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Scaling Up CareKit: Lessons Learned from Expansion of a Centralized Home HIV and Sexually Transmitted Infection Testing Program

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Background: Despite advances in implementing human immunodeficiency virus (HIV)/sexually transmitted infection (STI) services for men who have sex with men (MSM), many remain underserved because of barriers like stigma, low facility coverage, and provider competency. This article describes the implementation of centralized nationwide mailed HIV/STI home testing (CareKit).

Methods: The Emory Center for AIDS Research developed CareKit for research study participants to request HIV self-test kits, STI specimen collection kits, and condom/lubricant packs to be shipped to any mailing address in the United States. Sexually transmitted infection kits were customized according to study needs and could include materials to collect whole blood, dried blood spots, urine sample, and rectal and pharyngeal swab samples for syphilis, gonorrhea, and chlamydia testing. Specimens were mailed back to a central Clinical Laboratory Improvement Amendments–approved laboratory for testing, and results were returned to participants.

Results: CareKit was used by 12 MSM studies and mailed 1132 STI kits to 775 participants between January 2018 and March 2020. Participants returned 507 (45%) STI kits, which included 1594 individual specimens. Eighty-one kits (16%) had at least one positive STI test result: pharyngeal chlamydia ($n = 7$), pharyngeal gonorrhea ($n = 11$), rectal chlamydia ($n = 15$), rectal gonorrhea ($n = 12$), genital chlamydia ($n = 6$), genital gonorrhea ($n = 1$), and syphilis ($n = 54$). In this same 2-year period, 741 HIV self-test kits were mailed to 643 MSM.

Conclusions: CareKit successfully met studies' needs for home HIV/STI testing and diagnosed many STIs. These processes continue to be adapted for research and programs. The ability to mail home test kits has become increasingly important to reach those who may have limited access to health care services, particularly during the COVID-19 pandemic.

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Men who have sex with men (MSM) in the United States are disproportionately affected by sexually transmitted bacterial infections (STIs) including syphilis, *Chlamydia trachomatis* (CT), and *Neisseria gonorrhoeae* (GC).¹ Individuals with an STI are at increased risk for acquiring human immunodeficiency virus (HIV).¹ Men who have sex with men have a high prevalence of extragenital CT/GC infections in the pharynx and rectum, which are often asymptomatic and underdiagnosed.^{2,3} Routine HIV/STI screening among sexual minorities is key to early identification, treatment, and prevention of further transmissions.

The US Centers for Disease Control and Prevention currently recommend HIV and STI screening at all exposed anatomical sites for sexually active MSM at least annually and as often as quarterly for high-risk individuals.⁴ However, barriers including sexual stigma, provider competency, and lack of access to culturally competent clinics contribute to low testing frequency in this population.^{5,6} Testing for HIV and STIs is lower in MSM who live in rural areas than those who live in urban areas, and improved methods are needed to increase testing among those who might reside longer distances from lesbian, gay, bisexual, transgender, queer (LGBTQ)–friendly health services.^{7,8}

During the past decade, self-testing and self-collection of specimens have emerged as innovative solutions to screening barriers. The Oraquick in-home HIV test (OraSure Technologies, Inc., Bethlehem, PA) received Food and Drug Administration approval for the first over-the-counter HIV test in 2012.⁹ HIV self-tests and self-collection of specimens for STI testing have been found highly acceptable among MSM, particularly oral fluid tests and collection of swab samples.^{10,11} Studies on the scientific integrity of home tests and self-collected samples show comparable results to traditional point-of-care tests.^{10,11}

The Emory University Center for AIDS Research (CfAR) Prevention Science Core developed the CareKit service to help HIV prevention-focused research studies implement home testing using a centralized mail-out system at cost. Many of these studies

are technology-based interventions aimed at increasing access to care and prevention services among MSM.¹² Thus, these interventions had a need to deliver testing services remotely through study mobile apps. CareKit has supported research studies to provide highly customized home-based testing and sexual health prevention materials to their MSM participants, growing from 2 studies in 2017 to 13 in 2020. Here, we describe the lessons learned from program implementation and expansion in the hope that future research studies can apply these methods to maximize test kit return rates and testing feasibility.

MATERIALS AND METHODS

The Emory CfAR Prevention Sciences Core provides HIV researchers with services to support research effort at cost. Research studies with a focus on HIV prevention and LGBTQ health can submit a request for CareKit services through the CfAR Prevention Sciences Core program manager. During the 2-year period described, one study coordinator at 50% full-time effort facilitated CareKit services with support from the CfAR Prevention Science Core manager and a part-time graduate research assistant.

OraQuick in-home HIV self-tests, STI specimen collection kits, and 9 configurations of condom/lubricant combination packs were available to participating studies. Sexually transmitted infection kits include sample collection materials with illustrated instructions, pre-labeled tubes with study name and unique alphanumeric barcode ID, a prepaid overnight return mailer to ship specimens to the laboratory, a biohazard bag, return mailing instructions, and a welcome letter describing the contents of the kit and frequently asked questions. Based on study outcomes and required laboratory testing, studies can choose to collect whole blood, dried blood spot

(DBS) cards, urine sample, and rectal or pharyngeal swab samples for an available panel of syphilis, HIV antibody, hepatitis, gonorrhea, or chlamydia testing. In addition, blood samples can be tested for creatinine and tenofovir diphosphate for preexposure prophylaxis (PrEP) adherence monitoring, and urine specimens could be screened for drugs of abuse. Instructional and self-collection materials were initially developed for the PrEP@Home pilot study at Emory, informed by qualitative feedback and quantitative assessment.¹¹ Assembled STI test kits, HIV kits, and condom packs are shipped to an Amazon fulfillment center to be distributed through CareKit's Amazon Seller Central account for multichannel fulfillment by Amazon (FBA). Sexually transmitted infection kits with collection materials, administrative costs, and shipping range from \$50.26 for a DBS collection kit to \$69.51 for 3-site, whole blood and DBS collection kit; laboratory fees are additional.

Participants can either order kits or be automatically sent CareKit materials according to the study requirements. Participants who can order materials through their study are shown a list of available items with pictures and descriptions in an order survey hosted by a secure, Health Insurance Portability and Accountability Act-compliant server (SurveyGizmo; Alchemer LLC, Louisville, CO). Participants consent to provide the CareKit team with a name, mailing address, and contact phone number or e-mail address with their order. Results from the order survey are uploaded by CareKit staff for processing and shipment through an Emory Amazon account. This indirect order process prevents participants from receiving targeted advertisements after placing the order through a personal Amazon account. Information from the order survey, as well as Amazon fulfillment and tracking information, are saved in a master CareKit tracking spreadsheet on Emory's secure server, only accessible to CareKit staff.

TABLE 1. Participating Research Studies in CareKit Program, 2018 to 2020

Study Name	Affiliated Institutions	Target Population	CareKit Services Used	Specimens Collected	CfAR Laboratory Test Panel
MMI ¹³	Emory and CDC	Cisgender MSM in Atlanta, NYC, and Detroit	OraQuick, STI test kits, condom packs	Urine, rectal swab, throat swab, whole blood	Syphilis RPR
AMIS ¹⁴	Emory	Cisgender MSM aged 15+ y	OraQuick, STI test kits	Urine, rectal swab, throat swab, whole blood, saliva, nails	Syphilis RPR, 3-site CT/GC
Healthmindr ¹⁵	Emory	Cisgender MSM aged 18–34 y	OraQuick, STI test kits, condom packs	Urine, rectal swab, throat swab, whole blood	Syphilis RPR, 3-site CT/GC, drug screen
PrEP@Home ¹¹	Emory	Cisgender MSM aged 18–49 y	STI test kits	Urine, rectal swab, throat swab, whole blood, DBS	Syphilis RPR, creatinine
LYNX ¹⁶	iTech	Cisgender MSM aged 15–24 y	OraQuick, STI test kits, condom packs	Urine, rectal swab, throat swab, whole blood	Syphilis RPR, 3-site CT/GC
MyChoices ¹⁷	iTech	Cisgender MSM aged 15–24 y	OraQuick, STI test kits, condom packs	Urine, rectal swab, throat swab, whole blood	Syphilis RPR, 3-site CT/GC
COMPARE ¹²	iTech	Cisgender MSM aged 15–24 y	OraQuick, STI test kits, condom packs	Urine, rectal swab, throat swab, whole blood	Syphilis RPR, 3-site CT/GC
ePrEP ¹⁸	iTech	Rural, cisgender MSM aged 15–24 y	STI test kits	Urine, rectal swab, throat swab, whole blood, DBS	Syphilis RPR, creatinine
We Prevent ¹⁹	iTech	Cisgender MSM and transgender men aged 15–24 y	STI test kits	Urine, rectal swab, throat swab, whole blood	Syphilis RPR, 3-site CT/GC
Iowa TelePrEP ²⁰	University of Iowa	MSM in Iowa	STI test kits	Urine, rectal swab, throat swab, whole blood	Syphilis RPR, 3-site CT/GC, creatinine, HIV
Project Caboodle ²¹	University of Michigan	MSM aged 18–34 y	STI test kit assembly (no fulfillment)	n/a	n/a
iSTAMP	Emory, University of Michigan, UNC	Cisgender AA and Hispanic/Latino MSM	Condom packs	n/a	n/a

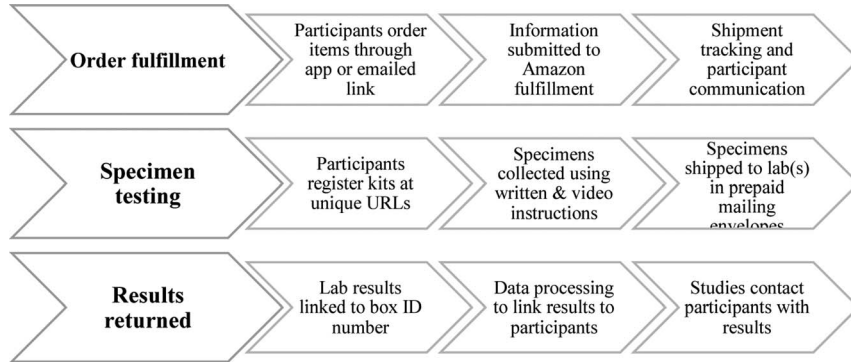


Figure 1. CareKit STI test kit process flow.

Once shipped, a CareKit team member sends a text message or e-mail with tracking information to participants. Orders arrive in a generic brown Amazon box within 3 to 10 business days after fulfillment. A follow-up text message or e-mail is sent to the participant, notifying them that their package was delivered and providing a CareKit contact number for questions, a link with video instructions, ideal days for blood specimen collection based on the laboratory processing schedule, and a link for the kit ID registration survey. The kit registration survey is used to link participants to their specimen samples via unique ID and allows specimens to be shipped to the laboratory deidentified.

OraQuick In-Home HIV tests detect antibodies in oral fluid and provide results within 20 minutes.⁹ These test kits do not require return shipment to the laboratory and are used for preliminary HIV screening. Studies with outcomes such as HIV testing frequency or compliance with screening guidelines may find OraQuicks preferable to laboratory-based HIV testing because of the ease of use and minimally invasive procedure of swabbing the upper and lower gums. Studies with HIV incidence as an outcome may prefer laboratory-based HIV testing so results can be directly accessed by the study team, and preliminary positives can be immediately retested. Studies interested in offering OraQuicks and capturing results can opt to send a survey at the time of kit delivery, requesting that participants upload a picture of the test kit.

After collecting specimens for testing, participants are asked to complete a laboratory requisition and place this form along with specimens collected in the provided packaging, which meets all federal regulations for shipment of Biological Substances, Category B. Participants ship their collected specimens via FedEx Standard Overnight to the designated laboratory in a pre-labeled mailer. Urine and swab samples sent to the Clinical Laboratory Improvement Amendments-waived CfAR Clinical Virology Lab are tested using the Abbott RealTime polymerase chain reaction assay (Abbott Laboratories, Abbott Park, IL) for CT/GC. Whole blood microtainer samples from a finger prick are tested for syphilis using the ASI Rapid Plasma Reagin (RPR) Card at a 1:4 dilution. For panels with tests not offered by the CfAR Clinical Virology Research Lab, the CareKit team worked with project managers to establish specimen shipping to multiple destinations adhering to laboratory specifications.

Once specimens are processed, the laboratory uploads an excel spreadsheet containing unique box IDs and paired testing results onto a secure Emory server. The CareKit team merges results with the kit ID verification data to share with studies via weekly results reports. When a positive result is uploaded, CareKit staff notifies the study as soon as possible, preferably within 1 business day. Study teams are responsible for contacting participants with positive results for follow-up and linkage to care, as well as reporting to the appropriate local health department.

To evaluate the success of the CareKit service, we examined the volume of HIV and STI test kits mailed, shipment timing, return of STI kits, and reporting of HIV results. For returned STI kits to the CfAR laboratory, results of the bacterial STI laboratory testing are reported by organism and anatomic site. Because some participating studies sent participants multiple test kits, we looked at return and results per kit rather than by participant.

RESULTS

Between January 2018 and March 2020, 12 research studies used CareKit services to varying degrees (Table 1). Most studies were based at Emory University with the PRISM Health team or with the Adolescent Trials Network U19 UNC/Emory Center for Innovative Technology (iTech).¹¹ Sexually transmitted infection kits were used by 11 of the 12 studies, and HIV kits were used by 6. Five studies had collected specimens from test kits processed at multiple laboratories. Test kits and condom packs fulfilled by CareKit were sent to addresses in 21 states with an average of 4.5 days between shipment and delivery. More than 6200 condom/lubricant packs were sent to participants across 7 studies (Fig. 1).

CareKit mailed out 1132 STI test kits to 775 study participants and 741 HIV kits to 643 study participants during this 2-year period. Of the 507 STI kits with at least one viable specimen returned to the CfAR laboratory, 81 had one or more positive/reactive result from 1594 individual samples tested (Tables 2, 3).

TABLE 2. CareKit Program STI Test Kit Return Rates, 2018 to 2020

Study	STI Kits Mailed	STI Kits Returned to	
		CfAR Laboratory, 2018–2020	STI Return Rate, %
Studies that provided incentives for kit return			
AMIS	200	131	66
ePrEP*	55	32	58
PrEP@Home*	161	86	53
(Subtotals)	416	249	60
Studies that did not provide incentives for kit return			
MMI	415	120	29
LYNX	40	9	23
MyChoices	25	10	40
Iowa TelePrEP	79	72	91
COMPARE*	11	5	45
We Prevent*	121	36	30
Healthmindr*	25	6	24
(Subtotals)	716	258	36
Total	1132	507	45

*Study is still open for enrollment, kit return rate incomplete.

TABLE 3. CareKit Program Self-Collected Specimens Tested by CfAR Laboratory Results

	Samples Returned	Samples Returned – Rejected	RPR Reactive	CT Positive	GC Positive
Whole blood	481	20	54 (11%)	n/a	n/a
Urine sample	369	0	n/a	6 (2%)	1 (.2%)
Rectal swab	371	0	n/a	15 (4%)	12 (3%)
Pharyngeal swab	373	0	n/a	7 (2%)	11 (3%)
Total	1594	20	54	28	24

Twenty (4%) of 481 whole blood samples returned were unable to be tested because of insufficient quantity or clotting. Kits returned from MMI, ePrEP and PrEP@Home had 3-site CT/GC and DBS testing conducted at outside laboratories and only submitted whole blood samples to CfAR.

For the AMIS study, all 200 participants received an OraQuick HIV test and were asked to report their in-home results using a secure survey e-mailed at the time of kit delivery. Participants received a \$50 gift card as an incentive for returning their self-collected specimens for STI testing and for reporting their at-home HIV test result. Of the 200 participants who received an OraQuick kit, 151 (76%) participants submitted results and all but 1 uploaded a picture of the test kit for verification. Six (4%) participants reported preliminary positive results, 1 participant reported indeterminate results, and 1 participant reported not understanding their results (Table 4).

Lessons Learned

There are several key takeaways from our experience facilitating home testing across a variety of MSM studies. Comparing the 10 studies for which we processed return STI specimens, offering an incentive raised the kit return rate by 24% on average (Table 2). The 3 participating studies that incentivized kit return (AMIS, ePrEP, and PrEP@Home) had a mean (SD) return rate of 60% (5.4%). However, the study with the highest kit return rate, Iowa TelePrEP, did not provide an incentive for kit return. The studies that incentivized kit return and Iowa TelePrEP all had study outcomes related to testing or required testing in their protocols. These studies dedicated resources to kit return, whether financial or personnel time spent following up with participants. In addition, undergoing regular HIV and STI screening was required for Iowa TelePrEP, ePrEP, and PrEP@Home participants to continue accessing PrEP medication, and therefore, these participants may have been more motivated to return their specimens for testing. Studies that offered STI testing as a bonus to their intervention without an incentive averaged about a 30% return rate (MMI, Healthmindr, LYNX, MyChoices, COMPARE, We Prevent). The 3 studies that incentivized kit return had willingness to self-collect samples as an inclusion criterion, whereas participants from other studies could order a kit out of curiosity or without the intention of returning.

In addition, offering extragenital self-collection at home was particularly successful. Of the 52 samples positive for chlamydia or gonorrhea, only 7 (14%) were genital specimens. Given limited availability of site-specific STI testing nationally, this presents an opportunity to address gaps in identification of pharyngeal or rectal cases of disease for MSM.⁴

Although OraQuick kits were mainly used by studies as an optional service, AMIS study participants who were asked to

report results with the possibility of an incentive had very high compliance (76%). Incentivized OraQuick self-reporting may be a viable alternative for study participants unable or unwilling to self-collect a blood sample for laboratory-based HIV testing, even for studies with HIV incidence as a primary or secondary outcome.

Program Evolution and COVID-19 Response

Despite the success of the CareKit service, there were significant challenges in scaling up the program. The highly customizable nature of the program created a complicated fulfillment and data management process, as studies with multiple testing laboratories and various combinations of specimen collection kits began to outnumber those using the standard testing flow. Also, by using Amazon fulfillment, we could not link individual test kit IDs to participants at the time of shipment. This led to establishing our kit registration system requiring participants to enter their test kit ID and contact information into a survey after delivery. Although kit registration worked the majority of the time (97% of kits were properly registered), there were 5 instances of unregistered kits with specimens returned to the laboratory that studies could not identify and results were unable to be returned.

In November 2019, CareKit established a partnership with Molecular Testing Labs (MTL; Blackfly LLC, Vancouver, WA), a Clinical Laboratory Improvement Amendments–certified laboratory with fulfillment capabilities, to take over assembly, shipment, and processing of home test kits for participating research studies as a new iteration of the program to address the concerns listed previously. This streamlined the order, shipment, and results return process significantly, with order data stored within the same secure, Health Insurance Portability and Accountability Act–compliant study portal as the laboratory results. Test kit IDs are linked to participants at shipment, which mitigates the risk of unidentifiable results. We transitioned 3 studies using CareKit to MTL in January 2020 (ePrEP, PrEP@Home, iSTAMP). Interruptions to both Amazon fulfillment services and the CfAR laboratory in March 2020 due to the COVID-19 pandemic response hastened the transition of our remaining participating studies (Healthmindr, COMPARE, and We Prevent), and the previously described CareKit process was phased out.

DISCUSSION

Studies that used the CareKit service between 2018 and 2020 had the most success when home testing was a central part of the intervention and kit return was incentivized. In addition, extragenital STI testing identified the majority of incident cases that may have otherwise gone undiagnosed. Lastly, self-reporting results from the OraQuick HIV home test kits had very high

TABLE 4. AMIS Study Participants OraQuick Results Reported

OraQuicks Ordered	Total Results Submitted	Negative Result Reported	Preliminary Positive Result Reported	Indeterminate Result Reported	Results Reported as Not Understood
200	151 (76%)	144 (95%)	6 (4%)	1 (0.1%)	1 (0.1%)

compliance when incentivized, reinforcing previous findings that oral fluid tests are preferable among MSM.^{10,11}

CareKit is shifting focus from building and administering test kits to knowledge translation of best practices for home HIV testing and STI self-collection. Since establishing a partnership with MTL, CareKit staff has consulted with 9 researchers interested in conducting home-based HIV and STI testing, providing advice and written materials on the home testing process. In addition, the CareKit team has been involved in the creation of a nationwide portal for test kit ordering supported by state and local health departments and the Centers for Disease Control and Prevention.^{22,23}

Reliable and rigorous home testing addresses barriers to in person screening such as stigma and facility access, barriers that are amplified for MSM and LGBTQ communities. Home testing options expand access from the limited, urban areas with LGBTQ-friendly testing to any home with a valid mailing address. With the end of the COVID-19 pandemic still out of sight, home HIV/STI testing can limit unnecessary exposure and, in conjunction with telemedicine, avoid contact with busy health care facilities altogether.^{24,25}

Although we describe our own experiences with in-home HIV/STI testing here, other researchers and health departments have been developing and implementing home testing systems such as One Thousand Strong, #Testathome, and I Want the Kit, among many others.^{26–28} The value of home HIV/STI testing is becoming increasingly recognized, and we hope sharing our trial and error will help move the field in the right direction. CareKit will continue to work on expanding home HIV testing and STI self-collection in research and beyond.

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