

# Predictors of oral pre-exposure prophylaxis (PrEP) uptake among individuals in a HIV vaccine preparedness cohort in Masaka, Uganda

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## Abstract

Oral pre-exposure prophylaxis (PrEP) significantly reduces human immunodeficiency virus (HIV) acquisition risk. However, data on predictors of PrEP uptake in sub-Saharan Africa are limited. We assessed predictors of PrEP uptake among HIV-uninfected high risk individuals enrolled in a HIV vaccine preparedness study in Masaka, Uganda.

Between July 2018 and October 2020, we recruited adults (18–40 years) from sex work hotspots along the trans-African highway and Lake Victoria fishing communities. We collected baseline data on socio-demographics and PrEP awareness, and provided HIV counselling and testing, information on PrEP, and PrEP referrals at quarterly visits. Urine pregnancy tests (women) and data collection on sexual risk behaviour and PrEP uptake were performed every 6 months. We analysed PrEP uptake among participants who had completed 6 months of follow-up.

Of the 588 cohort participants, 362 (62%) were included in this analysis. Of these, 176 (49%) were female, 181 (50%) were aged <24 years, 104 (29%) worked in sex work hotspots, 74 (20%) were fisher folk. Only 75 (21%) participants initiated PrEP. Predictors of PrEP uptake included having ≥6 sex partners (adjusted odds ratio [aOR] = 2.29; 95% confidence interval [CI] 1.26–4.17), engaging in transactional sex (aOR = 2.23; 95% CI 0.95–5.20), and residence in a nonfishing community (aOR = 2.40; 95% CI 1.14–5.08). The commonest reasons for not starting PrEP were pill burden (38%) and needing more time to decide (27%).

PrEP uptake was low and associated with HIV risk indicators in this cohort. Interventions are needed to improve access to PrEP especially in fishing communities.

**Abbreviations:** AIDS = acquired immunodeficiency syndrome, aOR = adjusted odds ratio, ART = antiretroviral therapy, CI = confidence interval, HCT = HIV counselling and testing, HIV = human immunodeficiency virus, MSM = men who have sex with men, OR = odds ratio, PrEP = pre-exposure prophylaxis, SSA = sub-Saharan Africa.

**Keywords:** cohort, high risk, human immunodeficiency virus, predictors, pre-exposure prophylaxis, Uganda, uptake

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## 1. Introduction

Despite various human immunodeficiency virus (HIV) prevention interventions, HIV remains a major global public health problem. In 2018, 1.7 million new infections were reported globally, with 66% of these infections occurring in sub-Saharan Africa (SSA).<sup>[1]</sup> Majority of these infections were among key populations (men who have sex with men, female sex workers, injecting drug users, others) and their sexual partners. The slow decline in new infections has been termed a prevention crisis by Joint United Nations Programme on HIV/acquired immunodeficiency syndrome (AIDS).<sup>[2]</sup> It has been suggested that in the absence of a cure and/or vaccine against HIV, acceptance of prevention interventions like pre-exposure prophylaxis (PrEP) needs to be increased rapidly.<sup>[1,3]</sup>

PrEP is widely considered as an effective prevention intervention for populations at high risk of acquiring HIV. Several trials demonstrated the efficacy of tenofovir disoproxil fumarate and emtricitabine (Truvada) in reducing the risk of HIV transmission.<sup>[4]</sup> Based on this evidence, the US Food and Drug Administration approved the use of Truvada as PrEP in 2012.<sup>[5]</sup> The World Health Organization also recommended the adoption of PrEP as one of the strategies to combat new HIV infections among key populations.<sup>[6]</sup> Countries in the developed world embraced PrEP earlier<sup>[7]</sup> and roll out is currently ongoing in other countries including in SSA.<sup>[3,8]</sup>

Despite these advances, uptake of PrEP has been slow in SSA. In 2016, a declaration was made by the United Nations General Assembly to provide oral PrEP to 3million people at risk of HIV infection by 2020, but by the end of 2017, only 350,000 people had ever taken PrEP with two-thirds of the users in the United States of America.<sup>[9]</sup> Expansion of PrEP provision in SSA will particularly require effectively engaging most at-risk populations who account for 25% of new HIV infections.<sup>[10]</sup> However, data on barriers and facilitators of PrEP uptake in this population are limited. The aim of this study was to assess predictors of PrEP uptake among adults at high risk of HIV infection who were enrolled in an HIV vaccine preparedness study in Masaka, Uganda.

## 2. Materials and methods

### 2.1. Study design and participants

This analysis used data from an HIV vaccine preparedness cohort study “The PrEPVacc registration cohort”. The aim of the PrEPVacc registration cohort study was to prepare a population of HIV-negative individuals who are at risk of acquiring HIV for possible participation in the PrEPVacc HIV vaccine efficacy trial.<sup>[11]</sup> The study was initiated in July 2018 and is taking place at 5 clinical research sites in South Africa, Mozambique, Tanzania, and Uganda.

In Uganda, the study was conducted at the Medical Research Council/Uganda Virus Research Institute and London School of Hygiene and Tropical Medicine Uganda Research Unit’s clinical research site in Masaka city, Masaka district. Study participants were recruited from sex work hotspots along the trans-African highway and fishing communities along the shores of Lake Victoria within a radius of approximately 80km from Masaka city. To be eligible for the study, individuals had to be 18 to 40 years old, HIV-negative, willing to provide locator information and available for follow-up, and be at risk of HIV infection as defined by any of the following: suspected/confirmed sexually transmitted infection or unprotected sex with  $\geq 2$  partners or unprotected sex with a new partner in the past 3 months or unprotected sex in exchange for money/goods in the past month.

### 2.2. PrEP services

The PrEP programme in greater Masaka region (Masaka district and 9 neighbouring districts) is implemented at 10 health facilities spread across the region under the stewardship of the regional implementing partner, Rakai Health Sciences Program. The programme is supported by the U.S. President’s Emergency Plan for AIDS Relief through the US Centers for Disease Control and Prevention – Uganda.<sup>[12]</sup> The health facilities are located within a range of 1 km (eg, The AIDS Support Organisation – Masaka clinic) to 74 km (eg, Lyantonde hospital) of the clinical research site in Masaka.

PrEP is provided according to the national guidelines to individuals who are considered to be at substantial risk of HIV acquisition as per the following criteria: unprotected vaginal sex with more than 1 partner of unknown HIV status in the past 6 months; anal sex in the past 6 months; transactional sex in the last 6 months; use or abuse of drugs especially injectable drugs in the last 6 months; more than 1 episode of a sexually transmitted infections within the last 12 months; partner of a discordant couple, especially if the HIV-positive partner is not on

antiretroviral therapy (ART) or has been on ART for less than 6 months or not virally suppressed; recurrent ( $>3$  times per year) postexposure prophylaxis; belonging to a key population and being unable or unwilling to achieve consistent use of condoms.<sup>[13]</sup> All PrEPVacc registration cohort participants were eligible for oral PrEP.

### 2.3. Sample size considerations

Assuming a PrEP uptake of 30% as reported in previous studies,<sup>[14,15]</sup> it was estimated that a minimum of 282 participants would provide more than 80% power to identify predictors that increase the likelihood of starting PrEP by an odds ratio (OR)  $\geq 2$ . A larger sample size would be needed if PrEP uptake were to be lower than 30%. For example, 344 participants would be needed if PrEP uptake were 20%.

### 2.4. Procedures

Prospective study participants were identified through HIV counselling and testing (HCT) outreaches in the study communities. Individuals who tested HIV-negative were provided brief information about the study and those who expressed interest invited to the study clinic for screening and possible enrollment.

Screening and enrollment were conducted at the same visit. Screening procedures consisted of provision of detailed study information, obtaining written informed consent, repeat HCT, urine pregnancy testing (women), eligibility assessment, and enrollment for those eligible. Enrollment procedures consisted of collection of locator, socio-demographics, and HIV risk behaviour data. An experienced study counsellor provided information on oral PrEP including its benefits and possible side effects, PrEP adherence counselling, and for individuals who were willing to initiate PrEP, a written referral to a PrEP provider.

At quarterly visits, participants received HCT and information and counselling on and referrals for PrEP as appropriate. Every 6 months, participants had a urine pregnancy test done (women) and completed questionnaires on HIV risk behaviour and PrEP uptake.

### 2.5. Laboratory methods

Blood was obtained by venepuncture for testing using HIV rapid test kits: Alere Determine HIV-1/HIV-2 (Alere Medical Co Ltd, 357 Matsuhidai Matsudo-shi, Chiba-ken 270- 2214, Japan) for screening, Stat-Pak HIV 1/2 (Chembio Diagnostic systems, New York, NY11763) for confirmation of positive results, and Standard Diagnostics Bio line (Standard Diagnostics, Kyonggi-do, South Korea) as tie-breaker.  $\beta$ -Human chorionic gonadotropin reagent strips (QuickVue hCG Combo, Quidel Corporation, San Diego, CA92121) were used to perform urine pregnancy testing.

### 2.6. Statistical analysis

Data management and analysis were conducted in OpenClinica (Community Edition) and Stata version 15.0 (College Station, TX), respectively. The analysis was restricted to those participants who had completed 6 months of follow-up. Participant characteristics were summarised using frequencies and percentages for categorical variables and means (standard deviation) and/or medians (interquartile ranges) for continuous variables.

Logistic regression models were fitted to identify predictors of PrEP uptake. Predictors that had a  $P$ -value  $\leq .2$  at bivariate analysis were included in the multivariable analysis. Variables were retained in the multivariable model if their  $P$ -value was  $\leq .1$  using backward selection (Wald). Only age and gender were included a priori. OR and 95% confidence intervals (CI) were reported at both univariate and multivariable analysis.

## 2.7. Ethical considerations

The PrEPVacc registration cohort study was approved by the Uganda Virus Research Institute Research Ethics Committee (GC/127/18/03/637), the Uganda National Council for Science and Technology (HS2392). All participants provided written informed consent before undergoing study procedures. Individuals who tested HIV-positive at any of the study visits were provided post-test counselling and referred for HIV care. Additionally, pregnant HIV-positive female participants were referred to prevention-of-mother-to-child HIV transmission services.

## 3. Results

By October 2020, a total of 862 individuals had been screened for eligibility of whom 588 (68%) were enrolled in the PrEPVacc registration cohort. The commonest reasons for ineligibility were being at low risk for HIV infection ( $n=265$ , 97%) and HIV infection ( $n=5$ , 2%). Of those enrolled, 362 (62%) had completed the month-6 follow-up visit. The mean age of participants in this group was 26 years (standard deviation = 6.0). Most were male (51%), single or divorced/separated/widowed (59%), and only had primary school education or less (67%) (Table 1).

### 3.1. Oral PrEP uptake and associated factors

At the month 6 visit, only 75 (21%) participants reported having started oral PrEP at 5 health facilities. Reasons for not starting oral PrEP included: pill burden (38%), needing more time to decide (27%), unavailability of PrEP in participant's area of residence (7%), fear of stigmatisation (6%), partner refusal/ needing more time to discuss with partners (6%), preference for condoms (5%), plans to change behaviour (4%), fear of side effects (1%), and being currently pregnant (1%). None of the participants who made it to the referral site was found to be ineligible for PrEP.

At bivariate analysis, being female (OR = 2.56, 95% CI 1.5–4.36), residence in a nonfishing village (OR = 2.34, 95% CI 1.31–4.18), occupation [sex worker (OR = 3.89, 95% CI 2.20–6.90); other (OR = 0.46, 95% CI 0.26–0.81)], transactional sex in the past month (OR = 4.14, 95% CI 1.91–8.98), condom use at last sex act (OR = 2.24, 95% CI 1.30–3.86), having a sexual partner who is older by 10 years (OR = 2.33, 95% CI 1.38–3.94),  $\geq 6$  partners (OR = 3.87, 95% CI 2.28–6.56) and awareness of PrEP at baseline (OR = 1.83, 95% CI 1.10–3.06) were associated with uptake of PrEP. At multivariable analysis, residence in a nonfishing village (adjusted odds ratios [aOR] = 2.40, 95% CI 1.14–5.08), occupation [salon/lodge/bar worker/market or street vendor (aOR) = 0.40, 95% CI 0.19–0.83]; Other (aOR = 0.41, 95% CI 0.19–0.89)] and having  $\geq 6$  sexual partners (aOR = 2.29, 95% CI 1.26–4.17) remained significantly associated with PrEP uptake. Transactional sex in past month was

**Table 1**

**Baseline socio-demographic characteristics of 362 at-risk individuals referred for oral PrEP at Masaka, Uganda.**

Characteristics	Frequency (%)
Total	362 (100)
Gender	
Male	186 (51)
Female	176 (49)
Mean age (SD)	26 (6.0)
Age	
$\leq 24$	181 (50)
25– to 34	142 (39)
$\geq 35$	39 (11)
Education	
Primary school and below	241 (67)
Secondary school and above	121 (33)
Marital Status	
Single	163 (45)
Married/cohabiting/relationship	148 (41)
Divorced/separated/widowed	51 (14)
Religion	
Christian	277 (77)
Muslim/other	85 (23)
Occupation*	
Sex worker	69 (19)
Subsistence fisheries worker	74 (20)
Salon/lodge/bar worker, market/street vendor	104 (29)
Other <sup>†</sup>	141 (39)
Residence	
Fishing village	140 (39)
Nonfishing village	222 (61)
Source of income	
Sex work	69 (19)
Other <sup>‡</sup>	293 (81)

SD = standard deviation.

Bold indicate the level of significance of the  $P$ -value  $< 0.05$

\* Multiple options allowed.

<sup>†</sup> Professional/technical worker, sales/service worker, office clerk, student, etc.

<sup>‡</sup> Formal/informal employment, family, spouse, etc.

marginally associated with PrEP uptake (aOR = 2.23, 95% CI 0.95–5.20) (Table 2).

## 4. Discussion and conclusions

Our study shows that uptake of PrEP was low (21%) among high risk individuals enrolled in an HIV vaccine preparedness study. This finding confirms literature which shows that adoption of PrEP in the real-world setting has been slow.<sup>[16]</sup> Demonstration projects among well-defined at-risk populations such as serodiscordant couples<sup>[17,18]</sup> and men who have sex with men (MSM),<sup>[19]</sup> have reported high PrEP uptake. However, in a population-based demonstration project in Uganda and Kenya, uptake of PrEP was low (27%)<sup>[20]</sup> and similar to that in our study. Consistent with previous studies,<sup>[19,21]</sup> we found that individuals who reported high-risk behaviour such as engaging in transactional sex and having multiple partners were more likely to take up PrEP than those who did not. This may be because such individuals perceive themselves as being at high risk of HIV infection. On the other hand, low perceived risk of HIV may explain the observed low uptake of PrEP among individuals whose reported primary occupation was not sex work. For example, although female bar workers commonly engage in transactional sex, they often do not perceive themselves to be at

**Table 2**  
**Logistic regression analysis of predictors of oral PrEP uptake.**

Characteristic	N	PrEP uptake (%)	Bivariate analysis		Multi-variable analysis	
			OR (95% CI)	P-value	aOR (95% CI)	P-value
<b>Overall</b>	<b>362</b>	<b>75 (21)</b>				
Gender						
Male	186	25 (13)	<b>Ref</b>		<b>Ref</b>	
Female	176	50 (28)	2.56 (1.50 to 4.36)	<b>.001</b>	1.53 (0.76 to 3.09)	.237
Age						
<24	181	42 (23)	<b>Ref</b>		<b>Ref</b>	
25 to 34	142	25 (18)	0.71 (0.41 to 1.23)		0.65 (0.35 to 1.18)	
≥35	39	8 (21)	0.85 (0.36 to 2.00)	.464	1.34 (0.51 to 3.48)	.227
Education						
Primary school and below	241	46 (19)	<b>Ref</b>			
Secondary school and above	121	29 (24)	1.34 (0.79 to 2.26)	.281		
Marital status						
Single	163	33 (20)	<b>Ref</b>			
Married/cohabiting/relationship	148	27 (18)	0.88 (0.50 to 1.55)			
Divorced/separated/widowed	51	15 (29)	1.64 (0.80 to 3.35)	.254		
Residence						
Fishing village	140	18 (13)	<b>Ref</b>		<b>Ref</b>	
Nonfishing village	222	57 (26)	2.34 (1.31 to 4.18)	<b>.004</b>	2.40 (1.14 to 5.08)	<b>.020</b>
Religion						
Christian	277	58 (21)	<b>Ref</b>			
Muslim/other	85	17 (20)	0.94 (0.52 to 1.73)	.852		
Occupation						
Sex worker	69	29 (42)	3.89 (2.20 to 6.90)	<b>&lt;.001</b>		
Subsistence fisheries worker	74	13 (18)	0.78 (0.40 to 1.51)	.454		
Salon/lodge/bar worker, market/street vendor	104	22 (21)	1.04 (0.59 to 1.82)	.897	0.40 (0.19 to 0.83)	<b>.014</b>
Other*	141	19 (13)	0.46 (0.26 to 0.81)	<b>.007</b>	0.41 (0.19 to 0.89)	<b>.024</b>
Used a condom at last sex						
No	270	46 (17)	<b>Ref</b>			
Yes	92	29 (32)	2.24 (1.30 to 3.86)	<b>.004</b>		
Transactional sex in past month						
No	103	8 (8)	<b>Ref</b>		<b>Ref</b>	
Yes	259	67 (26)	4.14 (1.91 to 8.98)	<b>&lt;.001</b>	2.23 (0.95 to 5.20)	<b>.065</b>
Has anonymous/casual sexual partners						
No	26	1 (4)	<b>Ref</b>			
Yes	336	74 (22)	7.06 (0.94 to 52.98)	<b>.057</b>		
Sexual partner is older by ≥10 yr						
No	195	28 (14)	<b>Ref</b>			
Yes	167	47 (28)	2.33 (1.38 to 3.94)	<b>.001</b>		
Number of sexual partners last 3 mo						
1–5	245	32 (13)	<b>Ref</b>		<b>Ref</b>	
≥6	117	43 (37)	3.87 (2.28 to 6.56)	<b>&lt;.001</b>	2.29 (1.26 to 4.17)	<b>.006</b>
Diagnosed with/treated for a STI in the past 3 mo						
No	219	40 (18)	<b>Ref</b>			
Yes	143	35 (24)	1.45 (0.87 to 2.42)	.155		
Awareness of PrEP at baseline						
No	221	37 (17)	<b>Ref</b>			
Yes	141	38 (27)	1.83 (1.10 to 3.06)	<b>.020</b>		

aOR=adjusted odds ratio, CI=confidence interval, N=number, OR=odds ratio, PrEP=pre-exposure prophylaxis, Ref=reference, STI=sexually transmitted infection.

Bold indicate the level of significance of the P-value <.05

\* Professional/technical worker, sales/service worker, office clerk, student, etc.

risk of acquiring HIV.<sup>[22]</sup> Studies have shown that self-perceived low risk of HIV infection is a major factor in the low uptake of PrEP.<sup>[2,3]</sup>

We found that residence was significantly associated with PrEP uptake with individuals who lived in nonfishing communities having higher odds of uptake. Compared to fishing communities, nonfishing communities in Uganda generally have better access to healthcare services.<sup>[24]</sup> Factors that impede access to healthcare in fishing communities include their usually remote locations, poor road infrastructure and the resulting high cost of travel to and

from healthcare facilities.<sup>[25,26]</sup> These findings are consistent with previous studies which have showed that residence in urban areas is associated with increased uptake of PrEP.<sup>[27,28]</sup>

Pill burden was the most common reason for not starting PrEP. Similar findings have been reported in studies among MSM<sup>[23]</sup> and other high risk populations.<sup>[29–32]</sup> This has been attributed to concerns about the pill size or other attributes, and the burden of daily pill-taking.<sup>[33]</sup>

Stigma was also a common reason for not starting PrEP. Stigma has been reported as a barrier to PrEP uptake in other



studies,<sup>[34–36]</sup> and has been attributed to concerns such as having to take the same pill that is used to treat HIV-positive persons and PrEP being largely provided at HIV treatment clinics. Studies have shown that PrEP is considered ART not just in the personal understanding of PrEP but also in expectations of how others perceive its use, thus causing fear of HIV-related stigma and discrimination.<sup>[37]</sup> This potential stigma has been reported among MSM in Kenya<sup>[38,39]</sup> and women at high risk of HIV infection in South Africa.<sup>[40,41]</sup>

Another common reason for not starting PrEP was the need for more time to consult partners on whether to take up PrEP or not. Studies have shown that individuals would want their partners to know whether they were taking PrEP or not,<sup>[42]</sup> while some want their partners to support them in decision making. A study in Uganda and Kenya reported that it was easier for men to initiate PrEP without discussing it first with their partners. However, women needed to seek permission from their partners to avoid suspicion that its use would lead to infidelity and mistrust.<sup>[43]</sup>

A strength of the current study is that participants were not offered PrEP by the study staff but referred to local PrEP providers that were independent of the research team. Hence uptake of PrEP required initiative from the participants and may reflect what might happen in the real-world outside demonstration and/or research projects in which PrEP is provided by project staff. Also, the longitudinal design of the study made it possible to collect information on referral and PrEP uptake and document reasons for nonuptake. Detailed qualitative research to understand the facilitators and barriers to PrEP uptake in this population is ongoing and will be reported separately. A major limitation of this study is that PrEP uptake was self-reported. We did not contact PrEP providers to verify the self-reports. Hence it is possible that some participants may have falsely reported that they had started PrEP. However, the fact that referrals were provided only to participants who expressed interest to start PrEP may have minimised this bias.

Uptake of PrEP in this cohort was low but associated with reported indicators for high HIV risk behaviour and area of residence. This points to the need for strategies that will help individuals to properly evaluate their risk for them to make informed decisions on whether to start PrEP or not. There is need to improve access to PrEP services particularly in communities with at risk populations and to devise strategies for reducing stigma associated with PrEP use.

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