



Perceptions and Experiences of Returning Self-collected Specimens for HIV, Bacterial STI and Potential PrEP Adherence Testing among Sexual Minority Men in the United States

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Abstract

Few studies among gay, bisexual and other men who have sex with men (GBMSM) have examined facilitators and barriers to self-collecting specimens for extragenital STI screening, and none have evaluated attitudes towards self-collecting hair samples that can be utilized for PrEP drug level testing to assess adherence. To address this gap, we interviewed 25 sexually active GBMSM who were offered a choice to self-collect and return finger-stick blood samples (for actual HIV testing), pharyngeal swabs, rectal swabs and urine specimens (for actual gonorrhea and chlamydia testing), and hair samples (to visually determine their adequacy for PrEP drug level testing): 11 who returned all, 4 who returned some, and 10 who did not return any. Participants found self-collecting finger-stick blood samples and rectal swabs more challenging than other specimens. Frequently discussed facilitators of return included an opportunity to confirm one's HIV or STI status, limited access to a healthcare provider and a desire to advance research focusing on home-based testing. Commonly cited barriers to return included low self-efficacy pertaining to self-collection and apprehension around the possibility of delay or loss of specimens during transit. Offering additional support such as real-time video conferencing may prove helpful in future field-based research with GBMSM.

Keywords HIV · Sexually Transmitted Diseases · Pre-exposure Prophylaxis · Self-testing · Sexual and Gender Minorities

Introduction

Despite representing approximately 2% of the United States

(US) population [1, 2], gay, bisexual and other men who have sex with men (GBMSM) currently account for almost two-thirds (63%) of the 1.2 million people living with HIV [3]. Among the 25,552 GBMSM who received an HIV diagnosis in 2019, the majority were 13–34 years old (65%) and identified as a racial or ethnic minority (75%) [3]. For every 100 GBMSM living with HIV, 15 are unaware of their serostatus [4]. The Centers for Disease Control and Prevention (CDC) recommends that all sexually active GBMSM be screened for HIV at least annually, and more frequently if warranted (e.g., every 3 or 6 months) based on their individual risk factors, local HIV epidemiology and local testing policies [5]. However, almost a quarter (23%) of GBMSM participating in the 2017 National HIV Behavioral Surveillance reported not being tested for HIV in the past year [6].

GBMSM in the US also bear a high burden of bacterial sexually transmitted infections (STIs). In 2018, the median national prevalence of gonorrhea at pharyngeal, rectal and urethral sites was estimated at 13%, 15% and 8%

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respectively, and that of chlamydia at these sites was estimated at 3%, 16% and 6% respectively [7]. STIs can elevate the risk of HIV acquisition by damaging the epithelium or increasing the availability of HIV target cells in mucosa of the rectum or urethra [8–10]. STIs can also elevate the probability of onward HIV transmission by promoting viral shedding in the genital tract [8–10]. Analogous to HIV testing, bacterial STI screening rates among GBMSM are sub-optimal. Less than half (42%) of the respondents to the 2017 American Men's Internet Survey reported testing for STIs in the past year, and a small proportion (16%) reported providing specimens for extragenital gonorrhea and chlamydia screening [11].

Testing is the gateway to accessing pre-exposure prophylaxis (PrEP) to prevent HIV, antiretroviral therapy to treat HIV and antibiotics to treat bacterial STIs. Impediments to regular HIV and STI screening cited by GBMSM include stigma, concerns around privacy and confidentiality, long distances to clinics, transportation problems and limited access to culturally competent healthcare [12–14]. Over the past decade, there have been growing calls to evaluate approaches to supplement HIV and STI testing in clinical settings such as the self-collection of specimens at home for rapid testing or their return by mail for laboratory processing [15–17]. In terms of scientific validity, self-collected specimen testing has been shown to achieve comparable results to traditional point-of-care testing [18–20]. Social distancing mandates and stay-at-home orders during the coronavirus disease 2019 (COVID-19) pandemic have also accelerated the demand for home-based HIV and STI testing options [21]. Given the positive attitudes of GBMSM towards this approach on account of an increased sense of privacy, convenience and autonomy [22–26], studies aimed at improving access to prevention and care services are increasingly requesting participants to self-collect and return specimens for HIV or STI screening [27–33]. Only few, however, have qualitatively examined facilitators and barriers to returning self-collected specimens [32, 33].

Daily oral PrEP is an established method of reducing one's risk of acquiring HIV but is highly dependent on adequate adherence for effectiveness [34–36]. Recent studies measuring PrEP drug levels among GBMSM via blood tests have found variable adherence. Specifically, concentrations equivalent to four or more pills per week have been observed in 20–84% of users after 24 weeks [37–40] and in 34–80% of users after 48 weeks of initiating PrEP [37, 38]. Some reasons for not adhering to the prescribed regimen include forgetting to take the pills, experiencing side effects such as nausea and headache, using alcohol and other substances, not being able to keep follow-up appointments and encountering challenges navigating a complex healthcare system [41, 42]. Hair is a non-biohazardous, easy-to-ship

specimen that can be utilized for PrEP drug level testing [43–47]. Returning self-collected hair by mail might hold promise as a remote PrEP adherence monitoring strategy that could allow for the identification of GBMSM who may benefit from digital medication reminders [48, 49], other adherence interventions, or the recently approved long-acting injectable PrEP formulation [50]. To our knowledge, no previous study has evaluated attitudes around self-collecting and returning a hair sample among GBMSM.

The paucity of data on facilitators and barriers to returning self-collected specimens as part of studies aimed at promoting the sexual health of GBMSM highlights the need for research in this domain, particularly among those at elevated risk for HIV and STIs. We sought to address this limitation by conducting an exploratory pilot study with young HIV-negative or unknown status GBMSM, at least half of whom identified as a racial or ethnic minority. Participants were offered a choice to self-collect and return any of the following: a finger-stick blood sample (for actual HIV testing), a pharyngeal swab, a rectal swab and a urine specimen (for actual gonorrhea and chlamydia testing), and a hair sample (to visually determine its adequacy for PrEP drug level testing). This manuscript presents results from in-depth interviews with participants who returned all, some and none of the specimens during which we discussed their perceptions and experiences of undertaking each type of specimen self-collection activity. Understanding why some GBMSM may choose to fully, partially or not engage in home-based testing is an important step in designing and implementing the next generation of effective public health interventions to improve screening rates for HIV and STIs, and to monitor and support adherence to PrEP.

Methods

Project Caboodle! sought to evaluate the acceptability and feasibility of self-collecting at home and returning by mail up to five biological specimens for HIV, bacterial STI and potential PrEP adherence testing among sexually active GBMSM recruited online from across the US. Details of the protocol have been published elsewhere [51]. Approval was obtained from the Institutional Review Board at the University of Michigan (HUM00153673). Study procedures were completed between March 2019 and April 2020.

Recruitment and Eligibility

Participants were recruited via advertising on Facebook and Grindr. Individuals who clicked on the advertisements were directed to the study's landing page, and those who provided consent were screened to determine eligibility.

Our eligibility criteria included being assigned male sex at birth, reporting a male gender identity, being 18–34 years of age, residing in the US or dependent areas, not known to be living with HIV, having ≥ 2 male sex partners in the past 3 months and willing to receive a specimen self-collection box. Individuals who met the eligibility criteria were asked to provide their full name, email address, mobile phone number and preferred mailing address. Those who did not provide consent, did not meet the eligibility criteria, or did not provide verifiable contact information were directed to the CDC's website on HIV and STIs.

Specimen Self-Collection and Return, Laboratory Processing and Test Results Delivery

GBMSM who provided verifiable contact information were emailed a link to a Web-based survey programmed in Qualtrics to collect data on their demographic and behavioral characteristics, for which they received a US \$40 Amazon e-gift card. Next, 100 participants who completed the survey were shipped a specimen self-collection box in plain unmarked packaging using United Parcel Service (UPS). The box contained instructions and materials to self-collect and return any of the following for laboratory processing: a finger-stick blood sample, a pharyngeal swab, a rectal swab, a urine specimen and a hair sample. Figure 1 depicts the box and its contents. Study staff tracked shipments and deliveries on an ongoing basis and no logistical issues were encountered. The boxes were delivered to participants between 1 and 13 days (with the mean and median times being 4 days), including 3 participants who resided rural areas, as designated by the Federal Office of Rural Health Policy [52]. Participants were given 6 weeks from receiving the box to return self-collected specimens of their choice using envelopes affixed with prepaid FedEx shipping labels. No monetary incentive was provided for completing this step. Returned finger-stick blood samples were screened for HIV with the OraQuick Advance Rapid HIV-1/2 Antibody Test [53], and pharyngeal swabs, rectal swabs and urine specimens were screened for gonorrhea and chlamydia using the Abbott RealTime PCR assay [54]. Hair samples were visually inspected to determine their adequacy for PrEP drug level testing. HIV and bacterial STI test results were delivered back to participants by a counselor with experience in the provision of HIV Counseling, Testing and Referral, and anyone who received a positive test result was contacted after 2 weeks of results delivery to confirm linkage to care.

In-depth Interviews

Upon completion of the above procedures, study staff invited a subset of 25 participants for in-depth interviews to

be conducted remotely via BlueJeans, a secure video conferencing platform that allows compliance with the Health Insurance Portability and Accountability Act (HIPAA). Purposive sampling was used to obtain data from those who returned all, some and none of the specimens, and to ensure that at least half the sample identified as a racial or ethnic minority. Up to three email reminders were sent at weekly intervals, and those who agreed to participate were contacted to schedule a session. Verbal consent for audio recording and transcription for future analysis was obtained at the beginning of each interview. During the session, a semi-structured interview guide created by the lead investigators (AS and RS) was used to discuss their perceptions and experiences of self-collecting and returning each type of specimen. Upon completing the interview, participants received a US \$40 Amazon e-gift card.

Data Analysis

In-depth interviews were transcribed using Scribie, following which the transcripts were checked for accuracy against the original audio files. Data were analyzed using template analysis, a style of thematic analysis that involves developing an initial coding template using a subset of the data, applying it to further data and refining it iteratively [55]. In this method, it is permissible to start with some *a priori* themes likely to be relevant to the analysis. Three analysts (AS, GS and LM) developed an initial coding template that included a mix of themes identified in advance (e.g., experiences with self-collecting a finger-stick blood sample, experiences with self-collecting a hair sample) and themes identified from three interviews (one each from participants who returned all, some and none of the specimens). The initial coding template was applied to additional transcripts, discussed with the qualitative research team and iteratively revised based on the identification of newly emergent themes. Five overarching themes were coded: (i) impressions of the specimen self-collection box; (ii) prior familiarity with different specimen self-collection methods; (iii) experiences with self-collecting each type of specimen as part of our study; (iv) facilitators and barriers to returning self-collected specimens; and (v) comparison of home-based and clinic-based testing. Each theme also had subthemes that emerged from the participants' narratives. The final coding template was applied to all transcripts using Dedoose software.



Fig. 1 Specimen self-collection box and its contents used in Project Caboodle!, United States, March 2019 to April 2020

Results

Sample Characteristics

Overall, 39 of 100 participants returned all five specimens (38 urban residents, 1 rural resident), 12 returned between one and four specimens (11 urban residents, 1 rural resident), and 49 did not return any specimens (48 urban residents, 1 rural resident). The mean and median times between receiving the specimen self-collection box at

one's preferred mailing address and returning self-collected specimens of one's choice for laboratory processing were 14 and 8 days respectively. One rectal swab tested positive for gonorrhea and two rectal swabs tested positive for chlamydia. One urine specimen tested positive for chlamydia. All participants who received a positive test result reported successfully obtaining antibiotic treatment when they were contacted by study staff after 2 weeks of results delivery.

Table 1 summarizes the demographic and behavioral characteristics of the 25 in-depth interview participants,

11 of whom had returned all specimens, 4 of whom had returned some specimens, and 10 of whom had not returned any specimens. The mean and median ages were 26 years, and the sample was racially and ethnically diverse with 9 participants (36%) identifying as Hispanic, 5 participants (20%) identifying as non-Hispanic Black and 4 participants (16%) identifying as Asian. The majority of participants had a college degree or higher educational level ($n = 18$, 72%), identified as gay ($n = 21$, 84%) and were single ($n = 22$, 88%). Less than half ($n = 10$, 40%) reported engaging in condomless anal sex and approximately three-fourths ($n = 19$, 76%) reported engaging in condomless oral sex with ≥ 2 men in the past 3 months. Almost everyone ($n = 24$, 96%) reported testing for HIV and approximately two-thirds ($n = 17$, 68%) reported testing for bacterial STIs in the past year. Regarding PrEP, 11 (44%) were currently using PrEP and 1 (4%) had discontinued PrEP use prior to enrollment.

Impressions of the Specimen Self-collection Box

Participants had positive impressions of the Project Caboodle! specimen self-collection box with respect to its external attributes and its internal organization.

Some appreciated that the box arrived in plain unmarked packaging with no reference to the nature of its contents or to the study.

“I would love it if we lived in a world where there is no stigma attached to sexually transmitted infection testing, but we don’t, I think it’s helpful to have it be inside of a nondescript box when it arrives.” – CAB002, 23 years, non-Hispanic White, returned none.

Others found the box to be well organized and noted that our use of different colored bags (i.e., red, blue, green, yellow and black) with matching color-coded instructions for self-collecting each type of specimen helped them easily navigate the process.

“Opening that was nice. It was colorful. I liked everything’s in a little bag. All the different kits were all in a neat bag like that, so I thought that was pretty nice and easy to use.” – CAB161, 24 years, non-Hispanic White, returned some.

“Each bag also had its own instructions... Yeah, it really helped that they were in different colors that you could refer back to the instruction sheet and decide or like choose which was which.” – CAB046, 20 years, Asian, returned all.

Prior Awareness of the Utility of Different Specimens

Participants had varying levels of previous knowledge regarding the utility of different types of specimens for HIV, bacterial STI and potential PrEP adherence testing.

Several knew that a finger-stick blood sample can be used for HIV testing, and some knew that this specimen can also be used for syphilis testing.

“That one was for HIV and... But from blood you can pretty much determine other... If you have syphilis. But I think you guys didn’t test for syphilis.” – CAB044, 28 years, Hispanic multiracial, returned all.

Some participants were unsure of the purpose of obtaining specimens from different anatomical sites to test for bacterial STIs.

“It didn’t seem like there was anything unique or new for that one [rectal swab], so I decided to skip it... But if I did them all together, I think I would have gone like, “Why do I need this in addition to the throat swab and the urine test? Why do I need a third one?”” – CAB161, 24 years, non-Hispanic White, returned some.

Interestingly, one participant who was previously aware of the concept of triple-site testing for gonorrhea and chlamydia commented that he had not been offered pharyngeal or rectal screening by a healthcare provider.

“I knew, before knowing about the study, that you can still have gonorrhea even if the urine sample comes out negative, ’cause there’s throat gonorrhea and rectal gonorrhea. So, I remember going to the doctor for an STI screening and he just said, “We’ll do some blood work and I need a urine sample”, and everything came back negative. But then I read up on it and he never offered throat or rectal testing.” – CAB051, 30 years, Hispanic multiracial, returned some.

Several participants knew that a hair sample can be used to detect evidence of substance use or for DNA testing but were previously unaware that it can also be used for PrEP drug level testing to assess adherence.

“I think I had absolutely no knowledge whatsoever of this. I don’t even remember what it was for... I think I’ve read of drug hair test or DNA hair test.” – CAB051, 30 years, Hispanic multiracial, returned some.

Prior Experiences with Specimen Self-collection

In general, participants had greater prior experience with self-collecting finger-stick blood samples and urine specimens compared to self-collecting pharyngeal swabs, rectal swabs or hair samples.

Some mentioned self-collecting a finger-stick blood sample in the past for reasons other than HIV testing.

“In my undergraduate, I did take a lab, I took an anatomy and physiology class where we had to... We did a blood lab on ourselves.” – CAB161, 24 years, non-Hispanic White, returned some.

“When I was learning how to do blood glucose tests, we were doing finger pricks.” – CAB024, 26 years, non-Hispanic White, returned none.

Table 1 Demographic and behavioral characteristics of 25 gay, bisexual and other men who have sex with men participating in Project Caboodle!, United States, March 2019 to April 2020

Characteristic	n	(%)
Age ^a		
20–24 years	11	(44.00)
25–29 years	10	(40.00)
30–32 years	4	(16.00)
Race and ethnicity		
Hispanic ^b	9	(36.00)
Non-Hispanic black	5	(20.00)
Asian	4	(16.00)
Non-Hispanic white	7	(28.00)
Educational level		
Associate's/Technical degree or lower ^c	7	(28.00)
Bachelor's degree or higher ^d	18	(72.00)
Employment status		
Work full-time or part-time ^e	20	(80.00)
Currently not working ^f	5	(20.00)
Health insurance coverage		
Insured	21	(83.00)
Uninsured	4	(17.00)
Region of residence		
Northeast	1	(4.00)
Midwest	10	(40.00)
South	11	(44.00)
West	3	(12.00)
Sexual orientation		
Gay	21	(84.00)
Other ^g	4	(16.00)
Relationship status		
Single	22	(88.00)
Partnered	3	(12.00)
Condomless anal sex with ≥ 2 men in the past 3 months		
Yes	10	(40.00)
No ^h	15	(60.00)
Condomless oral sex with ≥ 2 men in the past 3 months		
Yes	19	(76.00)
No ⁱ	6	(24.00)
Tested for HIV in the past year		
Yes	24	(96.00)
No	1	(4.00)
Tested for bacterial STIs in the past year		
Yes	17	(68.00)
No	8	(32.00)
PrEP use history		
Currently using	11	(44.00)
Previously used but discontinued	1	(4.00)
Never used	13	(52.00)

^aMean=26 years, Median =26 years, Range =20–32 years

^bIncludes 2 white, 2 American Indian/Alaska Native, 3 multiracial and 2 who did not indicate their race

^cIncludes 2 with an Associate's/Technical degree, 4 with some college education and 1 with a high school diploma or GED

^dIncludes 11 with a Bachelor's degree and 7 with a Master's/Doctoral degree

^eIncludes 19 who worked full-time (≥ 30 h per week) and 1 who worked part-time (1–29 h per week)

^fIncludes 2 students and 3 who were unemployed

^gIncludes 3 bisexual and 1 queer

^hIncludes 11 who engaged in condomless anal sex with 1 man and 4 who did not engage in condomless anal sex

ⁱIncludes 4 who engaged in condomless oral sex with 1 man and 2 who did not engage in condomless oral sex

Others described how they had previously self-collected a urine specimen as part of screening for substance use in the workplace or during a routine physical exam.

“That’s something I’m used to, because I do physical exams and drug tests, obviously, working... I have a job that does drug testing, random drug testing, and yearly physicals.” – CAB082, 32 years, Hispanic American Indian/Alaska Native, returned all.

“I had to take a drug test before I got my job... Had to pee in a cup there.” – CAB161, 24 years, non-Hispanic White, returned some.

One participant commented that he had never self-collected a hair sample despite being involved in prior research, and that this specimen sparked his curiosity.

“So the hair sample did a little bit intrigue me in terms of the novelty, I guess, to it... I’ve done similar studies and similar programs in the past and I’ve never really... This was the first time that I actually had to collect the hair sample.” – CAB082, 32 years, Hispanic American Indian/Alaska Native, returned all.

Study Experiences with Self-collecting a Finger-stick Blood Sample

On being asked to describe their experiences with self-collecting a finger-stick blood sample as part of our study, several participants reported that the prospect of pricking their own finger was anxiety provoking, and one mentioned seeking assistance from another person.

“The blood thing did a little bit scare me, because I hate blood, I hate needles... And then also, the sight of blood didn’t help either... Yeah, it was more triggering, more overwhelming definitely than all the other samples.” – CAB082, 32 years, Hispanic American Indian/Alaska Native, returned all.

“Okay. Who am I going to find to prick my finger ’cause I don’t like pricking my finger on my own, so I had to find somebody to do that. It was a co-worker... I had her prick my finger.” – CAB091, 32 years, non-Hispanic Black, returned all.

Others described challenges with trying to obtain a sufficient amount of blood to fill the transport tube.

“Sometimes I feel like it doesn’t necessarily just flow out, even though it goes with gravity. So it’s hard. It became a bit hard for me to actually get the amount that was necessary in the actual collection tube.” – CAB052, 31 years, non-Hispanic Black, returned all.

Study Experiences with Self-collecting a Pharyngeal Swab

Several participants found the process of self-collecting a pharyngeal swab as part of our study to be straightforward and reported they did not experience any physical discomfort.

“I hadn’t done throat swabs for this kind of testing specifically, but if you wanna get your ancestry DNA stuff done it’s really similar the entire way that it works. Or I guess not super similar, but it’s a similar idea... But yeah it was pretty straightforward, no discomfort or anything.” – CAB154, 21 years, Asian, returned all.

Some, however, described how their gag reflex acted as an impediment to self-collecting a pharyngeal swab.

“It was just a little uncomfortable because me, personally, I’m very sensitive in terms of... I gag easily. So, any wrong movement that I accidentally did, I would make myself gag.” – CAB075, 23 years, Hispanic, returned none.

One participant mentioned that he self-collected the pharyngeal swab in front of a mirror to ensure that he was swabbing his throat and not just his mouth.

“It was a bit awkward... Well, the whole getting it proper. I myself did it in front of a mirror. That way I knew I actually got that far down.” – CAB048, 22 years, Hispanic White, returned some.

Study Experiences with Self-collecting a Rectal Swab

On being asked to describe their experiences with self-collecting a rectal swab as part of our study, several participants reported that it was one of the more challenging specimens to self-collect as they were unsure about which posture to assume and experienced physical discomfort.

“I think I had the most trouble with that one... Just collecting the sample. I mean I just didn’t know how to do it at all. Like how to position my body to collect the sample, if that make sense, yeah... Just, this one was actually uncomfortable when I did it, felt like I was stabbing myself inside.” – CAB046, 20 years, Asian, returned all.

“It’s uncomfortable, so just gotta get through it. It wasn’t painful. It’s not the most comfortable experience.” – CAB052, 31 years, non-Hispanic Black, returned all.

One participant also commented that the prospect of self-collecting a rectal swab made him feel emotionally uncomfortable.

“Yeah, I didn’t like the rectal swab, that’s the one I didn’t like... I thought that was weird and inappropriate.” – CAB033, 27 years, non-Hispanic Black, returned none.

Study Experiences with Self-collecting a Urine Specimen

Several participants found the process of self-collecting a urine specimen as part of our study to be relatively straightforward.

“That one was really easy. ’Cause you use a little pipette and everything, so it made it really easy.” – CAB008, 28 years, non-Hispanic Black, returned all.

“The only thing you have to really make sure was that it was from the beginning of your stream, and that’s something I had to keep in mind. But besides that, it was pretty straightforward and there was a dropper in there, and you just fill it between the two lines.” – CAB154, 21 years, Asian, returned all.

Study Experiences with Self-collecting a Hair Sample

On being asked to describe their experiences with self-collecting a hair sample as part of our study, several participants found the process to be simple and did not encounter any issues.

“I had no problem with it, but I think it was probably the easiest, because especially if you can see my hair... I can just pass one finger through my hair, and I’ll have a bunch of hairs coming out because I have long hair, and with long hair, you can easily extract, retrieve a bunch of strands.” – CAB082, 32 years, Hispanic American Indian/Alaska Native, returned all.

Some, however, mentioned that they found the instructions confusing, and were unsure of which part of the hair had to be affixed to the aluminum foil with an adhesive label.

“I think the directions confused me just a little bit. There was some about fold up a sample in the foil. There was some that was like tape it to something. If it was short, you fold it in. Taping, I wasn’t sure which end to tape, where to tape it to... There were labels, there was the foil, there was a bag. There was a lot to it.” – CAB161, 24 years, non-Hispanic White, returned some.

Others indicated that they sought assistance from another person during the process and would recommend seeking assistance if one is concerned about a disruption of their hairstyle.

“I had my friend cut the hair for me... If I hadn’t just bleached my hair, yes, I could have done it on my own, but since I had just bleached my hair, I had to find a good section of it that wasn’t fully bleached.” – CAB048, 22 years, Hispanic White, returned some.

“I would definitely recommend somebody else to help you with the hair because... People who are very particular about their hair would probably be worried about taking off

a large part of their hair. I mean, if it’s not a concern, then it’s not that big of a deal. But if it’s something that does concern you, then I would suggest getting somebody else to help with it.” – CAB046, 20 years, Asian, returned all.

One participant revealed that he did not return a hair sample because he was bald.

“The thing is that actually I’m bald, so I don’t have hair, basically. So I couldn’t grab any of my hair to send in the collection.” – CAB041, 29 years, Hispanic White, returned none.

Facilitators of Returning Self-collected Specimens

Some participants reported utilizing our study as a comprehensive HIV and triple-site bacterial STI testing mechanism to supplement their established testing routines.

“I guess if there was a chance of something appearing or getting a positive, by doing all of them, you would cover all your grounds, rather than it just being one test and it coming either negative or positive.” – CAB105, 29 years, Hispanic American Indian/Alaska Native, returned all.

Others described how limited access to a healthcare provider, either due to long distances or due to recently relocating to a new city, served as a reason for returning their specimens.

“So the clinic is further away from where I live, and there’s not another one close by. So rather than driving an hour to, and an hour back, and waiting, etcetera, I felt like it was easier to mail these things in.” – CAB048, 22 years, Hispanic White, returned some.

“It’s only been a few months that I’ve moved to this area. I was in Chicago where there was... I’m spacing out on the name of the place, but it’s a place for the community and they do free testing. And they provide, obviously, free condoms and everything that has to do with safe sex and STD prevention. So, that’s where I normally would go. Again, I haven’t found any place similar yet here because I’ve only been here a few months.” – CAB082, 32 years, Hispanic American Indian/Alaska Native, returned all.

Several participants also mentioned that they were keen on contributing to research focusing on home-based testing, especially if it could benefit sexual and gender minorities or those residing in rural areas.

“I genuinely like doing studies like this to advance epidemiological studies. So anything that I can get back to whichever community, whether it’s the scientific community or the GLBTQ community, I’m all for it.” – CAB044, 28 years, Hispanic multiracial, returned all.

“I felt like it would be useful or helpful, what you guys were attempting to do, in order to get the tests sent to people’s homes rather than make them go to a clinic or a

hospital, especially for those communities in rural areas.” – CAB069, 27 years, Hispanic multiracial, returned some.

Barriers to Returning Self-collected Specimens

Some participants discussed how their wavering confidence around completing activities that they perceived to be challenging was an obstacle to undertaking specimen self-collection.

“I think I always doubt my own ability to accomplish literally any task. But especially something where I’m expecting something catastrophic and it doesn’t come back catastrophic. If I’ve administered it myself I think well I must have done something wrong. That is not the fault of any at-home testing kit.” – CAB002, 23 years, non-Hispanic White, returned none.

Others expressed reluctance about returning specimens by mail because they were concerned that the specimens might not reach the laboratory in time or at all.

“Don’t trust the mail system sometimes. Like if I’d be getting an Amazon package, and it gets handed over to the Postal Service, I’m watching it 24/7 to see when it’s gonna show up, because I’ve ordered items before and they’ve shown up four days past the delivery date.” – CAB120, 26 years, non-Hispanic White, returned none.

“I’m like that with anything I’m mailing, whether it was for this or I’m returning something that I bought online. But that’s just the general worry that I have, “Is it actually gonna get there?”” – CAB086, 23 years, Hispanic, returned none.

Specimen-specific barriers to mailing a finger-stick blood sample included the potential for loss during transit, and to mailing a urine specimen included the potential for leakage during transit.

“I wasn’t comfortable doing it [finger-stick blood sample] because it was more of the reason for sending it. It get lost in the mail and something happens to it, I don’t know. But that kind of stuff came through my mind. I was just like, “Oh, I don’t know if I want my blood out over there.” – CAB075, 23 years, Hispanic, returned none.

“I just felt like things would get messy. Like, say if it [urine specimen] broke mid-ship... I wouldn’t wanna deal with that... Like if I’m gonna give a urine sample, it’s gonna be in an office. Because if something breaks then it’s on them.” – CAB048, 22 years, Hispanic White, returned some.

Comparison of Home-based and Clinic-based Testing

Several participants discussed the pros and cons of home-based and clinic-based approaches to routinely test for HIV and STIs.

Commonly cited reasons for preferring home-based testing included the conveniences it offers such as not having to drive to a clinic and endure a wait, and the prospect of minimizing potentially stigmatizing encounters with health-care providers.

“I didn’t have to go anywhere, I did it in the comfort of my own home, I sent it off, and I didn’t have to pay anything as well... Granted, when I go get tested at whatever non-profit organization, I get the results right then and there, if it’s HIV. But that’s still time that I have to take out of my schedule and things like that, so I really like this experience.” – CAB044, 28 years, Hispanic multiracial, returned all.

“My experience with a doctor is that it’s always an older, straight male, and I feel like being a gay man, it’s kind of a weird conversation to have. I don’t know, I just don’t necessarily enjoy it... If I could just get something in the mail, take care of it, send it out. I think that’s way easier than trying to talk to my insurance company, talk to my doctor’s office, try and schedule an appointment to actually drive there, go to the appointment, sit through however long of sitting and waiting and sampling, all of that, and then going back. I would so much rather just do it at home.” – CAB161, 24 years, non-Hispanic White, returned some.

Some participants also described how out-of-pocket costs might influence their decision to pursue home-based or clinic-based testing in the future.

“If I could go somewhere to get a free test versus having to pay to do it at home, then I’d have to decide between that. But if the cost factor was the same, I think I would do it more often at home.” CAB015, 22 years, non-Hispanic White, returned all.

“If it’s [home-based testing] the same price as going to the doctor, then it’s easy if you do a cost-benefit analysis... I mean, you could say that going to the doctor, you get prescriptions or whatever, but you’re saving gas, you’re saving time, and you have the convenience and security of your own home and things like that. So, to me, doing it at home outweighs doing it at the doctor so I would if it’s the same price, and I usually pay \$15 if it’s my PCP or \$30 if it’s the specialist.” – CAB044, 28 years, Hispanic multiracial, returned all.

“Cost is certainly like a factor too, right? Like granted I don’t know how much these at-home kits cost, but you know obviously like going to a clinic, maybe you also have to consider like insurance coverage.” – CAB011, 24 years, non-Hispanic White, returned none.

Other discussed how clinic-based testing offers an opportunity to speak to a healthcare provider and seek immediate medical advice including treatment.

“I can look up information all day long on the internet, but I’m also really good at making information on the

internet be much more scary that it actually is, it's like, "Oh, let's go on WebMD and die." And that's not gonna happen at a doctor's office. I mean I feel much more comfortable with an actual trained professional there saying, "Here's what this means, here's why you don't need to freak out, or here are the next steps you can take." And especially if there's a symptom or something that I'm having, they're right there and they can start the treatment right away." – CAB002, 23 years, non-Hispanic White, returned none.

One participant commented that he wished to utilize in-person healthcare services because it would give him a reason to step outside during the COVID-19-related social distancing mandates and stay-at-home orders.

"It gives me a reason to go somewhere, see something, not stay inside, especially in the current quarantine climate." – CAB086, 23 years, Hispanic, returned none.

Discussion

Project Caboodle! is the only study to our knowledge to qualitatively explore perceptions and experiences of self-collecting and returning up to five specimens for HIV, bacterial STI and potential PrEP adherence testing among sexually active GBMSM recruited online from across the US. In addition to reporting on participants' impressions of our specimen self-collection materials, we present information on their prior familiarity with different specimen self-collection methods and varied experiences as part of our study. More importantly, we delineate facilitators and barriers to returning self-collected specimens, which has pragmatic implications for prevention researchers and practitioners interested in incorporating this approach into their work. Previous studies that have requested GBMSM to self-collect specimens for HIV or bacterial STI testing have noted average return rates of 60% when they offered an incentive and 30% when they did not offer an incentive [56]. Little is known about the perceptions and experiences of GBMSM regarding self-collection of hair samples for PrEP drug level testing to assess adherence. Our findings can help inform future comprehensive public health interventions aiming to improve screening rates for HIV and STIs, and to monitor and support adherence to PrEP.

Focusing first on the specimen self-collection box itself, our participants appreciated receiving it in plain unmarked packaging with no reference to the nature of its contents or to the study. Because of the stigma associated with HIV and STI testing and PrEP use, especially among GBMSM [57–59], shipping kits in discreet packaging is generally considered best practice [60, 61]. Another practical aspect to consider is the choice of shipping carriers (e.g., Amazon, DHL, FedEx, UPS, US Postal Service) because not all of

them deliver to rural areas. Although all participants in our pilot study provided a residential mailing address to receive kits (as opposed to a PO Box or self-service parcel locker) and the majority of them resided in urban areas, this might not be the case in large-scale implementation studies or public health programs. To enhance privacy, we also recommend asking participants if someone else such as a parent, roommate or partner could intercept their mail and offering alternatives such as the option to retrieve their package from a self-service parcel locker at a place and time they find convenient. Similarly, it could be helpful if the process for returning one's specimens avoids disclosing the nature of the destination (e.g., STI laboratory) or the contents of the package. Including prepaid return postage could be beneficial, particularly for rural residents who may encounter surcharges for package pickup from areas deemed to be less accessible by shipping carriers [62]. Attention to the possible size of the return package might also be warranted. For example, some participants in a study conducted in rural Appalachia were not able to fit packages containing self-collected finger-stick blood samples for HIV testing in their household mailboxes, necessitating travel to a post office which likely served as a barrier to specimen return for those having to travel long distances [63]. Our use of different colored bags (i.e., red, blue, green, yellow and black) with matching color-coded instructions for self-collecting each type of specimen elicited highly positive reactions from our participants. Marketing scholars have consistently touted the benefits of using different colors to separate multiple products in the same family from a visual perspective [64, 65]. Color coding is a simple yet useful strategy that allowed our participants to readily distinguish between the various specimen self-collection kits and easily revisit the corresponding instructions. Learned color associations (e.g., relating red with blood, relating yellow with urine) should also be borne in mind when designing packaging for different types of kits to minimize the potential for confusion.

Several participants in our study knew that finger-stick blood samples can be used for HIV testing but had limited prior awareness regarding the value of pharyngeal and rectal swabs for extragenital bacterial STI screening or the utility of hair samples for PrEP drug level testing to assess adherence. Given the frequently asymptomatic nature of gonorrhea and chlamydia in the throat and rectum [66–68], and the likelihood of missing 70–75% of extragenital gonococcal infections and 85–89% of extragenital chlamydial infections if only urine screening is performed [69, 70], educating GBMSM about triple-site bacterial STI testing is a necessary step in improving their overall sexual health literacy. Additionally, there appears to be a need to address provider-related barriers to offering extragenital bacterial STI screening. Some previously identified impediments

include discomfort with comprehensive sexual history taking based on personal bias or inadequate training and busy schedules [71–73]. Although self-collected pharyngeal and rectal swabs have been documented to be time-saving in clinical settings and equally valid in terms of sensitivity and specificity as those collected by healthcare providers [74], our participants reported limited prior experience with self-collecting either of these specimens for gonorrhea or chlamydia screening. Some participants, however, discussed having self-collected finger-stick blood samples or urine specimens in the past for purposes other than HIV testing (e.g., as part of laboratory coursework) or bacterial STI testing (e.g., as part of screening for substance use in the workplace) respectively. Not surprisingly, the hair sample intrigued several participants with respect to its novelty and utility. Despite being aware that hair can be used to detect evidence of substance use or for DNA testing (using the hair bulb), they were unfamiliar with the concept of analyzing a cut hair specimen to measure PrEP drug levels.

Regarding the ease of specimen self-collection as part of our study, participants considered finger-stick blood samples and rectal swabs to be more challenging compared to pharyngeal swabs, urine specimens or hair samples. Our results pertaining to self-collecting a finger-stick blood sample are analogous to prior research wherein some GBMSM expressed reluctance to prick themselves as they feared the sight of blood or worried about pain, and others reported being unable to obtain a sufficient quantity of blood to fill the transport tube [31, 32, 75, 76]. Participants in our study also mentioned being unsure about which posture to assume and experiencing physical or emotional discomfort when self-collecting a rectal swab. Our findings mirror narratives from recent work with male couples in which uncertainty about how deep the rectal swab needs to be inserted, pain and uneasiness about the possible presence of fecal residue in the rectum acted as barriers to self-collecting this specimen [33]. Providing support beyond written instructions in subsequent studies, such as access to real-time video conferencing before GBMSM attempt to self-collect finger-stick blood samples or rectal swabs, may prove useful in answering questions and allaying concerns. Although several participants found the actual process of self-collecting a hair sample relatively straightforward, some reported challenges with packaging it correctly because they found the instructions confusing. Specifically, they were unsure of which part of the hair had to be affixed to the aluminum foil with an adhesive label. PrEP drug levels are measured in the region of hair that is closest to the scalp (i.e., at the proximal end), therefore hair fibers should ideally be affixed to the foil with a label at the distal end. Offering supplemental assistance in the form of pre-recorded instructional videos could help alleviate this issue in the future [77].

Frequently discussed facilitators of returning self-collected specimens as part of our study included an opportunity to confirm one's HIV, gonorrhea and chlamydia status, having limited access to a healthcare provider and a desire to advance research focusing on home-based testing, especially if it could serve sexual and gender minorities or rural communities. In addition to providing a monetary incentive, underscoring the importance of HIV and need for triple-site bacterial STI testing in study materials, and recognizing research participation as an act of altruism might help achieve gains in the rate of self-collected specimen return in future research with GBMSM. Our participants also talked about the general benefits of home-based approaches to screen for HIV and STIs such as not having to travel to a clinic and experience variable wait times, and the potential to reduce anticipated or experienced stigma associated with receiving sexual health services in person. Several of these advantages have been described at length previously [15–17], and some were highlighted during the COVID-19-related social distancing mandates and stay-at-home orders. Many healthcare providers across the US pivoted to mailing specimen self-collection kits to their patients, coordinating with clinical laboratories to obtain test results, communicating test results back to their patients, supporting linkage to care and assuming responsibility for billing and case reporting [21]. In addition to the above-mentioned benefits, cost to patients is mitigated when providers prescribe HIV and STI testing as indicated and bill patients' insurance plans, reducing potential out-of-pocket costs. Issues around pricing and reimbursement are essential considerations for the scale up of home-based testing approaches to ensure that the advantages they offer are not outweighed by cost concerns [78, 79].

Commonly cited barriers to returning self-collected specimens as part of our study included low self-efficacy pertaining to self-collection and apprehension around the possibility of delay or loss of specimens during transit. Self-efficacy, an individual's perceived ability to execute a behavior in order to complete a task or achieve a goal [80], is a critical concept in undertaking specimen self-collection. Offering additional support such as real-time video conferencing during which participants can discuss questions or concerns related to self-collecting each type of specimen might be helpful in boosting their confidence. The availability of peer support can also provide an opportunity to freely talk about one's thoughts and feelings about the self-collection procedures themselves and the potential for positive test results. For example, GBMSM welcome the social support of their friends and partners during self-collecting oral fluid specimens for rapid HIV testing [23]. Seeking assistance during the process of obtaining certain specimens (e.g., finger-stick blood, hair) may also improve the

self-collection experience for some GBMSM. For example, collaborating with a partner to obtain pharyngeal and rectal swabs for bacterial STI screening has been described as a source of comfort and practicality by men in same-gender relationships [33]. Consternation about mailing one's specimens back to a laboratory could be relieved by using and informing participants about shipping carriers that would allow them to track their return shipment and receive a delivery confirmation via email or text message.

Limitations of our study include restricting our recruitment to Facebook and Grindr, resulting in a convenience sample of GBMSM with accounts on either or both platforms. Their perceptions and experiences of self-collecting and returning different types of specimens might vary from users of other social media or dating platforms, and from those who do not have an online presence by choice or on account of structural vulnerabilities (e.g., homelessness, incarceration). Therefore, caution must be exercised in generalizing our study's findings to all GBMSM. During our in-depth interviews, participants were asked to retrospectively reflect on each specimen self-collection activity, potentially subjecting our results to recall bias. Our interviews were only conducted in English, which could have posed language difficulties for some participants. Additionally, the majority of interviews were completed before the COVID-19-related social distancing mandates and stay-at-home orders went into effect. It is possible that some GBMSM may view specimen self-collection in a different light during the post-pandemic era.

Conclusion

Our study lends support to the growing acceptability and feasibility of home-based approaches to test for HIV and bacterial STIs among those at elevated risk [81–85], and provides new information on the potential for utilizing self-collected hair samples to measure PrEP drug levels. Our results on facilitators and barriers to returning self-collected specimens have practical implications for prevention researchers and practitioners who might be interested in employing this approach in future work with GBMSM. Unlike the Ora-Quick In-Home HIV Test, FDA-approved specimen self-collection kits to test for gonorrhea or chlamydia are not yet commercially available in the US. However, some companies (e.g., PlushCare, NURX) now offer clients the ability to order specimen self-collection kits online and connect with a medical team to discuss test results and receive treatment if warranted. During the COVID-19 pandemic, they also added remote PrEP clinical evaluations and prescriptions to their portfolios. Telehealth offerings are emerging as workable models that hold promise as they mature and

evolve beyond research settings and into clinical practice. Given our study's focus on home specimen self-collection and return by mail, we did not enquire about perceptions or experiences of provider-instructed specimen self-collection in point-of-care settings for HIV or bacterial STI testing. However, in light of recent advances in diagnostic technologies [21], we acknowledge the need for additional research on these aspects among diverse populations. Expanding access to screening by harnessing all available options and furthering innovative strategies to conduct remote PrEP adherence monitoring is vital to advancing public health efforts to prevent and mitigate HIV and STIs among GBMSM.

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Data Availability The data collected for this study are available from the corresponding author upon reasonable request.

Code Availability Not applicable.

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Consent to Publish Not applicable.

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