Perceived need of, and interest in, HIV pre-

exposure prophylaxis amongst men who

have sex with men attending three sexual

health clinics in London, UK

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Abstract

Background

HIV pre-exposure prophylaxis (PrEP) has proven efficacy in reducing the risk of HIV infection in men who have sex with men, but has not yet been commissioned in the UK. The aim of this study was to investigate perceived need and benefit (or experience of) PrEP among HIV-negative men who have sex with men (MSM) attending sexual health clinics.

Methods

HIV-negative men who have sex with men attending three sexual health centres were opportunistically invited to complete a questionnaire. Data collected comprised demographics and sexual and drug use behaviours as well as questions regarding perceptions of risk and need for PrEP. Logistic regression analysis was undertaken to identify variables predicting acceptability of, and intention to use, PrEP. In addition data were gathered in respondents already taking PrEP.

Results

839 questionnaires were analysed. The median age was 35 (IQR 28-41, range 18-78). 650 (77%) were of white ethnicity. 649 (77%) had a university education. 456 (54%) reported at least one condomless partner in the preceeding three months. 437 (52%) reported recreational drug use in the preceeding three months and 311 (37%) had been diagnosed with an STI within the preceding six months. 463 (64%) of 726 strongly agreed with the statement "I think I would benefit from PrEP". Multivariate logistic regression analysis demonstrated that having receptive anal intercourse without condoms, having an awareness of the risk of unprotected receptive anal intercourse (UPRAI), and having belief in the effectiveness of PrEP were independent predictors for someone thinking they would benefit from taking PrEP. 8% of respondents (59/724) had already taken or were currently taking PrEP.

Discussion

The results suggest that individuals at risk are likely to perceive themselves as benefiting from PrEP. The majority perceived their risk of acquiring HIV and benefit from PrEP accurately. Overall they appeared to have little concern over the use of PrEP and generally

positive attitudes. Further investigation is warranted to understand why those at risk do not perceive benefit from PrEP.

Introduction

HIV pre-exposure prophylaxis (PrEP) has demonstrated efficacy in reducing the risk of sexual acquisition of HIV infection. Based on placebo-controlled randomized trials [1-3], the US Food and Drugs Administration approved the use of daily Truvada (tenofovir and emtricitabine) as PrEP in 2012 [4]. In 2015 the UK PROUD study and French IPERGAY study both demonstrated a reduction of 86% in HIV incidence in men who have sex with men (MSM) taking daily or event based Truvada respectively [5,6]. Following these results the World Health Organisation issued a strong recommendation that PrEP be added to the HIV risk reduction package for MSM.

An estimated 103 700 individuals were living with HIV in the UK at the end of 2014. [7] Gay, bisexual, and other MSM are the population most at risk of acquiring HIV [7]. Despite an increase in HIV testing and a trend towards earlier initiation of antiretroviral therapy, [8,9] there had been no decrease in the numbers of new diagnoses reported each year in MSM for the past decade (numbering 3360 new diagnoses in 2014) [7] However, recent data have shown a reduction in new diagnoses of HIV in MSM in 2016 [10], thought likely to be as a result of the interplay between frequent testing, prompt initiation of antiretroviral therapy and the use of pre exposure prophylaxis. Although scale up of HIV testing and promotion of condom use remain important risk reduction measures, PrEP offers an additional approach for those whose condom use is inconsistent with partners whose HIV and treatment status is unknown.

Modelling suggests that introducing PrEP in the UK would be cost-effective and cost-saving if targeted to those most at risk of acquiring HIV [11] in the context of provision to an appropriate population [12]. Evidence thus far has demonstrated that PrEP is most likely to be used by those who engage in high-risk behaviour [13, 14].

At the time this study started, the commissioning process for PrEP in England and Wales was under review. The purpose of this study was to gain understanding of the perceived risk of acquiring HIV, need for PrEP and the likelihood of uptake amongst HIV-negative men who have sex with men (MSM) attending sexual health clinics in London to inform PrEP delivery.

Methods

Eligible participants were HIV-negative MSM aged over eighteen attending three sexual health centres in London. These clinics were all participating in the PROUD study and the questionnaire was implemented after the results were reported. At all sites the questionnaire was offered opportunistically when eligible participants were identified during clinic visits, or took a questionnaire from the waiting room. An accompanying patient information leaflet was provided containing information regarding PrEP and the intended aims of the study.

The questionnaire was available throughout October 2015 to February 2016 (Chelsea and Westminster), December 2015-January 2016 (Homerton) and April-May 2016 (St Marys).

The study protocol was approved by London Bridge Research Ethics Committee (15/EE/0364), as well as each participating Hospital Trust; Chelsea and Westminster Healthcare NHS Foundation Trust, London, UK; Homerton; University Hospital NHS Foundation Trust, London, UK; Imperial College Healthcare NHS Foundation Trust, London, UK.

The questionnaire was piloted among 20 intended respondents to check for understanding and acceptability of a broad range of questions: demographic, sexual history, drug use, history of sexually transmitted infections, and prior use of HIV post-exposure prophylaxis (PEP). Participants were also asked to respond to_a 10 point Likert-scale for HIV risk perception and perceived need/likely benefit of PrEP. For the purposes of analysis ≥8 was considered strong agreement. Participants were asked about their preferred regimen, whether they had already taken it and, if so, how they had sourced it. Those who had previously used PrEP were asked if their sexual behaviour had changed as a result.

The intended sample size was 1000. Bivariate and multivariate logistic regression analyses were undertaken to identify factors associated with perceived need/likely benefit of PrEP and intentions of use. For the purposes of this analysis the mean(which was the same as the median) response on Likert scale was used to create a dichotomous category. Data were collated in Microsoft Excel, and analysed in IBM SPSS (v24).

Results

(I) Demographic characteristics of respondents

The total number of questionnaires received was 859. Twenty six were completed by heterosexuals; 6 of these reported receptive anal intercourse (RAI) and their questionnaires were included in the analysis, leaving 839 questionnaires in the dataset. Respondents came from clinics across London, 150 from the Homerton, 71 from St Marys and 618 from Chelsea and Westminster with over half (550) from one Chelsea and Westminster clinic based in Soho (Dean Street).

Demographic and other characteristics of respondents are presented in Table 1. The median age of respondents was 35 (IQR 28-41, range 18-78). The majority were white, well educated and self-identified as homosexual. There were 82 different nationalities represented and half the respondents were born outside the UK.

(2) Risk behaviours and perceived risk of HIV

Regarding sexual behaviour in the preceding month, 739 (88%) of respondents reported anal intercourse (AI), 456 (54%) with at least one condomless partner in the preceding three months and 232 (28%) with 2 or more condomless partners in the preceding three months. The median number of sexual partners with and without a condom according to position in the preceding three months is demonstrated in Table 2.

Regarding drug use in the preceding three months, 437 (52%) reported use of any drug. The most commonly used drugs were mephedrone (30%), poppers (23%), and "G" (GBL/GHB)(22%). 9% had used crystal methamphetamine and 26 (3%) reported injecting (mephedrone, G or crystal methamphetamine). No respondents reported sharing of injecting drug equipment. 230 (27%) reported drug use specifically to facilitate sex (so called "chemsex") within the last month. Of this group, 74 (32%) reported sober sex without

drug use within the past week, but 33 (14%) last experienced sober sex more than three months ago.

Regarding sexually transmitted infections (STIs): 49 (6%) did not answer this question; 311 (37%) had been diagnosed with an STI within the preceding six months. Pharygeal and/or penile infection with chlamydia or gonorrhoea were the most common. Rectal infection was reported by 119 (14%), and syphilis by 52 (6%).

Just over half of respondents had undergone an HIV test within the preceding three months. Only 70 (9%) had not had a test in the preceding 12 months, although 63 (8%) did not answer this question. Use of post-exposure prophylaxis at any time was reported by 282 (34%) on a mean of 1.2 occasions (range 1-9) in the last year.

Respondents were asked to complete a table regarding their perceived risk of acquiring HIV in a number of different sexual scenarios, rating the risk level from I (low) to I0 (high). Table 3 shows the mean response to these questions.

(3) Knowledge of PrEP

The vast majority, 684 (82%), had heard of PrEP prior to completing the questionnaire. The perceived effectiveness of *pre*-exposure prophylaxis was high, with 608 (72%) rating this $\geq 8/10$ on the Likert scale (where I = not effective, and I0 = very effective). Only II (1%) rated effectiveness as $\leq 3/10$.

Respondents were also asked about their perceived effectiveness of *post*-exposure prophylaxis (PEP), (scale: completely, very, somewhat, not really, not at all). Only 246 participants answered this question and the majority 169 (69%) rated it as very effective, with 37 (15%) and 36 (15%) rating it completely or somewhat effective respectively.

(4) Perceived benefit from PrEP

We asked respondents to indicate their agreement with the statement "I think I would benefit from PrEP". Of 726 people responding to this question, 463 (64%) rated their agreement $\geq 8/10$ (where I = strongly disagree, and I0 = strongly agree). Of those strongly agreeing with this statement, 82 (18%) had not reported condomless sex in the last three months, although 47 (10%) reported other risk factors for HIV acquisition (PEP use, chemsex use and a rectal STI in the preceding six months), leaving only 35 (8%) who reported no risk but perceived a benefit from PrEP. Of the 98 (13%) who rated their agreement ≤ 3 , 15 (15%) reported anal intercourse without a condom with at least 2 people in the preceding three months. However 4 of these I5 (27%) had unprotected sex only with HIV positive people on treatment thus rationalising this view.

To better understand the factors associated with agreeing with the statement "I think I would benefit from PrEP" the mean response of 7 was used to create a dichotomous category of agreeing or disagreeing with this statement, (≥7 as agreement or <7 as disagreement). Univariate and multivaritate logistic regression analysis were then undertaken to identify variables independently predicting the likelihood of perceived benefit from PrEP. In the univariate regression analysis, having condomless insertive or receptive anal intercourse (UPIAI or UPRAI respectively) in the preceding three months, use of recreational drugs, chemsex use, having an STI in the preceding 6 months, having used PEP before, having belief in the effectiveness of PrEP, and being willing to pay for PrEP were all significantly associated with likelihood of perceived benefit of PrEP. As shown in table 4, in the multivariable regression analysis reporting UPRAI, having an awareness of the risk of UPRAI, and higher perceived effectiveness of PrEP were independent predictors for someone thinking they would benefit from PrEP. Having taken PEP before and being willing to pay for PrEP were also independent predictors of perceived benefit from PrEP.

Respondents were asked if they would have concerns about taking PrEP. Of 638 who did not have previous experience of PrEP and who answered this question, 253 (40%) scored ≤ 3 on a Likert scale of I=no concerns, to I0=high level of concern, 241 (38%) marked 4-7 and I44 (22%) marked 8-I0 implying they would have concerns. The proprotions remained the same when PrEP users were included. However, when asked specifically what those concerns would be, only I2 people (of all respondents) cited reasons: the majority (8) citing side effects. Respondents were then asked if having to make regular clinic visits would act as

a disincentive to being on PrEP, and 104 (15%) of 687 answering this question scored ≥8/10 on a Likert scale where 10=high level of concern).

Of 724 who answered the willingness to pay for PrEP questions (PrEP users and non users included), 236 (33%) strongly disagreed scoring ≤ 3 on a Likert scale , 308 (43%) were neutral scoring 4-7 and a quarter; 180 (25%) strongly agreed (180/724, ≥8/10). Respondents when then asked whether they agreed, disagreed or were not sure about six statements on provision of and payment for PrEP. The vast majority 640 (85%) of 754 agreed with the statement "I think PrEP should be available for free in sexual health centres to men who have sex with men. There was ambivalence about the statement "I think there should be a prescription charge for PrEP in most cases" with 227 (31%) of 743 agreeing; 323 (43%) disagreeing and 193 (26%) who were not sure.

When asked about the preferred regimen for PrEP 353 (54%) of 653 preferred a daily regimen and 282 (43%) preferred to take it before and after sex.

(5) Previous and current use of PrEP

Of 724 respondents 59 (8%) had already taken or were currently taking PrEP, of whom 23 (39%) had taken it for less than a month and 14 (23%) for more than a year. The majority 50 (80%) were taking it daily.

Nearly a quarter (14) of those who had taken PrEP had paid for their medication, either privately (8), online (4), or abroad (2), reporting costs of £150-£400 per month. Nearly half (26) had obtained post-exposure prophylaxis to use as PrEP and the remainder were on a trial (14) or used a friend or partner's medication (5).

Discussion

This questionnaire study of sexual health clinic attendees demonstrates good awareness of pre-exposure prophylaxis amongst a group men who have sex with men generally reporting high risk sexual and drug-taking behaviour.

Respondents were homogenous, (a highly educated, predominantly white, urban, British/European born group).

There are high levels of self reported STI in the preceding six months compared to the number of infections diagnosed in MSM attending GUM clinics in the UK[15] [16]. Use of post exposure prophylaxis in the past year was significantly higher than national surveillance data, with nearly 20% using it more than once. These risk behaviours are similar to what was demonstrated in the baseline characteristics of PROUD participants [17].

Respondents correctly perceived that receptive anal intercourse is riskier than insertive anal intercourse, and that antiretrovirals reduce this risk. Anal sex with an HIV positive partner on treatment was ranked higher risk than anal sex with a self reported HIV negative partner for both insertive and receptive positions. In retrospect this question did not state clearly self reported HIV status, and thus it is difficult to draw firm conclusions about this fact.

The regression analyses demonstrate that those who participate in high risk behaviour, such as recreational drug use, condomless anal sex and PEP use, have an awareness of the behaviours that increase risk and believe in the effectiveness of PrEP. Thus, this group feel they would benefit most from PrEP. The small group of men reporting high risk behaviour but not demonstrating an interest in PrEP merit further study. From a commissioning point of view, note is made that of 178 people who were unwilling to pay for PrEP (1-3 on Likert scale), 104 (58%) had at least one condomless partner in the preceeding 3 months.

Overall there appear to be little concern over the use of PrEP and generally positive attitudes towards its use. The preferences for regimen (54% daily vs 43% on demand) reflect patterns of use in the French national programme, and this emphasises the importance of offering choice. However it is interesting to note that there is disparity between respondents to this survey who are already using PrEP and choosing daily dosing (80%) versus survey respondents who said they would prefer daily dosing (54%). It is difficult to

know why this may be the case, although current users are a much smaller group in this sample.

There are several limitations to this study, in particular the lack of a random sampling framework. As questionnaires were offered opportunistically and also left for respondents in waiting rooms we do not have data on a response rate. Furthermore, we chose to conduct the study in clinics that were participating in PROUD, where awareness of PrEP is likely to be higher amongst staff and attendees. As a result the sample is highly selective and we cannot extrapolate to the general population of MSM. However, approximately 1 in 5 MSM attend sexual health clinics each year and over half will attend one of the participating PROUD clinics. The four clinics that took part in this study enrolled a significant proportion of the PROUD participants, and diagnosed more than 1 in 5 of HIV infections in MSM in England in 2015. These clinic populations would be the first to implement a national PrEP programme if it is commissioned.

During the course of this study, Truvada as once-daily PrEP was approved by the European Medicines Agency. Whilst the provision of PrEP remains a contested issue in the UK, it is clear that the respondents of this survey feel that PrEP should be widely available. This survey provides further information which may be useful for planning PrEP implementation; particularly that self identification of risk, which has shown to be a marker of true risk in other studies, may be a valid strategy for PrEP provision. The results add to the clamour of voices calling for provision of PrEP to populations at risk via the UK's established network of sexual health clinics.

Table I: Demographics and behavioural characteristics of respondents (N=839)

	Number	Percentage
Age		
18–25	108	13
26–35	380	45
36-45	215	26
>45	133	16
Missing	3	<0.5
Sexuality:		
Homosexual	770	92
Bisexual	57	7
Other	6	<
Heterosexual*	6	<
Educational Attainment:		
Degree	649	78
A levels	91	11
GCSE	33	4
Vocational	22	3
Ongoing	20	2
None	17	2
Other	4	<
Born in UK:		
Yes	421	50
No	417	50
missing	I	<0.5
Ethnicity:		
White	650	78

Asian/SE Asian/Chinese	53	6
Black Caribbean/ Black African/Black other	41	5
Mixed/other	95	11
Home Address:		
Inside London	727	87
Outside London	81	10
Missing	31	3
Anal sex in the <u>last month</u> :		
Yes	738	88
No	101	12
Recreational drug use in the last 3 months:		
Yes	437	52
No	402	48
Mephedrone	255	30
Poppers	195	23
GHB/GBL	186	22
Cocaine	184	22
Viagra	175	21
Ecstasy	121	14
Cannabis	121	14
Crystal meth	77	9
Ketamine	65	8
Amphetamines	51	6
Crack	6	<1
Injecting drug use:		
Yes	26	3
Mephedrone	9	I
Crystal Meth	9	I
GHB/GBL	2	<0.5
Cocaine	I	<0.5
Chemsex use:		
Yes	230	27
No	605	72

4	<0.5
74	9
34	4
26	3
22	3
33	4
311	37
480	57
48	6
199	24
119	14
52	6
28	3
8	I
8	1
3	<0.5
6	<
449	58
157	19
100	13
44	6
26	3
1	1
	74 34 26 22 33 311 480 48 199 119 52 28 8 8 8 8 3 6

^{*}Identifying as heterosexual but reporting receptive anal intercourse

Table 2: Number of reported partners in the last month, median, IQR and range

	Median number of partners	Median number of
		condomless partners
Insertive anal sex	2 (IQR 0-2, range 0-30)	I (IQR 0-2, range 0-30)
Receptive anal sex	2 (IQR 0-4, range 0-99)	0 (IQR 0-1, range 0-20)

Table 3: Assessing understanding of HIV acquisition risk by sexual act (N=481). Mean responses to each question shown. Only respondents answering all questions in the table were included (Where 0=No risk and 10=Very high risk).

YOUR	HIV STATUS OF YOUR PARTNER						
POSITION							
	HIV+ and not on	HIV+ and on	HIV negative	HIV status not			
	meds (SD)	meds		discussed			
Top /	7.11 (2.6)	3.31(2.9)	1.1 (2.1)	6.14 (2.8)			
active							
Bottom /	8.85 (2.4)	4.33 (3.1)	1.35 (2.5)	7.35 (2.7)			
passive							

Univariate analysis:

Table 4: Univariate and multivariate logistic regression models showing significant independent predictors of likelihood of agreeing with statement "I think I would benefit from PrEP" (confirmed by response above average (≥7))

Variable		Total	Agree			
				Odds	95% CI	p-value
		(726)	(n=463)	ratio		_
Education	Unknown	2	0(0.0)	0.0	(-)	0.105
	A levels or less	154	95(61.7)	0.88	(0.61 to 1.28)	
	Degree	570	368(64.6)	1		
Ethnicity	Other	69	51(73.9)	1.79	(1.02 to 3.14)	0.170
	Asian	24	18(75.0)	1.89	(0.74 to 4.84)	
	Black	22	15(68.2)	1.35	(0.54 to 3.36)	
	Black FRICAN	13	11(84.6)	3.47	(0.76 to 14.78)	
	Central/SA	12	8(66.7)	1.26	(0.37 to 4.23)	
	South East	22	14(63.6)	1.10	(0.46 to 2.67)	
	Asian	564	346(61.4)	1		
	White					
Total number			increase in odds	1.13	(1.06 to 1.19)	<0.001
insertive			per unit increase in total top			
partners			πιτοιαπιορ			
Total number	N/A	133	69(81.9)	0.74	(0.48 to 1.14)	<0.001
insertive	Unknown	42	24(57.1)	0.92	(0.47 to 1.79)	
partners	1	150	96(64.0)	1.22	(0.80 to 1.87)	
without a	2	77	57(74.0)	1.96	(1.11 to 3.48)	
condom	3	96	82(85.4)	4.03	(2.16 to 7.54)	
	0	228	135(59.2)	1		
Total number			increase in odds	1.16	(1.08 to 1.24)	<0.001
receptive			per unit increase in total bottom			
partners						
Total number			increase in odds	1.68	(1.39 to 2.04)	<0.001
receptive			per unit increase in no condom			
partners			III IIO CONGOIII			
without a						
condom						

Use of	Yes	373	270(72.4)	2.17	(1.60 to 2.96)	<0.001
Recreational	No	353	193(54.7)	1	, ,	
drugs			, ,			
Chem Sex Use	N/A	118	68(57.6)	0.96	(0.64 to 1.46)	<0.001
	Yes	203	158(77.8)	2.49	(1.69 to 3.66)	
	No	405	237(58.5)	1		
STI in 6	Yes	279	206(73.8)	2.09	(1.51 to 2.89)	<0.001
months	No	447	257(57.5)	1	, ,	
C/G rectum	Yes	109	94(86.2)	4.21	(2.39 to 7.43)	<0.001
	No	617	369(59.8)	1	, ,	
LGV	Yes	6	6(100.0)	-	-	-
	No	720	457 (63.5)			
Syphilis	Yes	46	36(78.3)	2.13	(1.04 to 4.37)	0.039
,	No	680	427(62.8)	1	, ,	
Perceived			increase in odds	1.97	(1.71 to 2.26)	<0.001
PrEP			per unit increase		, ,	
effectiveness			in perceived effectiveness			
Concerns			increase in odds	0.86	(0.81 to 0.90)	<0.001
about PrEP			per unit increase	0.00	(0.01 to 0.00)	10.00
			in concerns		((2 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	
Willingness to			increase in odds per unit increase	1.11	(1.05 to 1.17)	<0.001
pay for PrEP			in willingness to			
			pay			

Multivariate analysis

Variable	Adjusted		
	Odds ratio	95% CI	p-value
UPRAI		(1.01 to 2.13)	0.043
Perceived risk of UPRAI	1.42	(1.09 to 1.84)	0.008
PEP before			
Yes	4.01	(1.80 to 8.92)	0.001
No	1		
Perceived effectiveness of	1.59	(1.13 to 2.23)	0.008
PrEP			
Willingness to pay for PrEP	1.23	(1.06 to 1.43)	0.006

Adjusted for Sexual orientation, Education, Ethnicity, Heard PrEP, Anal sex in the last month,

IAI, RAI, Rec drugs: GHB/GBL, Mephedrone, Crystal Meth, Injecting drug use, Chem Sex use, STI within 6 months, C/G in throat/penis, C/G rectum, Syphilis, Taken PrEP before and other variables in the model

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Key points:

- I. PrEP has proven real world effectiveness in clinical trials and has now been approved by the EMA in the form of truvada once daily.
- 2. This survey demonstrates good awareness of PrEP and generally positive attitudes amongst a group of high risk MSM
- 3. In this study MSM who exhibit high risk behaviour accurately perceive their risk and need for PrEP.