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## Prevalence and factors associated with uptake of pre-exposure prophylaxis amongst women vulnerable to HIV who received HIV antibodies in Antibody Mediated Prevention HVTN703/HPTN081 trial in Harare, Zimbabwe: a cross-sectional study

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### Abstract

**Introduction**—There is limited evidence on pre-exposure prophylaxis (PrEP) uptake post-trial participation for women vulnerable to HIV. This study investigates the prevalence and factors associated with PrEP uptake post-participation in an HIV prevention trial.

**Methods**—Former Antibody Mediated Prevention (AMP) study participants were invited to the three AMP clinical research sites in Zimbabwe after at least a year of exiting the study. The AMP study evaluated the safety and efficacy of Vaccine Research Center 01 broadly neutralising

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**Contributors** All the authors contributed substantially to the design of the study proposal, protocol and questionnaires. BS and MC were actively involved in data collection. BN and BS analysed the data and prepared the tables. ZMC, FGSM and NMM provided supervision of the study. All authors reviewed, edited the draft manuscript, read and approved the final manuscript including providing responses to reviewer comments. All authors agree to be accountable to all aspects of the work. BS is the guarantor responsible for the overall content of the manuscript.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and the original trial and this study were both approved by Medical Research Council of Zimbabwe (MRCZ) reference numbers MRCZ/A/2037 and MRCZ/A/2768, respectively. All participants provided informed consent prior to questionnaire administration.

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monoclonal antibody in reducing acquisition of HIV-1 infection in women in sub-Saharan Africa. Participants vulnerable to HIV were enrolled and risk reduction counselling was done throughout study participation. In a cross-sectional study, semi-structured interview administered questionnaires were completed. The primary outcome was uptake of PrEP after the study exit.

**Results**—From February 2022 to August 2022, out of 434 participants enrolled in the AMP study, a total of 298 were invited and 225 participated in the study; 28% made an attempt to access PrEP after study participation, 20% used PrEP at some point after study participation and 15% were on PrEP at the time of questionnaire administration. PrEP uptake was associated with new sexual partners after study participation and higher average number of sexual encounters in the previous month. Challenges faced in accessing PrEP included those related to the health facility, transport problems and stigma.

**Conclusion**—The majority (85%) of former AMP participants were not on PrEP at the time of questionnaire administration. We observed poor uptake of PrEP post-study exit among participants who had received risk reduction counselling through study duration. Measures to improve PrEP uptake should be considered on participants vulnerable to HIV when exiting HIV prevention trials.

## BACKGROUND

Despite the global decline in new HIV infections in the last decade, women of reproductive age in sub-Saharan Africa (SSA) including Zimbabwe remain at risk of acquiring HIV.<sup>1</sup> Over the past decade, the HIV prevention toolkit has expanded from the sociobehavioural strategies to structural and biomedical interventions that include pre-exposure prophylaxis (PrEP).<sup>2</sup> Zimbabwe incorporated tenofovir-based antiretroviral (ARV) drugs into its Guidelines for Prevention of HIV in 2016.<sup>3</sup> This followed the WHO strong specific recommendation for HIV-negative individuals at substantial risk of HIV infection to be offered oral PrEP containing tenofovir for use as an additional prevention choice in September 2015.<sup>4</sup> PrEP in Zimbabwe is available for free at the primary care level for all HIV-uninfected individuals at substantial risk of HIV to reduce acquisition. Key populations, for example, sex workers, adolescent girls and young women, men who have sex with men and transgender people, among others, who are at an even increased risk of HIV infection, are actively offered PrEP.<sup>5</sup>

Evidence from the Partners PrEP and Partners Demonstration studies as well as other studies confirmed the efficacy of the ARV drug tenofovir for use as PrEP.<sup>6,7</sup> Tenofovir disoproxil fumarate and emtricitabine for PrEP reduce HIV by up to 90%–99% compared with placebo. However, efficacy is highly correlated to the degree of adherence.<sup>8,9</sup> Uptake and adherence to approved/registered PrEP chemoprophylaxis is variable even among women vulnerable to HIV and is influenced by several factors that can be classified into structural, social, clinical and behavioural barriers. These factors include risk perception for HIV, lifestyle and life circumstances, ease of accessing services and lack of knowledge about PrEP.<sup>10–13</sup> A consultative study done among key community stakeholders in Kenya in preparation of the PrEP rollout revealed that barriers and facilitators to PrEP uptake were population specific. For example, in sex workers, their vulnerability to HIV is worsened by the illegal status and secretive nature of sex work. As a result, they may not admit to engaging in sex work, making it difficult to reach them with HIV prevention interventions.<sup>14</sup>

A study in Zimbabwe showed that in the first 2 years of PrEP availability, 37.1% of female sex workers initiated oral PrEP and had at least one drug refill.<sup>15</sup>

Transitioning from clinical trials, where services offered often exceed local standard of care, to public care can be a sufficiently challenging experience to encourage sustained uptake especially in resource limited settings.<sup>16</sup> Within clinical trials, most of the barriers to healthcare are removed and intense support that facilitates continued use of medications is provided. Post-participation in the study, participants become susceptible. Studies of participant experiences trying to access public HIV prevention and treatment services after study participation have revealed both personal and significant facility level challenges and concerns.<sup>17 18</sup>

Although there is substantial literature on the uptake and adherence to PrEP within clinical trials, data on PrEP uptake after study participation is limited among women in Zimbabwe yet this information is crucial for implementation programmes so that we ensure continued access to PrEP and HIV prevention beyond study participation in this population vulnerable to HIV. In this substudy, we aimed to determine the prevalence of PrEP uptake after exit from an HIV-prevention trial in women vulnerable to HIV previously enrolled in the Antibody Mediated Prevention (AMP) HVTN703/HPTN081 study in Zimbabwe. We also aimed to identify factors associated with PrEP uptake in a non-study setting after participating in an HIV-prevention trial. To the best of our knowledge, this is the first study to evaluate PrEP uptake in women vulnerable to HIV after participating in an antibody-mediated HIV-prevention trial in Zimbabwe.

## MATERIALS AND METHODS

### Study design and participants

The AMP study was a phase 2b study to evaluate the safety and efficacy of Vaccine Research Center 01 broadly neutralising monoclonal antibody in reducing acquisition of HIV-1 infection in women in SSA, [clinicaltrials.gov \(NCT02568215\)](https://clinicaltrials.gov/ct2/show/study/NCT02568215). The study enrolled HIV uninfected females between 18 and 40 years of age vulnerable to HIV and in good health. A total of 1924 participants were enrolled in seven SSA countries and followed up monthly for 60 months during which they received bimonthly HIV monoclonal antibodies and comprehensive HIV risk reduction counselling throughout study participation. Between 2016 and 2018, Zimbabwe enrolled 434 participants across three clinical research sites (CRSs) and were exited from December 2018 to November 2020.<sup>19 20</sup> At study exit, participants were referred for PrEP access in the public health sector. From February 2022 to August 2022, we consecutively enrolled former AMP study participants who exited at the three CRSs in Zimbabwe into a cross-sectional study to evaluate PrEP uptake after study exit. The semi-structured interviewer administered questionnaire had dedicated sections collecting information on each study variable namely demographics, HIV testing, sexual history and PrEP access. The questionnaire helped to avoid response bias as it had different question types, not simple 'yes and no' questions but rather allowed for elaboration and mixed viewpoints (online supplemental material). The questionnaire was administered in a private counselling room.

PrEP uptake was defined as the proportion of enrolled participants who received at least 1 months' supply of PrEP tablets and were on PrEP at time of interview.

### Sample size calculation

The minimum sample size (n) required using Dobson's formula is:  $n = [(Z\alpha)^2 \times p(1-p)] / e^2$ ; where p is the expected proportion PrEP use among women vulnerable to HIV who participated in the AMP study,  $Z\alpha$  are values of standard normal distribution at  $\alpha$  level of significance, e is the margin of error for the prevalence estimate. Given that the total number of participants enrolled at the Zimbabwe CRSs in the AMP study was 434, assuming that  $p=50\%$ , using 5% acceptable margin of error, the sample size required at 5% level of significance is 223 after adjusting for 10% who may not have complete data.

### Sampling

Study participants who met the inclusion criteria were contacted using telephone and scheduled for a single study visit at the AMP study sites. The inclusion criteria comprised former AMP study participants who were HIV negative at study exit and had exited the study in at least a year prior. The exclusion criteria comprised participants who had relocated outside Zimbabwe or were unable to provide written informed consent for study participation.

### Data management and analysis

Data were collected using an Institutional Review Board approved semi-structured interviewer-administered questionnaire. Data collected from the interviews was captured electronically and analysed using statistics and data (STATA) software package. Study participants were identified using unique identification numbers only. Data cleaning was performed before and during statistical analysis. The mean and SD or median and full range, where appropriate, were used to summarise quantitative data. In bivariate analysis  $\chi^2$  test or Student's t-test were used to determine associated with PrEP uptake. In multivariate analysis, we used stepwise ( $p=0.005$ ) and backwise ( $p=0.001$ ) techniques in performing regression. Logistic regression was used to determine variables associated with PrEP uptake. All statistical decisions were concluded at 5% level of significance.

### Patient and public involvement

Participants were not directly involved in the design and conduct of the study. However, as participants were being called to come to the clinic, they were asked to inform other participants who were not contactable per phone and come along with them to the study clinics.

## RESULTS

Out of 434 participants in the AMP study, 225 (52%) were enrolled in this study. Six former participants who acquired HIV infection during the AMP study were excluded in the analysis because they were not eligible for PrEP. The time range from study exit to completing the survey was 1.25–3.2 years (median 2 years). Table 1 shows the demographic

and behavioural characteristics and bivariate analysis to determine factors associated with PrEP uptake.

The majority of participants (95%) had secondary education and above and most participants (74%) were gainfully employed. 216 participants (96%) reported to be sexually active, defined as vaginal intercourse on a minimum of 2 separate days in the last 30 days. 65 reported that they were at risk of HIV acquisition. 28% (n=61) of participants tried to access PrEP after the study exit, 20% (n=44) used PrEP at some point after study participation and 15% (n=33) were on PrEP at the time of the interview. Among those who tried to access PrEP, 61% tried to access PrEP from the local public clinics. Participants identified as single/separated/divorced used PrEP more than those who were married/cohabitating.

There was an association between the use of being faithful to one sexual partner for HIV prevention after study participation and PrEP use after adjusting for other study variables, the odds of taking PrEP among those who reported faithfulness to their partners as an HIV prevention strategy were 0.19 times that of participants who did not report faithfulness (p=0.048). Additional information is available in table 2.

### Challenges faced in accessing PrEP

61 participants (28%) tried to access PrEP. Among these 37 participants (61%) reported challenges in accessing PrEP. 30 participants (81%) reported health facility reasons, 4 participants (11%) reported transport challenges to reach the health facility while 3 participants (8%) reported challenges related to stigma. Health facility reasons included finding the clinic closed, no stock available or PrEP services not being offered at the clinic.

## DISCUSSION

The prevalence of PrEP uptake after AMP study participation was low, however more than a quarter had tried to access PrEP. Factors associated with PrEP uptake included a report of being faithful to a sexual partner, being single/separated/divorced, having more current and new sexual partners after AMP study participation. Participants on PrEP were less likely to be using condoms compared with those not on PrEP. Challenges faced in accessing PrEP included health facility, transport and stigma concerns.

PrEP programmes targeting individuals vulnerable to HIV have seen the number of initiators rising to between 30% and 60%,<sup>21</sup> in contrast to this study where only 15% took up PrEP.

This study shows that there is a positive correlation between number of sexual encounters, new sex partners and use of PrEP after study exit. This is consistent with findings of a recently published article in the Wales that showed a positive correlation between PrEP use and having more partners or using condoms less frequently, due to reduced anxiety about HIV.<sup>22</sup> Similar findings were also reported in a study among men who have sex with men which showed significant discontinuation in PrEP use among participants with fewer sexual partners during the COVID-19 lockdown.<sup>23 24</sup> This might be an indication that these participants felt they had an ongoing risk of HIV acquisition and hence the need for PrEP.

The association between PrEP uptake and less likely to use condoms can be explained by the phenomenon of sexual risk compensation. Risk compensation theory suggests that people typically adjust their behaviour in response to perceived levels of risk, becoming more careful where they sense greater risk and less careful if they feel more protected.<sup>25</sup> Sexual risk compensation is dire in individuals vulnerable to HIV on PrEP where they are more concerned about becoming HIV infected and engage in risky sexual behaviours like decreased use of condoms, a situation which predisposes them to a high risk of contracting sexually transmitted infections.<sup>26 27</sup> This might undermine prevention efforts. Furthermore, the use of PrEP and disclosure of its use to sexual partner may hinder the ability to negotiate condom use as condoms are generally perceived as a means to prevent HIV.<sup>28</sup>

Previous studies pointed to factors such as stigma, disclosure concerns and poverty as major challenges in accessing PrEP, however in this study, major challenges faced were related to the health facilities like finding the clinics closed and no stock available at the clinics.<sup>12 29</sup> <sup>30</sup> This is so because AMP HVTN703/HPTN081 participants were exited from the study during the COVID-19 epidemic were some clinics were closed and there were disturbances in the supply chain of medicines. Additionally due to the lockdown restrictions participants reported failure to reach the healthcare facilities as one of the major reasons of not accessing PrEP.<sup>31</sup>

In Zimbabwe, oral PrEP is available for free to all individuals who need it, even in the primary care setting.<sup>5</sup> HIV prevention researchers need robust, person-centred procedures for post-trial access of HIV prevention care. There is a need to strengthen the referral process at end of study participation so that participants vulnerable to HIV can continue to access sexual and reproductive health services including PrEP. To prioritise provision of healthcare services, ensuring continued access and availability of reproductive healthcare services during epidemics.

The study had two main limitations. The first was that the study relied on self-reported data which may cause bias due to impression management whereby individuals limit their reported behaviours to those that are socially acceptable. Additionally, there was limited prior research on PrEP uptake post-participation in an HIV prevention trial among vulnerable women and this restricted the literature review.

## CONCLUSION

There was low PrEP uptake post-AMP HVTN703/HPTN081 study participation. In addition to intense engagement with the community to raise awareness, measures to improve PrEP uptake should be considered for participants vulnerable to HIV when exiting HIV prevention trials.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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## Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information. Additional data can be available upon request and approval of the investigators of the study. The principal investigator of the study was Bekezela Siziba, and can be contacted via email (sizibabekezela@gmail.com).

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**WHAT IS ALREADY KNOWN ON THIS TOPIC**

- There is limited evidence on pre-exposure prophylaxis (PrEP) uptake post-trial participation for women vulnerable to HIV.

**WHAT THIS STUDY ADDS**

- PrEP uptake after study exit was low.

**HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY**

- There is opportunity for further research to explore reasons for low uptake of PrEP after exiting HIV prevention trial and strengthening referral processes could improve PrEP uptake.

Demographic and behavioural characteristics and bivariate analysis to determine factors associated with pre-exposure prophylaxis (PrEP) uptake after participation in Antibody Mediated Prevention HVTN703/HPTN081 trial

**Table 1**

Variable	PrEP use		P value
	No n (%)	Yes n (%)	
Marital status			
Married/cohabitating	117 (64)	15 (45)	0.039
Single/divorced or separated	67 (36)	18 (55)	
Religion			
Christian	133 (72)	23 (70)	0.362
African traditional	7 (4)	3 (9)	
Apostolic	36 (20)	7 (21)	
Other	8 (4)	0 (0)	
Employment status			
Employed	21 (11)	3 (9)	0.908
Not employed	46 (25)	9 (27)	
Self employed	117 (64)	21 (64)	
Ever tested for HIV after study exit			
No	29 (16)	0 (0%)	0.006
Yes	155 (84)	33 (100)	
Standard of care reason for HIV testing*			
No	100 (65)	24 (73)	0.244
Yes	55 (35)	9 (27)	
Voluntary reasons for HIV testing <sup>†</sup>			
No	58 (37)	4 (12)	0.002
Yes	97 (63)	29 (88)	
Social influence reason for HIV testing <sup>‡</sup>			
No	132 (85)	28 (85)	0.572
Yes	23 (15)	5 (15)	

Variable	PrEP use		P value
	No n (%)	Yes n (%)	
Number of times of sexual intercourse in the previous month, median (range)	8 (0–60)	30 (1–60)	<0.001
Number of current sexual partners, median (range)	1 (0–20)	4 (1–30)	<0.001
New sex partners after study exit <sup>§</sup>			
No	104 (57)	6 (18)	<0.001
Yes	80 (43)	27 (82)	
Last tested for HIV			
3 months	77 (42)	25 (76)	0.002
6 months	45 (24)	4 (12)	
12 months	34 (19)	4 (12)	
While in the study	28 (15)	0 (0%)	
Thinks is at risk of HIV			
No	41 (22)	2 (6)	<0.001
Yes	111 (60)	31 (94)	
Don't know	31 (17)	0 (0%)	
No response	1 (1)	0 (0%)	
Primary sex partner tested for HIV in the last 3 months			
No	116 (63)	16 (48)	0.115
Yes	68 (37)	17 (52)	
Use of condoms for HIV prevention after study exit			
No	50 (27)	2 (6)	0.005
Yes	137 (73)	31 (94)	
Has COVID-19 influenced interest in PrEP use?			
Reduced	19 (10)	3 (9)	<0.001
Increased	10 (6)	10 (30)	
No influence	155 (84)	20 (61)	

n=219.

The mean age was 33 years. The youngest was 23 years old, and the oldest was 49 years old. To determine factors associated with PrEP uptake, the demographic and behavioural characteristics of the participants were compared.

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To determine factors associated with PrEP uptake, the demographic and behavioral characteristics of the participants were compared.

\* Standard of care reason for HIV testing means provider initiated testing of HIV during routine care for example as part of investigation of symptoms or HIV testing offered during antenatal care.

‡ Voluntary reasons for HIV testing means self-motivated testing that is not prescribed by a health provider for example during an antenatal visit or influenced by social circumstance of a new relationship.

§ Social influence reason for HIV testing means testing of HIV due to a social pressure like when getting into a new relationship.

¶ No response for PrEP uptake for two participants.

**Table 2**

Multivariate analysis to determine factors associated with pre-exposure prophylaxis (PrEP) use after participation in Antibody Mediated Prevention HVTN703/HPTN081 trial

Variable	Adjusted OR (95% CI)	P value
Marital status		
Married/cohabitating	Reference	–
Single/separated/divorced	0.84 (0.29 to 2.46)	0.754
Number of current sexual partners, median 2 (range 0–30)	1.01 (0.92 to 1.12)	0.776
New sex partners after study exit		
No	Reference	–
Yes	1.44 (0.43 to 4.89)	0.555
Use of condoms for HIV prevention after study participation		
No	Reference	–
Yes	1.68 (0.28 to 10.07)	0.567
Use of being faithful to one partner for HIV prevention after study participation		
No	Reference	–
Yes	0.19 (0.04 to 0.98)	0.048*
COVID-19 influence on PrEP interest		
Decreased	Reference	–
Increased	4.05 (0.60 to 27.3)	0.151
None	0.43 (0.09 to 2.21)	0.316

\* Significant at 5% level.

OR, Odds Ratio.