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MAJOR ARTICLE

Feasibility and Acceptability of Home-Collected Samples for Human Immunodeficiency Virus Preexposure Prophylaxis and Severe Acute Respiratory Syndrome Coronavirus 2 Laboratory Tests in San Francisco Primary Care Clinics

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Background. Due to the difficulty of conducting laboratory testing during the pandemic shelter-in-place orders, the objective of this study was to examine the feasibility and acceptability of conducting home-collected samples for preexposure prophylaxis (PrEP) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) laboratory tests.

Methods. We conducted a pilot study among patients on PrEP in San Francisco primary care clinics. Individuals on PrEP provided home-collected laboratory samples using dried blood spot for fourth-generation human immunodeficiency virus antigen/antibody test, serum creatinine, syphilis antibody, and hepatitis C antibody, as needed; 3-site (oropharyngeal, rectal, and urine) swabbing for sexually transmitted infections; and nasopharyngeal swabbing for SARS-CoV-2 polymerase chain reaction. We examined feasibility and acceptability of collecting these laboratory samples using predefined benchmarks to determine feasibility or acceptability.

Results. Of 92 individuals who consented to participate, 73 (79.3%) mailed back their home-collected kit. Nearly 87.7% noted being extremely to moderately satisfied with the ability to complete the laboratory tests without having to come into a clinic. Approximately 49.3% of participants chose this home-collection method as their first choice for providing laboratory samples. Mean time from collection of samples by the participant to receipt of test results was reduced from the first quarter of the study (17 days) to the last quarter of the study (5 days).

Conclusions. We report high levels of feasibility and acceptability with the use of home-collected laboratory samples for patients on PrEP. Our results indicate that home-collected laboratory samples for patients on PrEP is a viable option that should be offered as an alternative to clinic-collected laboratory samples.

Keywords. HIV; pandemic; preexposure prophylaxis; SARS-CoV-2; self-test; home collection.

Human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) has resulted in significant reductions in HIV acquisition in numerous randomized trials [1–6], demonstration projects [7–9], and clinical settings [10]. However, despite data from the Centers for Disease Control and Prevention (CDC) estimating that nearly 1.2 million individuals had a PrEP indication in 2018, its coverage was as low as 18.1% [11]. In the wake of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, which is responsible for coronavirus disease 2019 (COVID-19), some clinics providing HIV prevention services closed [12]. Additionally, many patients were reluctant to go into medical establishments for fear of SARS-CoV-2 exposure [13]. This resulted in difficulties in the clinical management of patients who require frequent laboratory monitoring [12, 14].

Based on the CDC PrEP guidelines, patients require baseline and quarterly laboratory testing for PrEP initiation and continuation [15]. During the SARS-CoV-2 pandemic, the difficulty in obtaining laboratory testing prior to and during PrEP use based on the CDC PrEP guidelines resulted in a conundrum for many healthcare providers. Even though providers wanted to prevent against HIV and SARS-CoV-2 in their patient on PrEP, they were also concerned about potential harm related to drug toxicity or drug resistance if laboratory testing was not conducted despite continued PrEP. As a result, the medical necessity for options beyond clinic-collected laboratory samples intensified.

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Using our prior experiences with offering remotely conducted research and home collection of study specimens [16, 17], we partnered with an innovative laboratory solutions company to provide home-collected laboratory samples to study participants of a PrEP research project during the SARS-CoV-2 pandemic shelter-in-place orders. The objective of this study was to examine the feasibility and acceptability of conducting home-collected PrEP and SARS-CoV-2 laboratory samples among patients on PrEP in a real-world setting.

MATERIALS AND METHODS

This pilot study was nested in the PrEP Optimization Intervention (PrEP-OI) trial, which evaluated implementation of a PrEP panel management intervention across 12 San Francisco Department of Public Health (SFDPH) clinics [18]. The intervention consisted of a PrEP coordinator (support staff who coordinates interactions between patients and healthcare teams and augments the provider's role to conduct PrEP panel management activities more effectively) and a web-based panel management tool (called PrEP-Rx). Given the remote nature of this study, where patients were offered to conduct their visits with PrEP coordinators using telehealth, we were able to completely transition to a tele-PrEP model during the pandemic shelter-in-place orders to reduce exposure to staff and patients. All PrEP coordination services were provided collaboratively with the patient's healthcare provider. The main challenge we faced was the difficulty in collecting laboratory samples for patients interested in continuing PrEP. Similarly, patients reported difficulties in making laboratory appointments (including for SARS-CoV-2 testing) and challenges in getting to the COVID-19 testing sites.

We identified Molecular Testing Labs, a provider of diagnostic testing using self-collected samples, that was able to conduct laboratory testing using dried blood spot (DBS) on the Whatman DBS card for fourth-generation HIV antigen/antibody (Ag/Ab) test, serum creatinine, syphilis antibody, and hepatitis C antibody, as needed; 3-site sexually transmitted infection (STI) swabbing for oropharyngeal, rectal, and urine *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC); and nasopharyngeal swabbing for SARS-CoV-2 polymerase chain reaction (PCR). Based on data from the Molecular Testing Labs, their tests for HIV p24 Ag/Ab (GS HIV Combo Ag/Ab enzyme immunoassay [EIA] and Geenius HIV 1/2 Supplemental Assay confirmatory test [Bio-Rad Laboratories, Hercules, California]), syphilis antibody (Diamedix Phoenix Bio-Tech Trep-Sure EIA Assay [Thermo Fisher Scientific, Waltham, Massachusetts]), CT/GC assay (Cobas CT/NG 4800 Assay [Roche Diagnostics, Indianapolis, Indiana]), and SARS-CoV-2 PCR (TaqPath COVID-19 Combo Kit [Thermo Fisher Scientific]) have 100% analytical sensitivity and specificity [19]. The hepatitis C antibody test (Ortho hepatitis C virus [HCV] version 3.0 enzyme-linked immunosorbent assay) has a 96.9% sensitivity and 99.1% specificity [19]. Serum creatinine had a reference range of 0.84–1.21 mg/dL; HIV Ab/Ag, HCV antibody, and syphilis antibody were reported as "reactive" vs "nonreactive," and SARS-CoV-2 PCR and STI tests were reported as "detected" vs "not detected."

We included adults aged ≥18 years receiving care at 1 of the 12 SFDPH clinics being served by the PrEP-OI study who (1) were on oral PrEP (once-daily or event-driven PrEP) and due for quarterly PrEP laboratory testing; (2) were able to provide 5–10 drops of blood for DBS cards; (3) consented to use a home-collected sampling kit that included self-collection of urine, rectal, and pharyngeal swabs (for STI testing), nasopharyngeal swab (for SARS-CoV-2 PCR), and fingerstick blood (for DBS cards); (4) had access to either a mobile telephone or a computer with an email address to complete the consent form and the satisfaction survey; and (5) could speak/read English or Spanish. Those with a history of hemophilia or unable to conduct fingerstick at home were excluded. Patients who met inclusion criteria were offered the option for home-collected laboratory sampling. If accepted, study staff remotely consented patients using DocuSign (which allows individuals to sign electronic agreements) and notified Molecular Testing Labs to mail them a home-collected sampling kit. Participants were also emailed/texted written materials and videos which were developed in English and Spanish (preprx.ucsf.edu/prep-covid-home-testing) to assist in the collection of blood and urine samples and swabs. Patients were also given contact information of the study staff and PrEP coordinators in case of additional questions or concerns. After receipt of the completed home-collected sampling kit by Molecular Testing Labs, the study staff emailed/texted a satisfaction survey to participants to evaluate the acceptability of the study and the home-collected sampling.

We examined feasibility and acceptability and used predefined benchmarks to deem a variable feasible or acceptable (Table 1). Feasibility was evaluated based on time to recruit and number of enrolled participants, number of participants who conducted the tests and mailed back the kit, and mean number of days between test collection until kit receipt by Molecular Testing Labs. We examined acceptability using a satisfaction survey that was developed specifically for this study with the guidance of the University of California, San Francisco (UCSF) Center for AIDS Prevention Studies' Methods Core. In this survey, we examined satisfaction with various components of the study, challenges with the collection of blood sample and self-swabbing, and ease of following the written and video collection instructions. We inquired about preferences for this test collection method vs other methods (eg, attending clinic laboratory to collect blood and clinic-collected swabs for STIs). Additionally, the System Usability Scale (SUS) [20] was used to measure the usability of the home-collected samples.

Table 1. Feasibility and Acceptability Measures and Predefined Benchmarks

	Definition	Benchmarks
Feasibility	Total length of time to recruit participants	Overall duration of ≤6 months
	Number of enrolled participants	Minimum of 90 participants
	Number of participants who conducted laboratory tests appropriately and mailed back their home-based test kits	Minimum of 72 participants
	Mean number of days between test collection until kit receipt by Molecular Testing Labs	Mean of 7 business days from test collection to receipt
Acceptability	Satisfaction survey	>80% "extremely to moderately satisfied" with overall home-based laboratory test, finger prick and DBS, and 3-site STI self-swabbing
		>80% "extremely to moderately likely" to use home-based laboratory test kits if offered as part of regular clinical service
		>80% "extremely to moderately likely" to recommend this laboratory testing method to a friend
	SUS	Score >80[a]

Abbreviations: DBS, dried blood spot; STI, sexually transmitted infection; SUS, System Usability Scale.

[a]SUS range: 0–100. Scores >68 were considered above average.

All test results were sent to SFDPH medical records to be scanned into the patients' electronic health records. The PrEP coordinators communicated positive SARS-CoV-2 PCR test results to the patient's primary care provider, the on-call provider, and the nursing staff responsible for the patient's care within 24 hours of resulting and communicated any other abnormal test results by the following business day.

We entered the patients who completed the test and survey into a study raffle for 10 chances to win a $50 e-gift card. One-way frequency tables were generated for all feasibility and acceptability measures and measures of central tendency and variability were computed for continuous measures.

Patients' electronic consent was obtained. The design of the work was approved by the UCSF Institutional Review Board.

RESULTS

From 20 October 2020 through 12 April 2021, we approached 153 patients taking PrEP in 12 SFDPH primary care clinics. Among these individuals, 92 (60.1%) consented to participate and were enrolled. Among self-reported reasons for not participating, the most common reasons included preferring to go to clinic (n = 17 [11.1%]), not wanting to self-collect blood by fingerstick or lacking confidence in being able to complete the test correctly (n = 13 [8.5%]), and needing additional laboratory tests beyond those offered in this study or needing immediate STI testing/treatment (n = 10 [6.5%]). Approximately 79.3% (n = 73) mailed back their home-collected kit. Main reasons for the kit not being received by Molecular Testing Labs included the participant being lost-to-follow-up (n = 5 [5.4%]), feeling overwhelmed (n = 5 [5.4%]), struggling with fingerstick (n = 3 [3.3%]), having stopped PrEP after having consented (n = 2 [2.2%]), and other reasons (n = 4 [4.3%]). Total length of time to recruit 92 participants was 5.7 months. Table 2 summarizes the demographics of the 73 participants who completed the home-collected kit and the satisfaction survey. Among these individuals, mean age was 41.6 years, mostly identified as cisgender men (68.5%), gay (60.3%), and Latinx (37.0%). Overall, 27.4% reported part-time or full-time work, 64.4% had some college education, and 65.8% stated that they could barely get by or that they couldn't get by on the money they had.

Table 3 details the acceptability of the home-collected kit among the 73 participants who completed it. Participants rated the overall experience with home-collected samples as excellent to very good (73.9%). The vast majority noted being extremely to moderately satisfied with the ability to complete the laboratory tests without having to come into a clinic (87.7%), to self-swab for STIs at home instead of the clinic (89.0%), and to self-swab for SARS-CoV-2 at home instead of at a testing site (87.7%). Satisfaction with self-collecting blood by fingerstick instead of standard venipuncture was lower, with 63.0% being extremely to moderately satisfied, 24.7% being slightly satisfied to slightly unsatisfied, and 11.0% being moderately to extremely unsatisfied. Approximately 65.8% of participants had not received help from anyone in completing the home-collected kit. Mean time for the collection of blood and swabs was 28.4 minutes (standard deviation [SD], 16.8; median, 27.5). The majority noted high likelihood of recommending the home-collected samples to a friend (82.2%) and that they would complete a similar laboratory test if offered in the future (79.5%). The mean SUS score was 69.9, which is considered above average.

When asked to rank their comfort with places to complete blood draws, 49.3% of participants chose home-collected samples (using a fingerstick to collect blood drops) as their first choice, followed by having the phlebotomist come to their home while wearing a mask and face shield (47.9%) as their second choice, attending a clinic laboratory where the phlebotomist wears a mask and face shield (38.4%) as the third choice, and last, attending a makeshift laboratory tent outside of the clinic where the phlebotomist wears a mask and face shield (30.1%).

Mean time from study staff ordering a home-collected kit to receipt of test results was 23 days (SD, 13; range, 7–70; median,

Table 2. Characteristics of Participants (n = 73)

Characteristic	No. (%)
Age, y, mean (SD)	41.6 (12.3)
Sex at birth	
Male	55 (75.3)
Female	9 (12.3)
Intersex	2 (2.7)
Missing	7 (9.6)
Gender identity[a]	
Cisgender man	50 (68.5)
Cisgender woman	7 (9.6)
Other gender identity[b]	16 (21.9)
Prefer not to answer	1 (1.4)
Missing	6 (8.2)
Race/ethnicity	
Latinx	27 (37.0)
White (non-Latinx)	22 (30.1)
Asian (non-Latinx)	6 (8.2)
Black American (non-Latinx)	3 (4.1)
Other (non-Latinx)	6 (8.2)
Prefer not to answer	2 (2.7)
Missing	7 (9.6)
Sexual orientation	
Gay	44 (60.3)
Bisexual	8 (11.0)
Heterosexual	7 (9.6)
Other	6 (8.2)
Prefer not to answer	1 (1.4)
Missing	7 (9.6)
Work situation	
Working now (part-time or full-time)	20 (27.4)
Looking for work, unemployed	20 (27.4)
Student	5 (6.8)
Only temporarily laid off	5 (6.8)
Disabled, permanently, or temporarily	5 (6.8)
Other	6 (8.2)
Prefer not to answer	5 (6.8)
Missing	7 (9.6)
Education	
High school or less	13 (17.8)
Some college, no degree	12 (16.4)
Associate or bachelor's degree	24 (32.9)
Master's degree or higher	11 (15.1)
Prefer not to answer	6 (8.2)
Missing	7 (9.6)
Financial situation	
I have enough money to live comfortably	9 (12.3)
I can barely get by on the money I have	34 (46.6)
I cannot get by on the money I have	14 (19.2)
Prefer not to answer	9 (12.3)
Missing	7 (9.6)
Housing[a]	
Own house/apartment/room	32 (43.8)
Someone else's house/apartment/room	16 (21.9)
Parent's house/apartment	8 (11.0)
Other	8 (11.0)
Prefer not to answer	5 (6.8)
Missing	7 (9.6)

Data are presented as No. (%) unless otherwise indicated.

Abbreviation: SD, standard deviation.

[a]Total is >100% due to ability to choose all options that applied.

[b]Other gender identities include transgender woman (n = 5), gender nonbinary (n = 4), genderfluid (n = 3), transgender man (n = 1), questioning (n = 1), another gender [write in] (n = 2).

Table 3. Acceptability of Home-Based Testing for Preexposure Prophylaxis and Severe Acute Respiratory Syndrome Coronavirus 2 (n = 73)

Domain and Response	No. (%)
Overall experience with home-based laboratory testing	
Excellent	25 (34.2)
Very good	29 (39.7)
Good	14 (19.2)
Fair	2 (2.7)
Poor	3 (4.1)
Very poor	0 (0.0)
Satisfaction with completing labs without having to come into a clinic	
Extremely satisfied	49 (67.1)
Moderately satisfied	15 (20.5)
Slightly satisfied	2 (2.7)
Neither satisfied nor unsatisfied	4 (5.5)
Slightly unsatisfied	1 (1.4)
Moderately unsatisfied	0 (0.0)
Extremely unsatisfied	1 (1.4)
Prefer not to answer	1 (1.4)
Satisfaction with ability to collect blood droplets instead of regular lab blood draws	
Extremely satisfied	27 (37.0)
Moderately satisfied	19 (26.0)
Slightly satisfied	4 (5.5)
Neither satisfied nor unsatisfied	6 (8.2)
Slightly unsatisfied	8 (11.0)
Moderately unsatisfied	6 (8.2)
Extremely unsatisfied	2 (2.7)
Prefer not to answer	1 (1.4)
Satisfaction with ability to self-swab for STIs at home instead of going to clinic	
Extremely satisfied	54 (74.0)
Moderately satisfied	11 (15.1)
Slightly satisfied	2 (2.7)
Neither satisfied nor unsatisfied	3 (4.1)
Slightly unsatisfied	0 (0.0)
Moderately unsatisfied	0 (0.0)
Extremely unsatisfied	2 (2.7)
Prefer not to answer	1 (1.4)
Satisfaction with ability to self-swab for SARS-CoV-2 at home instead of going to a testing site	
Extremely satisfied	49 (67.1)
Moderately satisfied	15 (20.5)
Slightly satisfied	3 (4.1)
Neither satisfied nor unsatisfied	4 (5.5)
Slightly unsatisfied	0 (0.0)
Moderately unsatisfied	0 (0.0)
Extremely unsatisfied	1 (1.4)
Prefer not to answer	1 (1.4)
Satisfaction with security and privacy of the home-based lab testing	
Extremely satisfied	55 (75.3)
Moderately satisfied	10 (13.7)
Slightly satisfied	3 (4.1)
Neither satisfied nor unsatisfied	2 (2.7)
Slightly unsatisfied	2 (2.7)
Moderately unsatisfied	0 (0.0)
Extremely unsatisfied	1 (1.4)
Prefer not to answer	0 (0.0)

Table 3. Continued

Domain and Response	No. (%)
Satisfaction with level of information and staff support provided during the study	
Extremely satisfied	51 (69.9)
Moderately satisfied	17 (23.3)
Slightly satisfied	1 (1.4)
Neither satisfied nor unsatisfied	2 (2.7)
Slightly unsatisfied	1 (1.4)
Moderately unsatisfied	0 (0.0)
Extremely unsatisfied	1 (1.4)
Prefer not to answer	0 (0.0)
Satisfaction with mailing back the home-based lab testing kit	
Extremely satisfied	46 (63.0)
Moderately satisfied	19 (26.0)
Slightly satisfied	3 (4.1)
Neither satisfied nor unsatisfied	1 (1.4)
Slightly unsatisfied	1 (1.4)
Moderately unsatisfied	1 (1.4)
Extremely unsatisfied	1 (1.4)
Prefer not to answer	1 (1.4)
Helpfulness of communication with PrEP coordinators	
Extremely helpful	52 (71.2)
Very helpful	13 (17.8)
Moderately helpful	5 (6.8)
A little helpful	1 (1.4)
Not at all helpful	1 (1.4)
Prefer not to answer	1 (1.4)
Helpfulness of the video on the home-based lab testing	
Extremely helpful	38 (52.1)
Very helpful	19 (26.0)
Moderately helpful	5 (6.8)
A little helpful	1 (1.4)
Not at all helpful	6 (8.2)
Prefer not to answer	4 (5.5)
Helpfulness of the written instructions for the home-based lab testing	
Extremely helpful	35 (47.9)
Very helpful	21 (28.8)
Moderately helpful	6 (8.2)
A little helpful	7 (9.6)
Not at all helpful	3 (4.1)
Prefer not to answer	1 (1.4)
Receipt of help from someone for the collection of home-based lab testing	
Yes	23 (31.5)
No	48 (65.8)
Prefer not to answer	2 (2.7)
Likelihood of recommendation of home-based lab testing to a friend	
Extremely likely	46 (63.0)
Moderately likely	14 (19.2)
Slightly likely	6 (8.2)
Neither likely nor unlikely	2 (2.7)
Slightly unlikely	1 (1.4)
Moderately unlikely	1 (1.4)
Extremely unlikely	2 (2.7)
Prefer not to answer	1 (1.4)
Likelihood of completion similar lab testing at home in the future	
Extremely likely	44 (60.3)
Moderately likely	14 (19.2)
Slightly likely	6 (8.2)
Neither likely nor unlikely	3 (4.1)
Slightly unlikely	2 (2.7)
Moderately unlikely	1 (1.4)
Extremely unlikely	3 (4.1)
Prefer not to answer	0 (0.0)
Mean time to complete lab collection (blood sample and swabbing), mean (SD)	28.4 (16.8)
System Usability Scale, mean (SD)	69.9 (15.1)

Data are presented as No. (%) unless otherwise indicated.

Abbreviations: PrEP, preexposure prophylaxis; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SD, standard deviation; STI, sexually transmitted infection.

21) which was reduced from the first quarter of the study (mean, 29 days [SD, 12]; median, 24) to the last quarter of the study (mean, 16 days [SD, 7]; median, 14). Similarly, mean time from collection of samples by the participant to receipt of test results was 12 days (SD, 9; median, 9), with the duration decreasing from the first quarter of the study (mean, 17 days [SD, 8]; median, 15) to the last quarter of the study (mean, 5 days [SD, 2]; median, 5). Mean time from collection by participants to receipt by Molecular Testing Labs was 5 days (SD, 4; median, 5). Among the 73 participants who completed the home-collected kit, 13 (17.8%) tested positive for syphilis antibodies, 3 (4.1%) tested positive for GC (all oral GC), 2 (2.7%) tested positive for CT (1 anal and 1 urine CT), and none tested positive for SARS-CoV-2 PCR. All HIV Ag/Ab and hepatitis C tests were negative and all serum creatinine results were within reference range. In 1 kit the SARS-CoV-2 PCR test did not return results due to the sample being >7 days old, and in 12 completed kits there was insufficient blood to run all ordered laboratory tests.

DISCUSSION

In prior studies, PrEP-OI was noted to influence the PrEP continuum from PrEP awareness to adherence and retention in care in the PrEP-OI study [21] and being able to address barriers such as limited clinical space (providing PrEP services remotely via telehealth), medical mistrust (building rapport with patients and community), language barriers (hiring Spanish-speaking PrEP coordinators), education of providers and staff (providing regular educational presentation and emails to update clinics on new PrEP medications, dosing strategies, guidelines, etc), and limited provider time and comfort with PrEP (training PrEP coordinators to provide all PrEP services that do not require a medical degree). However, addressing the limited laboratory availability even before the pandemic was a challenge. Prior to the pandemic, laboratory hours were determined based on

staff availability and clinic capacity. With the closure of some clinics, allocation of staffing hours for pandemic response, and reluctance of patients to attend clinic laboratory visits, the challenges with laboratory availability became even more pronounced during the shelter-in-place orders. Here, we report the high level of feasibility and acceptability with the use of home-collected laboratory sampling for patients on PrEP. Our results indicate that home-collected samples for patients on PrEP is a viable option that should be offered as an alternative to in-clinic laboratory sampling.

In this pilot study, we met the predefined benchmarks related to mean time to recruitment, number of patients who consented, number of patients who conducted the laboratory tests and mailed back the home-collected kit, and mean time between test collection to receipt by Molecular Testing Labs. We were able to shorten the number of days from home-collected kit collection to receipt of results by 12 days from the beginning of the study until the end. This was mainly accomplished by frequent communication via phone calls and text messages to ensure that participants understood how to use the home-collected kit and frequent meetings with Molecular Testing Labs to identify the sources of delay after receipt of the completed test kit. From an acceptability standpoint, participants reported high satisfaction with nearly all aspects of the home-collected kit, except for the need to collect blood droplets, where 63.0% of participants were extremely to moderately satisfied. This was an expected finding given the minor pain that results from the lancet [22]. Given the number of samples of insufficient quantity of blood, we believe that future users of this test kit should be instructed to provide 10 drops of blood to complete all tests. The SUS was also slightly lower than the predefined benchmark (benchmark, >80; actual, 69.9). This level is still considered to be above average but would be worth the exploration to ascertain how the test can be further improved.

A previous study reported high feasibility and acceptability of self-administered rapid HIV and urine and rectal STI sample collection among 1071 gay and bisexual men across the United States (US) [23]. Additional studies have presented acceptability of home-collected samples for HIV and STI testing among gay and bisexual men in the US and Brazil [24–26]. Thus far, 1 study has reported acceptability of home-collected samples for all PrEP laboratory tests among 55 men who have sex with men on PrEP in a pilot trial [22]. Therefore, to our knowledge, the presented study is the first to examine home-collected samples for all follow-up PrEP laboratory tests including SARS-CoV-2 PCR self-swabbing in patients on PrEP in a real-world primary care setting. We believe these assessments are critical for those who may be unable to access laboratory testing due to financial burdens, transportation restrictions, stigma, disability, or in case of potential future pandemics, as well as reducing missing data and increasing generalizability of study findings [16, 27]. In the current era, the ability to provide remote research and clinical services is essential [17].

Additionally, despite a significant growth in the number of PrEP prescriptions, protective benefits from PrEP are not being fully realized by youth and minority men who have sex with men, which may be due to lower PrEP uptake, adherence, and persistence [28, 29]. PrEP persistence requires quarterly follow-up laboratory visits, which may pose a significant burden on patients. In interviews with participants in a pilot study where participants collected samples at home, increased likelihood of PrEP persistence was noted by one-third [22]. Therefore, by allowing patients to collect laboratory samples at home, providers may also increase PrEP persistence.

This study can also benefit future public health HIV prevention and treatment approaches. Quarterly laboratory testing for clinical PrEP management can burden the patient and the healthcare system. Healthcare access challenges such as lack of transportation disproportionately impact the youth and minority populations who also have disproportionately high risk of HIV acquisition [30, 31]. Therefore, offering home-collected laboratory kits can increase access to testing and help address disparities, to some extent. Additionally, as the CDC has estimated that there are nearly 1.2 million individuals who have a PrEP indication in the US [11], the healthcare system would be overtaxed with the number of laboratory visits if PrEP use was further scaled up.

Molecular Testing Labs' home-collected panel of tests for PrEP is now suggested by the CDC as an alternative to clinic-collected laboratory samples [32]. There is also guidance from Centers for Medicare and Medicaid Services clarifying the need for health insurance plans to cover PrEP services (including laboratory testing) without cost sharing [33]. We believe that the results of this study can be used to further justify ongoing home-collected laboratory samples for monitoring for PrEP safety and efficacy, SARS-CoV-2 testing, and other areas of medicine where home-collected laboratory sampling can potentially decrease the need for frequent clinic visits, increase persistence with medical treatment/prevention, and minimize exposure to respiratory viral infections.

This study has some limitations. We were able to include participants who were English- and Spanish-speaking, Latinx, and had varying degrees of financial security. However, most participants were cisgender gay men with high levels of education. Additionally, we conducted this pilot study among patients receiving care at SFDPH primary care clinics. Therefore, the results of our study may not be generalizable to others with different demographics or in other geographic locations. As Molecular Testing Labs uses the syphilis antibody, testing was unable to distinguish between previously treated syphilis vs active infections. Finally, given our sample size, we were unable to conduct meaningful bivariate analyses to examine patient preferences based on demographic differences.

Even though these data are focused on HIV PrEP, the results provide support for the expansion of home-collected laboratory tests to other public health settings. The ability to conduct laboratory sampling at home can reduce the burden on laboratory and clinical facilities, improve patient satisfaction, and increase persistence on long-term prevention and treatment strategies, particularly for people living with HIV or other chronic conditions that require frequent monitoring.

Notes

Author contributions. All authors have seen and approved the content and have contributed significantly to the work.

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All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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