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Clinical Infectious Diseases

BRIEF REPORT

Developing and Assessing the Feasibility of a Home-based Preexposure Prophylaxis Monitoring and Support Program

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We piloted PrEP@Home, a preexposure prophylaxis system of remote laboratory and behavioral monitoring designed to replace routine quarterly follow-up visits with home care to reduce the patient and provider burden. The system was highly acceptable and in-demand for future use, and more than one-third of participants reported greater likelihood of persisting in care if available.

Keywords. preexposure prophylaxis; PrEP; men who have sex with men; MSM; HIV prevention.

Human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) has high demonstrated effectiveness and efficacy for HIV prevention for men who have sex with men (MSM) [1]. The US Centers for Disease Control and Prevention (CDC) estimates that approximately 1.2 million US adults are eligible for PrEP, including 492 000 MSM [2]. PrEP prescriptions are growing significantly, yet the benefits of PrEP protection are accruing inversely to HIV acquisition risk, with young and minority MSM less likely to access and persist in PrEP despite higher risk [3].

Low persistence in PrEP care may be a substantial barrier to achieving substantial epidemic impact. As PrEP uptake scales up from clinical trials to real-world clinical implementation assessments, the importance of persistence in care is increasingly clear. PrEP clinics in 3 different states found high levels of PrEP adherence among those retained in care, but low persistence in PrEP care, with only 72% persisting in care at 3 months and 57% at 6-month follow-up [4].

To persist in PrEP care, individuals must attend quarterly follow-up visits to renew their prescriptions. Quarterly visits for an otherwise frequently healthy group may pose a substantial burden, and home PrEP care is one option to alleviate it [5]. When provided a hypothetical choice, PrEP-naive MSM preferred home-based PrEP care to standard care [6]. Furthermore, video-based in-clinic PrEP visits were acceptable in a small pilot study [7].

We developed and pilot-tested PrEP@Home, a home care system that includes all components of a PrEP follow-up visit and is designed to reduce annual in-person PrEP clinician visits from 4 per year to 1 per year. If successful, such a system could minimize the participant burden of PrEP, and potentially increase maintenance in PrEP care. This study describes the results of the pilot test.

METHODS

Participants

Participants on PrEP were recruited by their clinician at study sites in San Francisco, California; St Louis, Missouri; and Boston, Massachusetts. Participants were recruited from a variety of clinical settings: a municipal sexually transmitted disease clinic, a county health clinic, a federally qualified community health center, an online PrEP clinical service, a hospital-based infectious disease department, and a university-based infectious disease clinic. Eligibility criteria were as follows: (1) male sex at birth; (2) at least 1 male anal sex partner in the last year; (3) able to complete surveys in English; (4) prescribed PrEP at 1 of the study sites; (5) currently taking PrEP; (6) no history of hemophilia; (7) no feeling faint at the sight of blood; and (8) internet access to complete remote surveys. All participants completed informed consent procedures approved by the Emory University Institutional Review Board. Study data were collected using a Health Insurance Portability and Accountability Act of 1996 (HIPAA)–compliant electronic platform.

Intervention

PrEP@Home is an integrated system of participant self-collected specimens, centralized laboratory testing, and behavioral surveillance designed to be capable of replacing 3 of the 4 annual, in-person visits recommended by clinical guidelines [8]. PrEP@Home was pilot-tested by replacing a single standard PrEP visit with a home-care visit. Eligible and consenting participants received a discreet box mailed to their preferred address 2–3 weeks prior to their next scheduled PrEP follow-up visit. The box contained 4 specimen self-collection components.

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Each component was provided in a box with materials for specimen collection and detailed instructions that were informed by prior qualitative assessment [5]. Participants were asked to view a brief instructional video (https://vimeo.com/138977095) that complemented print instructions (see Supplementary Materials), and were provided with a prepaid overnight mailer for specimens, shipping instructions, and a 24-hour optional call line for assistance.

Laboratory and electronic behavioral survey results were collated and sent securely to the patient's clinician. If laboratory and behavioral survey results did not show any need for behavioral intervention, treatment, or repeated laboratory testing, the patient's clinician could renew their prescription without an in-person visit. For positive or concerning (eg, creatinine level) laboratory tests or issues identified in behavioral surveillance, clinicians were instructed to follow their standard care procedures. Study staff reported notifiable test results to local authorities per local laws.

Assessment

All laboratory specimens were tested in compliance with manufacturer recommendations regarding specimen storage medium and storage times. Specimens of urine, rectal swab, and pharyngeal swab were tested for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* using the Abbott RealTime polymerase chain reaction assay (Abbott Laboratories, Abbott Park, Illinois). A 100-μL specimen of finger prick whole blood was self-collected by participants in a gravity-fed microtube. The specimen was tested for creatinine using the Nova Statsensor (Nova Biomedical, Waltham, Massachusetts) point-of-care test system, for HIV using the Oraquick Advance Rapid HIV 1/2 Antibody test (Orasure Technologies, Bethlehem, Pennsylvania), and for syphilis using the ASI Rapid Plasma Reagin (RPR) Card at a 1:4 dilution. All tests were performed in a Clinical Laboratory Improvement Amendments–waived laboratory. Creatinine results were used to calculate glomerular filtration rate (GFR), an indicator of kidney function.

Behavioral surveys were conducted on a HIPAA-compliant survey platform, assessing areas recommended by guidance [9] such as medication side effects, HIV risk acquisition behaviors, symptomatic assessment for sexually transmitted infections (STIs) and acute HIV, and assessment of PrEP adherence. Research assessments in the survey included demographics, items to assess acceptability of the PrEP@Home system, and a modified version of the System Usability Scale (SUS), with scores >71 considered to indicate "good" acceptability [10].

Descriptive statistics were used to describe study participants, Likert-scaled items, and the acceptability of the PrEP@Home system. SUS scores were calculated according to guidance [10].

RESULTS

Of 58 consenting participants, 1 was lost to follow-up and 2 withdrew due to difficulty with blood collection, opting to remain in standard care. Supplementary Table 1 describes the demographic and behavioral characteristics for the 55 participants completing the pilot. Most participants were younger than 40 years and had attained some postsecondary education. More than half of the participants were white (30/55), 22% (12/55) were black, 11% (6/55) were Asian, and 13% (7/55) were mixed race or "other" race. Five participants (9%) were Hispanic. More than half (33/55) had been on PrEP for less than a year. Through electronic behavioral surveys, 75% (41/55) reported no missed PrEP doses in the last week. One-quarter (14/55) reported an increase in condomless anal sex since the last visit with a PrEP clinician, and 1 participant reported increased use of alcohol or drugs.

One participant had insufficient volume for remote testing of blood specimen and was referred to his local provider for testing. All participants returning blood specimen had nonreactive results for the HIV antibody test and for the syphilis RPR, and acceptable GFR values. More detailed laboratory results are provided in Supplementary Table 1. Results for rectal tests could not be obtained for 1 participant due to sample quality. This individual was referred to a local provider for testing and is engaged in ongoing PrEP care. The prevalence of rectal *C. trachomatis* was 13% (7/54) and was 7% for urethral *C. trachomatis* (4/55). Rectal *N. gonorrhoeae* prevalence was 4% (2/54) with none testing positive for urethral *N. gonorrhoeae*. No participants had pharyngeal *C. trachomatis*, and only 4% (2/55) had pharyngeal *N. gonorrhoeae*. From 57 patients with follow-up data, 4 required and received standard PrEP care: 2 unable to prick their finger and 2 with insufficient specimen collected. The majority (53/57 [93%]) were able to have their prescriptions renewed based on the PrEP@Home laboratory and behavioral surveillance results.

Overall, participants rated the PrEP@Home kit as "good" on the SUS scale with a mean score of 76.91 (standard deviation, 18.4). More than 85% of participants (48/55) indicated that if a kit were available, they would use PrEP@Home in place of a standard visit within the following year. A majority of participants rated their experience with each component of the kit as acceptable or highly acceptable (Figure 1). More than one-third (22/55) of participants reported that they would be more likely to persist in care if PrEP@Home were available.

In exit interviews conducted with 6 of the 11 clinicians implementing the pilot, the clinicians reported following their usual procedures for treatment of STIs. Clinicians also followed usual procedures for reports of increased condomless sex: Some always provided risk reduction counseling, and others provided counseling only if reported medication adherence was low.

DISCUSSION

PrEP is an extraordinarily promising intervention, but quarterly monitoring assessments place a burden on patients and the healthcare system. Challenges such as lower access to car transportation disproportionately impact the young and minority populations most impacted by HIV, and therefore may

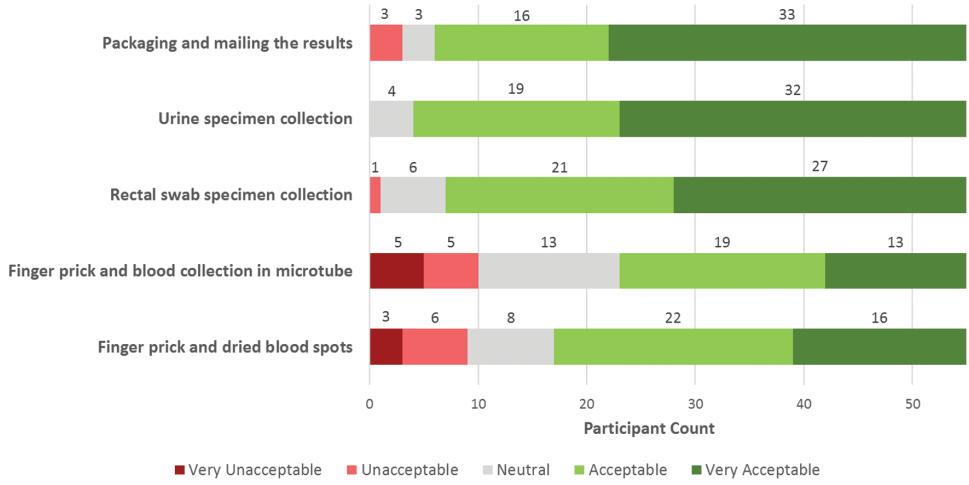

Figure 1. Ratings of the PrEP@Home system among 55 pilot study participants.

increase the burden for populations most in need of PrEP [11]. With the CDC estimating that >1.2 million individuals have an indication for PrEP, the healthcare system would be burdened with nearly 5 million visits annually if PrEP was brought to scale.

Our pilot test of PrEP@Home found the intervention to be acceptable and in demand for future use. Individual components of the intervention were highly rated, and all but 4 participants were able to collect sufficient amounts of specimen for required laboratory testing. More than one-third of participants reported that they would be more likely to remain on PrEP if PrEP@Home was available. An additional benefit is that such a system could facilitate more frequent testing for STIs, which has been shown to have substantial benefits [12].

This cross-sectional pilot study was conducted among a small number of users to explore the feasibility of home care. Selection bias, due to clinician recruitment of patients, may have influenced findings. We did not assess pharyngeal specimen collection acceptability, a consideration for future studies. A randomized clinical trial among MSM in 4 urban areas will compare the PrEP@Home intervention to a linkage to standard PrEP care control arm with primary outcome of effective retention in care, measured by protective levels of medication (tenofovir disoproxil fumarate/emtricitabine levels in dried blood spots). The study will oversample black MSM (target: 50% of total sample) and young MSM (target: 50% of total sample) to explore intervention efficacy for these highly impacted groups, and will analyze cost-effectiveness of the intervention. Technological advances in high-speed connectivity, smartphones, and laboratory testing are changing the landscape in which care can be delivered. Future research should explore how to leverage such changes toward decreasing health disparities.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Author contributions. A. J. S. and P. S. S. designed the study. A. J. S., K. H. M., A. Y. L., R. R. P., R. F., S. E. W., and C. S. K. contributed to data collection. All authors analyzed and interpreted the data. A. J. S. and L. M. A. drafted the manuscript. All authors reviewed, critically revised, and approved the final manuscript.

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