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ORIGINAL PAPER

Do High-Risk Young Adults Use the HIV Self-Test Appropriately? Observations from a Think-Aloud Study

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Abstract The purpose of this study was to understand high-risk young adults' use of the rapid human immunodeficiency virus (HIV) self-test. The highest rate of new HIV infections occurs in people between 15 and 24 years. Improving identification of young people infected with HIV is a critical public health priority. The first rapid HIV self-testing kit was approved in the US in 2012. Despite the product's promise, its use by untrained young adults is not well-understood. We conducted a mixed methods study using surveys, a think-aloud protocol, observations, and in-depth interviews. A systematic checklist was developed to assess participants' use of the test. A total of 21 racial and/or ethnic minority young adults aged 18–24 participated in this study. Analysis of our interview data was guided by the theory of reasoned action (TRA). Participants completed the initial procedures of the test with a mean time of 8:36 min (range of 2:04′–16:33′). On a 14-point checklist, participants had a mean score of 10.8 (SD 2.26, range 3–14). In the qualitative analysis of the participants' interviews, guided by the theoretical constructs of the TRA, the following themes emerged: "Did I use it correctly?", "Can I trust the results?" (attitude); "How will my partner react?!", "What will people think?" (subjective norm); "Quick, easy and blood free," and "Avoids the hassle of dealing with the healthcare system" (behavioral intention). This study provided evidence of the usefulness of the test perceived by young adults, especially in light of their concerns about lack of privacy in medical settings. Since many participants did not follow all of the instructions while using the test, it is not evident that young adults can correctly use the HIV self-test. Development of instructions manuals that are understandable and guide proper use of medical devices is a great need, especially in the context of home testing technology.

Resumen Este estudio se realizó con el propósito de comprender el uso de la "Prueba Rápida del VIH" en casa por parte de los jóvenes adultos de alto riesgo. La mayor tasa de nuevas infecciones con el virus de la Inmunodeficiencia Humana (VIH) se observa en personas entre 15-24 años. Mejorar la identificación de los jóvenes infectados con el VIH es una prioridad fundamental de la salud pública. La primera prueba autoexámen rápida para el VIH fue aprobada en los EE.UU. en el 2012. A pesar de la promesa de este producto, su uso por adultos jóvenes no entrenados no está aún bien estudiado. Se realizó un estudio de métodos mixtos a través de encuestas, un protocolo utilizando la técnica "Think-Aloud", observaciones y entrevistas con profundidad. Una lista de verificación sistemática fue desarrollada para evaluar el uso de la prueba por parte de los participantes. Un total de 21 adultos jóvenes de grupos raciales y/o étnicos minoritarios, entre las edades de 18-24 años participaron en este estudio. El análisis de los datos de la entrevista fue guiado por la Teoría de la Acción Razonada. Los participantes completaron los procedimientos iniciales de la prueba en un tiempo promedio de 8:36 minutos (rango de 2:04 '- 16:33′). En una lista de verificación de 14 puntos, los participantes tuvieron una puntuación media de 10,8 (DE 2,26, rango 3-14). En el análisis cualitativo de las entrevistas de los

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participantes, guiado por elementos conceptuales de la Teoría de la Acción Razonada, los siguientes temas surgieron: "¿La usé correctamente?", "¿Puedo confiar en los resultados" (actitud), "¿Cómo va a reaccionar mi pareja?!", "¿Qué pensará la gente?" (Norma Subjetiva), "Rápido, fácil y sin sangre" y "Evita la molestia de tratar con el sistema de salud" (Intención conductual). Este estudio proporciona evidencia de la utilidad de la prueba tal como es percibida por los adultos jóvenes, especialmente a la luz de sus preocupaciones sobre la falta de privacidad en entornos médicos. Dado que muchos participantes no siguieron todas las instrucciones durante el uso de la prueba, no es evidente que los adultos jóvenes puedan usar correctamente la prueba casera del VIH. La elaboración de manuales de instrucciones que sean fáciles de entender y que sirvan de guía para el uso adecuado de los dispositivos médicos es una gran necesidad, sobre todo en el contexto de la tecnología de pruebas caseras.

Keywords HIV self-test · Young adults · HIV testing · Homeless · Think-aloud

Introduction

Adolescents and young adults are the fastest growing age group of HIV+ individuals in the US [1]. The Centers for Disease Control and Prevention estimates that almost 40 % of new HIV infections in the US are in this age group [2]. Early diagnosis of HIV, through testing, is vital to avoid increased transmission and link patients to care, resulting in decreased morbidity and mortality [3]. Yet, many young people, even those with high-risk behaviors for HIV, have never been tested for HIV and are unaware of their HIV status. Nationwide, only 22.6 % of sexually active high school students have ever been tested for HIV [4]. While advances in drug regimens have transformed HIV into a chronic disease for most patients, this can only happen when patients are appropriately identified through HIV testing and linked to care [5]. Current research demonstrates that there is a failure to test youth who are at risk and this in turn fuels the high percentage of adolescents and young adults who have undiagnosed HIV infection [6].

HIV self-testing has been touted as a possible solution to improve the identification of those who do not know they are infected [7]. The HIV self-test may be of particular relevance to adolescents and young adults who are less likely to use clinic-based testing services because of coverage, stigma, and other priorities [8]. Ethnic minority youth face significant challenges accessing preventive and treatment services [9–12]. The HIV self-test may improve HIV testing rates and timely access to treatment after HIV diagnosis as well as promote risk-reduction behaviors in high-risk populations. There are a number of important considerations related to the HIV self-test that need to be understood better in adolescents and young adults so that this new technology can be used as a facilitator to improve health outcomes. A recent study evaluated supervised and unsupervised HIV self-tests among Ugandan males from rural areas and reported no significant difference in the result or interpretation of the test [13]. The study showed that 23.6 % of the unsupervised group reported problems with the timing of the test. In another study of the use of HIV self-tests in 84 gay men in New York City, men anticipated their reactions to their own positive HIV self-test as obtaining care, postponing sexual activity, and managing emotional distress [14]. In discussing their anticipated reactions to a partner's positive test, the theme of obtaining a confirmatory test result emerged and reinforces some of the doubt that may surround home test's accuracy.

The use of the HIV self-test by untrained or immature young adults is not well understood, but has the potential to decrease the high HIV incidence that currently exists among adolescents and young adults. Given the product's potential, further understanding of young adults' ability to use this test is critical [15, 16].

Methods

Recruitment

We recruited our study participants by posting fliers in bars, dance clubs, community events, and community-based organizations where young adults congregate.

Setting

All of our study activities were conducted in a private room at the Columbia Community Partnership for Health, a multipurpose space for conducting health research. This location had a private study room with a one-way mirror for observations.

Procedures

Prior to the start of our study activities, we secured approval from the Columbia University IRB and obtained a Certificate of Confidentiality from the NIH. Study participants completed a written informed consent form. Following the consenting procedures, participants completed surveys at our study site through Qualtrics, a secure, Web-based application designed to support data capture for research studies. We used surveys to collect demographic information and the Short Test of Functional Health

Literacy in Adults (S-TOFHLA) [17]. Following survey administration, we used a think-aloud protocol, video observations, and in-depth interviews to examine study participants' use of the HIV self-test. The think-aloud technique is one of two methods practiced when conducting cognitive interviewing [18]. Verbal probing and think-aloud techniques are the two main methods when conducting cognitive interviews. Verbal probing has the interviewer ask detailed probes after subjects answer a survey question [19]. Some researchers do not support this method arguing that the follow-up probes interfere with the actual process of responding to survey questions.

The think-aloud technique, which has a long tradition in clinical psychology, has been used to study writing, text comprehension, and decision-making [20, 21]. The think-aloud technique encourages participants to verbalize their thoughts while answering questions or completing a task [22]. This method reduces the possibility of the interviewer introducing any bias into the participants' answers. In contrast, the disadvantage to this method is that it does require training on the part of the participant, which can make the research process more burdensome [23].

To reduce the potential concern over interfering with the cognitive processing of our respondents, we chose the think-aloud technique since is it commonly used in the human computer interaction literature and is particularly relevant when evaluating the interaction between end-users and technology, particularly user interface design [18, 24, 25]. In the case of this study, young adults are the potential end-users and the HIV self-test serves as the technology.

We first explained the think-aloud protocol to the participants. In order to train our study participants, we asked them to do a practice task of counting the windows in their house/apartment while thinking aloud. Then, we reminded them that, "We are not really interested in how many windows you have, but in how you go about doing this task". Once we completed the training, we asked participants to describe what they were looking at, thinking, doing, and feeling as they used the HIV self-test [22].

Each participant was given the HIV self-test and the package insert. Participants were instructed to follow the written instructions included in the kit and were informed that a study team member was behind a one-way mirror while he/she used the test. The study team member observed the process of task completion and took notes on the participants' actions and verbalizations. The skills demonstration session was also videotaped, so that the research team would have a record of the participants' performance if further analysis were required. We developed a systematic checklist (Table 1) to assess participants' use of the test. The participant was not allowed to ask questions of the study team member. This was done to determine how well the participant followed label instructions without professional assistance, as they would have to at home.

Once the participant indicated that s/he had completed the procedures, the study team member returned to the room and asked the participant for his/her interpretation of the results. The researcher alerted him/her to any mistakes during administration or interpretation of the results, while providing instructions on correct use/interpretation. If a participant's results were positive, the participant was referred to an HIV facility for further evaluation and treatment.

In-depth Interview

Following the participants' interpretation of the HIV self-test result, we conducted an interview to understand the participants' experience of using the test.

We asked participants the following series of open-ended questions: (1) How do you feel about the actual procedures you just completed? (2) How do you anticipate you would feel if you had taken this test at home? (3) What if you had tested yourself in front of a partner, how do you anticipate you would feel?

Data Analysis

We had four sources of data for analysis of our study aims: (1) survey data (2) videos of participants using the self-test (3) observations of the interviewer and (4) audio recordings from interviews. Our data sources included both quantitative and qualitative data. To quantify the participants' performance using the HIV self-test, we coded the video recordings using our checklist (Table 1) to obtain a score per participant. Through the observation by the interviewer, as well as the review of the videos by the PI and graduate research assistants, we captured rich data of participants' use of the HIV self-test. The skills displayed using the self-test were measured to determine likelihood of correct use of the HIV self-test. Descriptive statistics were used to calculate demographic measures. Finally, the researchers coded the videos and the interviews by recording memos from the videos and the interview transcripts.

The transcripts were reviewed separately by two study authors. An initial set of codes was independently generated by two of the study authors (RS and RMJ), using open coding guided by the theory of reasoned action (TRA) [26]. Codes were then compared and synthesized to result in shared coding categories and sub-categories, all with definitions, inclusion and exclusion criteria, and examples. The coders discussed discrepancies until they reached consensus.

Table 1 Observational checklist for use of the HIV home test

Testing steps	Scoring guidelines
Open the package	+1
Read the instructions	+1
Do not use the test if subject has had anything to east drink or has chewed gum for at least 15 min	−1 if use within less than 15 min
Remove the device from its pouch	+1
Do not touch the flat pad	−1 for touching the flat pad
Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, do not use the test	+1 if participant checks for absorbent packet −1 if use with no absorbent packet
Place the flat pad above the teeth against the outer gum	+1
Gently swab completely around the outer gums, both upper and lower, one time around, using the flat pad	+1 upper gum +1 lower gum −1 swabbing more than once
Do not swab the roof of the mouth, inside of the cheek or the tongue	−1 for each of these locations
Insert the flat pad of the device all the way into the vial	+1
Make sure the flat pad touches the bottom of the vial	+1
The result window on the device should be facing the participant	+1
Start timing the test	+1
Do not remove the device from the vial while the test is running	−1 if participant removes the device
Read the results after 20 min but not more than 40 min in a fully lighted area	+1 if results are read during 20–40 min window period −1 if time is less than 20 min or more than 40 min −1 if lights are turned off
Interpret the result correctly. The test is Not Reactive if a line appears next to the C and NO line appears next to the T. The test is Reactive if a line appears next to both the C and the T	+2 if participant interprets correctly and understands that line needs to appear next to C for results to be valid

The TRA is based on the assumptions that human beings are usually quite rational and make systematic use of the information available to them. People consider the implications of their actions before they decide to engage or not engage in a behavior. The TRA is comprised of three constructs: attitudes, subjective norms and behavioral intention [26]. These constructs are determinants of health behaviors and, more specifically, HIV testing behaviors, in the case of our study.

Results

The study was done with a convenience sample of 21 young adults at high-risk for HIV. Participants were between 18 and 24 years of age.

Demographics

Table 2 shows the demographics of participants. Participants reported between 1 and 120 partners in their lifetime (mean 31.85 SD = 38.40). Thirteen of the 21 study participants (61.9 %) did not use a condom the last time they had sex. Four of our participants had been pregnant or gotten someone pregnant and 38 % of our participants reported having had an STD. Of note, 9 participants stated that they were currently homeless. The S-TOFHLA was completed by 19 participants who had adequate functional health literacy, meaning that he/she could read and interpret most health texts. Two participants did not complete the S-TOFHLA.

Skills Assessment

Participants completed the initial procedures of the test with a mean time of 8:36 and a range of 2:04–16:33 min. Out of a total of 14 points on the checklist, participants had a mean score of 10.8 (S.D. 2.26, range 3–14). All of the participants completed Step 1 by correctly opening the package. Only 11 participants started timing the test and only 12 participants checked to make sure that there was an absorbent packet inside the package. Although it was contraindicated in the package instructions, almost all of the participants swabbed their gum more than once (N = 18). All of our study participants were able to

Table 2 Demographic characteristics of study participants

Variable	N (%) total N = 21
Gender assigned at birth	
Male	16 (76.2)
Female	4 (19.1)
Prefer not to answer	1 (4.8)
Current gender identity[a]	
Male	16 (76.2)
Female	3 (14.3)
Transgender male	1 (4.8)
Transgender female	1 (4.8)
Genderqueer	2 (9.5)
Housing status	
Emergency Shelter	3 (14.3)
Transitional housing for homeless	3 (14.3)
Rented room, apartment or house	4 (19.0)
Stayed with family or friends	9 (42.9)
Race	
Black/African American	9 (42.9)
Asian	1 (4.8)
American Indian/Alaska native	1 (4.8)
Multiracial/other	9 (42.9)
Ethnicity (Hispanic/Latino)	10 (47.6)
Language spoken at home	
English	19 (90.5)
Spanish	1 (4.8)
Sign language	1 (4.8)
HIV/sexual history	
History of HIV test	17 (81.0)
History of vaginal intercourse	13 (61.9)
History of anal intercourse	18 (85.7)
History of oral intercourse	18 (85.7)

[a] Not all categories equal 100 % due to missing data and ability to select more than 1 response

interpret the test results correctly and all had a negative test result.

Video Observations

Through the review of the videos that included a record of the participants using the HIV self-test kit and their think-aloud data, we assessed the participants' use of the HIV self-test. Themes of HIV self-test use identified from the video recordings were related to: following the instructions, checking presence of absorbent packet, swabbing the gums, and interpreting the test results.

During the think-aloud protocol, participants reported that they understood most of the instructions. One participant said, "Of course I didn't eat nothing so basically you can't eat nothing before you do the test". There was confusion about the absorbent packet. Many of the participants did not check for it as indicted in the instructions. Other participants found the absorbent packet and didn't know what to do with it. For example one participant found the packet and said, "I also got this (absorbent pack)—what is this? What?" A number of participants expressed confusion on how to swab themselves as one participant asked, "Which side of the pad do I use?" Another participant said, "I be swabbing this through my gums up and down—this kind of complicated". These were the two areas in which the participants scored the worst at completing procedures correctly.

Participants also discussed the process of interpreting the results during the think-aloud procedures. One participant said, "I think I remember how to interpret it but I'm going to find the instructions anyways". Another participant commented on interpreting the results, "Basically the line will be in both of the letters". Similarly a participant correctly identified how to interpret the results, "Definitely a line next to C so it's not invalid. I don't see one so it means that it's non-reactive". A final participant couldn't remember how long he needed to wait until he could read the results and said to himself, "Let me read the instructions".

In-depth Interviews

Following the use of the HIV home test, we asked participants about their experience using the test. The following themes guided by the theoretical constructs of the TRA emerged: "Did I use it correctly?" "Can I trust the results?" (Attitude); "How will my partner react?!" "What will people think?" (Subjective Norm); "Quick, Easy and Blood Free," and "Avoids the hassle of dealing with the healthcare system" (behavioral intention). The theoretical constructs, associated themes resulting from our findings and representative quotations are presented in Table 3.

Attitude

Initially participants had a number of concerns with regard to the HIV self-test. Participants were ambivalent as to the whether they used the test correctly and whether the test results were accurate.

Did I Use it Correctly? The concern about making a mistake seemed to be allayed once participants tested themselves. One participant said, "It was easy (but) Needs to be even simpler, (with) less blocks of words". Another participant reflected that prior to this study experience, "I was like, what about if I make a mistake? I'd have myself worried and stuff, especially if I made a mistake myself.

Table 3 Constructs, themes and sample quotes from users of the HIV home test

Attitude	
Did I use it correctly?	It was my first time doing it by myself. I haven't got HIV-tested in a few months, but it's my first time doing it by myself so it was really interesting. I learned how to…being able to do it myself by the instructions and stuff. It was really exciting
Can I trust the results?	Well, it's not a hundred percent sure about the results
Subjective norm	
How will my partner react?!	I would have been nervous
What will people think?	I felt a little insecure and untrusting to go to a facility for it (HIV test)
Behavioral intention	
Quick, easy and blood-free	Because it lets you know information early, not like blood work that takes a couple of days…It's almost a little bit easier. It was quicker than any others
Avoids the hassle of dealing with the healthcare system	It was more simpler because usually when you do an intake with a counselor or a doctor, they ask you a lot of personal things and it's a lot of time being wasted. The home rapid test, I know my sexual history, so I don't have to ask any questions. I can just perform the test and it's less time and it's at a place where I feel secure at

But you can't really make a mistake with this; it's very easy". Overall, participants reported that the test was easy to use. But some did not follow all of the instructions. One study participant said, "And I didn't have to sit down and read the whole packet to figure out what to do". In summary, most participants thought that they had used the test correctly although our other findings do not support these sentiments. There were a few participants who were unsure if they completed the test correctly.

Can I Trust the Results? Participants had some concern about the accuracy of the results. Even if they did the test correctly, there were still remaining concerns as to whether an oral swab test was as accurate as a blood test. One participant commented, "There's only one disadvantage in the sense that, not for me personally but for other persons, they may think that because it's only the preliminary results and it's just a swab that they will want the blood work done as well, so that's the only disadvantage that it's not a blood work but other than that, it's again 99.9 % accurate, so it should be fine". Another participant specifically said that he would prefer a blood test because of its improved accuracy. "I actually kind of like the blood a little bit better. I just feel like it's a little bit more accurate, but I wouldn't know. I'm not into that type of thing. So I don't know. I just think anything with blood is a little bit more accurate".

Subjective Norm

Our findings suggested that there was a strong influence from people in our participants' lives on whether they would use the HIV self-test. Study participants expressed concerns over their partners' attitude toward using the HIV self-test as well as a more general concern about social prejudice. At the same time, social support was also identified as a motivating factor that influenced participants to get tested for HIV.

How Will My Partner React?! Participants presented a number of mixed emotions that may arise and how best to deal with feelings of anxiety and mistrust from their potential partners. One study participant suggested, "I guess I would delve in slowly or talk about the safety and good health of our bodies. And then I'd want to slowly delve into how it's important that we should know our status". Another participant explained, "I would ask them the last time they had been tested for anything. And since HIV is one of the main things that people are now getting, I would ask them if they wouldn't mind if we took the test together or if they take the test by themselves, whichever one makes them feel comfortable".

Overall participants expressed mixed feelings about testing themselves in front of a partner. For example one participant responded when questioned about testing in front of a partner: "Oh man. That's really uncomfortable. Well the thought of it is uncomfortable". Another participant explained, "I would be definitely scared [to test in front of a partner]. I don't know if it would have come out right or wrong in front of him". Participants expressed concerns over testing in front of a partner with one participant saying, "I'll be very nervous and thinking about everything".

Participants also were prepared that potential partners may react strongly to being asked to use the HIV self-test kit. One study participant said, "If they're educated and mature about it, they'll take the test. But any uneducated ignorant person would have a sudden shock reaction and

just go off afterwards because I guess they would think that I'm trying to imply that they have something because I want them to take this test". Another participant anticipated strong reactions from some people because "a lot of people aren't honest about their status. I've had that happen to me in relationships before".

On the other hand, one participant said, "That would be fine. I don't see a real challenge with that". Finally one participant summarized these mixed sentiments by saying "If it was a partner who I've trusted and established communication with over a long period of time, then I would feel, I would feel this is something I could trust and I would to explain to my partner about this".

What Will Other People Think? Participants noted that there is a stigma in seeking out HIV testing. Participants explained that when going to a clinic, they often feel that they are being judged for requesting an HIV test or because of their sexual choices. One participant noted that "If I were to seek treatment that would make the clinic and people around the city aware that I am sick. I wouldn't want that label". Another participant also described how people at the clinic might be prejudiced and so with the HIV self-test, "you don't have to worry about going to clinics and so forth, if you're kind of nervous about people learning about your sexuality, or what people may think of you". Participants made specific reference to privacy in using the HIV self-test, "It's easier doing it at home, it's more private". Specifically one participant commented on protecting his privacy and being concerned about his providers and said, "and don't have to go out there for somebody else to know your business, so it's more better for you if you don't trust the doctor or the nurse or whoever".

Behavioral Intention

Quick, Easy and Blood Free Participants reported an overall positive experience using the test. They found the HIV self-test kit to be an efficient option for HIV testing. Another participant said, "You can take it on the go, you can take it anywhere with you". A number of participants commented on how a bloodless test would facilitate them using it because they really don't like blood draws or pricks.

One participant described the test, "It's quick. It's easy. There's no pinching, no blood going anywhere… just a little swab". Another participant said, "It's easier and it's blood free, which is a good plus for me". One participant made specific reference to the advantage of having a blood-free test "It was fast and didn't have to draw blood or anything". Many participants thought that it was very easy to use and convenient. One participant said, "The directions are easy and the test doesn't take long. You can have a conversation while you are waiting for the results". Another participant said, "It's easy to do. It's not something that's very hard". Finally, another participant said, "You can take it on the go, you can take it anywhere with you. And it's safe in the packet. So nothing can happen to it".

Avoids the Hassle of Dealing with the Healthcare System Overall, participants were excited to have the HIV self-test available as an option because many described their cumbersome encounters with the healthcare system. Participants explained how being able to test at home is an enabler to testing for HIV because they don't need to bother with travelling to a clinic, waiting for a provider, answering questions from a clinician and then waiting for the test results or, in some cases, needing to return to the clinic to find out the results. One participant explained that using the HIV self-test "It's like, it's wasting less time taking trips to a center or hospital, or you know, wherever they do HIV tests". Another participant discussed how waiting 20 min for the test results was a long wait but echoed a similar sentiment and said, "It's still less time than you have to wait when you go to a lab or a clinic". In addition to avoiding the time travelling to and waiting at the clinic, participants were excited that they didn't need to wait a few days for the test results. To illustrate this, one participant said, "Because it lets you know information early, not like blood work that takes a couple of days".

Discussion

This is the first study that incorporated videotapes of participants using the HIV self-test, thus including a performance record that can be carefully studied to identify competency in the self-administration of the test. Our methodology of direct observation of individuals using the self-test through a one-way mirror and videotaping the event is novel because past research studies have not used these methods to observe skills related to correct use of the test. Think-aloud protocol is a methodology that has been used widely to understand the patients' use of medical devices and has not been specifically applied to understanding the use of the HIV self-test [27].

Recommendations to Improve Adherence to Testing Instructions

Findings from the Skill-demonstration advanced our knowledge of how young adults use the test and presented some of the limitations of their ability to use the test. None of our study participants tested positive; however, only one

study participant completed all of the steps according to the package insert. For instance, many of our study participants swabbed their gums multiple times which is not congruent with the package insert. Participants also had difficulty remembering to keep track of the time until their results were ready to be read.

All of our participants who completed the S-TOFHLA (19/21) had adequate functional health literacy. Even so, our study participants had difficulty using the test correctly, suggesting that the package insert may not provide adequate information for young adults to use the HIV self-test without assistance. Nonetheless, the areas in which participants had difficulty are addressable. Our study findings can be used to inform the development of educational materials. More specifically, the findings from our study point to the need to develop an instruction manual that is easier to follow with less cumbersome instructions. One of the challenges that is faced by manufacturers of medical devices in the US are the requirements by the FDA and the fear of liability by end-users. As a result of these two constraints, manufacturers must include package labelling and instructions that are very comprehensive, but usually not very understandable. This is similar to the widely published literature on the comprehension of consent forms [28]. Informed consent provides a legal basis for participation in research studies but 40–80 % of study participants do not understand at least one aspect of the consent form [28, 29]. In this study, we have revealed a similar phenomenon where even participants with adequate health literacy are not able to fully understand the package insert and instructions that are included with medical devices. This noteworthy finding points to the need for regulation agencies to ensure that package inserts do not simply serve as a mechanism for achieving a legal disclaimer but rather allow persons to accurately and effectively use medical devices.

Potential of Self-Testing to Target Specific Study Populations

Nearly half of our study participants reported being homeless or having unstable housing. The HIV self-test is of particular relevance to these study participants who are at the highest risk for being HIV infected and unaware of their status. HIV is a serious problem among the homeless and unstably housed populations in the US with 3.9 % of sheltered populations being HIV+ as compared to <1 % of all other persons living with HIV in the US [30]. The prevalence of HIV infection among the homeless and unstably housed individuals is higher in the US than in any other country worldwide. Homelessness and marginal housing is associated with higher incidence of drug use, HIV and sexual risk behaviors, HIV infections, and poorer health outcomes, making the detection of HIV and linkage to care particularly relevant. This study, which included homeless and unstably housed young adults, provides preliminary evidence on the usefulness and potential utility of the HIV self-test as a diagnostic and intervention tool for homeless young adults who are disproportionately affected by HIV.

Results from this study provide information on the potential to target HIV self-testing to populations who are most at-risk. The theoretical insights towards use of the HIV self-test suggests that those who are most at risk for HIV and least likely to get tested, such as vulnerable youth including homeless youth, are likely to benefit from the HIV self-test. In particular, youth are likely to share information about the ease of use and usefulness of the HIV self-test with others in their social network. Importantly, since many homeless youth are already stigmatized, which is often what has left them in their current housing situation, they are most likely to benefit from the use of a technology that does not require an encounter with a medical provider. Finally, the HIV self-test can be an empowering tool to allow high-risk youth to take care of their own health.

This study was conducted in New York City and consequently the findings are not necessarily generalizable to the other settings. Nonetheless, some of the results and the methodological principles from this study may have implications for the more generalized HIV epidemic in Sub-Saharan Africa. In particular, findings that support the use of the HIV self-test for people who cannot access or are not comfortable accessing healthcare services because of stigma are particularly relevant to Sub-Saharan Africa where access and stigma have both been well-documented [31–33]. Moreover, the methodological contributions of this work are substantial since it has demonstrated the usefulness of video observations, a systematic checklist and a think-aloud protocol in evaluating whether persons can accurately use the HIV self-test. Finally, this study is timely and innovative because point-of-care technology, such as the HIV self-test, is emerging as an enabler for delivering patient-centered services in the US healthcare system that is struggling to contain costs and allow patients to control their own health. In the near future, many in vitro tests will have the ability to be delivered at home [34]. As a result, it is critical to understand the challenges and benefits of the HIV self-test for addressing the current healthcare delivery disparity in young adults who are less likely to be tested for HIV than any other age groups.

Limitations

A limitation of our study methods is that participants used the HIV self-test in a controlled setting with video cameras. This was different from conducting the test in a more

natural setting where the presence of other people (including sexual partners), substance use, and potential urgency (i.e., conducting the test before sex) may affect self-testing. We tried to ameliorate some of the effect of the laboratory situation by leaving the participant alone and having the study team member behind a one-way mirror. However, using the test at our site in front of a one-way mirror and video camera may have been more anxiety-provoking than using the test in their home. While we acknowledge this limitation, we believe the findings are useful for assessing performance abilities of our participants in a setting without social pressures.

Conclusion

The recurrent theme of ease of use and privacy points to the acceptability and perceived usefulness of the test. Concerns over accuracy of results due to the test being complicated seemed to ease once the test was used. At the same time, almost none of the participants followed all of the instructions correctly, supporting the need for the development of new educational materials to clarify how to use the HIV self-test.

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Compliance with Ethical Standards

Conflict of interest The authors declare no conflict of interest.

References

1. The Kaiser Family Foundation. The HIV/AIDS epidemic in the United States. New York: Kaiser Family Foundation; 2013.
2. Center for Disease Control and Prevention (CDC). HIV among Youth Atlanta, GA2011 [cited 2012 November 2]. Available from: http://www.cdc.gov/hiv/youth/pdf/youth.pdf.
3. Paltiel AD, Weinstein MC, Kimmel AD, Seage GR 3rd, Losina E, Zhang H, et al. Expanded screening for HIV in the United States–an analysis of cost-effectiveness. N Engl J Med. 2005;352(6):586–95.
4. Balaji AB, Eaton DK, Voetsch AC, Wiegand RE, Miller KS, Doshi SR. Association between hiv-related risk behaviors and hiv testing among high school students in the united states, 2009. Arch Pediatr Adolesc Med. 2012;166(4):331–6.
5. Martin EG, Schackman BR. Updating the HIV-testing guidelines–a modest change with major consequences. N Engl J Med. 2013;368(10):884–6.
6. D'Angelo LJ. When will routine testing for human immunodeficiency virus infection be the routine for adolescents? Arch Pediatr Adolesc Med. 2012;166(4):385–6.
7. Paltiel AD, Walensky RP. Home HIV testing: good news but not a game changer. Ann Intern Med. 2012;157(10):744–6.
8. Schnall R, Rojas M, Travers J. Understanding HIV testing behaviors of minority adolescents: a health behavior model analysis. J Assoc Nurses AIDS Care. 2015;26(3):246–58. doi:10.1016/j.jana.2014.08.005.
9. Newacheck PW, Hung YY, Park MJ, Brindis CD, Irwin CE Jr. Disparities in adolescent health and health care: does socioeconomic status matter? Health Serv Res. 2003;38(5):1235–52.
10. Thomas JF, Temple JR, Perez N, Rupp R. Ethnic and gender disparities in needed adolescent mental health care. J Health Care Poor Underserved. 2011;22(1):101–10.
11. Starfield B, Riley AW, Witt WP, Robertson J. Social class gradients in health during adolescence. J Epidemiol Community Health. 2002;56(5):354–61.
12. Schnall R, Okoniewski A, Tiase V, Low A, Rodriguez M, Kaplan S. Using text messaging to assess adolescents' health information needs: an ecological momentary assessment. J Med Internet Res. 2013;15(3):e54.
13. Asiimwe S, Oloya J, Song X, Whalen C. Accuracy of un-supervised versus provider-supervised self-administered hiv testing in Uganda: a randomized implementation trial. AIDS Behav. 2014;18(12):2477–84.
14. Martinez O, Carballo-Diéguez A, Ibitoye M, Frasca T, Brown W, Balan I. Anticipated and actual reactions to receiving HIV positive results through self-testing among gay and bisexual men. AIDS Behav. 2014;18(12):2485–95.
15. Walensky RP, Paltiel AD. Rapid HIV testing at home: does it solve a problem or create one? Ann Intern Med. 2006;145(6):459–62.
16. HIV surveillance–United States, 1981–2008. MMWR Morb Mortal Wkly Report 2011; 60(21): p. 689–93.
17. Aguirre AC, Ebrahim N, Shea JA. Performance of the English and Spanish S-TOFHLA among publicly insured medicaid and medicare patients. Patient Educ Couns. 2005;56(3):332–9.
18. Schnall R, Cimino JJ, Bakken S. Development of a prototype continuity of care record with context-specific links to meet the information needs of case managers for persons living with HIV. Int J Med Inform. 2012;81(8):549–55.
19. Knafl K, Deatrick J, Gallo A, Holcombe G, Bakitas M, Dixon J, et al. The analysis and interpretation of cognitive interviews for instrument development. Res Nurs Health. 2007;30(2):224–34.
20. van Someren MW, Barnard YF, Sandberg JAC. The think aloud method: a practical guide to modelling cognitive processes. London: Academic Press; 1994.
21. Ward L, Traweek D. Application of a metacognitive strategy to assessment, intervention, and consultation: a think-aloud technique. J Sch Psychol. 1993;31(4):469–85.
22. Ericsson KA, Simon HA. Verbal reports as data. Psychol Rev. 1980;87(3):215–51.
23. Kuusela H, Paul P. A comparison of concurrent and retrospective verbal protocol analysis. Am J Psychol. 2000;113(3):387–404.
24. Nielsen J. Usability engineering. San Francisco: Morgan Kaufmann Publishers Inc; 1993. p. 358.
25. Sheehan B, Lee Y, Rodriguez M, Tiase V, Schnall R. A comparison of usability factors of four mobile devices for accessing healthcare information by adolescents. Appl Clin Inform. 2012;3(4):356–66.
26. Ajzen I, Fishbein M. Understanding attitudes and predicting social behavior. Englewood Cliffs: Prentice-Hall; 1980.
27. Lundgren-Laine H, Salantera S. Think-aloud technique and protocol analysis in clinical decision-making research. Qual Health Res. 2010;20(4):565–75.
28. Wendler D. CAn we ensure that all research subjects give valid consent? Arch Intern Med. 2004;164(20):2201–4.

29. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. Lancet. 2001;358(9295):1772–7.
30. U.S. Department of Housing and Urban Development OoCPaD. Annual Homeless Assessment Report to Congress 2010.
31. Kalichman SC, Simbayi LC. HIV testing attitudes, AIDS stigma, and voluntary HIV counselling and testing in a black township in Cape Town South Africa. Sex Transm Infect. 2003;79(6):442–7.
32. Weiser SD, Heisler M, Leiter K, Percy-de Korte F, Tlou S, DeMonner S, et al. Routine HIV testing in Botswana: a population-based study on attitudes, practices, and human rights concerns. PLoS Med. 2006;3(7):e261.
33. Perez F, Zvandaziva C, Engelsmann B, Dabis F. Acceptability of routine HIV testing ("Opt-Out") in antenatal services in two rural districts of Zimbabwe. JAIDS. 2006;41(4):514–20.
34. Price CP, St. John A, Kricka LJ. Point-of-care testing: needs, opportunity, and innovation. 3rd ed. Washington: AACC Press; 2010.