

# High Acceptance of HIV Self-testing Among PrEP Recipients before COVID-19 Era: A Cross-sectional Analysis from PrEP Demonstration Project of MSM in China

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## Research article

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# Abstract

**Background:** Many Pre-exposure prophylaxis (PrEP) users have difficulty attending the quarterly facility-based HIV testing, which leads to the potential risk of drug resistance in the context of breakthrough infection with low drug compliance. We explored the acceptance of HIV self-testing (HIVST) service among PrEP recipients.

**Methods:** MSM were recruited for the PrEP demonstration in four major cities in China from December 2018 to September 2019, provided with regimens of both daily and on-demand PrEP. Facility-based HIV testing was provided quarterly at clinic visits. Previous HIV testing history and acceptance of free HIVST kits to use between each quarterly clinic visit was collected. Correlates of levels of acceptance were analysed using multivariable ordinal logistic regression.

**Results:** We recruited 1,222 MSM. among which 48.5% preferred daily PrEP and 51.5% preferred on-demand PrEP. There was 26.8% (321/1222) had never been to any facility-based HIV testing previously, and the self-reported major reason was that they had already routinely used HIVST. A quarter of the participants (74.5%, 910/1222) had used HIVST previously. There were 1184 MSM (96.9%) accepted to use HIVST between each quarterly clinic visits during PrEP usage, composing 947 ( 77.5%) very willing to, 237 (19.4%) willing to, 29 (2.4%) unwilling to, and 9 (0.7%) very unwilling to. Participants preferred daily PrEP (vs. on-demand PrEP, aOR=1.8, 95% CI:1.3-2.4) and had less than 2 times of facility-based HIV testing in the past year (vs.  $\geq 2$ , aOR=1.4, 95% CI:1.1-1.9) were more likely to have higher level of acceptance of HIVST.

**Conclusions:** MSM had high acceptance of HIVST, especially among those preferred daily PrEP and with less facility-based HIV testing in the previous year. Offering HIVST services PrEP recipients is feasible and necessary. Above result is of great significance for promoting HIVST among PrEP users during COVID-19, improving awareness of their HIV infection status and ensuring compliance with medication. Future study should exam the impact of HIVST on HIV testing frequency among PrEP users.

**Trial registration:** ChiCTR1800020374 on 27<sup>th</sup> Dec 2018. <http://www.chictr.org.cn/searchproj.aspx>

## Background

World Health Organization (WHO) and Center for Disease Control and Prevention (CDC) (1) recommend users of oral pre-exposure prophylaxis (PrEP) to test for HIV quarterly, to avoid resistance to antiretroviral therapy (ART) by breakthrough infections (2). Medicine compliance to PrEP is barely 60% among users worldwide(3). Mutations that impact the efficacy of first-line ART can develop within 2 weeks of PrEP being administered every day to HIV-infected individuals (4). Although the number of cases of resistance to anti-HIV-1 drugs during PrEP is small (5–8) it remains one of the main concerns for HIV key populations for PrEP acceptance (9, 10).

In real world settings, even testing HIV every 3 months at facility-based HIV testing service is implausible among PrEP recipients. There were 75% of PrEP recipients missed their facility-based testing after PrEP initiation (11) and had difficulty attending one during PrEP (12) (13). Moreover, among HIV key populations such as men who have sex with men (MSM), there is only 38.0–65.1% had tested for HIV in the past 6–12 months worldwide, and only 47.0–83.6% had ever been tested for HIV in their lifetime (14–19). It is crucial to explore innovative HIV testing strategies to pair PrEP implementation.

In recent few years, HIV self-testing (HIVST) has changed the course of HIV testing among HIV key populations by reaching more first-time testers (18, 20) and increasing the HIV-testing frequency (21, 22) among them, especially in resource-limited settings (23, 24). HIVST allows people to take an HIV test and discover their result in their home or other private location (25). In 2016, the WHO published the first global guidelines on HIVST, in which HIVST was recommended as an additional approach to HIV-testing services (26). Seventy-seven countries have adopted HIVST policies, while many others are currently developing them currently (27).

HIVST has been offered to the HIV-negative partners of HIV-discordant couples and women at risk who were on PrEP to use between quarterly clinic visits (28) or biannual clinic visits (29). HIVST has demonstrated high acceptance, high use, and ease of use among PrEP recipients in the settings mentioned above (28, 30). Higher preference for HIVST than facility-based HIV testing during PrEP among female sex workers has been documented in one setting (31). However, HIVST uptake among MSM and its correlates are not known.

COVID-19 is still in a pandemic stage. Social distancing is still a primary to preventing the spread of SARS-COVI-2, causing a severe impact on maintaining the routinely traditional clinical-based HIV testing (32). Therefore, the need to develop HIVST in the COVID-19 era has become increasingly prominent. The CDC recommends that HIVST services be provided to PrEP users when other options are not available (33). But so far there is no report of PrEP MSM's willingness to apply HIVST. This study is of great significance for the promotion of the application of HIVST among PrEP users.

We aimed to assess acceptance of HIVST among PrEP candidates and explore its correlates, including demographics, HIV-testing history, preference for PrEP regimen, HIV-related behaviour. This study will shed light in the utility of HIVST in the era of PrEP, and provide evidence for paired HIV-testing strategy with PrEP implementation.

## Methods

### Design, setting and procedures

This cross-sectional study was conducted between December 2018 and September 2019 and leveraged the China Real-world study of Oral Pre-exposure Prophylaxis (CROPrEP) project for participant recruitment (clinical trial reference number here). The study sites were general hospitals equipped with HIV voluntary counselling and testing clinics (VCTs) and HIV treatment clinics with physicians specialising in infectious

diseases in four major cities in China: The YouAn Hospital of Capital Medical University in Beijing, The First Affiliated Hospital of China Medical University in Shenyang, The Chongqing Public Health Medical Center of Southwest University in Chongqing, and The Third People's Hospital of Shenzhen.

Participant recruitment was conducted offline and online using convenient samples and snowballing (i.e., chain referral sampling) by: (i) distribution of posters and brochures in the HIV VCTs at the four study sites for MSM who arrived for counselling and testing; (ii) postings in MSM chat groups and on the study sites' official WeChat™ and Tencent QQ™ accounts (two of the most widely used social media applications in China); (iii) outreach events run by community-based organisations (CBOs) in bars, public baths and parks that provided study information, and MSM peer referral.

All individuals who were interested in the recruitment advertisement of CROPrEP online and offline, needed to registered for and attend to an on-site screening appointment for eligibility of the CROPrEP trial. This on-site screening provides free testing for HIV infection and syphilis for adult MSM and transgender women. After providing written informed consent, participants willing to enrol underwent consultations with physicians and laboratory testing. The information of demographic, HIV related risk behaviour, HIV testing history and acceptance of HIVST was collected.

## Measures

Data were collected through self-administrated questionnaires on each participants' smartphone. Participants were surveyed for acceptance to use free HIVST kits between each quarterly clinic visit, previous experience of facility-based HIV testing, and HIVST (frequency of using each type of testing service, as well as the reasons for using and not using them), their preference for PrEP regimens (daily or on-demand), demographics (age, education level, marital status, monthly income), HIV-related risk behaviour in the past 3 months (frequency of homosexual anal intercourse, and existence of condom-less anal intercourse). The levels of acceptance of HIVST were defined as "very willing to accept", "willing to accept", "unwilling to accept" and "very unwilling to accept".

## Statistical analyses

We conducted statistical analysis by SPSS v20.0 (IBM, Armonk, NY, USA). Demographics, preference for PrEP regimen, history of HIV testing, and level of acceptance of HIVST among all participants were described using numbers and percentages. Univariable and multivariable ordinal logistic regression analyses was used to assess the predictors of an increased level of acceptance to use HIVST between each quarterly clinic visit. Variables with  $P < 0.2$  in the univariable analysis were included in the multivariable model. Variables in the final model were selected with an entry procedure. Model fitness was assessed by the goodness-of-fit statistics. Odds ratio and adjusted odds ratios were calculated by a general linear model.  $P < 0.05$  in the multivariate analysis was the cut-off for a significant difference.

## Results

A total of 1222 men participated in on-site screening and completed the relevant screening programs. Among these men, the median age was 30-year-old (Interquartile rang, IQR 25–36) and 79.4% (970/1222) had education level as undergraduate and above. There was 68.3% (835/1222) of them had unprotected anal intercourse during the previous 3 months. Among all participants, 48.5% (592/1222) preferred daily medication and 51.5% (630/1222) preferred event-driven medication (Table 1).

Table 1  
 Characteristics of PrEP candidates in four major cities of China, 2018–2019 (N = 1222)

<b>Variable</b>	<b>Number (%)</b>
<b>Preference of PrEP regimen</b>	
Daily	592 (48.5)
On-demand	630 (51.5)
<b>Age (years) [Median, IQR]</b>	
19–25	319 (26.1)
26 and above	903 (73.9)
<b>Education level</b>	
Senior high and below	252 (20.6)
Undergraduate and above	970 (79.4)
<b>Monthly income (US dollars)</b>	
0–857	649 (53.1)
≥858	573 (46.9)
<b>Marital status</b>	
Single	662 (54.2)
Married with a female, in a stable relationship with a male, Divorced or widowed	560 (45.8)
<b>Frequency of homosexual intercourse in the previous 3 months</b>	
Every day	15 (1.2)
Every week	434(35.5)
Every month	591(48.4)
Less than once a month	182 (14.9)
<b>Had condom-less anal intercourse in the previous 3 months</b>	
Yes	835 (68.3)
No	387 (31.7)
<b>Have heard of/known about HIVST</b>	
Yes	1145 (93.6)
No	77 (6.4)
<b>Have used HIVST before</b>	

Variable	Number (%)
Yes	910 (74.5)
No	312 (25.5)
<b>Have used a facility-based HIV testing before</b>	
Yes	901 (73.7)
No	321 (26.3)
<b>Times of using HIVST in the past year [Median, IQR]</b>	3 (2–5)
<b>Times of using facility-based HIV testing in the past year [Median, IQR]</b>	2 (1–4)

## Previous experience of HIV facility-based testing and HIVST

A total of 1145 participants (93.6%) reported that they had heard of HIVST, and 910 participants (74.5%) had used HIVST previously. The median number of times HIVST was used in the previous year was three (IQR 2–5). There were 321 participants (26.3%) had never used facility-based HIV testing before. The main reason given for the 321 participants who had never used facility-based HIV testing was that they undertook HIVST (49.2%, 158/321). The median number of times participants who undertook facility-based HIV testing in the past year was two (IQR 1–4). (Table 1).

## Acceptance of HIVST during PrEP and motives

Of 1222 participants, 1184 (96.9%) accept HIVST during PrEP. Of these, 77.5% (947/1222) were very willing to accept, 19.4% (237/1222) were willing to accept, 2.4% (29/1222) were unwilling to accept, and 0.7% (9/1222) were very unwilling to accept HIVST to use between quarterly clinic visits during PrEP. The main motives for acceptance of HIVST were “good privacy for HIV testing” (69.1%, 818/1184) and “ease of use” (68.9%, 816/1184). The main reasons for non-acceptance of HIVST were “fear of inaccuracy of the results of HIVST” (41.1%, 16/38) and “fear of needles/blood” (34.2%, 13/38) (Table 2).

Table 2  
Acceptance of HIVST and reasons among PrEP candidates in China, 2018–2019

Variable	Number (%)
<b>Acceptance to use HIVST between each quarterly clinic visit of PrEP (N = 1222)</b>	
Very willing to	947 (77.5)
Willing to	237 (19.4)
Unwilling to	29 (2.4)
Very unwilling to	9 (0.7)
<b>Reasons for acceptance (N = 1184)</b>	
Good privacy	818 (69.1)
Easy to use	816 (68.9)
Prevents drug resistance	150 (12.7)
Getting testing results is quick	611 (51.6)
Less pain	151 (12.8)
Other	3 (0.3)
<b>Reasons for non-acceptance (N = 38)</b>	
Afraid of needle/blood	13 (34.2)
Worry about the accuracy of HIVST	16 (41.1)
HIVST is not easy to use	6 (15.8)
It is unnecessary for HIVST as long as there is facility-based testing	10 (26.3)
I am not high-risk	3 (7.9)
Afraid of a positive result of HIVST	6 (15.8)
Afraid other people would see me using HIVST and think I am HIV-positive	6 (15.8)
Other	2 (5.3)

## Correlation of increased acceptance of HIVST during PrEP

Univariable ordinal logistic regression analysis revealed several factors to be correlated with an increased level of acceptance of HIVST ( $P < 0.05$ ): daily PrEP regimen; education level; monthly income; number of using facility-based HIV testing in the previous year; number of the times HIVST had been used in the previous year.

The multivariable ordinal logistic regression analysis revealed the significant and independent predictors of higher acceptance of HIVST use during PrEP. Participants who preferred daily PrEP were 1.8-times (95% CI: 1.3–2.4) more likely to have higher acceptance of HIVST than those who preferred on-demand PrEP ( $P < 0.001$ ). Compared with those with an education level of senior high school or below, men having an education level of undergraduate and above were 2.6-times (95% CI: 1.1–2.1) more likely to have higher acceptance of HIVST ( $P = 0.023$ ). Compared with people who had monthly income lower than 858 USD, men with monthly income above 858 were 0.7-times (95% CI: 0.5–0.9) more likely to have higher acceptance of HIVST ( $P = 0.017$ ). Compared with people who had  $\geq 2$  facility-based HIV tests in the previous year, those who did not were 1.4-times (95% CI: 1.1–1.9) more likely to have higher acceptance of HIVST ( $P = 0.014$ ). Compared with people who had  $\geq 3$  HIVSTs in the previous year, those who did not were 0.3-times (95% CI: 0.2–0.4) more likely to have higher acceptance of HIVST ( $P < 0.001$ ) (Table 3).

Table 3 Univariable and multivariable ordinal logistic regression models for predicting increased level of acceptance to use HIVST during PrEP among PrEP candidates in China, 2018–2019 (N = 1222)

Variable	OR (95%CI)	P value	aOR (95%CI)*	P value
<b>Regimen of PrEP</b>				
Daily	2.0 (1.5–2.7)	<0.001	1.8 (1.3–2.4)	<0.001
On-demand	1.0		1.0	
<b>Age (years)</b>				
19–25	1.0	0.600	--	--
26 and above	0.9 (0.7–1.2)		--	--
<b>Education level</b>				
Senior high and below	1.0		1.0	
Undergraduate and above	1.9 (1.4–2.6)	0.007	1.5 (1.1–2.1)	0.023
<b>Monthly income (US dollars)</b>				
0–857	1.0		1.0	
$\geq 858$	1.8 (1.3–2.5)	<0.001	0.7 (0.5–0.9)	0.017
<b>Marital status</b>				
Single	1.0		--	--
Married with a female, in a stable relationship with a male, Divorced or widowed	1.0 (0.3–0.9)	0.796	--	--
<b>Frequency of sex in the previous 3 months</b>				
Every day	1.0		1.0	
Every week	0.3 (0.0–2.4)	0.259	0.2 (0.0–1.7)	0.151
Every month	0.3 (0.0–2.1)	0.214	0.2 (0.0–1.6)	0.135
Less than 1 month	0.2 (0.0–1.8)	0.156	0.2 (0.0–1.6)	0.123
<b>Had condom-less anal intercourse in the previous 3 months</b>				
Yes	1.1 (0.8–1.5)	0.631	--	--
No	1.0		--	--
<b>Number of using facility-based HIV testing in the previous year</b>				
0–1	1.4 (1.0–1.8)	0.048	1.4 (1.1–1.9)	0.014
$\geq 2$	1.0		1.0	
<b>Number of using HIVST in the past year</b>				
0–2	0.3 (0.2–0.4)	<0.001	0.3 (0.2–0.4)	<0.001
$\geq 3$	1.0		1.0	

\*Variables with  $P < 0.2$  in the univariable analysis were included into the multivariable mode

## Discussion

We examined the acceptance of HIVST among PrEP candidates and its correlates in a multicentre oral PrEP demonstration project in China. The median times of HIVST and facility-based HIV testing in the past year of these candidates were 3 and 2 respectively. Nearly all (96.9%) of the PrEP candidates accepted HIVST. Men with a preference for daily PrEP and had used facility-based HIV testing less than twice in the

previous year were more likely to have higher level of acceptance of HIVST. This result showed the necessity and feasibility of offering HIVST service during PrEP.

The rate of acceptance of HIVST is high among PrEP candidates of MSM, which is in accordance with previous studies of sero-discordant couples and females using PrEP in Africa (28–31, 34). This high rate can be explained by the fact that HIVST had already become a main way of HIV testing among these MSM. Among these PrEP candidates, the median number of HIVST use in the previous year had already outnumbered that of facility-based HIV testing. Three-quarters of the PrEP candidates had used HIVST previously and nearly all of them have heard about HIVST before. The self-reported major reasons of this acceptance were good privacy, easy to use and getting testing results quickly. Also, this study was conducted before the COVID-19 pandemic, which indicates possibility of a higher acceptance of HIVST during the pandemic. This high acceptance of HIVST also suggests a method to maintain this ongoing PrEP trial, since the quarantine against COVID-19 is still required. Above results suggest feasibility to provide HIVST to MSM PrEP users.

This study also indicates necessity to provide HIVST to MSM PrEP users. The WHO recommends general MSM test for HIV every half year (35) and PrEP users test HIV at a facility-based testing service at least every quarter (36). However, there were more than a quarter of the PrEP candidates had never used any facility-based HIV testing before, which indicates potential hardship in maintaining their attendance to facility-based HIV testing during PrEP. Missed attending facility-based testing and difficulty in attending clinical visits leads to interruption and discontinuation of PrEP (12) (13). Fortunately, PrEP candidates with less than two facility-based HIV testing in the past year were more likely to accept HIVST. Providing PrEP users with HIVST can serve as additional options for HIV testing.

Preference for daily regimen of PrEP is also correlated with higher acceptance of HIVST during PrEP. This study allowed PrEP candidates to choose their regimen between daily and on-demand (37). Real-world studies have shown that, compared to those who chose on-demand PrEP, MSM chose daily PrEP were having more HIV-related risk behaviour (38, 39). Resistance to ART is more likely to occur with a higher selection pressure of the drug (4). Considering the higher exposure to HIV infection and generally low adherence to PrEP among MSM, with daily administration of PrEP to a HIV-infected person, mutations that affect the efficacy of first-line ART can develop in 2 weeks (4). Providing HIVST for daily users of PrEP could meet their needs. Nevertheless, challenges in supervision for on-demand PrEP must be addressed because non-daily use of PrEP becomes more common outside of controlled research settings (8).

This study has both strengths and limitations. This study explored acceptance of HIVST among MSM PrEP users for the first time, revealing the high necessity and feasibility to paired PrEP with HIVST. However, since fourth generation of HIVST, which could detect both HIV antibodies and p24 antigens, we provided the third generation HIVST to PrEP candidates. The high acceptance of HIVST reported in this study indicates better acceptance of fourth generation of HIVST among PrEP users in the future. Also, this study is a cross-sectional design, which cannot provide actual use in the follow-up and impact

of HIVST usage on behaviour of PrEP users. The data of actual usage of HIVST and its impact on behaviour among PrEP users will be reported soon.

## Conclusions

The MSM who participated in the first real-world PrEP trial in China had high acceptance to HIVST during PrEP. Inadequate facility-based HIV testing in the previous year and preference for daily PrEP was correlated with higher acceptance of HIVST. Providing HIVST to MSM PrEP users is feasible and necessary, especially during the time of social distancing and quarantine.

## List Of Abbreviations

HIV, human immunodeficiency virus; HIVST, HIV self-testing; PrEP, pre-exposure prophylaxis; COVID-19, coronavirus disease 2019; MSM, men who have sex with men; CBO, community-based organization;

## Declarations

## Ethical approval and consent to participate

The study protocol was approved by the ethics review board of the First Affiliated Hospital of China Medical University (IRB[2018]273) in Shenyang, China. Written informed consent was obtained from each participant before collecting study information or blood samples. Participants took part in the study voluntarily and had the right to refuse to answer any question. Participants had the right to withdraw from the study without penalty. The protocol for the CROPrEP trial has been published (37). This HIVST study among PrEP recipients was registered on Chinese Clinical Trial Registry (trial ID ChiCTR1800020374).

## Consent for publication

Not applicable.

## Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

## Competing interests

The authors declare that they have no competing interests.

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# Authors' contributions

Conceived and designed the experiment: JZ, JJX, HS; performed the study and experiments: JZ, JX, HYW, ZXC, QHH, XJH, YKC, HW, XQH, YL, LKZ, ZLH, RTB, SCL, HL, HBD, YJJ, WQG; drafted the study report: JZ, JJX, WMT. All authors reviewed and approved the final report.

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