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Retrospective Study of Incidence of Human Immunodeficiency Virus Infections in Pregnant Women on Pre-Exposure Prophylaxis in the Eastern Cape Province, South Africa

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Abstract

Background: South Africa bears the highest global burden of HIV, disproportionately affecting Black African women and young adults due to socio-economic disparities and structural inequalities. Pre-exposure Prophylaxis (PrEP) has demonstrated high efficacy in preventing HIV when adhered to consistently. However, adherence challenges among pregnant women limit its effectiveness, increasing the risk of breakthrough infections.

Methods: This study reviewed 150 medical records of HIV-negative pregnant women on PrEP attending antenatal care at Stanford Terrace Clinic, Mthatha. Socio-demographic characteristics, lifestyle risk factors and adherence-related behaviors were analyzed to assess their impact on breakthrough HIV infections.

Results: Participants ranged from 15-42 years, with 44% aged 22-28 years and 68% identifying as single. While 80% had secondary education, 66% were unemployed. Adherence challenges included inconsistent follow-up visits (24%), missed PrEP doses (6%) and discontinuation of PrEP (7%). Risk behaviors, such as inconsistent condom use (16%) and multiple sexual partners (5%), compounded vulnerability to HIV. A 29.3% incidence of breakthrough infections was observed, highlighting significant gaps in adherence and PrEP effectiveness.

Discussion: The findings reveal that socio-demographic and behavioral barriers, including low health literacy, unemployment and stigma, hinder effective PrEP use. Comparison with other studies highlights regional disparities in adherence, emphasizing the need for tailored interventions.

Conclusions: Addressing adherence barriers through community-based education, integration of PrEP into antenatal care and innovative service delivery models is critical to reducing breakthrough infections. These measures are essential to improving PrEP outcomes and reducing HIV transmission among high-risk pregnant women in resource-limited settings.

Keywords: HIV prevention; Pre-exposure prophylaxis; Adherence; Breakthrough infections; Pregnant women

Introduction

HIV, a virus transmitted through bodily fluids and blood, specifically targets $CD4^+$ T cells in the immune system, leading to a progressive weakening of immune defences and increased vulnerability to opportunistic infections [1,2]. South Africa has the highest burden of HIV globally, with approximately 7.8 million people living with the virus, a disproportionate number of whom are Black African women and young adults [3]. This demographic is particularly vulnerable due to socio-economic disparities, gender-based violence and structural inequalities, which exacerbate their risk of HIV infection.

Pre-exposure prophylaxis (PrEP), a daily oral antiretroviral medication, has been proven to reduce the risk of acquiring

HIV by over 99% when adhered to consistently [4]. However, its effectiveness is severely limited by adherence challenges such as stigma, misconceptions, low health literacy and side effects [5,6]. Non-adherence to PrEP not only diminishes its protective benefits but also predisposes users to the development of drug resistance [7,8]. Pregnant women face unique barriers to adherence, including biological changes during pregnancy, healthcare system limitations and cultural stigmas, further complicating their access to and effective use of PrEP [9,10].

While initiatives like the Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) program have sought to address these barriers, success has been constrained by systemic issues such as resource shortages, lack of comprehensive community engagement and persistent stigma surrounding HIV prevention strategies [10]. Breakthrough infections among HIV-negative pregnant women on PrEP remain underexplored, particularly in resource-limited settings like Mthatha, Eastern Cape, South Africa.

This study aims to address this critical knowledge gap by investigating the prevalence and causes of breakthrough infections among pregnant women on PrEP attending antenatal care in Mthatha. By identifying adherence challenges and contextual barriers, this research seeks to inform targeted interventions to improve PrEP protocols, strengthen community health education and support pregnant women in high-risk groups. The findings will contribute to evidence-based strategies to reduce new HIV infections and enhance maternal and neonatal health outcomes in similar high-prevalence settings [11,12].

Materials and Methods

This study utilized a retrospective analysis of secondary data extracted from patient records of HIV-negative pregnant women on Pre-exposure Prophylaxis (PrEP) attending Antenatal Care (ANC) at Stanford Terrace Clinic, Mthatha, Eastern Cape, South Africa, from January 2022 to December 2023.

Study design

The research was conducted at Stanford Terrace Clinic using a retrospective study design. Data were sourced exclusively from patient records, ensuring that the study analyzed records rather than directly involving patients.

Sample size

A total of 150 eligible patient records were reviewed to ensure statistical rigor. Simple random sampling was employed to minimize selection bias, granting each file an equal chance of selection.

Inclusion and exclusion criteria

Eligible records included files of HIV-negative pregnant women on PrEP during the study period, provided the data were complete. Records with incomplete information or those of patients lost to follow-up were excluded from the analysis.

Data collection

Data were extracted using a standardized checklist. Collected variables included demographic information, pregnancy and marital history, sexual history, details of PrEP prescribing, HIV diagnoses, timing of PrEP initiation and instances of PrEP failure. Information related to Sexually Transmitted Infections (STIs) was also collected. All extracted data were fully de-identified and securely stored in a password-protected spreadsheet.

Data analysis

Data entry was performed using Microsoft Excel, while SPSS (v29, IBM Corporation) facilitated initial statistical analyses. Advanced statistical analyses, including descriptive and inferential statistics, were conducted using Python and R.Descriptive analysis included frequency distributions and percentages. Weighted breakthrough HIV infection prevalence and incidence rates were calculated, with 95% Confidence Intervals (CI) providing precision estimates.

Results

Socio-demographic characteristics of pregnant women on PrEP

This study included a total of 150 medical records of pregnant women on Pre-exposure Prophylaxis (PrEP) attending antenatal care at Stanford Terrace Clinic. The participants were aged 15-42 years, with the majority (44%) between 22 and 28 years old. Most participants had 1-3 pregnancies (87%), while 13% reported having 4-5 pregnancies. Marital status showed that 68% of the women were single and 32% were married.

Educational levels varied, with 3% having no formal education, 4% with primary education, 80% with secondary education and 13% with tertiary education. Employment data indicated that 66% of participants were unemployed, while 34% were employed. Regarding household size, 68% lived in households of 2-4 members, while 32% lived in households of 5-6 members. These socio-demographic characteristics are summarized in **Table 1.**

Lifestyle risk factors of pregnant women on PrEP

Of the 150 women, various health conditions and behavioral factors were observed. A small proportion reported comorbidities such as asthma (3%), diabetes (1%), heart disease (1%), hypertension (3%), or receiving STI treatment (5%). Behavioral factors included discontinuation of PrEP (7%), inconsistent follow-up or missed appointments (24%), missed doses of PrEP (6%) and inconsistent condom use (16%). Additionally, 5% reported having multiple sexual partners and 5% reported alcohol use. Details are summarized in **Table 2.**

Incidence of breakthrough infections

Out of the 150 records reviewed, 46.7% of women tested HIV-negative post-delivery, while 29.3% experienced breakthrough HIV infections. The remaining 24% of cases were classified as unknown due to lost follow-up. These findings highlight that nearly one-third of HIV-negative pregnant women on PrEP experienced breakthrough infections. The results are presented in **Table 3.**

Table 1: Socio-demographic characteristics of pregnant women on PrEP.

Variable	Number of patients	Percentage (%)
Age (years)		
15-21	36	24
22-28	66	44
29-35	29	19.3
36-42	19	12.7
Number of pregnancies		
1-3	130	87
4-5	20	13
Marital status		
Single	102	68
Married	48	32
Education		
Non-formal education	4	3
Primary education	6	4
Secondary education	120	80
Tertiary education	20	13
Employment status		
Unemployed	99	66
Employed	51	34
Household size		
2-4	102	68
5-6	48	32

Table 2: Lifestyle risk and other factors of pregnant women on PrEP.

Variable	Number of patients	Percentage (%)
Asthma medication intake	4	3
Diabetes medication intake	2	1
Heart disease medication intake	1	1
Hypertension medication intake	5	3
STI treatment	7	5
Discontinued PrEP	11	7
Missed follow-up/appointment	36	24
Missed PrEP doses	9	6
None reported	37	25
Inconsistent condom use	24	16
Multiple sexual partners	7	5
Alcohol use	7	5

Table 3: Incidence of breakthrough infections.

Test result (5-6 weeks post-delivery)	Frequency	Percentage (%)
Negative	70	46.7
Positive	44	29.3
Unknown	36	24
Total	150	100

Discussion

Socio-demographic characteristics

The socio-demographic findings of this study highlight several risk factors associated with adherence to PrEP and the incidence of breakthrough HIV infections among pregnant women. The majority of participants (44%) were aged 22-28 years, a group often identified as high-risk for HIV acquisition in sub-Saharan Africa [13]. The high prevalence of single marital status (68%) among participants aligns with findings from other studies, which indicate that single women are more likely to face economic instability and social challenges, increasing their vulnerability to HIV.

Education levels among participants showed that 80% had secondary education, while only 13% attained tertiary education. Limited educational attainment has been widely reported as a barrier to health literacy, affecting adherence to PrEP and other HIV prevention methods [7]. Furthermore, the high unemployment rate (66%) reflects broader socio-economic disparities, which are known to exacerbate health inequities, including access to and consistent use of PrEP [10].

Lifestyle risk factors and PrEP adherence

Behavioral and health-related factors also contributed to PrEP adherence challenges. Notably, 24% of participants had inconsistent follow-up visits or missed appointments and 7% discontinued PrEP entirely. This is consistent with literature emphasizing the impact of structural barriers, such as stigma, lack of support and transportation issues, on adherence [7].

Inconsistent condom use (16%) and multiple sexual partners (5%) were notable risk behaviors. These factors increase exposure to HIV, undermining the protective effect of PrEP, particularly in the context of non-adherence [14]. Substance use, reported by 5% of participants, is another documented risk factor, as it can impair judgment and increase risky sexual behavior [9].

Incidence of breakthrough infections

The incidence of breakthrough infections, affecting 29.3% of the participants, is concerning and underscores the critical need to address adherence and other modifiable risk factors. Similar studies have reported breakthrough infections ranging between 5% and 25% among women on PrEP, depending on adherence levels and socio-economic context [15,16]. The high rate observed in this study may be attributed to the combined effects of socio-demographic and lifestyle risk factors, including inconsistent PrEP use and missed follow-up appointments.

Comparisons with other studies

This study's findings align with global and regional data indicating that younger women in low-resource settings are disproportionately at risk of HIV, even when enrolled in PrEP programs. For instance, a study in Kenya reported that adherence among women was significantly lower than among men due to stigma and partner-related challenges [16]. Similarly, studies in South Africa have shown that single, unemployed women with low health literacy are less likely to adhere to PrEP regimens [6].

Contrastingly, studies in higher-income settings, where support systems and education programs are more robust, have reported lower rates of breakthrough infections and better adherence outcomes [7]. These differences highlight the importance of contextual interventions tailored to address socio-economic and structural barriers in low-resource settings.

Implications

The findings underscore the need for targeted interventions to improve PrEP adherence and reduce breakthrough infections among pregnant women. Community-based health literacy programs focusing on the importance of consistent PrEP use and addressing misconceptions could significantly improve adherence. Additionally, integrating PrEP services into broader antenatal care frameworks, providing transportation support and reducing stigma through community campaigns are critical measures [12,13].

Innovative approaches, such as mobile clinics and telehealth consultations, may also help bridge the accessibility gap for women in rural settings like Mthatha. Furthermore, engaging male partners in education and support initiatives may alleviate relationship-related barriers to adherence.

Conclusion

This study underscores the significant socio-demographic and behavioral barriers contributing to breakthrough HIV infections among pregnant women on PrEP in Mthatha. High rates of inconsistent PrEP use, low adherence and structural challenges, such as unemployment and low health literacy, were identified as key factors influencing outcomes. The observed breakthrough infection rate of 29.3% emphasizes the urgent need for targeted interventions, including education programs, community engagement and accessible healthcare services, to address these challenges. By tailoring prevention strategies to the unique needs of this high-risk population, future efforts can enhance PrEP effectiveness and reduce HIV transmission rates, aligning with global HIV prevention goals.

Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Walter Sisulu University and approved by the Institutional Health Sciences Research Ethics Committee, Faculty of Medicine and Health Sciences, Walter Sisulu University (protocol code 086/2024, dated 01:08:2024).

Informed Consent Statement

Informed consent for this study was not obtained from the subjects involved in the study because the research involves no risk to the subjects, the primary data was collected for purposes of patient management and not for research and was de-identified to reduce the risk to privacy.

Data Availability Statement

The data that support the findings of this study are not publicly available due to privacy and ethical restrictions. The data contain sensitive information that could compromise the privacy of research participants. As such, access to these data is restricted and can only be provided upon reasonable request to the corresponding author, subject to approval by the relevant ethics committee.

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