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Research Article

Self-reported and Pharmacologic Adherence During a Demonstration Project on HIV Pre-exposure Prophylaxis among Men who have Sex with Men in Benin

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Abstract

Background and aim. The effectiveness of oral pre-exposure prophylaxis (PrEP) for HIV prevention relies on Adherence. Accordingly, the aim of this study was to compare self-reports that are commonly used in sub-Saharan Africa to monitor adherence with dried blood spots-based results.

Materials and methods. The study was part of an oral PrEP demonstration project conducted from August 2020 to December 2021 among 204 men who have sex with other men in Benin. The Mc Nemar test and bivariate log-binomial regression models using the GENMOD procedure were performed to compare adherence levels and explore the association between pharmacologic adherence and four indicators for oral PrEP initiation in Benin.

Results. Only 46% and 24.3% of men who provided dried blood spots had detectable drugs levels at month-6 and month-12, respectively. At month-6, perfect adherence for daily PrEP was 92% (self-reports) and 10% (pharmacologic measure; p-value<0.0001) and for event-driven, 49% (self-reports) and 31% (pharmacologic measure; p-value=0.008). At month-12, the corresponding values were 94% and 5% (p<0.0001), and 40% and 27% (p=0.005), respectively. In bivariate analyses, the p-values estimating the association between HIV risk factors and pharmacologic perfect adherence (≥1450 fmol/punch) were 0.173 for consistent condom use, 0.303 for NG and/or CT infections, 0.447 for drug or alcohol consumption, and 0.129 for multiple sexual partnership. Similar results were obtained for partial adherence (≥800 fmol/punch). In post-hoc analyses, three HIV seroconversions were observed in men with a pharmacologic drug concentration <400 fmol/punch.

Conclusions. Adherence was generally low and self-reported adherence tended to overestimate pharmacologic adherence. Oral PrEP should be implemented along with continuous adherence support interventions and other HIV prevention tools, including injectable PrEP, so that people can choose the method that adjust the best to their daily life conditions.

Keywords: HIV prevention; pre-exposure prophylaxis; men who have sex with men; sub-Saharan Africa; Benin; adherence; truvada

Introduction:

The human immunodeficiency virus (HIV) epidemic continues to be a major public health issue in sub-Saharan Africa where disproportionate rates of infections are occurring among key populations [1]. In 2022, in Western and Central Africa, 34% of all new HIV infections were estimated among key populations and their sexual partners [1]. In a study conducted from June 2016 to November 2018 in Benin, West Africa, HIV incidence was estimated at 59.1 per 1,000 persons-years (95% Confidence Interval, 95%CI: 4.46–7.85) among men who have sex with other men (MSM) [2]. In the general population, all ages included, it was estimated at 0.3 (0.23-0.44) and 0.1 (0.08-0.21) per 1,000 person-years in 2015 and 2021, respectively [3].

According to the UNAIDS annual estimates, many sub-Saharan African countries are achieving remarkable results in the fight against the epidemic. In 2023, for the first time ever, the number of new HIV infections estimated in this region was lower as compared to the rest of the world [1]. This optimistic result is partly due to a combination of interventions, such as early antiretroviral therapy for people living with HIV and oral pre-exposure-prophylaxis (PrEP) for HIV negative people [1, 3].

In 2015, the World Health Organization recommended oral PrEP for people who are at increased risk of HIV infection [4]. This decision was based on strong evidence from randomized clinical trials [5, 6]. To guide Beninese health authorities in their process to make this additional prevention tool available for key populations, we conducted, from August 2020 to December 2021, an oral PrEP demonstration study among MSM living in Cotonou, the major economic city of the country. The objective of the demonstration study was to assess, in real world conditions, the pertinence, acceptability and feasibility of a generic combination of tenofovir disoproxil fumarate-TDF 300 mg/emtricitabine-FTC 200 mg (TDF-FTC). Oral PrEP was added to other interventions such as condom distribution, screening and treatment of STIs, as well as early antiretroviral therapy. In the current study, we aimed to compare self-reported adherence (face-to-face questionnaire) with pharmacologic-based results using dried blood spots (DBS). Studying oral PrEP-taking behaviour through accurate adherence measures might help health authorities to develop friendly adherence support strategies and HIV control interventions that align with peoples' needs.

Materials and Methods:

Study setting and population: The PrEP demonstration project took place at the Dispensaire IST, the first public health centre dedicated to the management of sexually transmitted infections among female sex workers (FSWs) and MSM in the study catchment area that was the city of Cotonou. The city had 13 districts and was home to 3,000 HIV-negative MSM, approximately [7]. These men were eligible to participate in the study as far as they had at least 18 years of age, were members of one of the two MSM organizations in Cotonou and provided a written informed consent. Men with anti-Hepatitis C virus antibodies (IgG) and a creatinine clearance less than 60ml/min according to the Cockcroft-Gault equation could not participate [8]. The number of participants was limited to 204 HIV-negative men in order to minimize the overall research cost. To select these participants, we chose seven districts out of the 13. The number of men enrolled in each district by the study investigators was proportional to its size [9]. The enrolment process continued until reaching the sample size. The choice of the districts and the participants followed a random process as described elsewhere [9, 10].

At the beginning of the project, ten members from the two MSM organizations received training so that they could promote the study and mobilize their peers for participation. Each eligible man encountered by the ten peer-educators in the field received a voucher with a unique identification number and an appointment was settled at the study centre for completion of the enrolment process. Enrolment elapsed between August 24 and November 24, 2020. Follow-ups occurred quarterly and the last participants were seen in December 2021. Peer-educators visited the communities to look for participants who did not attend a follow-up visit. Men could visit the study centre any time and for any type of support or health service [9].

Data collection: At enrolment, month-6 and month-12, participants answered to a standardized questionnaire and provided biological samples. Trained investigators administered the questionnaires to collect information on sociodemographic characteristics, sexual behaviour, and adherence to oral PrEP [11]. A health worker collected a blood sample for HIV, HBV and HCV screening. HIV-negative status was validated using two consecutive tests: the One Step Multi-Infectious Disease Test (HBsAg/HCV/HIV/TP) followed by SD Bioline (). Men with a positive reaction to at least one of these two tests were excluded. Screening of HBV and HCV consisted in a rapid immuno-chromatographic test for HBV surface antigen (HBsAg) and HCV antibodies, and enzyme immunoassay (EIA) for HBV core antibodies (anti-HBc) as well as for surface antibodies (anti-HBs) [8, 9].

At study entry, each participant chose between daily PrEP (one pill every day) or event-driven PrEP (two pills 2–24 hours before sex, one after 24 hours and the fourth pill 48 hours after the first two pills) [8]. Daily PrEP was recommended for participants with active HBV. All participants received at study entry a 30-pill bottle of TDF-FTC. They renewed the drugs each month for daily PrEP. For the event-driven sub-group, refills were based on a schedule co-prepared and co-validated by the participant and the study doctor [9]. Refills occurred in the field through peer-educators or at the study centre by a trained nurse. Participants received at no cost, adherence support, condoms and lubricant gel on a monthly basis. During follow-up, participants were instructed to report switches between daily and event-driven PrEP. Adherence was assessed orally (self-reports) and through laboratory testing at months 6 and 12. For pharmacologic adherence, TDF diphosphate (TDF-DP) concentration in DBS collected and stored at -80°C was measured using a validated high-performance liquid chromatography-mass spectrometric method [12]. Pharmacologic adherence assessment was limited to 184/204 (90%) participants, due to financial constraints. The lower limit of quantification was 25.0 fmol/sample. The definition of perfect adherence was: (i) daily PrEP: taking 7 pills during the last week; (ii) event-driven PrEP: last 7 at-risk sexual intercourses covered; and (iii) pharmacologic adherence: ≥1450 fmol/punch. Partial adherence was defined as: (iv) daily PrEP: taking 4-6 pills during the last week; (v) event-driven PrEP: 4-6 episodes

out of the last 7 at-risk sexual intercourses covered; and (vi) pharmacologic adherence: ≥800 fmol/punch [9, 12]. The thresholds for TDF-DP were based on a validated and updated method of extraction and interpretation [12].

Statistical analysis: The data was validated before undergoing a double entry process with the EpiData software. Descriptive results were presented as means ± standard deviations (SD) or proportions (95% Confidence interval, 95%CI). Self-reported and pharmacologic adherence proportions were compared using Mc Nemar's test. Bivariate log-binomial regression models using the GENMOD procedure were performed with SAS (version 9.4, SAS Institute Inc, Cary, NC, USA), to explore the association between biological perfect and partial adherence and four indicators for oral PrEP initiation in Benin (unprotected sex, NG and/or CT infections, drug use or alcohol consumption during sexual intercourses, and multiple sexual partnership). Due to the limited number of events, it was not possible to perform multivariate analyses.

Ethical considerations: All participants provided a written informed consent and were given an amount of approximately 8 USD for transportation cost and time devoted to the study activities. Drugs were provided free of charge as per local guidelines. No major adverse effect was expected. The study was approved by the institutional ethics committees of the CHU de Québec–Université Laval, Québec, Canada (Projet 2020-5105/ Approbation finale) and the Benin National Ethics Committee for Health Research (N°_014/MS/DC/SGM/DRFMT/CNERS/SA-Avis favorable n°4 du 30 Janvier 2020). This approval included a partial disclosure authorization, which allowed researchers to withhold the information related to biological monitoring of drugs. Not withholding this information could have affected in a way or another participants adherence behaviour, the primary outcome of interest and become a source of bias.

Results:

Overall, 81% of the 204 men who participated in the PrEP demonstration project were single, 48% had a postsecondary education level (Table 1),

Characteristics	**n (%)**
Age	
Mean (±standard deviation)	25.9 (±4.76)
Marital status	
Maried/Cohabiting	34 (16.7)
Single	165 (80.9)
Other	5 (2.4)
Education	
Never attended school	1 (0.5)
Primary	14 (6.9)
Secondary	91 (44.6)
Postsecondary	98 (48.0)
Monthly guaranteed minimum average (FCFA)	
Yes	89 (43.6)
No	114 (55.9)
No answer	1 (0.5)
Receptive or versatile sexual role	
Yes	75 (36.8)
No	129 (63.2)
Number of male sexual partners during the last six months	
Mean (±standard deviation)	2.1 (±1.70)
Consistence condom Use during last six months	
Yes	70 (34.3)
No	134 (65.7)
Condom use during last sex†	
Yes	111 (59.4)
No	76 (40.6)

NG and/or CT anal infection	
Yes	32 (15.7)
No	172 (84,3)
Alcohol or Drugs Use during last six months	
Yes	10 (4.9)
No	194 (95.1)

Notes: %, Proportion; †, 17 missing values; F CFA, CFA francs (US$1 = 500 CFA francs, approximately); MSM, Men who have sex with men; n, number; PrEP, Pre-Exposure Prophylaxis

Table 1. Baseline synoptic description of 204 Men who have sex with other men initiating PrEP, Benin, 2020-2021

96% were from Benin, four out five had between 18 and 29 years of age, and 53% have reported at least two male sexual partners during the last six month. Receptive and versatile (receptive/insertive) anal sex roles were reported by 20% and 17% of men.

In total 84/184 (46%) and 42/173 (24.3%) men had detectable drugs levels at month-6 and month-12, respectively. During the two periods, perfect adherence using pharmacologic definition was 7% and 3%, respectively (p=0.003; Table 2).

Adherence measure	Category	Month-6, N=184 n (%)	Month-12, N=173 n (%)
TFV-DP, fentomole/punch	≥1450	13 (7.1)	5 (2.9)
	800 - 1450	13 (7.1)	6 (3.5)
	400 - 799	12 (6.5)	5 (2.9)
	<400	146 (79.3)	157 (90.7)
Self-reported (daily PrEP)	Yes	67 (48.6)	57 (50.9)
	No	71 (51.4)	55 (49.1)
Self-reported (event-driven PrEP)	Yes	31 (73.8)	48 (78.7)
	No	11 (26.2)	13 (21.3)

Notes: †Bowker's test of symmetry; %, Proportion; n, Number: PrEP, Pre-Exposure Prophylaxis.

Table 2. Perfect adherence using pharmacologic and self-report measures in 204 adult men who have sex with men initiating PrEP in Benin, 2020-2021.

Approximately, one man out of two (daily oral PrEP) and three men out of five (event-driven PrEP) have reported perfect adherence at both periods (p-values for comparisons >0.05). Partial adherence was 14% (month-6) and 6% (month-12) for pharmacologic measure (p<0.05). For self-reports, the corresponding proportions were 99% and 100% for daily oral PrEP (p=0.367), and 81% and 80% for event-driven oral PrEP (p=0.937).

Using within-subjects comparisons at month-6, perfect adherence was for daily PrEP, 92% (self-reports), and 10% (pharmacologic measure) on one side (p-value<0.0001) and for event-driven, 49% (self-reports) and 31% (pharmacologic measure) on the other side (p-value=0.008, Table 3).

		Pharmacologic perfect adherence			
Self-reported perfect adherence					
Month-6	Category	Yes	No	Total	P-value
Daily	Yes	11	108	**119 (92.2%)**	<0.0001
	No	2	8	10	
	Total	**13 (10.1%)**	116	129	
Event-driven	Yes	12	7	**19 (48.7%)**	0.008
	No	0	20	20	
	Total	**12 (30.8%)**	27	39	
Month-12	Category	Yes	No	Total	P-value
Daily	Yes	5	97	**102 (94.4%)**	<.0001
	No	0	6	6	
	Total	**5 (4.6%)**	103	108	
Event-driven	Yes	16	8	**24 (40.0%)**	0.005
	No	0	36	36	
	Total	**16 (26.7%)**	44		

Note: †Restricted to 168 participants with measures at month-6 and month-12

Table 3. Comparison of pharmacologic and self-reported perfect adherence among men who have sex with men initiating PrEP in Benin, 2020-2021†

At month-12, the corresponding values were 94% and 5% (p<0.0001), and 40% and 27% (p=0.005), respectively. In bivariate analyses, the p-values estimating the association between HIV risk factors and pharmacologic perfect adherence (≥1450 fmol/punch) were 0.173 for consistent condom use, 0.303 for NG and/or CT infections, 0.447 for drug or alcohol consumption, and 0.129 for multiple sexual partnership (Table 4).

	% (95%CI)	aPR (95%CI)
Consistent condom use, last 6 months		
No	9.0 (5.1-16.0)	0.7 (0.39-1.19)
Yes	13.3 (9.0-19.9)	
Condom use, last sex		
No	9.0 (4.3-18.5)	0.8 (0.39-1.46)
Yes	11.8 (8.1-17.2)	
NG and/or CT infection, last six months		
Yes	7.9 (4.0-16.0)	0.7 (0.32-1.42)
No	11.7 (7.8-17.7)	
Drug/alcohol consumption during sex, last six months		
No	5.4 (0.8-35.4)	0.5 (0.07-3.16)
Yes	11.3 (7.6-16.6)	
Number of sexual partners, last six months		
≥2	9.9 (6.5-15.0)	0.7 (0.38-1.13)
0-1	15.1 (8.6-26.2)	

Note: †Restricted to 168 participants with measures at month-6 and month-12; %, Proportion; aPR, adjusted proportion ratio (adjusted for oral PrEP type i.e., daily/event-driven and the visit i.e., month-6/month-12); CI, Confidence interval; CT, *Chlamydia trachomatis*; MSM, Men who have sex with other men; NG, *Neisseria gonorrhoeae*; PrEP, Pre-exposure prophylaxis

Table 4. Association between perfect pharmacologic adherence and risk-taking variables in MSM initiating PrEP in Benin, 2020-2021†

For partial adherence (≥800 fmol/punch), the corresponding results (aPR; 95%CI, p-value) were: consistent condom use (0.8; 0.51-0.36; 0.476), NG and/or CT infections (0.9; 0.50-1.64, 0.750); drug or alcohol consumption (0.7; 0.18-2.78; 0.628); and multiple sexual partnership (0.8; 0.49-1.34; 0.413). Similar results were obtained using self-reported perfect adherence, except for condom use during last six months: inconsistent 70.0% (62%-77%) versus consistent 76.7% (71%-83%), aPR 0.9 (0.82-0.99), p=0.037. In post-hoc analyses, three HIV seroconversions were observed in men with a pharmacologic drug concentration <400 fmol/punch.

Discussion:

The majority of the study HIV-negative MSM in this study were young, single and educated. According to the answers they provided during face-to-face interviews, half of them were taking seven pills per week for daily oral PrEP and more than 70% had their seven last at-risk sexual intercourses covered for event-driven oral PrEP. Suboptimal adherence to oral PrEP depends on reasons such as underestimation of one's actual risk of acquiring HIV and intersecting forms of stigmatization [13, 14]. The fact that men were more likely to adhere to event-driven oral PrEP may be due to more challenges occurring with daily oral PrEP such as violence from different community members who perceive people taking pills every day as HIV-positive or as individuals who take unnecessary risk [6, 13, 15, 16]. There was a discrepancy between adherence levels reported by men and pharmacologic-based measures. At month-6 and month-12, irrespective of the regimen type (daily or event-driven oral PrEP), perfect adherence was overestimated by self-reports as compared to pharmacologic assessment (p<0.005). Only 46% and 24% of men had detectable drugs levels in their blood at month-6 and month-12, respectively. In addition, perfect pharmacologic adherence declined by 57% between the two periods, from 7% to 3% (p<0.0001). The poor correlation between self-reports of oral PrEP adherence and pharmacology-based concentrations has already been described among MSM in Nigeria, a neighbouring country in the eastern side of Benin [17], and among FSWs in Benin [18]. Overall, the low rates of perfect adherence reported by participants, especially for daily oral PrEP, and of pharmacologic adherence were not consistent with the adherence support activities that were provided by experienced peer-educators. This discrepancy highlights the importance to adjust and reinforce continuously the adherence support activities and to include oral PrEP into a combination prevention package. Indeed, each prevention tool has its own barriers and facilitators and the probability to avert new HIV infections increases with access to different friendly biomedical, behavioural and community empowerment interventions [19]. These results also emphasized the need to scrutinize the introduction of injectable PrEP into the combination prevention package offered to MSM. Flexible injection schedules could increase retention in injectable PrEP programs and result into more effective protection levels [20].

In bivariate analyses (Table 4), men who had NG and/or CT infections in the past six months as well as those who reported at least two sexual partners or inconsistent condom use during last six months were less likely to have an adequate pharmacologic drug level (≥800 fmol/punch), as compared to their counterparts. However, the proportion ratio adjusted for time and type of oral PrEP regimen (daily versus event-driven) was not statistically different from the null value. Men reporting inconsistent condom use were also less likely to report perfect adherence (≥1450 fmol/punch). The proportion of men with adequate pharmacologic adherence among participants who did not report the use of a psychoactive substance during last six month was half that of their counterparts, even though the proportion ratio was not statistically significant. Since these four HIV risk factors and conditions are key

determinants for oral PrEP initiation in Benin [21], one may consider that the oral PrEP demonstration project was missing some of its primary targets, which could have a limited effect on new HIV infections in this key population. Indeed, it would have been encouraging if most-at-risk men, the primary target of oral PrEP, were those with acceptable adherence levels i.e ≥800 fmol/punch [22, 23]. Actually, two HIV seroconversions occurred during the demonstration project in the daily regimen and one in the event-driven regimen, resulting in a crude HIV incidence (95%CI) of 1.53 (0.31−4.50)/100 person-years [9]. In all three cases, pharmacologic adherence was <400 fmol/punch, a threshold inadequate to protect against HIV acquisition [12, 23]. It has been suggested that PrEP strategies based on risk assessment could increase stigmatization and be counterproductive in key populations [14]. Accordingly, future research needs to focus on adherence support interventions that conjointly account for the determinants of inadequate adherence (risky behaviour) as well as of adequate adherence (protective behaviour). Risky-behaviour will depend on emotional and social factors while protective behaviour will depend on factors such as personal efficacy and social norms [24, 25].

Limitations

This study conducted under quasi-routine practice conditions in a public hospital dedicated to key populations had some limitations. The drivers of adherence to PrEP may change overtime and limit the scope of the study results. Nonetheless, the literature review showed that self-reports consistently underestimate drugs concentration in the blood. Since questions related to sexual and pills taking behaviours are sensitive to social desirability bias, self-reported adherence during face-to-face interviewers could have been overestimated leading to the discrepancy with pharmacologic adherence. TFV-DP concentration using DBS correlates well with HIV prevention and there is no reason to believe that its pharmacokinetics that are subject to patient's susceptibility could have altered the main results [5]. Rather, DBS give an accurate average measure of TFV-DP [26]. Since biological drug monitoring was not extended to all 204 MSM who initiated oral PrEP, the study lack power to assess the association between HIV risk factors and perfect adherence. The restriction of the study sample to Men affiliated with identity-networks and attrition during follow-up may have limited the generalization of the findings. In sensitive analyses, participants who had pharmacologic-based measures were not different from the others on the main variables assessed in this paper (all p-value>0.05).

Conclusion:

In this oral PrEP demonstration project conducted among young and educated men who have sex with other men in Benin, adherence was generally low and self-reported adherence tended to overestimate pharmacologic adherence. Men who were at higher risk of acquiring HIV i.e., those who need oral PrEP the most, had inadequate pharmacologic adherence levels. Interventions that may help in targeting most-at-risk MSM with oral PrEP are still needed. In limited-resource settings such as Benin, oral PrEP should be implemented along with continuous adherence support interventions and other HIV prevention tools, including injectable PrEP, so that people can choose the method that adjust the best to their daily life conditions.

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