended provision of PrEP to pregnant and breastfeeding women at substantial risk for HIV infection (40). Despite the positive attitude and favourable intention to use PrEP among pregnant and breastfeeding women (89), there is evidence that actual use may be low. For example, a study conducted among 658 women not living with HIV seeking effective contraception postpartum showed PrEP uptake at approximately 1% (41). Continuation on PrEP equally remains a challenge among pregnant and breastfeeding women who

initiate PrEP (134, 135). Some of the barriers to uptake of and persistence on PrEP could be addressed through differentiated PrEP service delivery, which is a client-centered approach that simplifies and adapts PrEP service provision in ways that serve the needs of people and communities at substantial risk of acquiring HIV (136).

Discrete choice experiments (DCEs) elicit preferences for health care service delivery and can be used to optimize health services. It is a quantitative technique that is grounded in the economic theory of utility maximization and can be useful in eliciting key modifiable attributes among potential users (58, 137), including aspects of decision making related to health outcomes and health care services (59). In the context of HIV care delivery, most studies have focused on understanding preferences for service delivery among people on ART (72, 138). However, little evidence exists to guide program implementers on how best to deliver PrEP to pregnant and breastfeeding women. To inform PrEP roll-out in antenatal and postnatal settings, we conducted a study to estimate the (1) relative importance of different attributes of PrEP service delivery; (2) trade-offs between the attributes of service delivery, and (3) benefit respondents derive from PrEP service delivery in antenatal and postnatal settings.

Methods and materials

Study design and participants

We conducted a DCE study to quantify service delivery preferences for PrEP among pregnant and breastfeeding women not living with HIV in Lusaka, Zambia. Based on review of the existing literature— as well as a formative study that employed semi-structured in-depth interviews (n=24) and nominal group technique (n=10) (128) —we selected 5 attributes to study. Two of the

attributes had 3 response levels and three had 2 levels (Table 1), which yielded a total of 72 potential combinations of attribute levels in a full factorial design. We selected 12 choice sets using a D-efficiency design. This was done using the 'dcreate' command in Stata version 16 (StataCorp LLC, College Station, TX, USA), which uses the modified Fedorov algorithm (139).

We conducted this study at Chipata Level 1 hospital, a government facility that is located in peri-urban Lusaka. The facility has a catchment population of over 100,000 and an antenatal clinic that attends to about 400-450 new ANC attendees each month. The HIV prevalence among pregnant women attended to at this health facility is approximately 16%, a rate that is similar to the national prevalence for women (35). Study eligibility was restricted to pregnant and breastfeeding women aged 18 years or older with a documented HIV-negative result in their antenatal record. All pregnant and breastfeeding women who could not provide written consent or who could neither speak nor understand any of the three languages in which the questionnaire was translated (English, Nyanja and Bemba) were excluded from the study. We recruited study participants from the Maternal and Child Health clinic using convenience sampling. Probabilistic sampling techniques were deemed impractical, since they would have obstructed the flow of service for the high volume of patients seen at the facility.

Sample size calculation

To calculate the study's sample size, we used the formula: $n = \frac{1000c}{ta}$, where $\boldsymbol{n}$ is number of respondents, $\boldsymbol{t}$ is number of tasks per respondent (i.e., 12), $\boldsymbol{a}$ is the number of alternatives (i.e., 2) and $\boldsymbol{c}$ is the largest product of number of levels of any two attributes (i.e., 3×3=9), which allows comparison of all two-way interactions (140). We further adjusted the sample size upwards using

the 2013/2014 Zambia Demographic and Health Survey (ZDHS) response rate for urban women (95.8%) (35) to account for incomplete responses. Our target sample size was 389 pregnant and breastfeeding women.

Data collection

Study personnel described the study and obtained written informed consent from eligible candidates who were willing to participate. We then collected information about sociodemographic attributes and PrEP knowledge questions. Data were collected using a structured questionnaire developed by the study team. The instrument was pre-tested to evaluate feasibility and clarity of questions. The final version was translated into Nyanja and Bemba (commonly spoken local languages) and independently back-translated to English for verification. Trained study personnel administered the questionnaire using face-to-face interviews via paper forms.

To ensure that participants understood the choice sets, a study team member described the attributes and attribute levels that participants were going to encounter in the DCE. This was done using a sample DCE question which had one choice set. Participants were later presented with 12 choice sets and were asked to choose between the different scenarios which contained the following service delivery attributes of PrEP: (1) place where PrEP is dispensed; (2) waiting time at the facility; (3) travel time to the facility dispensing PrEP; (4) attitude of health care provider and (5) supply at each refill. In all the 12 tasks, the attributes remained constant while the attribute levels varied.

Statistical analysis

We summarized the background characteristics of participants using frequency (percentage) for categorical variables and median (interquartile range) for continuous variables. The primary outcome or utility was women's preferences for PrEP service delivery. We used McFadden's choice model (141) to fit our utility model, which can be expressed mathematically as follows:

$$u_i = X_i\beta + (z_i A)' + \epsilon_i$$

where u_i is the utility for case i, β is a $p\ x\ 1$ vector of alternative-specific regression coefficients, and $A = (\alpha_1, \ldots, \alpha_j)$ is a $q\ x\ J$ matrix of case-specific regression coefficients. The elements of the $J\ x\ 1$ vector ϵ_i are independent type 1 (Gumbel-type) extreme-value random variables with mean γ (the Euler-Mascheroni constant, approximately 0.577) and variance $\pi^2/6$. The utility model was estimated using mixed logit regression analysis in Stata 16 (StataCorp LLC, College Station, TX, USA).

We determined the relative importance of the attributes using the significance of the coefficients β_i and their size whereas willingness to wait was estimated as the rate at which participants give up one unit of waiting time for an increase in other attributes. We determined the benefit derived from alternative ways of providing the service using the estimated utility model for different scenarios of attribute levels.

Ethical approval

The study received approval from the University of Zambia Biomedical Research Ethics Committee in Lusaka, Zambia (934-2020) and the Human Research Ethics Committee at the University of the Witwatersrand in Johannesburg, South Africa (M200564 MED20-02-145).

Additional approvals were obtained from the Zambia National Health Research Authority and the Lusaka District Medical Office prior to study activation.

Results

We conducted face-to-face interviews with 389 pregnant and breastfeeding women receiving care at the study site's Maternal and Child Health Clinic between September and December 2021. Table 8 describes the sociodemographic characteristics of study participants and summarizes the women's knowledge about PrEP and their perceived risk for HIV infection. Fifty percent of the participants were aged below 26 years (IQR: 22 – 30) and the majority were married and cohabiting with a partner. More than half had acquired secondary education and the majority were not in formal employment (67.9%). Most women never used condoms with their regular sexual partner in the 30 days preceding the interview, and very few perceived themselves at high risk of HIV infection.

Table 8. Sociodemographic Characteristics of Pregnant and Breastfeeding Women (n=389)

Characteristic	n (%)
Age in years, median (IQR)	26 (22 – 30)
Marital status	
Single	44 (11.3)
Married (cohabiting with partner)	327 (84.1)
Married (not cohabiting with partner)	18 (4.6)
Education	
No formal education	22 (5.7)
Primary	130 (33.4)
Secondary	226 (58.1)
Tertiary	11 (2.8)

Employment status	
Not working	269 (69.2)
Employed for wages	27 (6.9)
Self employed	93 (23.9)
Maternal status	
Pregnant	172 (44.2)
Breastfeeding	217 (55.8)
Gestational age (pregnant women only, n=172))	
First trimester	10 (5.8)
Second trimester	70 (40.7)
Third trimester	92 (53.5)
Condom use in past 30 days	
Never	338 (86.9)
Sometimes	36 (9.2)
Always	15 (3.9)
Lifetime sexual partners, median (range)	2 (1- 25)
Partner HIV status	
Known	318 (81.8)
Unknown	71 (18.2)
HIV risk perception	
No risk	158 (40.6)
Low risk	102 (26.2)
Moderate risk	80 (20.6)
High risk	49 (12.6)
PrEP protects against HIV (n=141)*	
Yes	98 (69.5)
No	43 (30.5)

*Among women who reported being knowledgeable about PrEP prior to the interview

PrEP delivery preferences

Each patient in the study responded to 12 choice sets; cumulatively, 4668 choice sets were presented to study participants. Results from our mixed logit regression analysis (Table 9) show that all the attributes of PrEP service delivery, except location (p=0.98), were important considerations for pregnant and breastfeeding women when deciding to use PrEP. These included waiting time at the facility, travel time to the location dispensing PrEP, attitude of health care provider, and PrEP supply at each refill. Dispensing 3-month's supply of PrEP was the most valued attribute of PrEP delivery ($\beta = 1.68$; $p<0.01$), followed by positive health care provider attitude ($\beta = 0.97$; $p<0.01$). Waiting time at the venue dispensing PrEP ($\beta= -0.57$, $p<0.01$) was more important than travel time to venue dispensing PrEP ($\beta= -0.27$, $p<0.01$). The negative coefficients for waiting time and travel time to the facility show that participants in our study preferred lesser waiting times and shorter travel time to the venue dispensing PrEP. Travel time to the facility of less than 1 hour ($\beta = 0.27$; $p<0.01$) was less important compared to the other attributes of PrEP service delivery.

Participants had 30% increase in the odds of preferring travel time that is less than 1 hour compared to travel time of 1 hour or more (OR=1.30, $p<0.001$). For every one hour in waiting time, there was a 44% reduction in odds of choosing PrEP services (OR=0.56, $p<0.001$). The odds of preferring a health care provider with a positive attitude were 2.64 times the odds of preferring a healthcare provider with a negative attitude (OR=2.64, $p<0.001$). The odds of preferring 3-month's supply of PrEP were 5.38 times higher than that of receiving 1-month's supply, while the odds of preferring 2-month's supply of PrEP were 2.38 times the odds of preferring 1-month supply (Table 9). Pregnant and breastfeeding women in our study were willing to wait for approximately 2 additional hours in order to be attended to by a health care provider with a positive attitude. They

were willing to wait even longer hours (approximately 3 additional hours) in order to receive drugs enough to take them 3 months. The amount of additional time that participants were willing to wait in order to receive their preferred attributes of PrEP delivery suggests that 3-month's supply of PrEP was more important to participants than being attended to by a health care provider with a positive attitude. In stratified analysis, preferences for PrEP service delivery were similar between pregnant and breastfeeding women (Supplementary Table 1).

Table 9. Attribute's weight in decision making about PrEP uptake during pregnancy and breastfeeding

Attribute	Coefficient (β)	Robust std. error	p-value	Odds ratio	Willingness to wait (hours)[1]
Location					
facility	0.00	-	-	1.00	0.00
community	0.00	0.04	0.955	1.00	0.13
Travel time					
≥1 hour	0.00			1.00	0.00
<1 hour	0.27	0.07	<0.001	1.3	0.60
Time (hours)[2]	-0.57	2.00	<0.001	0.56	
Attitude					
Negative	0.00			1.00	0.00
Positive	0.97	0.19	<0.001	2.64	1.96
Supply at refill					
1 month	0.00			1.00	0.00
2 months	0.87	0.16	<0.001	2.38	1.77
3 months	1.68	0.54	<0.001	5.38	3.33

[1] Estimated by the ratio of each coefficient to time coefficient

[2] Measured on a continuous scale

Alternative strategies of delivering PrEP

We simulated alternative strategies of delivering PrEP in order to determine which model would offer the greatest utility to women who choose to initiate PrEP during pregnancy and breastfeeding.

Table 10 details the preference utilities and associated marginal time willingness to wait for different scenarios of delivering PrEP to pregnant and breastfeeding women. The base scenario of delivering PrEP is described by waiting time at the facility of approximately 3 hours; travel time to the nearest facility dispensing PrEP of 1 hour or more; negative health care provider attitude; and 1-month supply of PrEP at each refill. Assuming that we were to move from the base case scenario to an alternative one that changed only one attribute—while keeping all others constant—increasing the amount of supply of PrEP at each refill would provide women the highest utility from using PrEP. From our results, women were willing to wait an additional 12 hours (β= 3.38) in order to receive PrEP enough for three months.

We compared alternative scenarios that changed two attributes. Based on our responses, women would derive more value from using PrEP if they received 3-months' supply of PrEP at each refill and encountered a health care provider with a positive attitude (β= 4.35 and additional time willingness to wait of slightly over 15 hours). In the event that three attributes of PrEP service delivery were changed, women would benefit more if they received PrEP enough for 3 months, encountered a health care provider with a positive attitude, and waited not more than 1 hour at the facility (β= 4.89, and additional time willingness to wait of just slightly over 17 hours). Changing all the four attributes viewed as important considerations when deciding to use PrEP would yield a utility of 5.16 and women would be willing to wait an additional 18 hours for this change in PrEP service delivery. Since the utilities in the scenarios presented above are greater than 0, it means that pregnant and breastfeeding women would benefit from such changes in PrEP delivery.

Table 10. Estimated preference utilities and additional time willingness to wait for change in PrEP delivery

Waiting time	Location	Travel time	Attitude	Supply	Benefit score	Additional time willingness to wait
Base case						
3 hours	Health facility	1 hour or more	Negative	1 month	--	--
Changing only one attribute of PrEP service delivery						
1 hour	-	-	-	-	0.54	2.00
5 hours	-	-	-	-	-0.54	-2.00
-	-	Less than 1 hour	-	-	0.27	0.93
-	-	-	Positive	-	0.97	3.40
-	-	-	-	2 months	0.87	3.04
-	-	-	-	3 months	3.38	11.78*
Changing two attributes of PrEP service delivery						
1 hour	-	Less than 1 hour	-	-	0.81	2.93
1 hour	-	-	Positive	-	1.51	5.4
1 hour	-	-	-	2 months	1.41	5.04
1 hour	-	-	-	3 months	3.92	13.78
-	-	Less than 1 hour	Positive	-	1.24	4.33
-	-	Less than 1 hour	-	2 months	1.14	3.97
-	-	Less than 1 hour	-	3 months	3.65	12.71
-	-	-	Positive	2 months	1.84	6.44
-	-	-	Positive	3 months	4.35	15.18*
5 hours	-	Less than 1 hour	-	-	-0.27	-1.07
5 hours	-	-	Positive	-	0.43	1.40
5 hours	-	-	-	2 months	0.33	1.04
5 hours	-	-	-	3 months	2.84	9.78
Changing three attributes of PrEP service delivery						
1 hour	-	Less than 1 hour	Positive	-	1.78	6.33
1 hour	-	Less than 1 hour	-	2 months	1.68	5.97
1 hour	-	Less than 1 hour	-	3 months	4.19	14.71
1 hour	-	-	Positive	2 months	2.38	8.44
1 hour	-	-	Positive	3 months	4.89	17.18*
-	-	Less than 1 hour	Positive	2 months	2.11	7.37
-	-	Less than 1 hour	Positive	3 months	4.62	16.11
5 hours	-	Less than 1 hour	Positive	-	0.70	2.33
5 hours	-	Less than 1 hour	-	2 months	0.60	1.97
5 hours	-	Less than 1 hour	-	3 months	3.11	10.71
5 hours	-	-	Positive	2 months	1.30	4.44
5 hours	-	-	Positive	3 months	3.81	13.18
Changing four attributes of PrEP service delivery						
1 hour	-	Less than 1 hour	Positive	2 months	2.65	9.37
1 hour	-	Less than 1 hour	Positive	3 months	5.16	18.11*
5 hours	-	Less than 1 hour	Positive	2 months	1.57	5.37
5 hours	-	Less than 1 hour	Positive	3 months	4.08	14.11

*Alternative ways of providing PrEP delivery to pregnant and breastfeeding women yielding the highest benefit scores

Discussion

Our study revealed that waiting time at the facility, travel time to the facility dispensing PrEP, health care provider attitude and amount of PrEP supply at each refill were important attributes of PrEP service delivery among pregnant and breastfeeding women. These factors are in line with service preferences highlighted by the WHO for PrEP delivery (142). From our findings, optimizing the way PrEP is currently being delivered would be beneficial to women who choose to use it for HIV prevention during pregnancy and breastfeeding.

In this study, participants demonstrated a relatively strong preference for a 3-month supply of PrEP. In fact, this was the most preferred single attribute likely to influence PrEP uptake among pregnant and breastfeeding women in our study. There are a number of possible explanations. For example, it is possible that women preferred the 3-month supply (as opposed to shorter refill periods) to avoid costs associated with frequent clinic visits for PrEP refills. Multi-month refills can address other key barriers to PrEP uptake such as transport expenses and lost wages arising from long waiting hours at the facility. However, there may be disadvantages to such an approach. Caution should be taken to ensure that multi-month scripting of PrEP is not offered to women who intend to use PrEP for a short duration, who are uncertain of their period of risk, and/or have medical conditions that require more intensive monitoring (143).

Health care provider attitude was the second most preferred single attribute of PrEP service delivery among study participants, a finding similar to other studies in the region. In Kenya and Uganda, for instance, women highlighted the importance of health care providers with respect to PrEP messaging and adherence (36). Poor treatment by staff was cited as a reason for non-

adherence among some women in FEM-PrEP in Kenya and South Africa (144). In another PrEP study in South Africa, positive encounters (friendly, patient and respectful) with trial staff promoted participation (145). Similar findings on barriers to PrEP uptake were also reported elsewhere (61). Findings from our qualitative study among pregnant and breastfeeding women were similarly consistent: a negative health care provider attitude can discourage potential users from accessing PrEP for HIV prevention during pregnancy and breastfeeding (128).

Although circumstances surrounding uptake of PrEP may differ from those around HIV treatment, both PrEP and ART are biomedical interventions and lessons learnt from ART studies could inform PrEP delivery. In a DCE that was conducted in Zambia to quantify facility-based preferences for ART services, patients were willing to wait 19 hours more to see nice rather than rude providers. Patients were willing to accept a facility located 10 km from home (as opposed to 5) that required 5 hours of waiting per visit (as opposed to 1 hour) and that dispensed 3 months of medications (instead of 5) in order to access nice (as opposed to rude) providers (72). Similar findings were reported among patients on ART who were lost to follow up in Nigeria, Tanzania and Uganda (146).

Waiting time and travel time to the facility dispensing PrEP were equally important attributes that influenced the likelihood of PrEP uptake among women interviewed in our study. Participants preferred less waiting time and shorter travel time to the facility. These results are supported by several other studies that reported long waiting hours and long travel time to health facilities as health systems barriers to uptake of services. In one study, living far from the clinic created difficulties to visit the clinic while lengthy clinic visits were viewed as extremely disruptive and

demotivating, lack of consideration for participants' time (145). Similar findings were reported in other studies in the region (61, 104).

Our findings have important public health implications. Although waiting time, travel time to the facility, amount of PrEP supply and health care provider attitude all influenced the likelihood of PrEP uptake in our study population, addressing all barriers of service uptake amidst resource constraints may require adopting an incremental approach. This approach would require an understanding of the value derived from each of the preferred attributes. Our study quantifies the trade-offs that women are willing to make in order to derive value from using PrEP during pregnancy and breastfeeding. In view of our findings, prioritizing pregnant and breastfeeding women for multi-month dispensing of PrEP as well as improving client-health care provider relationships, through improved health care provider attitude may have a positive impact on PrEP uptake in antenatal and postnatal settings. Increased uptake of PrEP in the target population could significantly reduce the risk of maternal HIV infections and thereby avert the negative impact of HIV infections on women, including increased risk of maternal morbidity and mortality, reduced fecundity, miscarriages and still births (147, 148), among others. Further, this would contribute towards the attainment of sustainable development goal number 3 on the elimination of HIV mother-to-child transmission.

Despite the strengths of our work, we note several limitations. First, theoretical uptake of PrEP used in our study limits our understanding of preferences for PrEP delivery in real-life settings. At the time of study implementation, PrEP was not yet integrated into maternal and child health platforms, and so study findings were meant to inform programs that would do so. Second, we

limited the study to daily oral PrEP, since that was the only formulation available at the time that the study was conducted. Findings on preferences could be different with long-acting formulations such as injectable cabotegravir or the dapivirine vaginal ring; however, at this time, neither is approved for HIV prevention in Zambia. Third, we limited PrEP service delivery attributes to only five and therefore were unable to measure other attributes that could potentially influence women's decision making process, such as location for pick-up of PrEP within the health facility (e.g. ART department, out-patient department, maternal and child health department). However, presenting more attributes and attribute levels is associated with greater cognitive difficulty of completing a DCE for participants (137). Fourth, our sample was drawn from a peri-urban setting and therefore results may not be extrapolated to women in rural parts of Zambia. Fifth, we did not determine the proportion of women in sero-discordant relationships, and therefore did not fully characterize the risk of HIV faced by participants. Even with these limitations, our study is among the first to investigate preferences for PrEP service delivery among pregnant and breastfeeding populations and will help to inform PrEP scale-up in Zambia and other similar settings.

Conclusion

Our study shows that waiting time at the facility, travel time to the facility dispensing PrEP, health care provider attitude and supply at each refill are key attributes of service delivery likely to influence uptake of PrEP among eligible pregnant and breastfeeding women. As national programs seek to implement differentiated service delivery for PrEP—especially initiatives for pregnant and breastfeeding women—deliberate efforts to prioritize individual needs and preferences are urgently needed.

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PART 3

GENERAL DISCUSSION AND CONCLUSION

Part Three presents two chapters, Discussion as Chapter 6 and Conclusion and Recommendations as Chapter 7.

6.0. Chapter Six: General discussion

6.1. Thesis key findings and discussion

This chapter presents a summary of key findings of the overall thesis. Key findings are presented in relation to the specific objectives of the research and also in order of the chapters (Chapters 3 – 5). This discussion compares findings of the current study to those from similar studies. Below is the summary of key findings.

Table 11. Key findings of the thesis

Objective	**What was done**	**Key findings**
Objective 1. To explore the salient beliefs about PrEP use among HIV-negative pregnant and breastfeeding women.	Conducted in-depth interviews with 24 pregnant and breastfeeding women. Used both deductive and inductive coding and analysed data thematically.	Women had positive attitudes toward PrEP use. Most of them believed that people who are important to them, especially male partners, would not approve of their decision to use PrEP. Most women felt that lack of support from significant others would make it difficult for them to take PrEP during pregnancy and breastfeeding.
Objective 2. To determine the association between the salient beliefs and intention to use PrEP among HIV-negative pregnant and breastfeeding women.	Conducted a survey among 389 pregnant and breastfeeding women using interviewer-administered questionnaires. Pearson moment correlation (r) was used to determine correlations between salient beliefs and intention to use PrEP. Multiple linear regression was used to determine the strength of association while adjusting for confounders.	Women had positive attitudes, anticipated support from significant others, felt that PrEP use would be under their control and had favourable intentions to use PrEP during pregnancy and breastfeeding. Breastfeeding women reported more positive attitudes and intentions compared to pregnant women. Subjective norms had the greatest influence on women's intention to use PrEP during pregnancy and breastfeeding.
Objective 3.	Conducted in-depth interviews with 24 pregnant and breastfeeding women to identify initial attributes	List of attributes from IDIs included location dispensing PrEP, waiting time, distance to facility, health care provider attitude, gender of health care

To explore service delivery attributes of PrEP likely to influence its uptake among HIV-negative pregnant and breastfeeding women.	and attribute levels of PrEP service delivery. Used a nominal group technique to come up with final list of attributes and attribute levels for the discrete choice experiment.	provider, frequency of HIV testing, supply at each refill, location (MCH vs. ART clinic). Final attributes for the DCE were location dispensing PrEP (health facility vs. community); waiting time (1 hour, 3 hours and 5 hours), travel time to the location dispensing PrEP (<1 hour, 1hour+), health care provider attitude (positive vs. negative); and supply at each refill (1 month, 2 months, 3 months).
Objective 4 To estimate the relative importance of different attributes of PrEP service delivery among HIV-negative pregnant and breastfeeding women.	Conducted a discrete choice experiment in which women were presented with 12 choice sets, having 2 alternatives each. Mixed logit regression analysis was used to get marginal utilities and associated p-values for each attribute level in the DCE.	All attributes used in the DCE except for location, were important in influencing considerations for PrEP use during pregnancy and breastfeeding ($p<0.01$). Three-months supply of PrEP was the most preferred attribute followed by health care provider attitude. Travel time to the location dispensing PrEP was the least preferred attribute of PrEP service delivery in antenatal and postnatal settings.
Objective 5 To estimate the benefit that HIV-negative pregnant and breastfeeding women derive from PrEP service delivery in antenatal settings.	Using data for 389 women who participated in the DCE, and using marginal utilities obtained from mixed logit regression analysis, willingness to wait (WTW) analysis was conducted. This was done by getting the ratio of coefficients of attribute level to the coefficient for waiting time.	Women were willing to wait almost 6 hours in order to receive PrEP to take them 3 months. They were willing to wait just about 3 hours in order to be attended to by a health care provider with a positive attitude. Women were willing to wait for 5 hours at the facility, walk for more than an hour to a facility dispensing PrEP, and encounter a health care provider with a negative attitude just in order to receive PrEP enough for 3 months.

6.2. Emerging themes from the research findings

Below is a presentation of themes that emerged from the overall findings of the study: (1) Knowledge about PrEP among pregnant and breastfeeding women and the communities where the women live; (2) HIV risk perception; (3) Salient beliefs about PrEP use during pregnancy and

breastfeeding; (4) Intention to use PrEP; (5) Preferences for PrEP service delivery during pregnancy and breastfeeding.

6.2.1. Knowledge about PrEP

Most of the pregnant and breastfeeding women who participated in our study did not know about PrEP prior to the interviews. This was the case in both the qualitative and quantitative components of the study. Even among the few that reported being aware of PrEP, a number of them still mistook it for post-exposure prophylaxis, with others reporting that PrEP was used to treat sexually transmitted infections. Most women who participated in the qualitative interviews also expressed concern about low PrEP awareness in the communities where they lived. The low PrEP awareness was seen as a potential barrier to PrEP uptake because significant others and community members would conflate PrEP with ART and therefore women who would use PrEP during pregnancy and breastfeeding would be labeled and would experience stigma. Overall, the low PrEP awareness within the community would negatively impact PrEP uptake.

6.2.2. Perceived risk for HIV infection

According to WHO, population-level HIV incidence is an important determinant of individual-level risk of HIV acquisition (142). Although the study site has a relatively high HIV prevalence among ANC attendees, few women in our study perceived themselves to be at moderate or high risk for HIV infection. This could suggest pregnant and breastfeeding women's limited ability to correctly assess individual risk for HIV acquisition. The low risk perception was reported amidst low condom utilization during the 30 days preceding the interviews. Some studies conducted in

sub-Saharan Africa reported low uptake of PrEP among pregnant and breastfeeding women who did not perceive HIV risk (51). The low risk perception in our study could possibly contribute towards the low uptake of PrEP reported in antenatal and postnatal settings in the country. Drawing from results of another study conducted in Zambia that showed a higher proportion of postpartum women who tested HIV positive among those that perceived their risk for HIV infection to be low, it is likely that some of our participants who reported low risk perception could actually be at high risk of HIV acquisition, which poses great risk of maternal seroconversion and onward mother-to-child transmission of HIV. Therefore, enhancing women's ability to correctly assess their own risk of HIV infection could improve uptake of PrEP in antenatal and postnatal settings.

6.2.3. Salient beliefs about PrEP use during pregnancy and breastfeeding

Pregnant and breastfeeding women who participated in our study expressed positive attitudes in both the qualitative and quantitative components of the study. Although participants in the quantitative study demonstrated favourable subjective norms and perceived behavioural control, most participants in the qualitative study felt that people who are important to them would not support the idea of PrEP use during pregnancy and breastfeeding, and women reported that they felt that PrEP use would not be entirely under their control. Some of them even feared that they would not use PrEP if their partners did not approve. The mixed feelings about whether significant others would approve or disapprove PrEP use during pregnancy and breastfeeding have been observed in several other studies. Pregnant and breastfeeding women in some studies reported anticipated and actual support from partners and other community members (50, 55) while other studies reported fear of HIV-related stigma and PrEP stigma as reasons for discreet use of PrEP and non-use among those that declined to use it (43, 56, 57).

6.2.4. Preferences for PrEP service delivery during pregnancy and breastfeeding

Our study found that the most preferred attribute for PrEP service delivery during pregnancy and breastfeeding is the amount of PrEP supply given to women. Health care provider attitude was the second most preferred attribute. Women also preferred less waiting time at the facility. Although women in both the qualitative and quantitative studies did not want to wait long hours at the facility, findings from the qualitative study suggest that waiting long hours would be expected, with some women reporting that those who would want to wait for short hours had the option to go to the facility very early. The same was observed with respect to travel time to the place dispensing PrEP. Women who participated in the qualitative study reported that much as they preferred shorter travel time in order to access PrEP, they did not think that the long travel time would stop them from accessing it. Others even gave examples of how ART patients in their communities go to the extent of borrowing transport money just to ensure that they got their refills. The fact that travel time was the least preferred could also speak to the belief by women that it's a barrier that they could easily overcome as shown from our qualitative study (128). Women seemingly showed preference for those attributes of PrEP service delivery that they would not have much control over, such as supply of PrEP and health care provider attitude.

Women in the qualitative study exhibited mixed feelings about the location for PrEP pick-ups. While some preferred home delivery as a way of increasing PrEP awareness in the community, others felt that it would result in them being stigmatized. The fact that some participants who preferred accessing PrEP from a health facility opted for a facility that was not located within their community also suggests anticipated PrEP stigma. These results from the qualitative study were also corroborated by findings from our DCE where participants did not show a clear preference

for health facility or community-based delivery. In fact, location was not an important attribute of PrEP delivery among women who participated in the discrete choice experiment. The difference in preference for PrEP dispensing location observed in our study demonstrates the diversity in the needs of pregnant and breastfeeding women who may want to use PrEP. It is therefore imperative for program implementers to ensure that both groups of women (those who prefer health facility and those who prefer community-based delivery) are catered for and that none is disadvantaged.

6.3. Way forward in improving uptake of PrEP during pregnancy and breastfeeding

In response to the SDGs on elimination of mother-to-child HIV transmission, the take away messages border on improving PrEP awareness as a way of demystifying PrEP. This has the potential to minimize both anticipated and experienced PrEP stigma and onward improvement in uptake, adherence and retention in care among pregnant and breastfeeding women that initiate PrEP. The second take home message concerns the amount of PrEP supply at each refill. Multi-month dispensing would reduce the number of clinic visits and therefore address the other structural barriers to PrEP uptake including transportation costs and opportunity costs associated with the long waiting time at each of the clinic visits for PrEP refills. However, caution should be taken to ensure that multi-month dispensing of PrEP is only given to women who intend to use PrEP for longer periods and those that do not have medical conditions requiring safety monitoring. Mechanisms should also be devised to minimize wastage that may arise from unused medications among women on this model.

6.4. Methodological considerations

This section highlights methodological aspects of the study and how these could have influenced the results obtained. To be specific, we highlight the strengths and limitations of the study which should be considered when interpreting results presented herein.

6.4.1. Strengths of the study

An important strength of this research is the use of mixed methods to explore and determine factors likely to influence uptake of PrEP in antenatal and postnatal settings in Zambia. Most of the studies conducted in this population have been qualitative with only a few quantitative studies. The adoption of two established theoretical frameworks used simultaneously to explore and determine factors likely to influence PrEP uptake and our ability to estimate the relative importance of each salient belief in influencing intention to use PrEP is something that has not yet been done in the target population. Our study therefore gives important insights about PrEP in pregnancy and breastfeeding, most of which could improve our understanding of contextual factors likely to influence uptake of biomedical health interventions. Further, the ability of our study to use a discrete choice experiment to quantify preferences for a number of service delivery factors that could potentially influence uptake of PrEP is novel given the limited literature on preferences for service delivery in the target population.

6.4.2. Study limitations

The main limitation of the study is the hypothetical nature employed in understanding factors likely to influence PrEP uptake in antenatal and postnatal settings. Some evidence suggests that people's reactions in a hypothetical scenario could be different when faced with real-life situations.

Specifically, the belief disparity hypothesis argues that people hold more positive beliefs about hypothetical behaviours compared to when the behaviour is enacted in real life (127). As such, we cannot assume with certainty that the positive attitudes, subjective norms, perceived behavioural control, and favourable intentions would be exactly the same among pregnant and breastfeeding women with experience using PrEP. However, studies that have examined both intention and actual behavior have reported a strong association between the two and therefore intention can be used as a proxy for actual behavior.

The second limitation is linked to low general PrEP awareness in the study population. Most participants in both the qualitative and quantitative studies were only learning about PrEP from the interviewer. This could have introduced social desirability bias as some women's responses could not have been based on thorough evaluation of PrEP but rather the responses could have been influenced by what participants thought was the right thing to say under the circumstance. This bias could have resulted in the over-estimation of reported positive attitudes, favourable intentions, anticipated approval from significant others and perceived behavioural control about PrEP use. However, the triangulation and corroboration of study findings from both the qualitative and quantitative studies minimize the extent to which the potential bias could have influenced the final results on beliefs and preferences for PrEP service delivery in our study population.

The third limitation relates to the cognitive difficulty associated with responding to questionnaires with many choice sets, a limitation that is inherent in most DCEs. However, we minimized this by ensuring that participants only responded to 12 tasks, a number that has been shown to be bearable for participants in other studies. Fourth, our findings may not be generalizable to all pregnant and breastfeeding women, especially those in remote parts of the country as the study was conducted at one facility only, which is located in an urban setting.

7.0. Chapter Seven: Conclusion and recommendations

This section presents a summary of findings of this thesis, and also highlights recommendations for future research, policy and PrEP programming.

7.1. Conclusion

Improving PrEP uptake in antenatal and postnatal settings would contribute significantly to the elimination of mother-to-child transmission. The positive attitudes and favourable intentions to use PrEP exhibited by participants in our study are encouraging. Interventions aimed at increasing uptake of PrEP among pregnant and breastfeeding women would have to address low PrEP awareness using a community-based approach in order to minimize HIV and PrEP-related stigma. Policy makers and stakeholders in HIV programs should device means of ensuring multi-month dispensing of PrEP for pregnant and breastfeeding women in order to reduce the number of PrEP service related clinic visits and the associated direct and indirect costs, especially for women who intend to use PrEP for longer periods and those who do not have medical conditions requiring constant monitoring.

7.2. Recommendations

7.2.1. Future research

1. Investigate the role of salient beliefs in influencing actual uptake of PrEP in antenatal and postnatal settings.
2. Explore and understand the lived experiences of women who have used PrEP during pregnancy and breastfeeding.

3. Determine factors associated with adherence and retention in PrEP care during pregnancy and postpartum.
4. Implementation research to evaluate the effect of a PrEP awareness and HIV risk education intervention on PrEP uptake in antenatal and postnatal settings.
5. Explore beliefs about PrEP use during pregnancy and breastfeeding among male partners of pregnant and breastfeeding women.
6. Implementation research to identify best approaches to actively engage male partners of women considering PrEP use during pregnancy and breastfeeding since male partners were cited as key referents concerning PrEP use during pregnancy and breastfeeding.
7. Explore beliefs about and factors likely to influence uptake of long acting injectable formulations of PrEP such as cabotegravir among pregnant and breastfeeding women.
8. Determine preferences for different formulations of PrEP (oral PrEP, injectable PrEP, and the vaginal ring) among pregnant and breastfeeding women in different age groups.

7.2.2. Policy and PrEP programming implications and recommendations

PrEP can play a critical role in efforts to achieve the targets adopted by the United Nations General Assembly on reducing the number of new HIV infections to less than 370 000 by 2025 and 335 000 by 2030, and number of children 0-14 years of age newly infected with HIV per year to 15 000 by 2030 (149). Moreover, implementation of PrEP is also recognized as a key action in achieving the goals set out in the 2022–2030 Global Health Sector Strategies on HIV, Viral Hepatitis and Sexually Transmitted Infections (34). The adoption of PrEP into national guidelines, specifically its extension to antenatal and postnatal settings by the Zambian Ministry of Health

(40) further demonstrates the importance that Government places on PrEP as an effective combination strategy for HIV prevention.

Beliefs that women hold about PrEP use with respect to benefits and disadvantages, anticipated reactions of people who are close to them and beliefs around anticipated barriers to PrEP uptake and perceived power to overcome anticipated barriers all play a critical role in influencing PrEP uptake. This study has shown that some women perceive disapproval and lack of support from significant others and community members at large. Based on our findings and in line with the 2019 – 2023 Zambia National HIV and AIDS Communication and Advocacy Strategy, we reiterate the need for stakeholders to support awareness-building and demand-creation efforts through multimedia, including the use of radio, television, social media to reach communities with oral PrEP messages. Such campaigns and open discussions about PrEP have the potential to address myths about PrEP including PrEP-related stigma and may result in more supportive attitudes for women who opt to use PrEP during pregnancy and breastfeeding. The Strategy also recognizes the need to actively engage men who act as gatekeepers for women considering starting oral PrEP. Given findings of the current study, this need cannot be overemphasized, seeing that male partners were the most cited referents in PrEP-related decision making among pregnant and breastfeeding women.

The low PrEP awareness among pregnant and breastfeeding women themselves calls for the integration of PrEP-related education in routine ANC and postnatal care (e.g. family planning) programs. Most pregnant and breastfeeding women are well aware about birth preparedness and maternal complications owing to the mandatory routine health talks that they receive when they go for their ANC visits. Women would benefit from the integration of PrEP into already existing

maternal and child health care services. Finally, taking into account end-user preferences, specifically prioritizing pregnant and breastfeeding women for multi-month scripting of PrEP, and improving the attitude of health care providers towards potential PrEP users would increase the benefit that women derive from using PrEP and thereby improve its uptake in antenatal and postnatal settings.

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Appendix 1: Information and Consent Form- In-depth Interviews

Consent to Participate in a Research Study- In-depth Interview

Title of Study: Preferences and Intention to Use PrEP among Pregnant and Breastfeeding Women in Zambia

UNZABREC #: 934-2020 **WITS HREC #:** M200564 MED20-02-145 **UNC IRB #:** 20-1655

Principal Investigator: Ms. Twaambo E Hamoonga
Principal Investigator Department: Public Health
Principal Investigator Phone number: +260 979810922
Principal Investigator Email Address: tehams24@gmail.com

Supervisor 1: Professor Benjamin Chi (Department of Obstetrics and Gynecology, UNC at Chapel Hill).
Supervisor Contact Information: +1 919 445 4174, E-mail: Benjamin_chi@med.unc.edu

Supervisor 2: Dr. Wilbroad Mutale (Department of Health Systems Management and Policy, University of Zambia).
Supervisor Contact Information: +260 967780284, E-mail: wmutale@yahoo.com

Supervisor 3: Dr. Jude Igumbor (Department of Public Health, University of the Witwatersrand).
Supervisor Contact Information: +27 727915927, E-mail: Jude.Igumbor@wits.ac.za

Funding Source and/or Sponsor: UNC-UNZA-Wits Collaboration for HIV and Women's Reproductive Health (D43 TW010558).

Study Contact Telephone Number: +260979810922 , **Email**: tehams24@gmail.com

Good day, my name is……., and I am a member of the research team on factors influencing PrEP use in antenatal settings. We would like to invite you to participate in our study.

Concise Summary

Pregnancy and the period after delivery have been associated with high HIV risk. Taking daily oral PrEP is effective in preventing HIV infection when taken consistently. PrEP is the use of anti-retroviral drugs (ARVs) by HIV-uninfected people to protect them from getting infected with HIV.

The Ministry of Health recommends offering PrEP to pregnant and breastfeeding women at high risk for HIV infection. However, not much is known about what women consider when they make a decision to take PrEP. Therefore, this study seeks to learn about factors likely to influence women's uptake of PrEP. Findings from this study can help the Ministry of Health to determine how best to deliver PrEP to pregnant and breastfeeding women in need. If you agree to participate in this study, you will be required to respond to questions that the interviewer will ask you. The interview is expected to last between 45 to 60 minutes.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, or your health care provider.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this of this study?

The purpose of this research study is to identify factors that affect PrEP use among HIV-negative pregnant and breastfeeding women in Zambia. These findings can help the Ministry of Health determine how best to provide PrEP to pregnant and breastfeeding women. The study will explore beliefs and preferences for PrEP service delivery among HIV-uninfected pregnant and breastfeeding women at Chipata first level hospital. This will be done through conducting interviews with HIV-uninfected pregnant and breastfeeding women who agree to participate in this study.

Are there any reasons you should not be in this study?

You should not be in this study if you are HIV positive, below the age of 18 years and if you are not willing to provide written consent to participate in this study and to have the interview audio-recorded.

How many people will take part in this study?

Approximately 20 pregnant or breastfeeding women receiving antenatal/postnatal care at Chipata 1st Level hospital will take part in this study.

How long will your part in this study last?

It is anticipated that the interview will last between 45 to 60 minutes. This will be the only study activity; there will be no follow-up visits afterwards, except if you agree to participate in the second part of the study. The second part of the study will take the form of a discussion to come up with the final list of factors that will be generated from these interviews.

What will happen if you take part in the study?

The interviewer will ask you a list of questions and you will be required to answer the questions asked. You can skip or refuse to answer any questions for any reason.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study. However, findings from this study may help to improve PrEP programs for pregnant and breastfeeding women in the future.

What are the possible risks or discomforts involved from being in this study?

You may feel uncomfortable to discuss matters relating to your sexual behaviour. However, you can skip or refuse to answer questions that you may not want to answer.

How will information about you be protected?

All data collected during the study will be secured on a password-protected laptop and backed up on an external hard drive which will be secured under lock and key. Participant names will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. Data will be kept for a period of five years after which it will be deleted and audio-recorders and hard drive overwritten.

Although every effort will be made to keep research records private, there may be times when state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the study team will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University of the Witwatersrand, research sponsors, or institutional review boards (IRBs) for purposes such as quality control or safety.

All interviews will be audio-recorded as a condition for participation. If you agree to take part, we will make an audio recording of the discussion so that we have a record of the conversation. Your name will not be captured in the recording. The audio recording will be stored on a secured computer server that can only be accessed by members of the study team. The recording will be transcribed by a member of our research team or an outside professional transcriber. We will destroy all recordings within five years of conducting this study.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow

instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected will be destroyed and no additional data will be collected.

Will you receive anything for being in this study?

You will be receiving K50 as transport reimbursement for taking part in this study. This money will be given to you by the interviewer at the end of the interview.

Will it cost you anything to be in this study? It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the U.S. National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Chairperson (Dr. Soddy Munsaka), University of Zambia Biomedical Research Ethics Committee (UNZABREC) on telephone: 260-1-256067 or by email: unzarec@unza.zm.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study. By signing my name, I also confirm that I have given permission to be audio recorded during the interview.

_____ _____

Signature or Thumb Print of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature or Thumb Print of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

_____ _____

Signature or Thumb Print of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign Date

_____

Printed Name of Witness

Appendix 2: Consent to Participate in a Research Study- Nominal Group

Title of Study: Preferences and Intention to Use PrEP among Pregnant and Breastfeeding Women in Zambia

UNZABREC #: 934-2020 **WITS HREC #:** M200564 MED20-02-145 **UNC IRB #: 20-1655**

Principal Investigator: Ms. Twaambo E Hamoonga

Principal Investigator Department: Public Health

Principal Investigator Phone number: +260 979810922

Principal Investigator Email Address: tehams24@gmail.com

Supervisor 1: Professor Benjamin Chi (Department of Obstetrics and Gynecology, UNC at Chapel Hill)

Supervisor Contact Information: +1 919 445 4174, E-mail: Benjamin_chi@med.unc.edu

Supervisor 2: Dr. Wilbroad Mutale (Department of Health Systems Management and Policy, University of Zambia)

Supervisor Contact Information: +260 967780284, E-mail: wmutale@yahoo.com

Supervisor 3: Dr. Jude Igumbor (Department of Public Health, University of the Witwatersrand)

Supervisor Contact Information: +27 727915927, E-mail: Jude.Igumbor@wits.ac.za

Funding Source and/or Sponsor: UNC-UNZA-Wits Collaboration for HIV and Women's Reproductive Health (D43 TW010558).

Study Contact Telephone Number: +260979810922 **Email**: tehams24@gmail.com

Good day, my name is……, and I am a member of the research team on factors influencing PrEP use in antenatal settings. We would like to invite you to participate in our study.

Concise Summary

Pregnancy and the period after delivery have been associated with high HIV risk. Taking daily oral PrEP is effective in preventing HIV infection when taken consistently. PrEP is the use of anti-retroviral drugs (ARVs) by HIV-uninfected people to protect them from getting infected with HIV.

The Ministry of Health recommends offering PrEP to pregnant and breastfeeding women at high risk for HIV infection. However, not much is known about what women consider when they make a decision to take PrEP. Therefore, this study seeks to learn about factors likely to influence women's uptake of PrEP. Findings from this study can help the Ministry of Health to determine how best to deliver PrEP to pregnant and breastfeeding women. If you agree to participate in this study, you will be required to respond to questions that the interviewer will ask you. The interview is expected to last between 45 to 60 minutes.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, or your health care provider.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to identify factors that affect PrEP use among HIV-negative pregnant and breastfeeding women in Zambia. These findings can help the Ministry of Health determine on how best to provide PrEP to pregnant and breastfeeding women. The study will explore beliefs and preferences for PrEP service delivery among HIV-uninfected pregnant and breastfeeding women at Chipata first level hospital. This component of the study seeks to come up with the final list of factors that will be used in the second part of the study. This will be done through selecting and ranking/scoring the best five factors that you would have chosen. Scores given by each participant will be written down and the whole group will agree on final list of factors that women consider when deciding to use PrEP. You are being asked to be in this study because you participated in the first part of the study where the initial list of factors was generated.

Are there any reasons you should not be in this study?

You should not be in this study if you are HIV positive, below the age of 18 years and if you are not willing to provide written consent to participate in this study.

How many people will take part in this study?

Approximately 10 pregnant and breastfeeding women who participated in the first component of the study (the first interviews) will take part in this study.

How long will your part in this study last?

Your participation in this second part of the study will last approximately one hour to one hour and 30 minutes. There will be no follow-up visits afterwards.

What will happen if you take part in the study?

The group will be asked to quietly and individually select factors from the list that was generated from the first interviews we had with you. Each individual will score/rank their best five factors that they would have chosen. A separate time will be set aside to allow individuals to share with the group reasons for their selection. The group will then put together the scores from individual participants so as to arrive at the final list of factors to be used in the next part of the study. The discussion will be audiotaped so that we can have a record of this discussion.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study. However, findings from this study may inform scale-up of future PrEP programs for pregnant and breastfeeding women who may choose to use PrEP.

What are the possible risks or discomforts involved from being in this study?

We do not anticipate any risks or discomfort to you from being in this study. Even though we will emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can, but remain aware of our limits in protecting confidentiality.

How will information about you be protected?

Every effort will be taken to protect your identity as a participant in this study. Participant names will not be identified in any report or publication of this study or its results. Your name will not appear on any transcripts; instead, you will be given a code number. The list which matches names and code numbers will be kept in a locked file cabinet. After the recorded tape has been transcribed, the tape will be destroyed, and the list of names and numbers will also be destroyed. We may use de-identified data from this study in future research without additional consent.

All interviews will be audio-recorded as a condition for participation. If you agree to take part, we will make an audio recording of the discussion so that we have a record of the conversation. Your name will not be captured in the recording. The audio recording will be stored on a secured computer server that can only be accessed by members of the study team. The recording will be transcribed by a member of our research team or an outside professional transcriber. We will destroy all recordings within five years of conducting this study.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will be receiving K50 as transport reimbursement for taking part in this study.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the U.S. National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Chairperson (Dr. Soddy Munsaka), University of Zambia Biomedical Research Ethics Committee (UNZABREC) on telephone: 260-1-256067 or by email: unzarec@unza.zm.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study. By signing my name, I also confirm that I have given permission to be audio recorded during the discussion.

_____ _____

Signature or Thumb Print of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature or Thumb of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

_____ _____

Signature or Thumb Print of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign Date

_____

Printed Name of Witness

Appendix 3: Consent to Participate in a Research Study- Questionnaire

Title of Study: Preferences and Intention to Use PrEP among Pregnant and Breastfeeding Women in Zambia

UNZABREC #: 934-2020 **WITS HREC #:** M200564 MED20-02-145 **UNC IRB #:** 20-1655

Principal Investigator: Ms. Twaambo E Hamoonga
Principal Investigator Department: Public Health
Principal Investigator Phone number: +260 979810922
Principal Investigator Email Address: tehams24@gmail.com

Supervisor 1: Professor Benjamin Chi (Department of Obstetrics and Gynecology, UNC at Chapel Hill)
Supervisor Contact Information: +1 919 445 4174, E-mail: Benjamin_chi@med.unc.edu

Supervisor 2: Dr. Wilbroad Mutale (Department of Health Systems Management and Policy, University of Zambia)

Supervisor Contact Information: +260 967780284, E-mail: wmutale@yahoo.com

Supervisor 3: Dr. Jude Igumbor (Department of Public Health, University of the Witwatersrand)

Supervisor Contact Information: +27 727915927, E-mail: Jude.Igumbor@wits.ac.za

Funding Source and/or Sponsor: UNC-UNZA-Wits Collaboration for HIV and Women's Reproductive Health (D43 TW010558).

Study Contact Telephone Number: +260979810922
Study Contact Email: tehams24@gmail.com

Good day, my name is……, and I am a member of the research team on factors influencing PrEP use in antenatal settings. We would like to invite you to participate in our study.

Concise Summary

Pregnancy and the period after delivery have been associated with high HIV risk. Taking daily oral PrEP is effective in preventing HIV infection when taken consistently. PrEP is the use of anti-retroviral drugs (ARVs) by HIV-uninfected people to protect them from getting infected with HIV.

The Ministry of Health recommends offering PrEP to pregnant and breastfeeding women at high risk for HIV infection. However, not much is known about what women consider when they make a decision to take PrEP. Therefore, this study seeks to learn about factors likely to influence women's uptake of PrEP. Findings from this study can help the Ministry of Health to determine how best to deliver PrEP to pregnant and breastfeeding women in need. If you agree to participate in this study, you will be required to respond to questions that the interviewer will ask you. The interview is expected to last between 45 to 60 minutes.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, or your health care provider.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them , any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to identify factors that affect PrEP use among HIV-negative pregnant and breastfeeding women in Zambia. These findings can help the Ministry of Health determine how best to provide PrEP to pregnant and breastfeeding women. The study will explore beliefs and preferences for PrEP service delivery among HIV-uninfected pregnant and breastfeeding women at Chipata first level hospital. This will be done through conducting interviews with HIV-uninfected pregnant and breastfeeding women who agree to participate in this study.

Are there any reasons you should not be in this study?

You should not be in this study if you are HIV positive, below the age of 18 years and if you are not willing to provide written consent to participate in this study and to have the interview audio-recorded.

How many people will take part in this study?

Approximately 392 pregnant or breastfeeding women receiving antenatal/postnatal care at Chipata first level hospital will take part in this study.

How long will your part in this study last?

It is anticipated that the interview will last between 45 to 60 minutes. This will be the only study activity; there will be no follow-up visits afterwards.

What will happen if you take part in the study?

The interviewer will ask you a list of questions and you will be required to answer the questions asked. You can skip or refuse to answer any questions for any reason.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study. However, findings from this study may help to improve PrEP programs for pregnant and breastfeeding women in the future.

What are the possible risks or discomforts involved from being in this study?

You may feel uncomfortable to discuss matters relating to your sexual behaviour. However, you can skip or refuse to answer questions that you may not want to answer.

How will information about you be protected?

All data collected during the study will be secured on a password-protected laptop and backed up on an external hard drive which will be secured under lock and key. Participant names will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. Data will be kept for a period of five years after which it will be deleted and audio-recorders and hard drive overwritten.

Although every effort will be made to keep research records private, there may be times when state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the study team will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University of the Witwatersrand, research sponsors, or institutional review boards (IRBs) for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected will be destroyed and no additional data will be collected.

Will you receive anything for being in this study?

You will be receiving K50 as transport reimbursement for taking part in this study. This money will be given to you by the interviewer at the end of the interview.

Will it cost you anything to be in this study? It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the U.S. National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Chairperson (Dr. Soddy Munsaka), University of Zambia Biomedical Research Ethics Committee (UNZABREC) on telephone: 260-1-256067 or by email: unzarec@unza.zm.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature or Thumb Print of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature or Thumb Print of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

_____ _____

Signature or Thumb Print of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign Date

_____

Printed Name of Witness

Appendix 4: Consent for Recording

Title of Study: Preferences and Intention to Use PrEP among Pregnant and Breastfeeding Women in Zambia

UNZABREC #: 934-2020 **WITS HREC #:** M200564 MED20-02-145 **UNC IRB #:** 20-1655

Principal Investigator: Ms. Twaambo E Hamoonga
Principal Investigator Department: Public Health
Principal Investigator contact: +260 979810922; tehams24@gmail.com

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Good Day.
We would like to request your permission to audio-record the interview so that we have a record of the conversation. Your name will not be captured in the recording. The audio recording will be stored on a secured computer server that can only be accessed by members of the study team.

The recording will be transcribed by a member of our research team or an outside professional transcriber. We will destroy all recordings within five years of conducting this study. Transcripts of the interview may be reproduced in whole or in part for use in presentations or written products that result from this study. Neither your name nor any other identifying information (such as your voice) will be used in presentations or in written products resulting from this study.

Participant's Agreement:
By signing my name, I am confirming that I have given permission to be audio recorded during the interview. I also understand that this consent for recording is binding until the date when the tape will be destroyed.

_____ _____

Signature or Thumb Print of Research Participant Date

_____

Printed Name of Research Participant

Appendix 5: Distress protocol

In the event that a participant shows signs of distress or feels uncomfortable (e.g. crying, getting upset) during the interview, the following actions will need to be taken by the interviewer:

Step 1

- Suggest that they take a break, have a drink of water.
- Ask them how they are feeling, listen with empathy and offer support

Step 2

- If the participant would like to continue, explain that they can take a break from the interview at any time. Also refer participants for further support external to the study.
- If the participant would like to stop or appears highly distressed, the following actions in **Step 3** will be followed:

Step 3

- Stop the interview and for:
    - Mild distress: Encourage the participant to speak to a psychosocial counsellor for support
    - Moderate distress: Immediately inform or offer to call a family member or friend and ask them to come and collect the participant. Stay with the participant until the person contacted arrives.

Follow-up actions

- Offer to follow them up with a phone call the following day.
- Offer them the opportunity to withdraw from the study and for their data to be deleted if appropriate.
- Recommend the participant to seek external support services if they continue to feel distressed (see below link for useful contacts):
    - UNZA Counseling Centre: Next to UNZA Clinic, University of Zambia, Great east Road campus, Lusaka, Zambia. Call 0211 291 840

- Lifeline-Childline Gender Based Violence Call Centre: Plot 33 Joseph Mwila Road, Rhodespark, Lusaka, Zambia. Call 933
- Women and Law in Southern Africa – WLSA Zambia: Plot 4, G Close, off Simon Mwansa Kapwepwe road, Avondale, Lusaka, Zambia. Call 0977 450 034
- PsycHealth Zambia: Godfrey House, Corner Kabelenga and Longolongo road, Lusaka, Zambia. Call 0955 264 975

Appendix 6: **SSI guide to identify salient beliefs about PrEP use and service delivery attributes and attribute levels**

Please take a few minutes to answer the following questions.

When you think about taking oral PrEP every day during pregnancy/breastfeeding,

- What do you believe are the advantages of taking daily oral PrEP during pregnancy/breastfeeding?
- What do you believe are the disadvantages of taking daily oral PrEP during pregnancy/breastfeeding?
- Is there anything else you associate with your own views about taking daily oral PrEP during pregnancy/breastfeeding?

- Are there any individuals or groups who would approve of your taking daily oral PrEP during pregnancy/breastfeeding?
- Are there any individuals or groups who would disapprove of your taking daily oral PrEP during pregnancy/breastfeeding?
- Is there anything else you associate with other people's views about taking daily oral PrEP during pregnancy/breastfeeding?

- What factors or circumstances would enable you to take daily oral PrEP during pregnancy/breastfeeding?
- What factors or circumstances would make it difficult or impossible for you to take daily oral PrEP during pregnancy/breastfeeding?

- Are there any other issues that come to mind when you think about taking daily oral PrEP during pregnancy/breastfeeding?

If you were to take oral daily PrEP during pregnancy/breastfeeding, how best do you think PrEP should be delivered to support your use of PrEP? *probe for the following:*

a. Venue/place to collect PrEP from
b. Travel time from home to the clinic (time taken to get to the facility)
c. Waiting time in the queue before you can collect PrEP
d. Frequency of HIV tests
e. Amount of supply at each refill
f. Attitude of health care provider
g. Gender of health care provider

Nominal Group Technique: Consider the list of attributes and choose only five. Please rank the selected five attributes according to your preference from 1(most preferred) to 5 (least preferred).

Appendix 7: Survey questionnaire

Section 1: Social demographics and sexual behaviour

1. **Age at last birthday: _____**

2. **Marital status:**
    1. Single, never married
    2. Married (living with partner)
    3. Married (not living with partner)
    4. Widowed/divorced

3. **Educational attainment**
    1. No formal education
    2. Primary
    3. Secondary
    4. Tertiary

4. **Employment status**
    1. Not working
    2. Employed for wages
    3. Self employed
    4. Student
    5. Other (specify)

5. **Maternal status**
    1. Pregnant
    2. Breastfeeding

6. **If pregnant, gestational age**
    1. First trimester
    2. Second trimester
    3. Third trimester

7. **Number of sexual partners in the last 30 days:__**

8. **Condom use in the last 30 days**
    1. Never
    2. Sometimes
    3. Always

9. **Sex under the influence of alcohol in the past 30 days**
    1. Yes
    2. No

10. **Transactional sex in the past 30 days**
    1. Yes
    2. No

11. **Number of lifetime sexual partners ……**

12. **Male partner HIV status**
    1. Known
    2. No male partner
    3. Unknown

13. **Syphilis**
    1. RPR non-reactive
    2. RPR reactive

14. How do you perceive your risk for HIV infection?

1. No risk
2. Low risk
3. Moderate risk
4. High risk

15. Before this interview, were you aware of PrEP?

1. Yes
2. No

16. If yes to Q15, did you know that PrEP, when taken consistently can protect individuals from getting infected with HIV?

1. Yes
2. No

17. If yes to Q16, what was your source of this information?

1. Health facility staff
2. Mass media (TV, radio, face book, etc.)
3. Family member
4. Friends
5. Other, specify……

Section 2: Attitude, subjective norm, perceived behavioural control and intention to use PrEP

1	If I take daily oral PrEP, I will feel that I am doing something positive for myself	Unlikely	1	2	3	4	5	6	7	Likely
2	Taking daily oral PrEP would reduce my risk of HIV infection	Unlikely	1	2	3	4	5	6	7	Likely
3	If I take daily oral PrEP, it will protect me from getting infected with HIV	Unlikely	1	2	3	4	5	6	7	Likely
4	If I take daily oral PrEP, my baby will not get infected with HIV	Unlikely	1	2	3	4	5	6	7	Likely
5	The health facility where I'd have to collect PrEP from is far	Unlikely	1	2	3	4	5	6	7	Likely
6	I would have to wait for long hours at the facility in order to get PrEP	Unlikely	1	2	3	4	5	6	7	Likely
7	If I am to take PrEP, I would have to get permission from my partner	Unlikely	1	2	3	4	5	6	7	Likely
8	I would have to do regular HIV tests while on PrEP	Unlikely	1	2	3	4	5	6	7	Likely
9	Having an HIV-negative baby as a result of taking daily oral PrEP is	Extremely undesirable	-3	-2	-1	0	1	2	3	Extremely desirable
10	Reducing my risk of HIV infection by taking daily oral PrEP would be	Extremely undesirable	-3	-2	-1	0	1	2	3	Extremely desirable
11	Doing something positive for myself is	Extremely undesirable	-3	-2	-1	0	1	2	3	Extremely desirable
12	For pregnant/breastfeeding women, protecting oneself from getting infected with HIV is	Extremely undesirable	-3	-2	-1	0	1	2	3	Extremely desirable
13	People who are important to me would	discourage me to take daily oral PrEP during pregnancy/breastfeeding	-3	-2	-1	0	1	2	3	encourage
14	My partner would	disapprove of my taking daily oral PrEP during pregnancy/ breastfeeding	-3	-2	-1	0	1	2	3	approve
15	Most of my friends who are pregnant/ breastfeeding would take daily oral PrEP	would not take daily oral PrEP during pregnancy/breastfeeding	-3	-2	-1	0	1	2	3	would
16	My family members would	disapprove	-3	-2	-1	0	1	2	3	approve

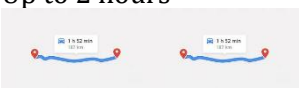
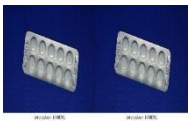
		of my taking daily oral PrEP during pregnancy/ breastfeeding								
	Overall I think that taking daily oral PrEP would be									
17		Harmful	1	2	3	4	5	6	7	Beneficial
18		Pleasant	1	2	3	4	5	6	7	Unpleasant
19		Wrong	1	2	3	4	5	6	7	The right thing to do
20		Good practice	1	2	3	4	5	6	7	Bad practice
21	Doing what most of of my friends who are pregnant/breastfeeding is important to me	Not at all	1	2	3	4	5	6	7	Extremely
22	The approval of my partner with respecting to taking daily oral PrEP is important to me	Not at all	1	2	3	4	5	6	7	Extremely
23	Doing what most people who are important to me would encourage me to do is important to me	Not at all	1	2	3	4	5	6	7	Extremely
24	My family members' approval of my taking daily oral PrEP is important to me	Not at all	1	2	3	4	5	6	7	Extremely
25	I am	Less likely to take daily oral PrEP if the health facility where to collect PrEP from is far	-3	-2	-1	0	1	2	3	More likely
26	I am	Less likely to take daily oral PrEP if I have to wait long hours at the facility	-3	-2	-1	0	1	2	3	More likely
27	I am	Less likely to take daily oral PrEP if I have to get permission from my partner	-3	-2	-1	0	1	2	3	More likely
28	I am	Less likely to take daily oral PrEP if I have to do frequent HIV tests	-3	-2	-1	0	1	2	3	More likely
29	People who are important to me would approve of my taking daily oral PrEP	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
30	I expect to take daily oral PrEP during pregnancy/breastfeeding when it is available	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
31	I would feel under social pressure to take daily oral PrEP during pregnancy/ breastfeeding	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
32	I am confident that I can take daily oral PrEP during pregnancy/breastfeeding if I want to	Strongly disagree	1	2	3	4	5	6	7	Strongly agree

33	Whether I take daily oral PrEP during pregnancy/breastfeeding would be entirely up to me	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
34	For me to take daily oral PrEP during pregnancy/breastfeeding would be	Easy	1	2	3	4	5	6	7	Difficult
35	I would want to take daily oral PrEP during pregnancy/breastfeeding	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
36	It would be expected of me that I take PrEP during pregnancy/breastfeeding	Strongly disagree	1	2	3	4	5	6	7	Strongly agree
37	I intend to take daily oral PrEP during pregnancy/breastfeeding	Strongly disagree	1	2	3	4	5	6	7	Strongly agree

Adapted from Francis et al. (2004) (85)

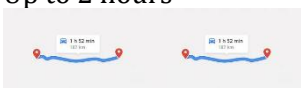
Section 3: Discrete Choice Experiment- Choice 1

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community (including home delivery) 	NONE: I wouldn't choose any of these
Travel time	Up to 1 hour 	Up to 2 hours 	
Waiting time	Up to 5 hours 	Up to 3 hours 	
Attitude	Negative attitude 	Positive attitude 	
Supply	2 months 	3 months 	
	[ ]	[ ]	[ ]

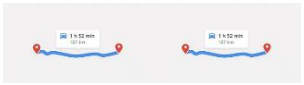
Discrete Choice Experiment: Choice 2

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community (including home delivery) 	NONE: I wouldn't choose any of these
Travel time	Up to 2 hours 	Up to 2 hours 	
Waiting time	Up to 3 hours 	Up to 5 hours 	
Attitude	Positive attitude 	Negative attitude 	
Supply	1 month 	3 months 	
	[ ]	[ ]	[ ]

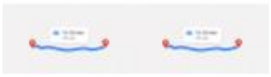
Discrete Choice Experiment: Choice 3

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Travel time	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 5 hours 	Up to 1 hour 	
Attitude	Positive attitude 	Negative attitude 	
Supply	3 months 	1 month 	
	[ ]	[ ]	[ ]

Discrete Choice Experiment: Choice 4

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Distance	Up to 1 hour 	Up to 2 hours 	
Waiting time	Up to 5 hours 	Up to 1 hour 	
Attitude	Positive attitude 	Negative attitude 	
Supply	1 month 	2 months 	
	[ ]	[ ]	[ ]

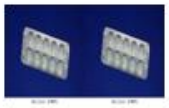
Discrete Choice Experiment: Choice 5

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Community 	Health facility 	NONE: I wouldn't choose any of these
Distance	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 1 hour 	Up to 3 hours 	
Attitude	Positive attitude 	Negative attitude 	
Supply	1 month 	3 months 	
	[ ]	[ ]	[ ]

Discrete Choice Experiment: Choice 6

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Distance	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 5 hours 	Up to 3 hours 	
Attitude	Positive attitude 	Positive attitude 	
Supply	3 months 	2 months 	
	[ ]	[ ]	[ ]

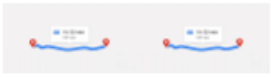
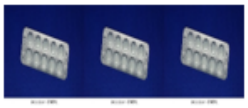
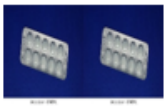
Discrete Choice Experiment: Choice 7

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Community 	Health facility 	NONE: I wouldn't choose any of these
Distance	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 3 hours 	Up to 5 hours 	
Attitude	Positive attitude 	Negative attitude 	
Supply	3 months 	2 months 	
	[ ]	[ ]	[ ]

Discrete Choice Experiment: Choice 8

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Distance	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 1 hour 	Up to 5 hours 	
Attitude	Negative attitude 	Positive attitude 	
Supply	3 months 	2 months 	
	[ ]	[ ]	[ ]

Discrete Choice Experiment: Choice 9

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Distance	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 3 hours 	Up to 1 hour 	
Attitude	Negative attitude 	Positive attitude 	
Supply	1 month 	3 months 	
	[ ]	[ ]	[ ]

Discrete Choice Experiment: Choice 10

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Distance	Up to 2 hours 	Up to 1 hour 	
Waiting time	Up to 3 hours 	Up to 1 hour 	
Attitude	Positive attitude 	Negative attitude 	
Supply	2 months 	1 month 	
	[ ]	[ ]	[ ]

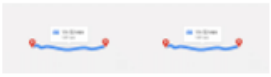
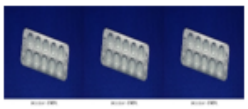
Discrete Choice Experiment: Choice 11

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Community 	Health facility 	NONE: I wouldn't choose any of these
Distance	Up to 1 hour 	Up to 2 hours 	
Waiting time	Up to 3 hours 	Up to 1 hour 	
Attitude	Negative attitude 	Positive attitude 	
Supply	3 months 	2 months 	
	[ ]	[ ]	[ ]

Discrete Choice Experiment: Choice 12

If you were offered options A and B below, which one would you choose in terms of PrEP delivery during pregnancy and breastfeeding?

	Option A	**Option B**	
Where	Health facility 	Community 	NONE: I wouldn't choose any of these
Distance	Up to 1 hour 	Up to 2 hours 	
Waiting time	Up to 1 hour 	Up to 5 hours 	
Attitude	Positive attitude 	Negative attitude 	
Supply	3 months 	1 month 	
	[ ]	[ ]	[ ]

Thank you for participating in this survey!

Appendix 8: UNC Human Research Ethics Committee Approval Letter

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Ben Chi
Obstetrics and Gynecology-Global Health

From: Office of Human Research Ethics

Date: 7/23/2020
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 20-1655

Study Title: Z 32005 - Preferences and Intention to use PrEP among Pregnant and Breastfeeding Women in Zambia

This submission, Reference ID 291314, was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (e or l) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

Purpose: To explore and describe factors associated with intention to use PrEP among HIV-negative pregnant and breastfeeding women in Zambia so as to inform the country's scale-up of future PrEP programs.

Participants: The study population will be all HIV-negative pregnant and breastfeeding women aged 18-49 years presenting at Chipata first level hospital for antenatal and postnatal care services.
Procedures (methods): The methodology for the study will be presented in two phases; a qualitative component followed by a quantitative component. The first part of the study will be formative research; the findings will inform the development of a structured questionnaire that takes into account the local context of the study population.
Through his work with the Fogarty grant awardees, Dr. Chi's role in this project is to provide mentoring and consultation for the local investigator conducting the project. Dr. Chi will not interact with participants nor see any personally identifiable data.
Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

CC:
Cheryl Hendrickson, Institute for Global Health and Infectious Diseases

Tania Hossain, Institute for Global Health and Infectious Diseases
Jennifer Wu , Obstetrics and Gynecology-Urogynecology and Reconstructive Pelvic Surgery

Appendix 9: University of Zambia Biomedical Research Ethics Committee Approval Letter

UNIVERSITY OF ZAMBIA
BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
Federal Assurance No. FWA00000338

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia
E-mail: unzarec@unza.zm
IRB00001131 of IORG0000774

4th September, 2020.

Your REF. No. 934-2020.

Ms. Euphemia Twaambo Hamoonga,
University of Zambia,
School of Public Health,
Department of Community and Family Medicine,
P.O Box 50110,
Lusaka.

Dear Ms. Hamoonga,

RE: "PREFERENCES AND INTENTION TO USE PrEP AMONG PREGNANT AND BREASTFEEDING WOMEN IN ZAMBIA" (REF. NO. 934-2020)

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 3rd September, 2020. The proposal is **approved**. The approval is based on the following documents that were submitted for review:

a) **Study proposal**
b) **Questionnaires**
c) **Participant Consent Form**

APPROVAL NUMBER : REF. 934-2020

This number should be used on all correspondence, consent forms and documents as appropriate.

- **APPROVAL DATE : 3rd September 2020**
- **TYPE OF APPROVAL : Expedited**
- **EXPIRATION DATE OF APPROVAL : 2nd September 2021**
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the UNZABREC Offices should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING**: All SAEs and any other serious challenges/problems having to do with participant welfare, participant safety and study integrity must be reported to UNZABREC within 3 working days using standard forms obtainable from UNZABREC.
- **MODIFICATIONS**: Prior UNZABREC approval using standard forms obtainable from the UNZABREC Offices is required before implementing any changes in the Protocol (including changes in the consent documents).

- **TERMINATION OF STUDY**: On termination of a study, a report must be submitted to the UNZABREC using standard forms obtainable from the UNZABREC Offices.
- **NHRA:** You are advised to obtain final study clearance and approval to conduct research in Zambia from the National Health Research Authority (NHRA) before commencing the research project.
- **QUESTIONS**: Please contact the UNZABREC on Telephone No.256067 or by e-mail on unzarec@unza.zm.
- **OTHER**: Please be reminded to send in copies of your research findings/results for our records. You're also required to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study. Use the online portal: unza.rhinno.net for further submissions.

Yours sincerely,

Munsaka.

Sody Mweetwa Munsaka, BSc., MSc., PhD
CHAIRPERSON
Tel: +260977925304
E-mail: s.munsaka@unza.zm

Appendix 10: University of the Witwatersrand HREC Approval Letter

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

09 June 2020

To Whom It May Concern

SUBJECT: **CONFIRMATION OF PROVISIONAL APPROVAL OF STUDY**

Protocol Ref No: M200564 MED20-02-145

Protocol Title: Preferences and intention to use HIV pre-exposure prophylaxis among pregnant and breastfeeding women in Zambia

Principal Investigator: Mrs Twaambo Hamoonga-Nkweendenda

Department: School of Public Health

This letter serves to confirm that the Human Research Ethics Committee (Medical) has provisionally approved the above mentioned study. In order for a clearance certificate to be issued, the researcher is required to submit written approval to conduct the study in your district/institution.

The researcher has been informed that this letter is not a clearance certificate and that the study cannot commence without your approval and receipt of a clearance certificate from the HREC (Medical).

Should you have any queries, you may contact me at tel: 011 717 1252/1234/2700/2656 or by email zanele.ndlovu@wits.ac.za;HREC-Medical.ResearchOffice@wits.ac.za

Yours Faithfully,

Ms Zanele Ndlovu
Administrative Officer
Human Research Ethics Committee (Medical)

UNIVERSITY OF THE WITWATERSRAND
OFFICE OF THE DEPUTY VICE CHANCELLOR RESEARCH
09 JUN 2020
RESEARCH OFFICE
JOHANNESBURG

Appendix 11. National Health Research Authority Approval Letter

NATIONAL HEALTH RESEARCH AUTHORITY
Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA
Tell: +260211 250309 | Email: znhrasec@gmail.com | www.nhra.org.zm

Ref No: NHRA000010/14/09/2020 **Date: 14th September, 2020**

The Principal Investigator
Ms. Euphemia Twaambo Hamoonga
University of Zambia
Department of Community and Family Health
P.O Box 50110
Lusaka, Zambia.

Dear Ms. Hamoonga,

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"PREFERENCES AND INTENTION TO USE PRE-EXPOSURE PROPHYLAXIS AMONG PREGNANT AND BREASTFEEDING WOMEN IN ZAMBIA."** I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, this study has been **approved** on condition that:

1. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
2. Progress updates are provided to NHRA quarterly from the date of commencement of the study;
3. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University leadership, and all key respondents.

Yours sincerely,

Prof. Godfrey Biemba
Director/CEO
National Health Research Authority

All correspondences should be addressed to the Director/CEO National Health Research Authority

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"*PrEP protects us*": Behavioural, normative, and control beliefs influencing pre-exposure prophylaxis uptake among pregnant and breastfeeding women in Zambia

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Background: Although pre-exposure prophylaxis (PrEP) is recommended for pregnant and breastfeeding women at elevated HIV risk, uptake has been low in Zambia.
Methods: In in-depth interviews, we explored beliefs about PrEP among 24 HIV-negative pregnant and breastfeeding Zambian women. Thematic analysis was used to identify behavioural, normative and control beliefs likely to influence PrEP uptake.
Results: Most women viewed PrEP as a good method of protecting themselves and their babies from HIV infection. Partners were cited as key referents in decision making about PrEP use. Many women felt that PrEP use was not entirely in their control. Most reported that they would not use PrEP if their partners did not approve. Health care providers with negative attitudes, long distance to clinics, and extended waiting times were cited as barriers to PrEP uptake.
Conclusion: HIV-negative pregnant and breastfeeding women had a positive attitude towards PrEP but barriers to uptake are multifaceted.

KEYWORDS

PrEP, beliefs, pregnant, breastfeeding, theory of planned behaviour, intention, Zambia, sub-Saharan Africa

Introduction

In sub-Saharan Africa, pregnancy and breastfeeding are periods of increased risk for HIV acquisition. In two meta-analyses, HIV incidence during these periods were at or above the World Health Organization's threshold for high risk (3.0 infections per 100 person-years) (1, 2). The risk of HIV acquisition during pregnancy has been attributed in part to health facility-related factors (e.g., inadequate education about HIV prevention among antenatal care (ANC) attendees (3, 4)), social and behavioral factors [e.g., low condom utilization (5–8)] and low rates of HIV status disclosure to sexual partners (9, 10). Biological, physiological and immunologic alterations also contribute to the elevated HIV risk observed in pregnant and postpartum populations (11–16).

Biomedical interventions such as pre-exposure prophylaxis (PrEP) have the potential to reduce the risk of maternal HIV acquisition (17) and may play an important role in the elimination of HIV mother-to-child-transmission. The World Health Organization (WHO) endorses the use of PrEP during pregnancy and breastfeeding for HIV-negative women who are at higher risk of HIV acquisition, depending on individual behaviour and the characteristics of sexual partners (17). This recommendation is based on PrEP's efficacy and its safety track record across numerous studies in pregnancy (18). While many national programs have introduced PrEP for pregnant and breastfeeding populations (19), there is need to identify and engage people at risk for HIV and further improve demand for PrEP (20, 21).

The Zambia Ministry of Health first introduced PrEP as a key strategy for HIV prevention in 2016 (22). In line with WHO recommendations, the country's 2020 HIV treatment and prevention guidelines extended the provision of PrEP to HIV-negative pregnant and breastfeeding women at substantial risk for HIV acquisition (23). However, to date, uptake of these services in antenatal and postnatal populations has been limited, with some studies reporting rates as low as 1% (24), despite the high rate of mother-to-child transmission (25). The increasing burden of new infant HIV infections can be traced to incident maternal HIV during pregnancy and breastfeeding (26) which may go undiagnosed and therefore untreated. Taking PrEP during pregnancy and breastfeeding has the potential to reduce the risk of maternal seroconversion and onward mother-to-child transmission of HIV. However, factors that may influence uptake of PrEP in this population largely remain unknown.

To better understand facilitators and barriers to PrEP uptake in antenatal settings, we conducted a qualitative study guided by the Theory of Planned Behaviour (TPB) framework. We applied the TPB to understand behavioural, normative and control beliefs that pregnant and breastfeeding women have about PrEP. The TPB assumes that individuals act rationally, according to their attitudes, subjective norms, and perceived behavioral control. According to this theory, in order to predict whether a person intends to engage in a health behaviour, it is important to know whether the person is in favour of doing it (attitude), how much the person feels social pressure to do it (subjective norm), and whether the person feels in control of the behaviour in question (perceived behavioural control) (27). Strategies that are able to modify these three factors can raise a woman's intention to take PrEP and, by doing so, increase the likelihood that she actually takes up the intervention (28).

Materials and methods

Study design and population

In this qualitative study, we recruited HIV-negative pregnant and breastfeeding women from Chipata Level 1 Hospital in Lusaka, Zambia. This government health facility has a catchment population of over 100,000 and an antenatal clinic that attends to about 400–450 new ANC attendees each month. The HIV prevalence among pregnant women attended to at this health facility is approximately 16%, similar to the national prevalence for women (29). Purposive sampling was used to recruit study participants from the Maternal and Child Health clinic, where they were receiving either antenatal or postnatal care services. Pregnant and breastfeeding women aged 18 years or older and with a documented HIV-negative result in their antenatal record, were eligible. We enrolled 24 participants between November 2020 and March 2021. The sample size was determined using the principle of theoretical saturation, the point where additional interviews did not add any new insights on beliefs that women held about PrEP (30).

Data collection

We used a semi-structured questionnaire which had two components: the first part which was structured was used to collect data on socio-demographic characteristics of study participants (i.e., age, educational attainment, employment status and marital status), risky sexual behaviour as well as knowledge about PrEP. The second part which took the form of an interview guide was developed based on the Theory of Planned Behaviour questionnaire (27). The Theory of Planned Behaviour questionnaire has been used in several studies focusing on health-related behaviour to predict both intention and actual behaviour (31–36). The interview guide focused on behavioural beliefs (beliefs about advantages and disadvantages of taking PrEP), normative beliefs (beliefs about how other people expect pregnant and breastfeeding women to behave with respect to whether or not to take PrEP), and control beliefs (how much control pregnant and breastfeeding women have over taking PrEP) (28). Women in our study were asked what they believed were the advantages and disadvantages of taking PrEP during pregnancy and breastfeeding; who they believed would approve or disapprove of their decision to take PrEP; and what they believed were potential facilitators and barriers to PrEP use. The interview guide also included questions aimed at exploring preferences for PrEP delivery in the target population.

The interview guide was piloted to ensure that questions were appropriately phrased and understood. Minor revisions were made based on this feedback and the revised guide was translated into two local languages (Nyanja and Bemba). SSIs were conducted by trained research assistants fluent in English, Nyanja, and Bemba. Prior to enrollment, interviewers described the study and emphasized the voluntary nature of participation. Written informed consent was obtained prior to any study activities. At the beginning of the interview, study staff described PrEP as medicine that HIV-negative people who feel that they might be at risk of acquiring HIV could take to prevent new infections. The following description was read to participants: "PrEP is the use of anti-retroviral drugs by HIV-uninfected people to protect them from getting infected with HIV. Daily oral PrEP is effective in preventing HIV infection when taken consistently." Interviews were conducted in English and local languages (Nyanja, and

Bemba), based on the participant's preference. All interviews were audio-recorded, and later transcribed and translated to English.

Data analysis

Thematic analysis (37, 38), was used to identify beliefs and preferences that may influence PrEP uptake in antenatal and postnatal settings. Two study team members developed independent codebooks; differences were resolved through consensus and consolidated into a final version. Prior to data coding, we engaged in an iterative process of reading transcripts, which was accompanied by memoing, to identify common and unique content from the transcripts. This process was followed by categorizing content from each transcript under the sub-themes that were identified and later the broad themes (Theory of Planned Behavior constructs) based on the final codebook that was developed. Codes relating to advantages and disadvantages of using PrEP were categorized under attitude towards PrEP while codes relating to people who would approve or disapprove of the women's decision to use PrEP were categorized under subjective norm. Control beliefs comprised codes relating to presence of factors that would make it easy or difficult for women to use PrEP during pregnancy or breastfeeding. We also had several codes representing preferences for PrEP delivery during pregnancy and breastfeeding. Data were summarized using a framework matrix. The main themes and sub-themes are presented in Table 1. We used NVIVO v.12 (QSR International, Burlington, MA, USA) for data management and analysis.

Ethical approval

The study received approval from the University of Zambia Biomedical Research Ethics Committee (Lusaka, Zambia) and the Human Research Ethics Committee at the University of the Witwatersrand (Johannesburg, South Africa). Additional approvals were obtained from the Zambia National Health Research Authority and the Lusaka District Medical Office prior to study activation.

Results

We conducted in-depth interviews with 24 HIV-negative pregnant and breastfeeding women. Baseline characteristics of study participants are presented in Table 1. Fifty percent of the women were aged below 24 years (IQR: 22–30 years) and the majority were married and living with their partners (18 of 24). Few women perceived themselves to be at high risk for HIV infection, the majority knew their partner's HIV status.

TABLE 1 Respondent characteristics: HIV-negative pregnant and breastfeeding women ($N = 24$).

Characteristic	*n* (%)
Age in years, median (IQR)	24 (22–30)
Length of interview in minutes, median (range)	14 (8–43)
Marital status	
Never been married before	5 (21)
Married (living with partner)	18 (75)
Married (not living with partner)	1 (4)
Educational attainment	
Primary	7 (29)
Secondary	17 (71)
Employment	
Not working	17 (71)
Working for wages	1 (4)
Self employed	6 (25)
Maternal status	
Pregnant	13 (54)
Breastfeeding	11 (46)
Condom use in the last 30 days	
Never	18 (75)
Sometimes	6 (25)
Transactional sex in the last 30 days	
Yes	2 (8)
No	22 (92)
Partner HIV status	
Known	21 (88)
Unknown	3 (12)
Perceived HIV risk	
No risk	3 (13)
Low risk	13 (54)
Moderate risk	6 (25)
High risk	2 (8)
PrEP awareness before interview	
Yes	10 (42)
No	14 (58)

Beliefs about PrEP

Most women (14 of 24) did not know about PrEP prior to the interview. Among the few that reported having knowledge about PrEP, some mistook PrEP for post-exposure prophylaxis while others described PrEP as treatment for sexually transmitted diseases. Beliefs that women held about PrEP were categorized into three broad themes based on the Theory of Planned Behaviour framework: (1) behavioural beliefs; (2) normative beliefs, and (3) control beliefs. We also asked specific questions about service delivery preferences for PrEP. Because these are related to control beliefs, these perspectives were included in that latter section. Table 2 is a summary of the broad and sub-themes from the interviews.

Behavioural beliefs about PrEP

Participants were asked what they thought were the advantages and disadvantages of taking oral PrEP every day during pregnancy and breastfeeding. The women expressed both positive and negative views. After learning about PrEP from the interviewer, participants felt that PrEP was good for them and their babies as it had the potential to protect them from acquiring HIV.

TABLE 2 Main themes and sub-themes from the study.

Behavioral beliefs	**Advantages of taking PrEP** • Protects pregnant/ breastfeeding woman from contracting HIV • Protects the baby from contracting HIV **Disadvantages of taking PrEP** • Concerns about side effects to the woman • Concerns about side effects to the baby • Pill burden • Stigma/labelling from family, friends and community members	*"I would want to protect myself, and my baby as well, so that we do not contract HIV…. as you know…you can't just be trusting him just because you live with him… it's important to just drink the medicine so that you protect yourself." (Participant 007).* *"I think I can be scared of taking this medication in the sense that I can be taking it [PrEP] without being sick and yet experiencing side effects like weight gain and so on. This can discourage me from taking this medication…" (Married, pregnant).*
Normative beliefs	**People who would approve or disapprove** • Partner • Other family members **What other people would think** • Stigma associated with HIV status • Promiscuity	*"My grandmother can disapprove, even my parents, like my mother… she would say no, you should just be using protection [condoms], things like that (Single, pregnant).* *"…my husband can disapprove. He can think that I can be sleeping around since I know that I won't get sick because of taking PrEP. This would make it difficult for me to take PrEP." (Married, breastfeeding).*
Control beliefs and preferences for PrEP service delivery	**Facilitators and Barriers to PrEP use** • Support from family and the community • Community awareness of PrE **Preferences for PrEP delivery** • Attitude of health care providers • Venue for collecting PrEP • Distance to the facility • Waiting time in the queue • Gender of health worker giving PrEP	*"There is too much stigma! If I tell my friend that I am taking this medication, she will go round telling people that I am sick [HIV positive]. This is what happens in our communities…the community does not support in any way." (Married, breastfeeding).* *"Their attitude should be good; it just has to be good! Otherwise I would stop coming to collect PrEP if I found rude health care providers." (Married, pregnant).* *"Any [whether male or female] is okay with me, as long as they have a good attitude." (Participant 007).*

> *"What I feel is the advantage of taking PrEP is that, PrEP protects us. It is good in the sense that one cannot easily be infected with HIV/AIDS. For example, my husband can have sex with another woman who may be HIV positive but when he sleeps with me, I may not be infected because PrEP will protect me from getting sick. So I feel oral PREP is good." (Married, breastfeeding).*

In addition, lack of trust for the partner was seen as a motivating factor to initiate PrEP during pregnancy and breastfeeding as a way of ensuring that they remained HIV-negative. According to some participants, trusting anyone, including one's own husband was a difficult thing to do. They argued that it was impossible for a woman to know all the whereabouts of her partner, adding that men would engage in multiple sexual relationships and in some instances, they would not even disclose to their spouses that they are on antiretroviral therapy. Women were of the view that, in such circumstances, PrEP could protect them from HIV infection if they had an unfaithful partner or had sex with someone who was HIV positive.

> *"… it is so hard to trust someone these days. It is also hard to trust your own husband. This world is cruel, you can find that your husband is on ARVs [HIV treatment] and you do not know about it. So it is better for me to be taking PrEP in order to protect myself from contracting HIV/AIDS… taking PrEP can protect me from contracting HIV/AIDS." (Married, pregnant).*

Despite the positive impressions about PrEP in general, some women raised concerns about its use during pregnancy or breastfeeding. Fear of side effects, pill burden, and forgetfulness were some of the major issues that were seen as disadvantages of taking PrEP during pregnancy and breastfeeding. Women reported that they were given several other medications during pregnancy (e.g., iron supplements) and that adding more medications could be burdensome. They also reported that they did not want to deal with the side effects of PrEP.

> *"I think I can be scared of taking this medication in the sense that I can be taking it [PrEP] without being sick and yet experiencing side effects like weight gain and so on. This can discourage me from taking this medication because I wouldn't want to experience side effects when I know that I am not sick." (Married, pregnant).*

> *"I think I have some reservations because I fear that my baby can be born prematurely because of taking PrEP." (Single, pregnant)*

Other women did not view PrEP negatively in itself. The disadvantage they reported was linked to how others might view women who take PrEP when they are not sick [HIV-negative]

> *I have not seen any disadvantage of taking PrEP. The only problem is with people who may end up laughing at you that you are taking medication yet you are not sick. This can discourage someone from taking PrEP (Participant 02).*

Normative beliefs about PrEP use

We asked women to tell us about who they thought would approve and/or disapprove of their decision to take PrEP during pregnancy. Community and family members, especially male partners, were often cited. Stigma and being labeled to be on ART seemed to be a major concern that would hinder uptake of PrEP by pregnant and breastfeeding women.

> *"There is too much stigmatization in the community. If I tell my friend that I am taking this medication, she will go round telling people that I am sick [HIV positive] and that is why am taking the medication when in the actual sense, I am protecting myself. This is what happens in our communities, we are used. The community does not support in any way." (Married, breastfeeding).*

Women also felt that people in their communities did not know much about PrEP, and that most community members would mistake PrEP for HIV treatment. The alleged lack of knowledge and stigma were seen as factors that would lead to pregnant and breastfeeding women being labeled as being HIV-positive once seen taking PrEP.

> *"Sometimes you can decide to share with your friends about the medicine you are drinking [PrEP], they can think that you are taking ARVs [HIV treatment] and not PrEP, as you know knowledge levels are different among people in the community. There are people who are educated and those that are not educated and wouldn't understand how PrEP works. They would say that PrEP is just the same as ARVs [HIV treatment] and that the difference is just the colour [of the pills]." (Married, pregnant).*

Other participants viewed PrEP as something that would promote promiscuity among women. They argued that the mere knowledge that PrEP would protect one from contracting HIV would make women engage in risky behaviour including having multiple sexual partners.

> *"I think people can take advantage of the fact that PrEP protects them from contracting HIV/AIDS. They can start misbehaving because they know that they will not get sick. This is the disadvantage I can think of." (Married, breastfeeding).*

Control beliefs about PrEP use

Pregnant and breastfeeding women were asked to describe circumstances that would make it easy and those that would make it difficult for them to take PrEP. For most women, whether or not to take PrEP would depend on approval from family members, including their male partners. In most cases, approval and support from their partners was seen as an important consideration when deciding to take PrEP. Women viewed the lack of support or approval from family members as a possible barrier to taking PrEP during pregnancy and breastfeeding.

> *"I think my husband can make it difficult for me to take this PrEP. It can be difficult in that I do not take any pills. He may ask why I am taking PrEP because he knows I do not take any pills and he also knows that I use the injection as my contraceptive…he would wonder why I am taking this medication. He may also seek advice from his family and friends who could end up misleading him by making him believe that I am taking ARVs [HIV treatment]and not PrEP." (Married, breastfeeding).*

Some of the women stated that they would not take PrEP if their partners did not first approve.

> *"…my husband can disapprove. He can think that I can be sleeping around since I know that I won"t get sick because of taking PrEP. I will need to explain to him the benefits of taking PrEP and if he is to understand then I can go ahead… but I would not drink it if he were to disapprove." (Married, pregnant).*

Although all acknowledged the important role of the partner, some women felt that they would still go ahead and take PrEP even without the support of their spouses. The final decision as to whether or not to take PrEP during pregnancy and breastfeeding was entirely up to them.

> *"I think my husband can disapprove…. I can listen to him but that does not mean that I have to follow everything that he tells me to do. If at all I have decided to take the medication on my own, then he will have no right to stop me from taking it." (Married, pregnant).*

Daily dosing was also reported as a potential barrier to PrEP uptake. Women likened the idea of taking PrEP to taking oral contraceptives. They argued that there was no guarantee that they would remember to take PrEP on a daily basis when they were already having challenges taking oral contraceptives consistently during non-pregnant intervals. Some women were of the view that perhaps taking PrEP in form of injections would make it easier for them to use PrEP.

> *"I think the issue of taking it [PrEP] daily is a problem because I can forget. It would be better if at all the medication was in form of an injection for 3 or 5 months. Taking tablets on a daily basis is dangerous because a person can forget to take it sometimes. We sometimes forget to take family planning pills, what would make us not to forget to take PrEP?" (Married, breastfeeding).*

A few women made reference to structural factors when asked about barriers to PrEP use. Despite reporting that long distances and lack of transport money to the facility would make it difficult for them to take PrEP, most of the women felt that this would not stop them from using PrEP.

> *"The distance does not matter as long as you know the importance of taking this medication. I can give an example of the people who are on ARVs [HIV treatment], they move for long distances in order for them to access ARVs. They even keep transport money or look for transport money in order for them to collect their medication. (Married, pregnant).*

Preferences for PrEP delivery

Women were asked about health systems-related factors that could make it easy or difficult for them to use PrEP during pregnancy and breastfeeding. They described the attitude of health care providers as having the potential to either promote or hinder uptake of PrEP during pregnancy and breastfeeding. Women felt that health care providers needed to be polite, kind, patient, good-hearted and maintain confidentiality. They reported that a good attitude would encourage women to use PrEP. A bad attitude, on the other hand, could lead to discouragement for starting and maintaining PrEP.

> *"Some nurses are rude and when they are talking, you are able to tell that they are rude. They should be kind to us because sometimes, you can get upset and some of us are emotional. They should be good and polite to us, because if they continue being rude, people can be discouraged from taking PrEP because it is like we are forcing them to do what they do not want to do." (Married, breastfeeding).*

Women were asked whether the gender of the health care provider dispensing PrEP mattered when it came to influencing uptake of PrEP during pregnancy and breastfeeding. For most women, gender did not seem to be an issue with respect to PrEP uptake. However, among those who had a preference for a specific gender, choices were based on different factors, including attitude and ability to relate to their experiences; some felt that female health care providers were more understanding compared to males.

> *"They should be female because I am not comfortable with male health care providers…, I would feel shy when talking to a male health care provider. I can easily answer any question that a female nurse will ask me, but for a male nurse, I may not be free to answer accordingly." (Married, breastfeeding).*

We asked women whether waiting time at the health facility would be a source of concern when it came to using PrEP during pregnancy and breastfeeding. The majority of them reported that they would not want to be in the queue for a long time. The amount of time that women would be willing to wait at the facility in order to get PrEP ranged from 5 min to about 4 h. Most viewed waiting time as being dependent on how early one arrived at the facility and how many people they found already waiting in the queue. They also reported that waiting at the facility was something that they were used to doing and that it was normal practice to do so.

> *"Queues will always be there; it all depends on how fast the queue is moving. If one does not want to spend too much time in the queue, then they have to come [to the facility] early." (Married, pregnant).*

Women preferred a health facility close to where they lived as this would make it easier for them to get to the facility to access PrEP. The amount of time they were willing to spend en route to the facility dispensing PrEP ranged from 15 min to 2 h. Although women preferred a facility that was closer to their homes, they reported that even if the facility was far, they would still make an effort to overcome this barrier in order to get PrEP. All women reported that they wanted to get PrEP from a health facility, either a clinic or hospital. When asked whether they would want PrEP to be delivered to their homes, women had differing views. Home delivery of PrEP would address the challenges associated with transportation to and from the health facility. It would also provide a positive opportunity for other community members to learn about PrEP.

> *"I think it would be good if they delivered the medicine at my home. Home is actually better because other people can also get to learn about PrEP." (Married, breastfeeding).*

For other women, getting PrEP from the clinic was viewed negatively, as it would lead to discrimination and stigma. They expressed concern that queueing up for PrEP at the facility would make other people think that the women were actually on ART. For some women, getting PrEP from other facilities where people did not know them was seen as a better option.

> *"If we collect from the clinic, isn"t it that we are supposed to be in a queue and other people who see us may think that we are sick or that we are getting ARVs [ART]? It is even better to collect from a clinic where people do not know you. People have a tendency of concluding." (Married, breastfeeding).*

Summary of findings

In summary, we find that HIV-negative pregnant and breastfeeding women have positive attitudes towards PrEP use as a way of protecting themselves and their babies from HIV infection. Partners were cited as key referents when it comes to decision making on health-related matters and that their approval was critical if women were to use PrEP during pregnancy and breastfeeding. Women also believed that location for PrEP pick-up, attitude of health care providers, waiting time and distance to the facility may influence their decision to take PrEP during pregnancy and breastfeeding. These findings are mapped to the Theory of Planned Behavior conceptual model in **Figure 1**.

Discussion

Women's perceptions about PrEP, particularly as they relate to the health of their children, have the potential to promote or hinder uptake during pregnancy and breastfeeding (39). Several of our key findings, particularly on women's behavioural beliefs and knowledge about PrEP echo results from other qualitative studies (7, 40), including one conducted by team members in Zambia

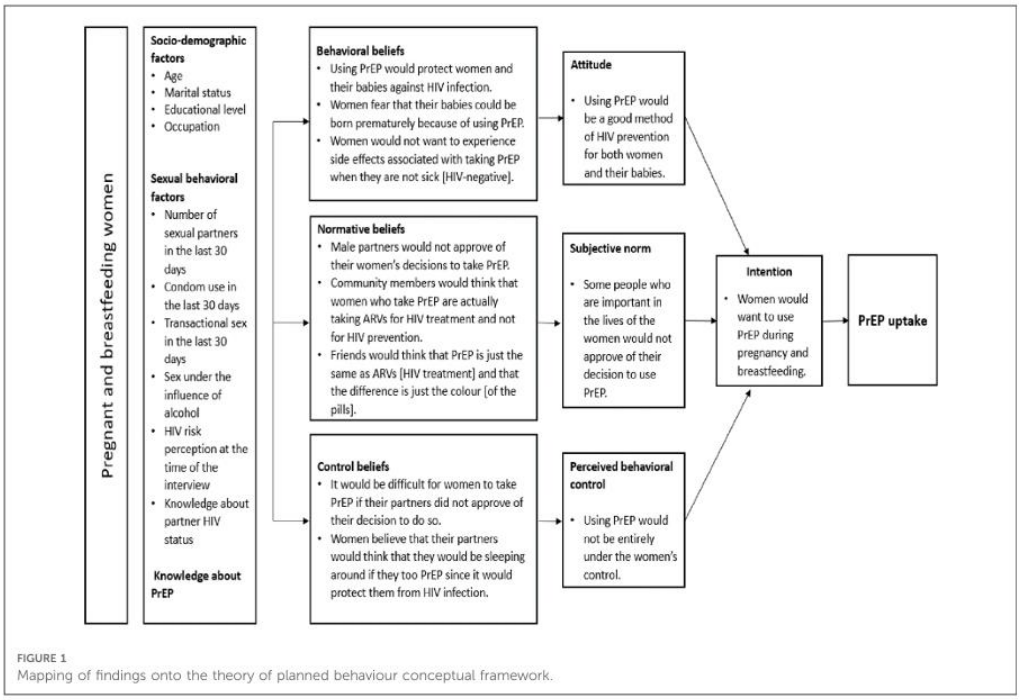


FIGURE 1
Mapping of findings onto the theory of planned behaviour conceptual framework.

and Malawi in 2017–2018 (41). Interestingly, despite the time that elapsed, many of the concerns remain the same, suggesting that more work is needed in outreach and education among prospective PrEP users.

Although women generally viewed PrEP as a good method to protect themselves and their infants from HIV infection, some participants expressed concerns that the availability of PrEP would encourage other women to engage in risky sexual behaviour. Health care providers in Kenya reported that PrEP users were sometimes confused, even frustrated, with their insistence on using condoms in addition to PrEP (40). Similar fears around the potential for PrEP to reduce condom use were reported in Eswatini (42). Davey et al. also noted that the perceptions that PrEP would lead to more risk or more condom-less sex was a potential barrier to uptake and adherence (39).

Stigma and misinformation are often cited as barriers to PrEP use (43). From our results, women feared that, if they took PrEP, people would label them as being HIV-positive and not being truthful about their HIV status. They attributed this to inadequate knowledge about PrEP in their communities. In a similar study conducted in Uganda, South Africa and Zimbabwe, participants mentioned that they would refrain from taking PrEP because of its association with antiretroviral drugs and HIV-related stigma. This was a key barrier to uptake as participants linked taking daily tablets to people living with HIV (44). HIV-related stigma is common in Zambia (45, 46) and could negatively impact PrEP uptake, adherence, and retention in care at a time when women need it the most to ensure that their infants and themselves stay HIV-negative. Deliberate efforts aimed at developing community-based education programs with a focus on demystifying PrEP may have a significant impact on PrEP uptake among HIV-negative pregnant and breastfeeding women.

The level of male partner support may influence women's decision to take PrEP during pregnancy and breastfeeding. Evidence suggests that men are generally viewed as head of house and ultimate decision makers who are actively involved in health-related decision-making during pregnancy and breastfeeding (47, 48). Our study found that women had divergent views about who would approve of their decision to take PrEP during pregnancy and breastfeeding. The key referents, however, were mostly women's partners. Similar findings have been reported in similar settings. In a study that contextualized male roles and participation in PMTCT programs in Malawi and Zambia, for instance, both men and women reported that they had to consult and seek approval from their partners on decisions that related to their health (47). Other studies also reported that men were the primary advisors and key decision-makers on health-related decisions during pregnancy and breastfeeding (41, 49, 50).

From our findings, male partners may, to a greater extent, determine actual uptake of PrEP by women during pregnancy

and breastfeeding. Similar findings were reported elsewhere (50). Such gender-based power differentials, specifically the lack of autonomy among women to make decisions concerning their health may present a barrier to PrEP uptake during pregnancy and breastfeeding. Male involvement in promoting PrEP uptake among pregnant and breastfeeding women could increase the use of PrEP in this target population. In some circumstances, such engagement may be challenging and this should be recognized. Programs should offer these women additional support for HIV prevention, whether through PrEP or other proven modalities.

Participants in our study expressed concern about the gender of health care providers. Interestingly, however, gender was rarely discussed in isolation, but rather with reference to the attitude of health care providers. Women who preferred to be attended to by male health care providers viewed female health care providers negatively. This finding is supported by prior research where respondents complained about the poor attitude of health care providers, especially female nurses being disrespectful, rude and using abusive words (48). Participants in our study reported that health care providers who had a bad attitude would make it difficult for women to use PrEP during pregnancy and breastfeeding. Some women felt that they would not use PrEP if the health care providers dispensing PrEP were rude to them. Our findings on the impact of health care provider attitude on PrEP uptake are consistent with other studies (44).

Distance and waiting time are structural factors that may have a negative impact on PrEP uptake and retention in care. Women in our study reported that having a health facility nearer to where they lived would make it easier for them to take PrEP. A study in Uganda also found that walking time to the clinic of thirty minutes or greater was associated with decreased odds of uptake of PrEP (51). Although distance was cited as a barrier in our current study, it is possible that its effect on PrEP uptake could be indirect as women may have taken into consideration the transport-related costs of remaining in PrEP care if they decided to initiate PrEP in the future. Waiting time in the queue was also cited as a potential barrier to PrEP uptake. Women did not want to wait for a long time at the facility in order to collect PrEP. Similar to our findings, a study conducted in Botswana, Tanzania and Uganda reported that lost wages due to waiting time was a barrier to adherence among individuals on antiretroviral therapy (52). These findings are corroborated by those from a recent study conducted by our team (36).

Strengths and limitations

The main strength of this study is our use of an established theoretical framework to determine potential barriers and facilitators to PrEP use in pregnant and breastfeeding women. The perspectives shared are specific to this population, providing important insights during an important period in women's lives. At the same time, we also recognize some limitations. First, this study focused on individual-level cognitions and did not explore other unconscious influences that could potentially account for variances in PrEP uptake behavior. However, evidence suggests that interventions resulting in large changes in intention are likely to also change behavior (53). Second, our results are a mix of beliefs held by women who were and those who were not knowledgeable about PrEP prior to study participation. Responses of the latter could be prone to social desirability bias. Third, we enrolled only pregnant and breastfeeding women in our study. While this was viewed as a strength overall, we acknowledge our limited ability to compare these responses to those of other women outside of this window. Further, it is possible that some participants' responses may not have specifically focused on PrEP use during pregnancy and breastfeeding intervals, owing to their limited awareness about PrEP prior to the interviews and lack of experience using PrEP. Nevertheless, their perspectives still offer useful insights on beliefs likely to influence PrEP uptake in antenatal and postnatal settings. Exploring and documenting the lived experiences of women who have used PrEP during pregnancy and breastfeeding could enhance our understanding of facilitators and barriers to PrEP uptake and onward adherence and retention in care in this population. This represents a gap for further research. Fourth, the study was based at a single facility and, therefore, our results may not be generalized to the larger antenatal and postnatal populations in Zambia—or in the sub-Saharan African region. As with all qualitative studies, we instead focus on the depth of participant beliefs and preferences to inform future PrEP implementation in antenatal settings. Fifth, PrEP was not readily accessible at the study site at the time this study was implemented. The hypothetical nature of PrEP in the study only provided partial understanding of facilitators and barriers to PrEP uptake as the views of women interviewed may differ from those of women who have experience taking PrEP during pregnancy and breastfeeding. Nevertheless, the positive attitude towards PrEP use among participants was reassuring and provides an avenue to promote uptake of PrEP during pregnancy and breastfeeding.

Conclusion

Our study suggests that HIV-negative pregnant and breastfeeding women have positive attitudes towards PrEP but barriers to PrEP uptake are multifaceted. To ensure that PrEP implementation in antenatal settings is successful, there is need to address the inadequate knowledge about PrEP among pregnant and breastfeeding women—and the broader community as well. Interventions that promote male involvement in female-initiated methods for HIV prevention may result in improved knowledge and a more supportive attitude among men towards women who wish to use PrEP during pregnancy and breastfeeding. Addressing contextual barriers—including distance, waiting time at the facility, and health care provider attitude—could have a significant impact on PrEP uptake. Above all, exploring the lived experiences of pregnant and breastfeeding women who have used PrEP before would be critical to the design of effective PrEP implementation strategies in this population in need.

Data availability statement

The datasets presented in this article are not readily available because the qualitative nature of these data make it difficult for us to share them publicly, mainly owing to the potential for identification. However data will be made available through the University of Zambia, School of Public Health (deansoph@unza.zm) for researchers who meet the criteria for access to confidential data. Requests to access the datasets should be directed to Dean-School of Public Health, deansoph@unza.zm.

Ethics statement

The studies involving human participants were reviewed and approved by The University of Zambia Biomedical Research Ethics Committee (UNZABREC #: 934-2020) and the Human Research Ethics Committee at the University of the Witwatersrand (Wits HREC #: M200564 MED20-02-145. The patients/participants provided their written informed consent to participate in this study.

Author contributions

TEH, BHC, JI and WM conceptualized the study and TEH analysed the data. TEH wrote the first draft of the manuscript. All authors contributed to the interpretation of results, reviewed the manuscript and approved the final version.

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Conflict of interest

LMH reports receiving research funding from Gilead Sciences. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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RESEARCH ARTICLE

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Salient beliefs and intention to use pre-exposure prophylaxis among pregnant and breastfeeding women in Zambia: Application of the Theory of Planned Behaviour

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ABSTRACT

Primary HIV prevention is a priority for pregnant and breastfeeding women in sub-Saharan Africa; however, such services should be designed to optimise uptake and continuation. Between September and December 2021, we enrolled 389 women who were not living with HIV into a cross-sectional study from antenatal/postnatal settings at Chipata Level 1 Hospital. We used the Theory of Planned Behaviour to study the relationship between salient beliefs and intention to use pre-exposure prophylaxis (PrEP) among eligible pregnant and breastfeeding women. On a seven-point scale, participants had positive attitudes towards PrEP (mean = 6.65, SD = 0.71), anticipated approval of PrEP use from significant others (mean = 6.09, SD = 1.51), felt confident that they could take PrEP if they desired (mean = 6.52, SD = 1.09) and had favourable intentions to use PrEP (mean = 6.01, SD = 1.36). Attitude, subjective norms, and perceived behavioural control significantly predicted intention to use PrEP respectively ($\beta = 0.24$; $\beta = 0.55$; $\beta = 0.22$, all $p < 0.01$). Social cognitive interventions are needed to promote social norms supportive of PrEP use during pregnancy and breastfeeding.

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Introduction

Pregnant and breastfeeding women in sub-Saharan Africa remain at high risk for HIV infection (Drake et al., 2014; Graybill et al., 2020). In 2018 alone, an estimated 140,000 women in sub-Saharan Africa acquired HIV infection while pregnant or breastfeeding (UNAIDS, 2019). Biological, physiological and immunologic alterations that pregnant women experience further contribute to the elevated HIV risk observed during this period (J. Kinuthia et al., 2015; MacIntyre et al., 2015; Masson et al., 2015; Morrison et al., 2014; Sappenfield et al., 2013). This population is also of particular interest because incident maternal HIV infection during pregnancy poses an increased risk for mother-to-child transmission (MTCT) (De Schacht et al., 2014; Drake et al., 2014). Mothers who are acutely infected with HIV are twice as likely to transmit HIV to their children compared to their counterparts with chronic infection (Dunn et al., 1992). In Zambia, maternal seroconversion

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during late pregnancy and breastfeeding contributes significantly to the paediatric HIV burden (Johnson et al., 2012), accounting for about 13% of child infections (UNAIDS, 2021). Unfortunately, for most pregnant and breastfeeding women, HIV prevention has emphasised condom use, counselling, and education (Homsy et al., 2019; Villar-Loubet et al., 2013). Until recently, access to biomedical interventions has been limited.

PrEP is effective in preventing HIV infection to pregnant and breastfeeding women and could thus contribute towards the prevention of mother-to-child HIV transmission (PMTCT). In accordance with the World Health Organization guidelines recommending offering PrEP to at-risk populations (WHO, 2016), the 2020 Zambia HIV prevention guidelines extended the provision of PrEP to pregnant and breastfeeding women at risk for HIV infection (MOH, 2020). Despite these recommendations and several health benefits of PrEP at the individual and population level, both knowledge and uptake of PrEP among pregnant and breastfeeding women still remain low (Zimba et al., 2019). Unfortunately, there is paucity of knowledge about factors likely to influence uptake in the target population.

Qualitative studies that have explored reasons for low uptake of PrEP among young African women indicated the need for social support from their partners and significant others, and reported fear of their partners reactions about product use (van der Straten, Stadler, Montgomery, et al., 2014). Women also reported concealing use of PrEP and even hiding it for fear of being mistaken to be HIV positive (van der Straten, Stadler, Luecke, et al., 2014). PrEP studies conducted among pregnant and breastfeeding women in sub-Saharan Africa have mainly been integrated within demonstration projects and have been qualitative in nature, with recent studies focusing on how best to integrate PrEP in antenatal settings Most were conducted in Kenya and South Africa (Joseph Davey et al., 2021; Joseph Davey et al., 2022; John Kinuthia et al., 2020), and none of them have determined salient beliefs and their relative importance in influencing pregnant and breastfeeding women's intention to use PrEP. This research gap is even more evident in Zambia where there is limited literature on facilitators and barriers to PrEP uptake in antenatal settings. Determining modifiable antecedents of PrEP uptake, such as beliefs about PrEP and how these influence pregnant and breastfeeding women's intentions to use it may provide useful information that could inform interventions aimed at improving demand for PrEP in the target population.

Overcoming the social and structural barriers to universal access to combination HIV prevention services such as PrEP, requires an understanding of modifiable social cognitive antecedents of the target health behaviour (in this case, PrEP uptake). The Theory of Planned Behaviour (TPB) is a useful framework in understanding such relationships. According to this theory, behaviour is seen as a product of positive, pro-behaviour intentions. These intentions are in turn determined by attitudes toward using PrEP, subjective norms surrounding PrEP use, and perceived behavioural control (the perceived ease or difficulty of taking PrEP) (Ajzen, 1991). Intention can be used as a proximal determinant of behaviour (Francis et al., 2004). In the context of low PrEP uptake, understanding beliefs influencing intention could provide useful information on target behaviours that could influence actual PrEP uptake. The TPB has been used in several health related studies to predict both intention and actual behaviour such as cervical cancer screening (Abamecha et al., 2019), HIV testing (Mirkuzie et al., 2011), human papillomavirus vaccine uptake (Gerend & Shepherd, 2012), condom use (Asare, 2015; Teye-Kwadjo et al., 2017), and PMTCT (Igumbor et al., 2006). We applied the TPB to determine salient beliefs (attitude, subjective norm, perceived behavioural control) and their association with intention to use PrEP among pregnant and breastfeeding women not living with HIV in Zambia.

Methodology

Study design and setting

We conducted a cross-sectional quantitative study to determine women's attitudes, subjective norms, and perceived behavioural control, and how these theorised constructs influence intention

to use PrEP during pregnancy and breastfeeding. This study was conducted at the maternal and child health clinic in Chipata Level 1 Hospital (Lusaka, Zambia). The site was purposively selected based on the volume of pregnant women seen at the facility. Each month, it averages 400–450 new antenatal patients and 900–1000 return antenatal visits.

Study population and procedures

We recruited study participants using convenience sampling. We recruited pregnant and breastfeeding women aged 18 years or older with a documented HIV-negative result in their antenatal record. This study was part of a larger discrete choice experiment (DCE) whose aim was to determine preferences for PrEP delivery among pregnant and breastfeeding women not living with HIV and its sample size (n = 392) was based on those analyses. In this study, we did not offer PrEP to participants as part of the study procedures. However, it was available at the health facility where the study was conducted. Women who reported that they would like to use PrEP for HIV prevention were referred to the maternal and child health clinic within the hospital to discuss their interest to use PrEP with the health care providers.

Study personnel described the study and obtained written informed consent from eligible participants. The questionnaire was translated to Nyanja and Bemba (local languages commonly spoken in the study area) and then back translated to English for validation. It was further pre-tested to evaluate feasibility and clarity of questions. The questionnaire was administered to the women using face-to-face interviews in a private place within the hospital premises.

Measurement

The first part of the questionnaire included questions on the women's sociodemographic and obstetric characteristics, PrEP-related knowledge, engagement in risky sexual behaviour as well as HIV risk perception. The second part of the questionnaire collected information pertaining to the women's beliefs about PrEP use during pregnancy and breastfeeding. To do this, we selected an existing 37-item survey based on the TPB (Francis et al., 2004) and used it to guide the phrasing of questions for our questionnaire. Since the TPB questionnaire has not been validated in the Zambian context, we conducted a separate elicitation study (n = 24) in order to inform the development of PrEP-specific questions that would comprehensively capture beliefs likely to influence pregnant and breastfeeding women's intention to use PrEP, in Zambia. In this formative work, we asked women questions about the most frequently perceived advantages and disadvantages of taking PrEP; the most important people or groups of people who would approve or disapprove of using PrEP; and the perceived barriers or facilitating factors which could make it easier or more difficult to use PrEP during pregnancy and breastfeeding. This information was used to develop items that we used in the current study to measure attitudes towards PrEP, subjective norms about PrEP and perceived behavioural control of PrEP, respectively. This process was informed by the TPB framework. We used the Chronbach's alpha as a measure of internal consistency reliability to select the final items that were used to measure each of the TPB constructs.

The dependent variable, intention to use PrEP, was measured using a 3-item scale which was: 'I intend to take PrEP during pregnancy and breastfeeding'; 'I expect to take PrEP during pregnancy and breastfeeding'; 'I want to take PrEP during pregnancy and breastfeeding' ($\alpha = 0.80$). Participants responded to each item on a 7-point Likert scale with responses ranging from strongly disagree (1) to strongly agree (7). A composite score for intention was obtained by getting the mean of the three items. The independent variables were attitudes towards PrEP, subjective norms about PrEP and perceived behavioural control of PrEP use. The scale measuring attitudes towards PrEP included four items: 'Overall, I think that taking daily oral PrEP would be: harmful (1) to beneficial (7)'; 'Overall, I think that taking daily oral PrEP would be not helpful (1) to helpful (7)'; 'Overall, I think that taking daily oral PrEP would be bad (1) to good (7)'; 'Overall, I think that

taking daily oral PrEP would be wrong (1) to right (7)' ($\alpha = 0.78$). A composite score for attitude towards PrEP was obtained by calculating the mean of the four items.

The subjective norms were measured with the following item: 'It would be expected of me to take daily oral PrEP during pregnancy and breastfeeding'. The perceived behavioural control scale was measured with the following single item: 'I am confident that I could take daily oral PrEP during pregnancy/breastfeeding if I wanted to'. Responses for both subjective norms and perceived behavioural control ranged from strongly disagree (1) to strongly agree (7). For all of the measures (attitudes, subjective norms, perceived behavioural control and intention), higher scores indicate more favourable attitudinal beliefs, greater perceived normative influence, greater perceived efficacy/controllability and more favourable intentions towards PrEP use.

Data analysis

We used descriptive statistics (frequencies and proportions) to describe background characteristics (socio-demographics, sexual behaviour and knowledge about PrEP) of study participants. Means and standard deviations were used to summarise the TPB constructs. Pearson Product Moment Correlation (r) was used to determine the correlation between intention to use PrEP and the three TPB predictor variables. We used simple linear regression to obtain unadjusted estimates for the association between intention to use PrEP and each of the TPB predictor variables, stratified by maternal status. Next, we used multivariable linear regression analysis using robust standard errors to obtain adjusted estimates of the association between intention to use PrEP and the predictor variables, including maternal status (pregnant or breastfeeding), while adjusting for other significant background characteristics (age, education, marital status and employment status). Associations were considered statistically significant at $p < 0.05$ at the 95% level of significance. We used the r-squared values from the stata output to determine the variance in intention to use PrEP explained by the models. We also assessed multi-collinearity in the final model using the variance inflation factor (VIF). VIFs greater than 10 were suggestive of presence of multi-collinearity. All analyses were conducted using Stata v.16 (StataCorp LLC, Lakeway Drive College Station, Texas 77845, USA).

Ethics approval

The study received approval from the University of Zambia Biomedical Research Ethics Committee (Lusaka, Zambia) and the Human Research Ethics Committee at the University of the Witwatersrand (Johannesburg, South Africa). Additional approvals were obtained from the Zambia National Health Research Authority and the Lusaka District Medical Office prior to study activation. All participants provided written informed consent prior to initiating study activities.

Results

Between September and December 2021, we administered a structured questionnaire to 389 pregnant and breastfeeding women not living with HIV who were receiving care at the study facility. Table 1 shows that participants had a median age of 26 years (IQR: 22–30) and the majority were married and cohabiting with a partner (84.1%). More than half of the participants (58.1%) had acquired secondary education and about one-third (33.4%) had acquired primary education. Very few women had acquired tertiary education (2.8%) and the majority were unemployed (69.2%). More than three quarters (86.9%) of the women never used condoms with their regular sexual partner in the 30 days preceding the survey, and a cumulative one-third of women perceived themselves to be at either moderate risk (20.6%) or high risk (12.6%) of HIV infection. The majority (63.7%) were not aware of PrEP prior to the survey. Among those who knew that PrEP protects against HIV infection, the majority (65.3%) cited health facility staff as their source of information.

Table 1. Characteristics of study participants (n = 389).

Characteristic	Total n (%)
Age in years, median (IQR)	26 (22–30)
Age group (years)	
15–24	161 (41.4)
25–34	181 (46.5)
35+	47 (12.1)
Marital status	
Not married	44 (11.3)
Married (cohabiting with partner)	327 (84.1)
Married (not cohabiting with partner)	18 (4.6)
Education	
No formal education	22 (5.7)
Primary	130 (33.4)
Secondary	226 (58.1)
Tertiary	11 (2.8)
Employment status	
Not working	269 (69.2)
Employed for wages	27 (6.9)
Self employed	93 (23.9)
Maternal status	
Pregnant	172 (44.2%)
Breastfeeding	217 (55.8%)
Lifetime sexual partners	
1 partner	119 (30.6)
2–3 partners	179 (46.0)
>4 partners	91 (23.4)
Condom use (past 30 days)	
Never	338 (86.9)
Sometimes	36 (9.2)
Always	15 (3.9)
Partner HIV status	
Known	318 (81.8)
Unknown	71 (18.2)
HIV risk perception	
No risk	158 (40.6)
Low risk	102 (26.2)
Moderate risk	80 (20.6)
High risk	49 (12.6)
PrEP awareness prior to interview	
Yes	141 (36.2)
No	248 (63.7)
Source of information about PrEP	
Health facility staff	64 (65.3)
Mass media	8 (8.2)
Family member	13 (13.3)
Friends	9 (9.2)
Other	4 (4.1)

Results from Table 2 show that participants in our study had favourable intentions towards PrEP use (mean = 6.01, std. dev. = 1.36) and positive overall evaluation of taking PrEP (mean = 6.65, std. dev. = 0.71). Participants also responded to items on social norms for PrEP and perceived behavioural control about PrEP use with high levels of agreement (mean = 6.09, std. dev. = 1.51 and mean = 6.52, std. dev. = 1.09), respectively. Results in Table 2 also show that all the three predictor variables were positively correlated with intention to use PrEP: attitude ($r = 0.37$, $p < 0.001$); subjective norms ($r = 0.74$, $p < 0.001$); perceived behavioural control ($r = 0.48$, $p < 0.001$).

In simple linear regression, stratified by maternal status, intention to use PrEP was statistically significantly associated with all the three constructs of the TPB both among pregnant and breast-feeding women, separately (all $p < 0.01$). However, coefficients for the association between PrEP

Table 2. Self-reported intention, attitude, subjective norms and perceived behavioural control regarding PrEP use and Pearson correlations among the Theory of Planned Behaviour constructs.

TPB construct	Min–Max	Mean[a] (Std. Dev.)	Mean[b] (Std. Dev)	Mean[c] (Std. Dev)	PrEP intention	PrEP attitude	PrEP subjective norms	PrEP perceived behavioural control
PrEP intention	1–7	6.01 (1.36)	5.72 (1.51)	6.24 (1.18)	r = 1	r = 0.37 *P* < 0.01	r = 0.74 *P* < 0.01	r = 0.48 *P* < 0.01
PrEP attitude	1–7	6.65 (0.71)	6.59 (0.78)	6.69 (0.65)	–	r = 1	r = 0.28 *P* = <0.01	r = 0.41 *P* < 0.01
PrEP subjective norms	1–7	6.09 (1.51)	5.81 (1.75)	6.31 (1.25)	–	–	r = 1	r = 0.42 *P* < 0.01
PrEP perceived behavioural control	1–7	6.52 (1.09)	6.44 (1.14)	6.58 (1.05)	–	–	–	r = 1

[a]Mean scores and standard deviation among both pregnant and breastfeeding women.
[b]Mean scores and standard deviation among pregnant women.
[c]Mean scores and standard deviation among breastfeeding women.

intention and attitude (β = 0.83, $p < 0.01$) as well as subjective norms (β = 0.72, $p < 0.01$) were higher among breastfeeding compared to pregnant women (β = 0.55, $p < 0.01$ and β = 0.61, $p < 0.01$). (Table 3). Among both pregnant and breastfeeding women combined (Table 4), intention to use PrEP was statistically significantly associated with: attitude (β = 0.70, $p < 0.01$); subjective norms (β = 0.67, $p < 0.01$); perceived behavioural control (β = 0.60, $p < 0.01$); and maternal status (β = 0.52, $p < 0.01$). Women who had more positive attitudes, those who held more positive subjective norms and those who felt more confident in their ability to take PrEP during pregnancy and breastfeeding also reported higher levels of PrEP intention. Breastfeeding women reported higher levels of PrEP intention compared to their pregnant counterparts. Subjective norms explained 55% of the variance in intention to use PrEP while perceived behavioural control explained 23% of the variance in intention to use PrEP. Attitude explained 13% while maternal status explained 4% of the variance in intention to use PrEP during pregnancy and breastfeeding.

In the second model (Table 4), we adjusted for all the theoretical constructs of the TPB. In this model, all the TPB predictor variables were positively associated with intention to use PrEP: attitude (β = 0.24, $p = 0.03$); subjective norms (β = 0.57, $p < 0.001$); perceived behavioural control (β = 0.21, $p = 0.01$). This model explained 60% of the variance in intention to use PrEP ($p < 0.01$). In the third and final model, we adjusted for all the TPB constructs, maternal status and sociodemographic characteristics of participants. All the predictor variables were positively associated with intention to use PrEP: attitude (β = 0.24, $p = 0.03$); subjective norms (β = 0.55, $p < 0.01$); perceived behavioural control (β = 0.22, $p < 0.01$); breastfeeding (β = 0.24, $p = 0.01$). Participants who scored higher on the attitude, subjective norms and perceived behavioural control scales, as well as breastfeeding women, reported greater intention to use PrEP both in the unadjusted and adjusted models. Subjective norms had the strongest association with intention to use PrEP. The final model explained 61% of the variance in intention to use PrEP among pregnant and breastfeeding women. There was no evidence of multi-collinearity in the final model as defined *a priori* (i.e. variance inflation factors less than 10 for all the variables included).

Table 3. Unadjusted estimates for intention to use PrEP stratified by maternal status.

	Unadjusted estimates among pregnant women				Unadjusted estimates among breastfeeding women			
Predictor variable	β (95% CI)	Std. error	t	*p*-value	β (95% CI)	Std. error	t	*p*-value
Attitude	0.55 (0.26–0.83)	0.14	3.82	<0.01	0.83 (0.61–1.04)	0.11	7.56	<0.01
Subjective norms	0.61 (0.52–0.70)	0.05	13.16	<0.01	0.72 (0.64–0.80)	0.04	17.34	<0.01
Perceived behavioural control	0.68 (0.51–0.86)	0.88	7.80	<0.01	0.51 (0.37–0.64)	0.07	7.36	<0.01

Table 4. Unadjusted and adjusted estimates for intention to use PrEP among HIV-negative pregnant and breastfeeding women.

	Model 1 Unadjusted estimates				Model 2 Adjusted estimates[a]				Model 3 Adjusted estimates[b]			
Predictor variable	β (95% CI)	Robust Std. error	t	*p*-value	β (95% CI)	Robust Std. error	t	*p*-value	β (95% CI)	Robust Std. error	t	*p*-value
Attitude	0.70 (0.52–0.88)	0.09	7.77	<0.01	0.24 (0.03–0.45)	0.11	2.23	0.03	0.24 (0.02–0.45)	0.11	2.15	0.03
Subjective norms	0.67 (0.60–0.73)	0.03	21.63	<0.01	0.57 (0.47–0.68)	0.05	10.76	<0.01	0.55 (0.45–0.66)	0.05	10.44	<0.01
Perceived behavioural control	0.60 (0.49–0.71)	0.06	10.86	<0.01	0.21 (0.06–0.36)	0.08	2.75	<0.01	0.21 (0.06–0.36)	0.08	2.82	<0.01
Breastfeeding	0.52 (0.25–0.79)	0.14	3.81	<0.01					0.24 (0.06–0.42)	0.09	2.57	0.01
R-squared				**0.60, p<0.01**				**0.61, p<0.01**				

[a]Model 2 adjusted for the Theory of Planned Behaviour constructs only (attitude, subjective norms and perceived behavioural control).
[b]Model 3 adjusted for the Theory of Planned Behaviour constructs and maternal status, alongside key characteristics of study participants (i.e. age, marital status, education, employment status, HIV risk perception).

Discussion

In this study, we showed that PrEP attitudes, subjective norms, and perceived behavioural control were associated with PrEP use intentions among PrEP-naïve pregnant and breastfeeding women. Further, we demonstrated that pregnant and breastfeeding women not living with HIV have positive attitudes towards PrEP. Women in our study believed that people who are important to them would support their decision to use PrEP during pregnancy and breastfeeding. They also believed that they could easily take PrEP if they desired. Our study demonstrates that women who held favourable beliefs about the benefits of PrEP (attitude) had higher intention to use it during pregnancy and breastfeeding. A similar positive association on intention was observed among women who anticipated PrEP approval from others (subjective norms) and those who were confident that they could take PrEP during pregnancy and breastfeeding if they desired (perceived behavioural control).

One-third of women in our study perceived themselves to be at moderate to high risk of HIV infection, but the majority never used a condom with their regular sexual partners during pregnancy and breastfeeding. This is despite the generally high HIV prevalence – across multiple populations – reported in the catchment area of the study site. In a population characterised by low education and employment, women may face challenges in negotiating safer sex practices with their male partners. This is exacerbated by the gender and power imbalances within relationships already inherent in such societies that tend to operate in a synergistic manner to further elevate these women's vulnerability to HIV infection (Wingood & DiClemente, 2000). Designing interventions aimed at sensitising women on risk factors for HIV infection could empower them with knowledge to help them better assess their own HIV risk and hopefully enable them to appreciate the importance of taking PrEP in order to protect themselves and their infants against HIV infection.

The majority of women in our study who knew about PrEP cited health facility staff as their source of information. Women and the broader community members who rarely seek health care from health facilities may never get to know about PrEP. This could be even worse for men, who tend to avoid health facilities because health services are considered to be for the sick, weak and generally female and children spaces (Mweemba et al., 2022). Therefore, concentrating PrEP education at health care facilities, especially Maternal and Child Health clinics, may further lower the prospects of men ever getting to know about the benefits of PrEP to the family and the community at large. Without this knowledge, men would be less likely to support their female partners who choose to initiate PrEP during pregnancy and breastfeeding. The more community members know about PrEP, the more they are likely to have positive attitudes towards PrEP – and the more they are likely to support women who choose to use PrEP during pregnancy and breastfeeding.

Compared to pregnant women in our study, those who were breastfeeding showed more positive attitudes, subjective norms and control beliefs about PrEP use. They also reported higher PrEP intention. In qualitative studies, pregnant women generally raised persistent concerns about infant safety with antiretroviral exposure (Beima-Sofie et al., 2019; Pintye et al., 2017). Furthermore, pregnant women could have been more sceptical about product use compared to their breastfeeding counterparts due to the value placed in a woman's ability to bear children, especially in our context, where most often than not, failure to have a child is viewed as a threat to the stability of the relationship (Pintye et al., 2017). PrEP messaging should therefore emphasise the importance of initiating PrEP early on in order to stay HIV-negative throughout the maternal period when the risk for seroconversion and onward MTCT is highest.

Our finding of a positive association between women's positive attitude towards PrEP and the intention to use PrEP corroborates results of previous studies. For example, African American women who had positive perceptions and attitudes towards PrEP showed willingness to use PrEP (Ayangeakaa et al., 2022; Hill et al., 2021). Similar observations on the association between

attitudes and intention were observed among women who inject drugs (Tran et al., 2021). In the United States, women's perceptions of the beneficial outcomes of PrEP were associated with intention to use PrEP in the next three months (Teitelman et al., 2020). It is imperative that PrEP messaging focuses on factors that may influence PrEP attitudes such as increasing PrEP knowledge and awareness on the benefits of PrEP in HIV prevention, as well as accurate HIV risk assessment in the target population (Aidoo-Frimpong et al., 2020). Behavioural interventions that target these factors could lead to positive attitudes which could translate to improved demand and actual uptake of PrEP by pregnant and breastfeeding women (Ajzen, 1991).

Women's broader social contexts may influence their decision to take PrEP and adhere to it. Young and McDaid argue that these social and cultural factors significantly influence women's perception and decisions regarding their use of HIV prevention methods including PrEP (Young & McDaid, 2014). In our study, we found that women who anticipated positive peer norms or less disapproval from people who are important to them were more likely to intend to use PrEP during pregnancy and breastfeeding. Our findings corroborate those from similar studies conducted among women, that found an association between receiving encouragement and support from loved ones and other women on PrEP and intention to use PrEP (Ayangeakaa et al., 2022; Calabrese et al., 2018; Goparaju et al., 2017; Pasipanodya et al., 2021; Scott et al., 2022; Teitelman et al., 2020). Together, these findings reiterate the need for interventions that advocate for the adoption of social norms that promote PrEP uptake by emphasising PrEP benefits for pregnant and breastfeeding women.

Since male partners are key decision makers in health-related decisions during pregnancy and breastfeeding (Montgomery et al., 2015; Mweemba et al., 2022; Roberts et al., 2020), it is important that male partners are engaged in female-controlled HIV prevention initiatives such as PrEP. This is even more critical for populations such as our study population where the majority of women are unemployed and may be dependent financially on their male partners. A lack of this anticipated approval from significant others may negatively influence pregnant and breastfeeding women's intention to use PrEP and ultimately uptake (Ayangeakaa et al., 2022). PrEP education messages that target broader communities, including couple-based approaches could improve community members' understanding about PrEP. This could address potential barriers to PrEP uptake, such as PrEP stigma, posed by negative social norms about PrEP (Goparaju et al., 2017).

Women in our study felt confident that they could take PrEP if they desired. This is contrary to the socio-culturally acceptable norm where women have to consult and seek approval from their partners on decisions that relate to their health, which is commonplace in Zambia (Mweemba et al., 2022). This also contrasts the common belief that women have limited control over their sexual and reproductive health choices and practices (Blanc, 2001; Darteh et al., 2019). It is possible that women in our study felt confident about their ability to take PrEP because they believed that people who are important to them would approve of their decision to use PrEP during pregnancy and breastfeeding. This confidence could also be based on the premise that PrEP provides women an increased sense of empowerment in directing their own sexual health (Pasipanodya et al., 2021), including control when they cannot control their partner's behaviour or where barrier protection fails (Flash et al., 2014).

Our findings further show a positive association between perceived control beliefs and intention to use PrEP. Women who felt confident about their ability to take PrEP had high intention to use it. These results corroborate findings from similar studies conducted among women (Pasipanodya et al., 2021; Tran et al., 2021). In light of our findings, the importance of empowering women so that they can have more control over their own health cannot be over-emphasised. Women in power-imbalanced relationships tend to depend on their male partners because men usually tend to bring more financial assets (i.e. money, status) to the relationship. As the economic inequity between men and women increases, and favours men, women will be more likely to experience adverse health outcomes (Wingood & DiClemente, 2000). Hence, empowering women economically may give them some level of control over PrEP-related decisions including its uptake.

Our study makes a significant contribution to the body of knowledge on salient beliefs that may influence intention to use PrEP in a population that is disproportionately affected by HIV. To the best of our knowledge, this is the first study to investigate psycho-social correlates of PrEP and how these correlates influence intention to use PrEP among pregnant and breastfeeding women not living with HIV in Zambia. However, we do note some limitations. First, because of limited PrEP availability in antenatal settings, we were only able to determine beliefs associated with intention (as opposed to actual PrEP uptake). According to the belief disparity hypothesis, people hold more positive beliefs about hypothetical behaviours compared to when the behaviour is enacted in real life (Ajzen & Driver, 1992). Therefore, it is possible that participants' perceptions of PrEP could change when given an opportunity to take it. Second, very few women knew about PrEP prior to their participation in this study. Their responses were mainly dependent on the description of PrEP provided by interviewers and could also have been influenced by social desirability. Third, we did not identify factors associated with the observed positive attitude towards PrEP use during pregnancy and breastfeeding. However, findings from a related qualitative study suggested that pregnant and breastfeeding women's attitudes toward PrEP were influenced by the belief that it has the potential to protect them and their infants from contracting HIV. PrEP was viewed as a way of protecting themselves in the event that their partner was cheating or secretly on ART (Hamoonga et al., 2022). Fourth, the cross-sectional nature of the data limits our ability to make causal conclusions on the association between the theorised TPB beliefs and intention to use PrEP since both exposures and outcome were measured at the same time. Despite these limitations, intention has been proven in several studies as a reliable antecedent to actual behaviour. Therefore, our findings are still valid and informative regarding beliefs that may influence uptake of PrEP in antenatal settings.

Conclusion

Consistent with the Theory of Planned Behaviour, our findings show that women's attitudes, subjective norms and perceived behavioural control are important correlates of intention to use PrEP during pregnancy and breastfeeding. Our findings suggest that social cognitive interventions aimed at generating demand for PrEP among pregnant and breastfeeding women should promote positive attitudes, subjective norms and control beliefs about PrEP use. Future studies should investigate how attitudes, subjective norms, perceived behavioural control, and intentions influence actual PrEP uptake in antenatal and postnatal settings.

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Data availability statement

The data that support the findings of this study are available from the corresponding author, [TEH], upon reasonable request.

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