Bridging barriers to clinic-based HIV testing with new technology: translating self-implemented testing for African American youth

J. A. Catania, Ph.D.,^{1,5} M. M. Dolcini, Ph.D.,¹ G. W. Harper, M.P.H., Ph.D.,² D. P. Dowhower, M.P.H.,¹
L. G. Dolcini-Catania,⁶ S. L. Towner, M.S., Ph.D.,¹ A. Timmons, M.A.,³ D. N. Motley, B.A.,³ D. H. Tyler, Ph.D.⁴

¹College of Public Health and Human Sciences,
Oregon State University, Corvallis,
OR, USA

²School of Public Health,
University of Michigan, Ann Arbor,
MI, USA

³Department of Psychology,
DePaul University, Chicago, IL, USA

⁴DePaul Family and Community
Services, Chicago, IL, USA

⁵School of Social and Behavioral
Health Sciences, College of Public
Health and Human Sciences,
Oregon State University, 401 Waldo
Hall, Corvallis, OR 97331, USA

⁶Departments of Psychology and
Sociology,
University of Oregon, Eugene, OR,
USA

Correspondence to: J Catania
catania1951@comcast.net

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Abstract

Numerous barriers to clinic-based HIV testing exist (e.g., stigmatization) for African American youth. These barriers may be addressed by new technology, specifically HIV self-implemented testing (SIT). We conducted a series of formative phase 3 translation studies (49 face-to-face interviews, 9 focus groups, 1 advisory panel review) among low-income African American youth (15–19 years) and providers of adolescent services in two US cities to identify potential translation difficulties of the OraQuick SIT. Based on content analysis, we found that providers and African American youth viewed SITs positively compared to clinic-based testing. Data suggest that SITs may reduce social stigma and privacy concerns and increase convenience and normalization of HIV testing. Challenges with SIT implementation include difficulties accessing confirmatory testing, coping with adverse outcomes, and instructional materials that may be inappropriate for low socioeconomic status (SES) persons. Study results underscore the need for translation studies to identify specific comprehension and implementation problems African American youth may have with oral SITs.

Keywords

HIV self-implemented testing, Implementation, Fidelity, Phase 3 studies

INTRODUCTION

Overview

The Centers for Disease Control and Prevention has mandated a comprehensive HIV prevention approach (CHPA) for implementation throughout the USA and its territories [1–3].

CHPA reflects a sea change in HIV prevention that emphasizes biomedical prevention [4]. CHPA includes enhanced HIV testing services targeting high risk persons, linkage-to-care, treatment with AIDS antiretrovirals, treatment adherence/retention programs, partners' prevention programs, and behavioral interventions focused on high risk persons. Underlying CHPA's successful implementation are a variety of organizational, social, and behavioral processes [5, 6] (e.g., test-seeking, treatment adherence).

Implications

Practice: African American youth in low-income urban areas find oral self-implemented HIV testing desirable, but both youth and service providers of this population see potential translation problems that need to be resolved (e.g., implementation fidelity) before wider dissemination is possible.

Policy: Oral testing has the potential to supplement clinic-based testing in reaching national testing goals.

Research: Research is needed to examine barriers to implementation fidelity, identify strategies for improving fidelity, and investigate potential negative outcomes (e.g., negative emotional responses) to self-implemented testing.

HIV testing for high risk persons is a key stepping stone in the CHPA system [5]. HIV testing leads to identifying HIV-positive persons and linking them to biomedical and behavioral prevention programs. In this context, the national goal is to test 90 % of HIV-positive persons by 2015 [7]. This is an ambitious goal and it is currently unclear how successful venue-based testing will be in reaching this outcome.

Clinic-based testing is the norm in the USA [8]. National data indicate that approximately 87 % of people are HIV tested at medical facilities (e.g., 41 % at sexuality transmitted infection or community health clinics, 14 % at correctional medical facilities), while only 7 % are tested at community-based organizations and 6 % at substance abuse treatment centers [8]. In general, there are significant barriers to clinic-based HIV testing for adolescents, including inconvenience (e.g., time, location, transportation), confidentiality concerns, and fears of being socially stigmatized if observed attending a testing site [9–14]. HIV self-implemented testing (SIT) offers a viable option for addressing these problems by increasing privacy and convenience [e.g., see 15]. HIV self-testing approaches are posited to provide an important addition

to the menu of testing options so as to increase HIV testing in population segments not reached by venue-based approaches [16–18]. Understanding how to best translate SIT programs to at-risk populations is an important step in this process. In this context, we conducted a series of formative studies focused on HIV self-testing with African American adolescents 15–19 years of age and with community service providers.

African Americans at high risk

In the USA, the highest levels of HIV risk behavior, transmission cofactors, and HIV diagnoses occur among those in late adolescence and young adulthood [19–24]. Across ethnic/racial groups, African Americans have the highest rate of HIV infection (62.0/100,000) and among youth, African American, gay/bisexual males [22] and heterosexual females have the highest lifetime risk of HIV diagnosis [25]. Moreover, African American youth residing in low-income neighborhoods have very high rates of sexually transmitted infections (STIs) and sexual risk behaviors suggesting that this population segment is at substantial risk for new HIV infections [26–28].

Unfortunately, HIV testing rates are low among adolescents and young adults, as suggested by the fact that approximately 59 % of HIV infections among 13–24-year-olds are estimated to be undiagnosed [29]. National population-based surveys corroborate this perspective in indicating that those in late adolescence and early adulthood report low levels of HIV testing overall (15–19 % past year, 32–39 % ever; [30]), with somewhat higher but still low testing levels among African Americans and those reporting an HIV risk factor (20–28 % past year; [24, 30, 31]).

In general, increasing HIV testing rates among at-risk African American youth and young adults may best be accomplished by a multi-faceted approach that augments current HIV testing strategies (e.g., clinic-based, counselor model) with self-implemented testing methods [5]. Increasing HIV testing rates in these population segments is a significant goal and critical to the CDC's CHPA. In particular, increasing repeat testing rates among high risk populations is essential for identifying HIV-positive individuals as early as possible post-infection. Repeat testing is much more likely to occur if the consumer can directly control the process of testing (e.g., see [15]).

To achieve the goal of testing 90 % of HIV-positive persons, HIV testing will need to increase significantly among at-risk African American youth and young adults. This may best be accomplished by a multi-faceted approach that augments current HIV testing strategies (e.g., clinic-based, counselor model) with self-implemented testing methods and innovated dissemination through nontraditional testing sites [5].

Self-implemented HIV testing: OraQuick

In 2012, the Federal Drug Administration approved the retail sale of an over-the-counter SIT [32, 33].

OraQuick uses an oral collection technique that is painless and preferred over finger stick methods by a significant margin [15]. In addition, OraQuick may be purchased over-the-counter through selected retail pharmacies by persons 17 years and older. The OraQuick HIV SIT requires consumers to self-implement three core components: (a) specimen collection and testing, (b) interpretation of results, and (c) use of OraSure's consumer support center for counseling and referrals for confirmatory testing and linkage-to-care in the individual's geographic area. In addition, OraSure seeks to implement their SIT with high fidelity by training consumers appropriately (package instructions and online video) [34]. In brief, OraQuick is a self-implemented program imbedded in a retail dissemination system.

Limitations of clinical trials

Glasgow et al. describe a five-phase translation process [35, 36]. Within their framework, randomized clinical trials of new treatments, programs, and technologies typically occur during phase 2; much of the National Institutes of Health-supported research tends to focus on this and stage 1 research [35, 36]. Phase 3 translation studies involve research directed at understanding how to increase uptake and implementation of evidence-based programs or technology in everyday settings across diverse populations. Unfortunately, phase 3 research, the focus of the current work, is conducted less frequently [35].

The first step in considering the dissemination of SIT is to insure that targeted populations can use SITs correctly. To date, three translation relevant studies of OraQuick have been conducted by the parent company and have shown that participants are able to understand the procedural instructions, execute them properly, read results correctly (<2 % failed tests), and report few adverse events [32, 33]. Although these clinical trials have examined SIT fidelity in high risk samples (e.g., gay and bisexual men), African American youth have been poorly represented. For instance, the largest clinical trial (approximately 5,000 participants) included only 89 adolescent respondents, of whom less than 50 % were African American [32, 33]. Thus, it is unknown how the OraQuick SIT program translates to African American youth in low-income neighborhoods. Research by non-industry scientists, however, suggests that adults in a range of international contexts find SITs to be acceptable and reports that SITs reduce social barriers to testing (e.g., privacy, social stigma) and facilitate partner and repeat testing [15]. It is unknown if these advantages extend to African American youth. In order to begin to address this issue, we conducted a series of qualitative translation studies with African American adolescents and community program providers who serve adolescents, to assess perceptions of SIT program components and dissemination strategies in economically disadvantaged urban areas.

METHODS

The present work is part of a larger community-based qualitative investigation examining ecological factors that impact social and sexual development among urban African American heterosexual youth. The study is focused on low-income African American neighborhoods in Chicago and San Francisco. The institutional review boards (IRB) at all sponsoring institutions approved study procedures.

Samples and procedures

Overview—The series of studies reported here were conducted between 2011 and 2012. OraQuick was moving through the FDA approval process during this time period. As information on OraQuick details became known, they were included in the study protocol. The original project consisted of a series of qualitative projects using face-to-face one-on-one interviews (two surveys, approximately 1 year apart) and nine focus groups conducted with adolescents (16–19 years of age) and service providers from community-based organizations and school health clinics in the communities where our adolescent participants lived. We also constructed an advisory panel of providers who individually reviewed an OraSure Kit and OraSure's online video ($N=5$). Study procedures and measures are described below. Questions regarding SITs were not asked of our first survey cohort, so those data are excluded. Comments in this regard have been added to the text, all focus group participants received a set of SIT-related questions, and the advisory panel received SIT kits and a set of relevant questions (see following subsection). Prior publications describe our research methods in greater detail [37, 38].

Adolescent cohort survey: procedures and samples—In each city, participants were recruited from several youth-serving, community-based agencies in low-income neighborhoods containing significant concentrations of African American youth. Only a subset of those youth surveyed ($N=49/73$) received SIT-related questions, because FDA approval of OraQuick did not occur until after data collection was initiated. Several approaches were used to identify potential participants including nominations by agency staff, approaching youth at the agencies, and snowball sampling. Eligibility was determined by screenings conducted by study staff. Inclusion criteria included being African American, heterosexually oriented, sexually active (penis-in-vagina intercourse, penis-in-anus intercourse reported since age 12), and between the ages of 15–17 years of age (54 % male, 46 % female). Approximately, 50 % had been HIV tested (58 % females) in the past; none were HIV-positive. This cohort was interviewed in 2011 following notification that OraSure's SIT application was moving toward FDA approval. Although some of the details of the final product were unknown at the time, sufficient information was available to describe to respondents the basic concept of SIT. Semi-structured interviews were conducted by highly trained ethnic minority males and females with clinical

training in psychology and in conducting of qualitative interviews. We obtained written informed consent from parents/guardians and assent from youth. Youth received cash remuneration for their participation (\$40). Interviews were typically about 2.0 h and were digitally recorded, transcribed verbatim, and checked for accuracy by staff.

Adolescent cohort survey: measures—Participants were asked a range of HIV prevention questions including a question on SITs:

“There are new tests being developed for HIV. One new type of test can be done at home. The next questions are about home HIV tests. This is how home HIV tests work. A person goes to a clinic [note: At this juncture, it was unclear how OraQuick would be disseminated, consequently, we picked a familiar location without designating it as an HIV testing clinic, it could be any type of health clinic] to pick up an HIV home test kit, takes it home and does the HIV test at home. That way, the person knows if they have HIV or don't have HIV.” [A series of additional probes were then asked:] “Do you think this is a good idea for teens? What makes it a good/not a good idea? What if the idea was to test yourself at home three times a year for HIV. Do you think this is a good idea? Why or why not?”

Adolescent focus groups: procedures and sample(s)—Coincidental with FDA approval of OraSure's SIT in July 2012, we conducted focus groups in Chicago ($N=5$ groups; six to nine participants/group; total $N=29$; 48 % males, 52 % females) with adolescents aged 16–19 years. Four groups were single gender only, and one was mixed gender. Only sexually experienced youth with some sexual health risk history were recruited to better represent the population that would utilize HIV/STI prevention programs. Risks included a history of STIs, pregnancy, pregnancy scare, sexual concurrency, or having had multiple sexual partners in the past year. Focus groups were conducted at De Paul University's communication sciences center in Chicago. The focus group setting provided privacy for groups, an observation room for video and audio recording, audio hook ups for meeting rooms, and accommodations. Refreshments and transportation vouchers were provided. Group facilitators were African American and gender matched except in the mixed gender group where there were two facilitators (male and female). Facilitators were trained by a highly experienced focus group trainer who has worked extensively with African American focus groups and by our research team. Facilitators participated in several mock focus groups prior to conducting the study groups.

Adolescent focus groups: measures—Among the topics discussed in the focus groups, we included a series of questions on SITs and provided visual aids showing the components of OraSure's SIT kit. We first asked,

"How many of you have heard about HIV tests that you can take at home?" We then further introduced the topic for discussion: "We have heard from some youth that they would like to make the HIV testing process easier. With an HIV home test, you might be able to find out the result in 30 min or so in the privacy of your home. If you had questions about the result you could call a counselor whose number is provided with the kit to get more information. Usually if the test is positive (meaning you might have HIV disease/AIDS) they want you to come in and get another test to confirm the result. If you are positive, they would want to counsel you and refer you to a doctor for treatment. The home test has been shown to be very accurate." We then showed participants a series of slides depicting the SIT kit and how it works. Following this, we sought their opinions on the general idea of SIT, on the OraSure SIT specifically, and on SIT costs.

Provider focus groups: procedures and sample—We conducted focus groups in 2012 with experienced providers (>10 years) of sexual health or social services for adolescents in San Francisco and Chicago ($N=4$ groups; two/city; four to seven participants/group; total $N=22$; 32 % males, 68 % females; age range 19–73 years; 50 % African American, 32 % Caucasian; 18 % other). Providers were recruited from agencies that serve gay/bisexual youth and heterosexual adolescents and young adults in the low-income neighborhoods of the adolescent cohort survey participants. Focus group (two/city) participants were selected based on recommendations by study investigators and service providers in Chicago and San Francisco. Participants represented 19 different agencies/programs. In each city, the focus groups were stratified to represent two broad classes of professional experiences with regard to sexual health: (a) the first group represented individuals from settings that were more highly focused on sexual health matters including schools (e.g., sex education teachers, school-based reproductive health clinics), medical (e.g., sexual health clinic), and community-based organizations (CBOs) (e.g., frontline staff with direct interactions with youth in programs about sexual health), and (b) the second group represented individuals from settings that included general services to youth or social service programs wherein sexual health was not a special focus. These members represented CBOs (e.g., after school sports and education programs; programs for homeless youth) and medical settings (e.g., from primary adolescent or pediatric health care clinics). Through this stratification method, we hoped to generate a broader range of opinions on SITs. Focus groups were conducted at De Paul University's communication sciences center in Chicago or at a commercial focus group lab in San Francisco. The focus group setting provided privacy, observation rooms for video and audio recording, audio hook ups for meeting rooms, and accommodations. Refreshments and transportation vouchers were provided. Facilitators were trained as described previously and participated in mock focus groups prior to conducting their first study groups.

Provider focus groups: measures—Focus group participants were asked about a range of HIV/STI prevention topics. The issue of SITs was introduced as follows: "Next, I'd like for us to talk about HIV home tests. When we interviewed youth about what they thought about HIV home tests, there was not complete agreement about the acceptability of these tests for them. Some youth thought they were a good idea and others did not. There may not be complete agreement about HIV home tests in our focus group here today, either on a personal or organizational level, so I encourage you to be candid about what you think because we may hear a variety of perspectives." We then introduced the OraSure SIT kit: "HIV home tests recently received FDA approval to be sold over-the-counter to individuals who are 17 or older. The availability of these tests presents another approach to encourage HIV testing, with individuals learning in the privacy of their homes whether or not they are infected with HIV. Next, we presented a series of slides showing details of the SIT kit, including the OraQuick Support Center (e.g., "...will be available 24 h a day, 7 days a week, via a toll free number where a representative will assist with any questions about performing the test or linkages to a local healthcare provider. All calls will be completely confidential.") and procedures consumers are to follow if they obtain an HIV test. We then asked a series of questions regarding their opinions on OraSure's SIT and its various components (e.g., "Based on your experiences working with youth, what advantages come to mind in thinking about HIV home tests as an option to encourage testing among youth?" "What concerns do you have with youth using HIV home tests?").

Provider SIT evaluation interviews: procedures and sample—In October of 2012, OraSure SIT kits became commercially available for sale through national drug store chains. The full SIT program including an online instructional video and national consultation service was available to the public age 17 and older without prescription. In November 2012, we mailed or delivered OraSure kits with a cover letter to our advisory panel of providers ($N=5$). Providers represented agencies that served gay/bisexual youth and heterosexual adolescents and young adults in the low-income neighborhoods of our adolescent study participants; providers represented a range of adolescent services (HIV, homeless services, patient coordination, health education). Each advisory panel member was instructed in the accompanying cover letter to, "Please read the instructions that come with the kit, look at the kit itself, and view the OraSure video by [link instructions].... Take some notes about your reactions to the material. We want you to think about African American youth aged 17–19. Please identify: (a) problems that may occur with regard to errors in following testing procedures and/or (b) misunderstandings that may occur about when to test, what the test means, or how to link to treatment if positive. You may also identify other problems, and we are interested in hearing about these. If you identify positive aspects of the

instructions or the video, let us know about those as well. It would be good to organize your material into barriers/negatives and facilitators/positive.” Approximately 1 week following receipt of the kits, providers were interviewed by telephone by one of the study investigators. Interviews were recorded by two note takers during each call.

Provider SIT evaluation interviews: measures—The telephone interview queried specific elements of the OraSure kit and its related components including, for example: “What challenges do you see in following the written directions on the back of the box and the flip chart materials that came with the kit?” “What challenges do you see with the video?” [including probes on various specific sub topics]. “Taking the box instructions and video together, what challenges might a young man or woman have in following the procedures and using the test correctly?” We then asked about challenges in interpreting the results (“What challenges do you see for youth in reading or interpreting test results?”) and OraSure linkage to care or follow-up testing services (e.g., “Both the video and the written instructions provide a phone number where youth can speak with a counselor and can get referrals. Do you think that youth would notice this information?; is it obvious enough? Do you think youth will use this call in resource? If a youth tests positive and calls to talk to a counselor, do you think they will follow through on the instructions for getting a confirmatory test and the referral to a health care facility near them? In general, what challenges do you see in linking positive youth to confirmatory tests and to health care?”). We then probed what participants “liked” about each of the elements mentioned previously.

Data analysis

The study team, consisting of a five-person coding team, extracted all one-on-one interview transcript materials on HIV testing and then on SITs. These data were further coded by the study investigators to identify content codes and themes. Content analyses were conducted to identify themes by using a team approach similar to that described by Stern [39]. Then, using a directed content analysis approach [40], we continued to analyze for themes until no new themes emerged [41]. Approximately 20 % of interviews were re-reviewed to identify missing data and/or identify coding discrepancies and disagreements in interpretations. All inconsistencies were discussed and coders/investigators came to consensus. Focus groups and advisory panel interviews were reviewed in their entirety by two investigators, and relevant material was extracted and organized through a series of meetings by the investigators (consensus building). Survey and focus group data were organized/coded into general categories regarding perceived advantages or disadvantages of SIT. Specific types (themes) of advantages/disadvantages were identified. Each study

addressed the advantages and disadvantages at a different level of specificity. Advisory panel evaluation data were categorized by kit components (print instructions, video training, testing procedures, and linkage-to-care) and specific themes extracted around each component.

RESULTS

Perceptions of SIT

A majority of adolescent participants in one-on-one interviews (65 %; 32/49) favored self-implemented HIV testing (SIT). Advantages of SIT included increased convenience, privacy, confidentiality, and reduced embarrassment and delays related to standard testing (see Table 1). A majority of respondents (76 %; 38/49) also favored SIT for repeat testing (see Table 1). Adolescents expressed concerns related to potential procedural errors in using an SIT, in receiving false-positive results, as well as challenges in accessing care, and in obtaining emotional support if results are positive. Example quotes are presented in Table 1.

Adolescent focus group participants, who were presented a more detailed description and pictures of the OraQuick SIT system, expressed advantages and concerns observed in the earlier survey data and provided additional insights. Advantages of OraQuick SIT were again noted as including improved privacy, confidentiality, and convenience and reduced social stigma relative to clinic-based testing (Table 2). Concerns were raised with regard to accuracy of the test, making procedural errors and misunderstanding instructions, being discovered using the test at home, and high retail costs (\$40.00+) (Table 2). Specific concerns were raised regarding being “alone” and getting test results, including the distress of having a false-positive result and negative emotional reactions to a positive result (Table 2).

Provider focus groups also noted a number of SIT advantages and concerns (Table 3). Providers perceived advantages for teens using SIT to include increased confidentiality, privacy, convenience, normalization of testing in the community, and access to testing. They also believed that SIT would decrease stigmatization and potentially lead to improved public health outcomes (linkage-to-care, increased partner testing). Providers noted that SIT might increase access for adolescent males in particular.

Providers also discussed a number of concerns regarding adolescents using SIT including problems that may occur in performing the tests related to difficulties reading print instructions, misunderstanding instructions, and with following the testing procedures (e.g., what the 3-month window means, need for confirmatory tests if positive) (see Table 3). Like the adolescent participants, providers also felt there may be emotional challenges for youth who test positive and difficulties for youth in accessing care if they receive a positive result.

Table 1 | One-on-one interviews: adolescents' perceptions of SIT

Advantages of SIT	
[Privacy, convenience]	"If they don't want everybody in their business. Instead of waiting for the paperwork to come, or waiting for a phone call, you can get it right there now and do something about it right there now."
[Privacy, stigma]	"Some people don't want to go to a clinic, 'cause people—they see you walk into a clinic, they all, 'He goin' to go get tested' ...So, I would just rather do it in my own private little room. Have my own little privacy..."
[Embarrassment, privacy, stigma]	"...I think that sounds a lot more comfortable for me to just go get my test, pick it up at the doctor's, because I'd be shy, you feel weird, it's better to go home and take the test and find out if they got it, and that can stop them from being scared, because that's why most teens around here are scared to go because of that risk of people knowing that they got it, even the doctor..."
[Embarrassment, privacy, convenience]	"...it's always a little bit awkward when...some older person you don't know, like, poking around your body and checking for things. So, if you can just can go in and get it and just bring it home, you can take it on your own time and... just do it by yourself."
[Repeat testing]	"So you could always have an update on it, be sure, be safe. You never know if your girlfriend cheated on you and gave it to you."
SIT disadvantages	
[Procedures]	"...some people are like, I don't read instructions. I can do it at home, and they mess up, and 'I don't have HIV.' They're not going to have it because they messed up on their test..."
[Procedures]	"...or people would set the thing up wrong and nothing will happen."
[False positives, no examination]	"...Like I wouldn't do it based off like what happens with pregnancy tests. Sometimes pregnancy tests be lying saying that you're pregnant when you're not, or saying that you're not when you are...I might as well go to a clinic where a doctor actually can sit there and tell me..."
[Lost linkage to care opportunity]	"It might not be good because if they find out they have it, they might just be like okay, whatever. I have it. Then let that be it. And just not go to the doctor and get the care that they need."

Provider advisory panel's evaluation of OraQuick procedures

The advisory panel members provided a detailed assessment of specific OraSure components in terms of the appropriateness of SIT use by the youth with whom they work. We summarize key findings from these interviews below and provide supporting text data in Table 4 (note: although an effort to accurately recorded statements verbatim was made, there were some minor edits that occurred after comparing the

two note takers records, but the factual substance of recorded statements across note takers were consistently confirmed).

Instructions—Although the written SIT instructions (flip charts, package) were thought to have many positive features, numerous fundamental concerns arose. All providers agreed there were potential terminology problems (see Table 4). In addition, the length and density of the instructions, and print size were thought

Table 2 | Focus group: adolescents' perceptions of SIT

Advantages of SIT	
[Privacy/confidentiality]	"Because a lot of people don't want to go see the doctor."
[Privacy/confidentiality]	"They isn't got to be sitting in the doctor's office looking at everybody, like I can't believe I'm in here."
[Privacy/confidentiality]	"I hate going to the doctor, and everybody, oh, what are you here for? And I be like, I need to get tested, and they be like, huh?"
[Privacy/confidentiality]	"...in my school...they have free HIV testing...So if they see you go to [the] trailer...like why are you getting yourself checked baby?...And they might start rumors."
[Convenience]	"So it's fast. So you find out right away."
[Convenience/repeat testing]	"...You always have it on hand. Like, you can buy, like, two or three and just keep it in your, like, medicine cabinet. And, like, you want to check it every three—you want to check yourself every 3 months..."
SIT disadvantages	
Procedural difficulties:	
[Instruction reading level]	"You might have to read it with your auntie or somebody. You know what I'm saying?"
[Misreading the test stick]	"How to read it [test stick] correctly."
[Poor implementation leading to erroneous results]	"...If you do it wrong and then you get like the wrong result..."
[False positives]	"But you'll be thankful at the same time 'cause you went home and it say positive, but you go to the doctor it say negative, you're like, 'Yeah, well, I have a feeling I isn't got it.' But bullshit I'm going to get my money back. Like, this test didn't work, so go on here..."
[Negative emotional reactions]	"...like some people don't react to that in the proper way. Like some people might go suicidal..."
[Being discovered using the test]	"Who will find out. Like, if I'm not trying to tell my mother and then she walk in the bathroom while I'm like swabbing myself, then you just like, uh, see."
[Costs]	"...Dang, \$40.00?"

Table 3 | Focus group: providers' perceptions of SIT

Advantages of SIT	
[Privacy/confidentiality]	"... it's private, ... most of us know already what most of our youths when they go for service anyhow they don't necessarily go in their own neighborhoods, so at the very least they're going to have some privacy..."
[Privacy/confidentiality—males]	"Males don't tend to go to the doctor unless they're sick. So I think it will be an advantage for them and a privacy issue for them."
[Stigma reduction]	"...decreasing the stigma so that this would be kind of the same as a pregnancy test..."
[Convenience]	"You're at school this time, you're at cheerleading practice, you're at basketball practice, now you're home...How can you possibly get away to go take an HIV test if that's what you want, but if you have a friend get it for you, slides it to you, you take it in your room..."
[Increased access]	"...I think that it's all about access and this would really increase access for young people..."
[Increased partner testing]	"... you know how we always tell you to get tested with your partner...if they have the option to go buy the test, you know, together in a room and let's get tested right here together...administer it to ourselves and watch the results...—you can't go in the room with your partner if you go to a clinic or wherever to get the HIV test, so it would give them more intimacy."
[Normalize HIV testing]	"But on the flipside, we are going to normalize the HIV test... This is obviously a step in that direction..."
[Enhanced linkage-to-care]	"...an advantage would simply be more cases and more treatment."
[Enhanced linkage-to-care]	"...it could prevent them from spreading it. It could encourage them to go get processed with medication and counseling and all of that."
SIT disadvantages	
[Difficulties reading results]	"...sometimes when a test is positive the line does not come in as clear as in that picture... and that could be a person who would be super open to seeking treatment but may think they tested negative is really concerning."
[Reading and interpretation problems]	"...in my experience of working with simpler things that kids are to do at home... it's amazing how they read things and they interpret it very different than what is actually suppose to happen."
[Re-test procedure challenges]	"... I'm not sure how well the youth would understand that if it is positive to go get that confirmatory blood test."
[Delays in counseling and linkage-to-care]	"...would they go to see a provider afterwards if they found out they were positive?...and continue to have sex, versus being in a clinical setting whereas there's counselors there... to guide them... getting meds..."
[Delays in social support, adverse events]	"...the idea that somebody would be receiving a positive result and not have somebody be there that supports them...especially for young people who can feel really alone and really isolated...I would be afraid that people might inflict self-harm..."

to potentially inhibit youths' motivation to read instructions thoroughly. Other instructional limitations noted were (a) print materials do not sufficiently "show-case" the availability of the online video, (b) challenges reading the expiration date, and (c) the fact that the package's plastic seal when removed can tear a large portion of the instructions from the box.

Testing procedures—Providers expressed concerns regarding adolescents' ability to cognitively process procedural instructions such as the need to not eat/drink prior to testing, test stick use, reading of the test lines, and understanding what a false-positive result means.

Video—The video received the most favorable comments. Using a video for instruction was universally seen as positive, particularly since it was felt that teens were more likely to use the video than the written instructions/flip charts. The pace and use of multiple (verbal and visual) channels to double-cover key information and the ability to scroll through the video were seen as positives. However, a number of concerns were raised about the content, setting, and actor in the video: the setting was viewed as too advantaged, and the (black male) actor was felt to be inappropriate in terms of age, language use, clothing style, attributed sexual orientation (for heterosexual males), and unrealistic in terms of the degree of emotional calm (rather

than acknowledging distress or concerns) for someone about to self-test. Lastly, the video did not cover as much material as the written instructions, leading to concern that there could be a problem for those who rely more on the video than the package instructions.

Linkage-to-care—A common concern was the challenges youths may face with the linkage-to-care features of the SIT program, including inability to follow-up with a call to the online counseling service or referred medical providers for confirmatory tests or care, emotional and stigmatization barriers to follow-up actions to confirm being HIV-positive, and challenges in low-income communities to obtain needed transportation to access care.

DISCUSSION

Overview

The present study examined HIV SIT for African American adolescents and young adults, with a specific focus on the OraQuick SIT, which has been found to be a preferred method of self-testing [15]. Study questions yielded information on potential adolescent SIT consumers and disseminators' perceptions of the

Table 4 | Provider advisory: panel's evaluation of OraQuick for youth

Package instructions	
Packaging and print	<ul style="list-style-type: none"> • “A lot of information gets torn off because of the adhesive on the back. It’s a big deal... all the correct information needs to be there.” • “The packaging outside didn’t promote the video. Didn’t mention the video until you open the flipchart. No mention of video on box instructions.” • “Checking expiration date wasn’t obvious.” • “Print is very small.” • “The flip chart printing is pretty small.”
Reading comprehension/terminology	<ul style="list-style-type: none"> • “It would be hard to do if reading level was low. It needs to be at 5th grade reading level. Any person should be able to read or hear. Explicit risk information is lacking...” • “hepatitis, tuberculosis—how many young people know this?” • “The whole explanation of what the test is...in-vitro test... too sophisticated.” • “[Complexity of instructions] ‘very wordy’ If you read the box, open and see all the words, you might just skip it and look at the pictures...” • “Youth probably wouldn’t read them all, they would just skim the instructions...they just don’t want to read.” • “some youth will watch only video, some information will be lost” • “Instructions are a little complex” • “... Some word meanings [are a] problem...[for instance words such as] confirmative... primary care physician...”
Video	
Overall	<ul style="list-style-type: none"> • “Video helps.” • “Video...could help with comprehension.” • “[video] Scroll on scroll bar...back and forth...[this is] good [because it] makes it easier to look back...Video tells you what you need to know at the time.”
Actor	
[Strength]	<ul style="list-style-type: none"> • “[video] casting of actor attractive, man of color, speaks clearly even though [youth] may not relate to the speech”
[Concerns]	<ul style="list-style-type: none"> • “...they would be less likely to listen to the guy due to his affluence, age. They may have some anger issues...not be able to relate with his housing, affluence...So the youth won’t listen to video as carefully” • “targeting young—the actor does not fit the description...He’s a 29/30 year old man with a nice, furnished apartment—the youth won’t relate...This is an individual that would be a little more responsible, versus a youth that’s a little scared. He’s too calm... doesn’t reflect the real world.” • “for a heterosexual male... the actor may seem too gay” • “For a hetero girl—they would think he’s cute. For a homosexual male—they would think he’s cute.” • “Heterosex males may think the actor is gay and be turned off by it, associating further HIV with being gay. He’s not talking white but he’s not talking ebonic...” • “Actor [needs to be] younger closer to youth age would be better...Actor’s dress more relatable: hat, football jersey the clothes...” • “Maybe better if younger” • “Actor is too affluent...actor is too old”
Setting	<ul style="list-style-type: none"> • “...more relatable environment...” • “Home setting is not like the youths” • “different environment better”
Content	<ul style="list-style-type: none"> • “Video...Lacking in guidance with what to do next even if it is negative or positive.” • “Instructions in video on how to time test- A little confusing. Different in the video then in the flip chart.” • “Pace—a little too fast” • “using test stick to get sample from mouth—If you see the video, NO. If you use the pictures—maybe. Might be problematic without the video” • “[Video States:] Test isn’t for you if you are HIV Test participant—What does this mean?”
Procedures	<ul style="list-style-type: none"> • “Youth would have problems, they would have the time but just ate. Snack all the time, challenge not to eat right before the test. Need to have more upfront that they can’t eat.” • “Eating or drinking—he thought that was different; they don’t do that in clinic now. Might be hard for people to comprehend.” • “Test stick problems—yes, there will be problems. I have walked people through this task, and they still mess it up.” • “[stick] Instructions say Swipe 1 bottom then 1 top—do I used same side of stick?”

- “[Using test stick to get sample from mouth] Youth could have challenges with this.”
- “[Issues with spilling the liquid] would be good to have a back up in the package”
- “faint line could be confusing—bring more attention to the faint line in the instructions”
- “Youth don’t understand- they may not understand that there’s a chance the test could be wrong. They may trust the test so much that they don’t seek confirmatory care.”

Linkage-to-care concerns

- “A lot of people who will know they are HIV-positive- and not know what to do about it. There is not counselor to be that helping hand, to encourage them to get through, to make the next step.”
- “No. Because if they’re youth, do things secretly, privately is very hard. Seeking medical service without a parent is hard”
- “Transportation issues—definitely a problem. If I can’t do xyz, where am I going to get money to go to a doctor.”
- “youth might have difficulty acting on the preliminary positive test”
- “transportation is a big issue in Chicago...Especially in the poverty stricken areas”
- “[barriers to care] ... no access to healthcare, geographic location to doctor, must be affordable, transportation... HIV stigma going to particular health care places”

concept and value of SITs vs. venue/clinic testing. In addition, test specific information was gathered on perceptions of the OraQuick SIT’s procedures and training materials, test result validity, retail costs, linkage-to-care and emotional consequences of SITs, and the value of SITs for repeat and partner testing among African American adolescents and young adults, particularly among those in impoverished settings.

In general, both providers of adolescent health services and African American youth residing in low-income urban areas tended to view SITs positively compared to clinic-based testing. In accord with data from adult samples [15], the present study suggests that both youth and providers perceive advantages to SIT use (vs. clinic testing) in terms of reducing social stigma and privacy concerns, increasing convenience, and facilitating normalization of HIV testing in the community. These are important and potentially powerful outcomes that current HIV venue-based testing does not adequately address. Moreover, these potential outcomes of SIT would be expected to contribute to public health goals by increasing HIV testing, repeat testing, and partner testing by adolescents and young adults. To reach these positive outcomes, a number of translational adaptations may be required.

Participants raised a number of caveats regarding SITs in general, as well as with the OraQuick SIT program specifically. A major concern with SITs was that those testing positive would not follow through for confirmatory testing or treatment and/or may experience adverse psychological outcomes without an “onsite” support person. Based on OraSure’s clinical trial research and the use of self-implemented testing in adult populations, there is very little evidence that adverse psychological outcomes occur. However, these studies have not examined youth. The last 30 years of clinic-based testing would seem to suggest that adverse reactions by adolescents and young adults to testing or testing positive are not a common occurrence. That said, the situation with SITs is somewhat different, and investigation of this issue in future dissemination studies is warranted.

In some instances, there were misperceptions that led to negative attributions. For instance, some participants incorrectly saw SITs as a confirmatory test rather than as a screening test that requires confirmatory testing to verify positive results. Moreover, consumers are advised to conduct repeat testing at regular intervals to reduce the chances of a false negative. OraQuick in particular needs to address public perceptions of the test, so it is clear that it is a screening test that requires these additional steps. Consumer education that is presented in a developmentally appropriate manner so that adolescents and young adults can understand these concepts is warranted.

With regard to OraQuick, a number of specific barriers were identified including the high retail cost (>\$40/unit in pharmacies) for this socioeconomic status (SES) group, packaging concerns (e.g., seals that, when removed, destroy box instructions), as well as instructional and procedural challenges that reflect poor program fit with some young low-income African American consumers in terms of cognitive abilities (e.g., comprehension of technical language and complex instructions), sociocultural factors (e.g., instructional video that appears to be a poor fit in terms of socioeconomic status), and emotional expectations of consumers (e.g., video actor appears too calm and, therefore, not how younger consumers may feel). These issues are discussed further in the following sections.

Fidelity challenges of self-implemented testing

As noted previously, OraQuick has the components of a basic health program geared towards self-implemented testing. The program supports consumers in implementing the SIT components with high fidelity by training consumers through written package instructions and an online video. Although the present study does not directly assess program fidelity, our findings do suggest that there may be challenges with the OraQuick training component that may pose difficulties for some consumers in attaining high implementation fidelity. Program fidelity [42] here means that consumers will perform all procedures and recommendations competently enough to

obtain a valid result (compliance and competence fidelity) within the limits of the test. Translational research is needed to examine if low-income African American youth can consistently perform all OraQuick SIT procedures with high fidelity (specimen collection and testing, interpretation of results, and contact OraSure's consumer support center for counseling and referrals).

Best practices for performing self-implemented programs with high fidelity are, in general, not sufficiently researched. Implementation of the FDA-approved at-home pregnancy test provides an instructive example. Although these tests have been sold for over 40 years, and clinical trials research suggested at-home pregnancy tests could be implemented with high fidelity, subsequent studies provide convincing evidence that various population segments continue to have significant challenges with implementing at-home pregnancy tests [43–46]. Both SITs and at-home pregnancy testing require that program features fit the diverse populations that may use them, and those at highest risk may have characteristics (low income, poor education) that require different instructional strategies. Fit is defined as the compatibility or match of a program's components to the characteristics of the person receiving the program. In the case of SITs, this translates as the fit between various self-implemented program components and the person executing the self-implemented program. Program fit is consistently identified as important to successful program implementation [47] and represents a potential point of intervention in efforts to increase program fidelity. Although a number of HIV prevention studies have shown that poor program-client fit by agency-implemented programs results in low program fidelity [42, 48–53], none of this work has examined self-implemented programs.

This type of translation research underscores and needs for phase 3 studies, as highlighted in the Glasgow et al. implementation framework [35], that involve research directed at understanding uptake and implementation of evidence-based programs or technology in everyday settings across diverse populations. By identifying areas of poor fit and weak fidelity, we inform studies designed to develop improvements and test these program modifications within the context of innovative SIT dissemination strategies. The degree of fit between the SIT program and a given dissemination strategy is expected to influence the rate of adoption of the innovation and success of dissemination in organizational and nonvenue (e.g., street intercepts) settings.

Challenges to integrating SITs and venue testing

Another translation challenge is how to best integrate SITs within current HIV testing networks in a geographic area. In the field of HIV testing, SITs are not a standalone strategy, rather they are supplemental to venue-based HIV testing programs. That is, SITs are screening programs, and parallel confirmatory testing

venues are needed. Consequently, testing venues need to reduce barriers further for young clients so those testing HIV-positive on SITs are able to obtain confirmatory tests. Presumably, those screening positive will be motivated to seek confirmatory testing and care. Research with adults suggests that SIT users who test positive are motivated to seek confirmatory testing and linkage-to-care [15]. That OraSure provides assistance with linking persons to test sites and treatment centers is supportive of this effort. However, it is unknown if the provided referral sites are workable for low-income persons, who may have transportation challenges [11]. It is also unknown if the reputations of the provided referral sites are perceived by young African Americans as racist, homophobic, or unwelcoming of younger persons. The utility and cultural acceptability of the referrals offered through OraSure's LTC program have not, to our knowledge, been examined.

Furthermore, although CHPA funds expanded HIV testing through "Expanded HIV Testing for Disproportionately Affected Populations" cooperative agreements, recent evidence suggests that these expanded programs may have translation problems for younger populations [11]. Hyden et al. [11] surveyed HIV test sites in New York City ($N=164$) and were unable to contact or obtain access information from 48 % of those sites. Further, 23 % of contacted sites did not offer testing outside of standard business hours (9 am to 3 pm, Monday–Friday), thereby limiting access for students and day-workers. These data indicate significant logistical and service flaws exist in the expanded HIV testing program that may adversely influence HIV test-seeking by 17–24-year-olds. Integration of SITs into the venue-based testing networks requires that those networks function adequately.

Implications for HIV testing

The present study underscores the need for simulation studies that identify specific comprehension and implementation problems youth may have with oral SIT kit components and instructional sets. This work would provide a basis for developing supplemental strategies that can then be employed in subsequent translational studies to examine their efficacy in real-world settings. Moreover, future studies should examine the behavioral and emotional responses that youth may have to the self-testing experience and the experience of obtaining HIV-positive or HIV-negative test results under conditions where immediate counseling services are not available except by telephone.

Limitations

Although useful in identifying potential problems with SIT, our formative studies are based on opportunistic samples with limited sample sizes and do not address how adolescents and young adults actually implement SITs. Additional studies are needed to identify the frequency and types of fidelity errors youth make and identify strategies to improve SIT fidelity.

Summary

To test 90 % of HIV-positive persons by 2015, we will need to significantly increase testing among at-risk African American youth and young adults, particularly among low SES segments of this population. This may best be accomplished by a multi-faceted approach that augments current HIV testing approaches (e.g., clinic-based counselor model) with self-implemented testing and innovated dissemination strategies [5, 54, 55]. The present study points out a wide range of variables that may impact SIT implementation fidelity, which require further testing in laboratory and field settings.

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