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Adolescent perceptions about participating in HIV-related research studies

A.P. Simons-Rudolph[a,*], **B.J. Iritani**[a], **F.S. Odongo**[b], **S. Rennie**[c], **A. Gilbertson**[a], **D. Kwaro**[b], **W.K. Luseno**[a]

[a]Pacific Institute for Research and Evaluation (PIRE), Chapel Hill, USA

[b]Kenya Medical Research Institute (KEMRI), Kisumu, Kenya

[c]Department of Social Medicine, UNC Center for Bioethics, University of North Carolina at Chapel Hill, Chapel Hill, USA

Abstract

The rising incidence of infection among youth in sub-Saharan Africa makes HIV-related research among younger people a top priority. There remains, however, a lack of consistent and unambiguous ethical principles and guidance for researchers wishing to conduct HIV studies with adolescents. The overarching aim of our research was to better understand youths' experiences with HIV studies. The present study explored four questions: (1) What strategies are effective for recruiting youth for HIV studies? (2) What motivates youth to participate in these studies? (3) How do study participants perceive HIV testing within the context of a research study? (4) What do participants understand about the risks of study participation? These data are essential to inform guidelines for the responsible conduct of research with young people. We interviewed 82 adolescents (aged 15–19) in Kenya taking part in a study examining ethical issues pertaining to their involvement in HIV-related research. Pursuant to our research questions, we found that direct study recruitment combined with encouragement from female relatives was the greatest facilitator to study enrolment among young people. Most young participants expressed that they were motivated to join the study in order to (1) learn their HIV status (n = 49) and (2) receive HIV-related education (n = 26), even though both are already free and widely available. Participants largely preferred testing in a place they deemed "private," although both the health clinic and home were regarded by adolescents as locations with greater privacy. Adolescents largely did not accurately perceive risks of the study two months after baseline, although they could remember the benefits with great clarity. This work can inform researchers, policymakers, and ethics review committees on approaches to maximize efficiency in recruitment and data collection, and to enhance understanding of risks and benefits in HIV-related research among adolescents. While

*Corresponding author at: PIRE, 101 Conner Dr., Ste 200, Chapel Hill, NC 27514, USA. ASimons-Rudolph@pire.org.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data statement.

Based on consultation with our IRB, we have determined the data are not suitable for sharing due to the assurances stated in the consent form.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.childyouth.2020.105262.

further research is needed, these data may be used by others conducting HIV research in this region to improve recruitment strategies and more effectively engage and appeal to young people.

Keywords

HIV; Ethics; Adolescents; Kenya; Research; Recruitment; Participation

1. Introduction

Current surveillance data highlight the ongoing need to prioritize HIV prevention and treatment research among adolescents. Globally, in 2018, there were an estimated 1.6 million young people aged 10–19 living with HIV and 190,000 new infections and 33,000 AIDS-related deaths in this age group (UNAIDS, 2019a). Since the late 2000 s, the global community has encouraged researchers to enroll adolescents in HIV prevention trials and emphasized the need to balance the safety and efficacy of new drugs, therapies, and other prevention strategies with protection of adolescents' welfare and rights (Jaspan et al., 2008; Karim & Dellar, 2014; Pomfret, Karim, & Benatar, 2009; Rennie et al., 2017; UNAIDS, 2019b). Thus, over the past two decades there has been a steady increase in the number and quality of HIV-related studies with adolescent populations, including in low- and middle-income countries (LMICs), which have advanced knowledge about engaging this vulnerable group in HIV prevention and treatment services (Casale, Carlqvist, & Cluver, 2019; Chandra-Mouli et al., 2019). Yet, despite an increase in HIV research among adolescents, there remains a lack of consistent, specific and unambiguous ethical principles and guidance for researchers wishing to conduct studies with adolescents (Jaspan et al., 2008; Marsh et al., 2019; McClure, Gray, Rybczyk, & Wright, 2004; National AIDS and STI Control Programme (NASCOP) and Kenya Medical Research Institute (KEMRI), 2015; Pace, Siberry, Hazra, & Kapogiannis, 2012; Pomfret et al., 2009; Slack, Strode, Fleischer, Gray, & Ranchod, 2007). To address this gap, there is a need for empirical data on ethical considerations related to involving adolescents in HIV-related research.

In this paper, we present data from Kenya, where adolescents under age 18 are classified as children or minors and deemed not to have reached age of majority, with exceptions for emancipated and mature minors (Republic of Kenya, 2018). Ethical guidelines for research involving human subjects in Kenya stipulate: that (1) children should not be involved in research that can be conducted with adults; (2) the research purpose should be to generate knowledge that is relevant for the health needs of children; (3) permission must be obtained from a parent or legal guardian and the child must assent to participate in the research; (4) the risk of interventions that will not benefit the child should be low and commensurate with the knowledge to be gained; and (5) interventions that are intended to provide therapeutic benefit should at a minimum be as advantageous to the participating child as available alternatives (NASCOP and KEMRI 2015; Republic of Kenya, 2005). In response to the need for guidance specific to adolescents, the Government of Kenya built on the existing ethical framework for research with children and, in 2015, published 10 guiding principles for adolescent participation in HIV and sexual and reproductive health research (NASCOP and KEMRI, 2015). Of note, the guidelines recommend the use of effective adolescent-friendly

consent procedures and require that adolescents enrolling in research understand the purpose, procedures, risks, benefits, and alternatives of the research (NASCOP and KEMRI, 2015). Here, we explore effective strategies to recruit adolescents for HIV-related research, their motivations to participate in research, their perceptions about research, and their understanding about the risks and benefits of research participation.

Our study could benefit researchers, ethics review committees, and policymakers who are charged with the responsibility of ensuring the ethical conduct of research among adolescents, e.g. by informing recruitment and informed consent procedures to ensure understanding about the research and adequate protections from research-related risks for young study participants. While adolescent participation in research is increasing (Casale et al., 2019) and evidence suggests that youth can understand research and make informed decisions about their participation (Afolabi et al., 2018), concerns remain that research with adolescents living with HIV or engaged in high risk behaviors could result in the inadvertent disclosure of their status or behaviors, and lead to harms such as community isolation, stigma, and violence (Jaspan et al., 2006). Although awareness about the disease is high among adolescents in sub-Saharan Africa (SSA) (Finlay et al., 2019) and many HIV-related studies are conducted in Kenya (Oketch, 2019), many people living with HIV and adolescents engaged in risk behaviors face high levels of stigma and discrimination, which prevent these groups from accessing HIV services, including provider-initiated testing (Nyblade, Singh, Ashburn, Brady, & Olenja, 2011). To know their status while minimizing exposure to negative social experiences, adolescents living in heavily researched areas may be disposed to getting tested through participation in HIV studies (Rennie et al., 2017).

2. Aims

We conducted a mixed methods observational cohort study to better understand youths' experiences with HIV studies (Luseno et al., 2020). For the qualitative study presented here, we conducted in-depth interviews to address four questions: (1) What strategies are effective for recruiting youth for HIV studies? (2) What motivates youth to participate in these studies? (3) How do study participants perceive HIV testing within the context of a research study? (4) What do participants understand about the risks of study participation?

3. Data and methods

3.1. Study setting

The study setting was the Nyanza region around Lake Victoria in western Kenya, the region with Kenya's highest HIV prevalence and incidence among young people. Among young men and women aged 15–24, the national HIV prevalence is 1.5% and 2.5%, respectively, compared to 4.1% and 7.0% in Nyanza (UNAIDS, 2019a). In 2018, young people aged 15–24 from Nyanza comprised almost half (49% or 7,800) of the estimated 16,000 new infections nationally among young people (UNAIDS, 2019a).

4. Sample and procedures

Study staff conducted community awareness activities and recruitment meetings with young potential participants and their parent/guardians. Eligible participants for the cohort study were aged 15–19, had never tested positive for HIV, and had not been tested for HIV in the last six months. Participants were screened for eligibility and recruited between June 2016 and December 2017 to participate in baseline data collection.

Four thousand and ninety-six participants completed the cohort study's baseline survey and received rapid HIV testing and results on-site. Participants also received pre-and post-HIV test counselling and were referred for further testing and/or medical care as necessary. Three sub-counties in Nyanza region comprised the strata. Participants were randomly assigned by village clusters within these sub-counties to be administered the baseline survey and HIV test in a health facility (clinic arm) or at home (home arm). Adolescents were required to have a parent or guardian over the age of 18 present with them during baseline procedures (i.e., data collection and HIV testing). Each adolescent participant was given the choice of whether their test result would be disclosed to them while their supporting adult was present or given to their supporting adult separately.

We sought to conduct qualitative follow-up interviews (See Appendix A for interview questions) at two-months post baseline with all participants with HIV positive (reactive) or inconclusive test results. Among those with HIV negative (non-reactive) test results, we selected every 30th adolescent by venue, gender and age for follow up. Of the 17 respondents who had reactive test results, 15 (88%) completed an in-depth interview (IDI). Of the 26 participants with indeterminate (inconclusive) test results, 20 (76.9%) completed an IDI. Indeterminate HIV tests can have many causes including faulty or damaged test kits, testing error or the presence of other viral antibodies in the blood. Confirmatory testing ultimately revealed that all inconclusive HIV tests were non-reactive. However, of those 20 participants with inconclusive results, 11 did not know their final HIV results at the time of the two-month IDI and one participant learned of the HIV results on the same day as the interview.

In addition, of the 70 participants with HIV-negative test results selected for follow up, 47 (67.1%) completed an IDI. In total, 83 participants completed a two-month follow-up interview and one participant was later deemed ineligible. The final sample size of participant interviewees was 82, split evenly between males and females. Most were aged 15–17 (69%) and from the clinic arm (60%). Full demographics are shown in Table 1.

Interviews were conducted in the participant's home or nearby in a location that offered privacy and confidentiality (i.e., no parents or guardians present). Interviews ranged from 14 to 48 min long and averaged approximately 24 min each. They were conducted in *Dholuo*, English, and *Kiswahili* and participants were encouraged to use their language of preference or a blend. All interviews were recorded with participant permission, and later transcribed and translated verbatim into English by Kenyan study staff. During the IDIs, participants were asked about their experiences with HIV testing and disclosure of results and perceptions about their involvement in the study. Interview questions were in the form of

open-ended prompts with probes for additional information (see Appendix A). Interview questions covered all research aims and questions. Questions were asked or otherwise answered in the context of other questions.

5. Consent

The study was approved by the ethics review boards of the Pacific Institute for Research and Evaluation (PIRE) and Kenya Medical Research Institute (KEMRI). All participants underwent informed consent procedures wherein they were told that the purpose of the study was, “to learn about how best to conduct HIV research studies involving adolescents.” Older adolescents (aged 18–19) and the parents of adolescents provided written informed consent for study procedures (i.e., baseline and follow up data collection, including the IDIs and HIV testing) and adolescents provided assent. In the case of an emancipated minor (e.g. married, pregnant), a waiver of parental written informed consent was obtained. Study staff reviewed the consent form information again with participants prior to their follow up interview. All study participants received a t-shirt for their participation in the study. Those who underwent baseline procedures at a clinic also received KSh300 (about 3 USD) as reimbursement for travel costs.

6. Data analyses

Following Miles and Huberman (1994), data analysis used a deductive coding approach to identify and explore core study aims and questions. All transcripts were coded using Atlas-ti (Version 7.5.18; ATLAS.ti GmbH, 1993–2020, Computer Software, Berlin). The first five transcripts were coded by two analysts and then compared line by line to ascertain coding agreement. Inter-coder reliability checks were more frequent at the beginning of the coding process to improve the coding as well as to identify emergent codes that did not initially appear to fit the initial coding scheme. It was used with approximately 20% of the data. The overall coding agreement was 92%.

Participants reflected on several study-related experiences and benefits. Although we recognize that these motivations and experiences are interrelated, we tried to identify them individually for the sake of analysis and discussion. We asked about recruitment method effectiveness, motivations for participation, study understanding, and study-related concerns and reflections (two-months post baseline) and participant responses are discussed below. Exemplary quotes, including basic participant demographic details (HIV test result, age group, and gender), are used to better illustrate aspects of particular findings and the perspectives of our participants.

7. Findings

Except regarding HIV testing venue, there were no significant differences in participants’ perspectives by age group (younger vs. older adolescents), gender, and HIV status. Participants described being recruited by study staff, but the decision to participate was partially motived by support from loved ones, particularly people serving in a parental or caregiving role. The expectations of HIV testing and related ‘teachings,’ (see below) and the

(false) hope of ongoing financial assistance also motivated participants to join the study. Our data shows that confidentiality is important for youth and that the participants considered testing in terms of who might have access to the results and the advice and encouragement they received during counselling. Most participants could not recall risks associated with study participation highlighted during informed consent procedures. However, the few who did were able to accurately recall the risks.

8. Effective strategies for recruiting and engaging youth in study participation

Echoing the UNAIDS Guidelines for Good Participatory Practice (UNAIDS, 2011), a combination of individual and community-level strategies created a sense of trust and provided the impetus for youth to join the study. For example, one of the most effective strategies involved hiring a community mobilizer with the responsibility to connect with individual youth and their larger communities. This mobilizer facilitated informational talks about the study given by research staff to groups of adolescents and their parents in schools as well as through one-on-one/door-to-door recruitment in villages. Active, direct contact between study staff and youth, in conjunction with encouragement from close family members and community gatekeepers, was a more effective participant recruitment strategy than the passive use of recruitment fliers and posters. Most participants (n = 55) reported hearing about the study from research staff in a group setting (e.g., schools).

Participants often remembered the inclusion criteria and interpreted their eligibility as an invitation to join the study. This is illustrated by the following quote from an HIV-positive, older adolescent male: ‘The (screener) questions that I answered and told that I had qualified. That was what drove me (to join). The questions that I was asked and answered correctly and I joined.’

Once the research staff made the study well known to the community, other key stakeholders encouraged adolescents to join. In 13 cases, participants reported encouragement from their mother or other (female) guardian (e.g., grandmother or sister). Neighbors, especially those identified as friends or extended family members, also encouraged participation as recounted by an HIV-negative, younger adolescent female: ‘It is our neighbor who told my grandmother that they wanted people who are between 15 years to 17 years.’

Four participants reported being contacted and encouraged to join by a community health worker (CHEW). Although CHEWs were not employed by or affiliated with the study, according to a study participant, one CHEW presented the study in an effective way by emphasizing the confidentiality provided by HIV testing through a research study:

> There is a certain mother working as a community health volunteer. She is the one who told me…There are people who are doing testing there at [clinic name] and they are people whom you don’t know. They are not the ones that you normally fear in the hospital.
>
> (HIV-positive, older adolescent, female)

The CHEW in this case recognized that the adolescent had a desire to be tested, but a hesitancy to do so through the clinics available to the potential research participant.

Many participants reported hearing about the study from multiple sources (relatives, neighbors, and friends of their parents). This appears to have a priming effect on later study participation—youth that had already heard about the study elsewhere were more likely to join when approached at school or through door-to-door recruitment efforts by study staff. However, most youth heard about the study from key adults in their lives. Few participants (n = 6) reported first hearing about the study from another peer or friend. There was not much evidence of 'peer pressure' to join the study. In sum, multiple person-to-person recruitment techniques were most effective in recruiting research participants.

9. Youths' motivations to participate in the research study

Even though HIV-related research is prominent in Kenya and HIV testing is free and widely offered in local clinics, our interviewees (n = 47) indicated that HIV testing and knowing one's status were the most important motivators for study participation. As one interviewee, a HIV-negative, older adolescent, male, explained: 'What I saw with my eyes is HIV testing and this made me happy because it had taken long from the time I last tested for HIV.'

Before and after HIV testing, participants received counselling as part of study procedures. Respondents interpreted this counselling as 'teachings' which they regarded as a benefit. Participants' expectations of high quality and accurate HIV prevention information were prominent. They were particularly emphatic about the value of sexual health and HIV-related teachings that they (and their parent/guardian) associated with research participation. The study team employed no intentional 'teaching' about HIV prevention, and our informed consent process did not state education as a benefit of the study. Nonetheless, about one-third of interviewees, including a full 20 of the 41 participants from one remote sub-county, anticipated that the study would educate them in some way about HIV. Participants explained it to us this way:

> 'What made me join this study is because you said there are some teachings that you will be teaching us when you will be back about HIV and AIDS. How some, an adolescent, can take care of themselves.'
>
> (HIV-negative, older adolescent, male)

While it is possible that the participants inferred this additional education from study recruitment, recalling it two months post testing highlights the salience of HIV-related information to study participation.

Other reasons for joining the study were related to the monetary compensation promised in the study recruitment materials and during informed consent. Seven participants believed that the study was designed to 'help' them. Although not directly stated in each case, context clues suggest that this 'help' was financial and ongoing throughout the study. This kind of ongoing help was not offered in the study and not discussed during the informed consent. The following quote illustrates the hope of future monetary compensation:

> I understand that there may be some help in the coming days. They told me that if I respond well to the question and the computer chooses me then they will look for me later and there will be some money that will be given.
>
> (HIV-negative, adolescent, male)

10. Perceptions about HIV testing in the context of a research study

All participants, regardless of HIV status, generally reported positive experiences concerning their participation in the study and HIV testing therein. This was universal across study sites, age groups, and gender. When asked what they appreciated about their study participation, participants noted the confidentiality and convenience of HIV testing during the study.

Recall that half of respondents were randomly assigned to be tested at a local health clinic and the other half in or near their home. However, both those assigned to the clinic (n = 12) and home (n = 5) study arms cited confidentiality as the primary advantage of their testing location. When asked at the 2-month follow-up visit where they would have preferred to have been tested, participants gave mixed answers. Wherever the participant considered more private was typically considered the ‘best’ place to test. This was particularly true for younger (n = 11) versus older adolescents (n = 6).

> Clinic participants valued quiet rooms and being able to be tested without family members overhearing the results. Here, an older adolescent respondent shares why she preferred the confidentiality provided in the clinic: ‘At home, everybody could have known. But in the hospital, I am the only one who knew.’
>
> (HIV-positive, older adolescent, female)

Home participants were also largely satisfied with place of testing. In contrast to respondents randomized to clinic testing, home participants mentioned concern that clinic staff would spread rumors about their HIV status. Home respondents also cited concerns related to seeing friends and relatives at the clinic and seeing familiar people as they walked home from the clinic as illustrated by the following quote:

> ‘At home it is a secret between two people. But in the clinic even if it is a secret between two people, it takes long from home to the clinic.’
>
> (Indeterminate, adolescent, female)

Interestingly, seven participants preferred home testing for the opposite reason: they wanted to share their HIV results with family members (particularly parents) and thought that home testing was more convenient. An HIV-negative, older adolescent, male explained his preference for home testing as follows:

> Me, I can like home (testing) because for hospital sometimes the hospital is far and when I receive the result I have to tell my grandmother who is at home. We cannot carry her when we are going there (hospital). That is wastage of time. So those people can come home, test and tell her my results too.
>
> Many participants (n = 45) used the word ‘advice’ while others used the word ‘encouraged’ (N = 11) to describe how they felt about their pre/post HIV test

counselling, for example: ‘When I sat down to be tested, I was first encouraged, and the encouragement made me not to be afraid.’

(HIV-negative, older adolescent, male).

Participants described being encouraged and advised to adopt and/or maintain safe sex behaviors as well as to enroll in HIV care, if HIV-positive. Almost all respondents reflected that they trusted the HIV counsellors to give good advice and that the counsellors gave this advice in an appropriately kind and respectful way.

She talked to me politely and I felt nice. I understood the importance of taking the drugs such that even if I could refuse it would be upon me and I would have no one to blame. The counselling she did to me was very good and she taught me a lot.

(HIV-positive, older adolescent, female).

11. Participants’ understanding about the risks associated with the research study

More than half of respondents did not reflect an understanding of risks associated with the research study, including those related to mental health and a HIV-positive result. Twenty-three respondents could not recall being told of the risks related to the study and 12 remembered being told about risks but could not recall what they included. When an interviewer asked a participant whether he was told about the risks involved in the study, the participant responded: ‘No. Maybe I was told but I don’t remember because I was only concentrating on the benefits that I would get.’ (HIV-negative, older adolescent, male).

When respondents (n = 33) could remember the risks, they were generally accurate. The most frequently discussed risks were pain related to the needle prick (n = 24) and psychological impact of a ‘bad result’ (HIV-positive) (n = 19). Other less frequently cited risks included discomfort answering difficult questions (n = 5) and people finding out about one’s HIV status (n = 2). In addition, three respondents specifically mentioned the risk of committing suicide if they got a positive test result; the consent form mentioned a risk of being upset but did not say committing suicide.

12. Discussion

We used qualitative data to examine four ethical considerations pertaining to youth engagement in an HIV-related research study: effective recruitment strategies, motivations to participate in HIV-related studies, perceptions about HIV testing in the context of a study and understanding about risks associated with research participation. Given the nuances of working with adolescents, and the ethical concerns surrounding informed consent, this study offers potential ways to maximize efficiency in recruitment, improve ethical protections, and enhance the research study experience for adolescent participants. Direct contact with study staff was an important way to recruit adolescents and to ensure dissemination of accurate information about the study. Additionally, encouragement to join the study came from within communities, most commonly via someone influential in the life of a youth, such as a mother, but also school staff and lay healthcare workers. Additionally, our study found

shortfalls in understanding about research-related risks that highlight a need for improvements in current informed consent procedures for adolescents.

Findings from this study suggest that recruitment of adolescents for HIV research may be enhanced by efforts to ensure that key community stakeholders are given adequate information about the study benefits, procedures, and risks. In accordance with the UNAIDS recommendations for "good participatory practices for stakeholder education" (UNAIDS 2011), we found that the strategy of regularly holding community awareness meetings with local leaders, school and health facility administrators, and parents/guardians greatly facilitated our recruitment efforts. This recruitment strategy is also consistent with ethical recommendations to engage key community stakeholders in adolescent studies '… to offset power differentials and mistrust, increase transparency, and improve identification of risks that may be hidden to investigators who are less familiar with the sociocultural setting' (Bekker, Slack, Lee, Shah, & Kapogiannis, 2014). Thus, HIV researchers who work with adolescent populations should consider including community awareness activities for stakeholders as a component of their recruitment activities.

Youth motivations to participate in our study included a desire to receive HIV testing and pre/post-test counseling, as well as to learn how to reduce risk behavior. Similar results have been found among adults (Colfax et al., 2005; Odero et al., 2019; Woodsong et al., 2012). In addition, confidential HIV counseling, testing and disclosure of results was important for our adolescent participants. Similar to adult research participants, we found that among adolescents, HIV testing within the context of a research study was preferred to testing provided by healthcare workers (Odero et al., 2019). This was true even when respondents were randomly assigned to obtain HIV testing administered by study staff at a local clinic. Our findings suggest that confidentiality concerns among youth may stem more from who does the testing (i.e., research staff vs. clinic staff) and less from where the testing takes place (i.e., at home vs. a clinic). The perception that rural health facility staff do not protect confidentiality is not new (Audet, Groh, Moon, Vermund, & Sidat, 2012; Gourlay et al., 2014; Sanga et al., 2018). Moreover, although pre- and post-test counseling mirrored services provided at the local clinics, participants expected study-provided information to be much greater and more useful. Again, participants anticipated that "outsiders" could provide more accurate and compelling HIV education than what was available locally. Our findings suggest that to enhance acceptability, global research collaborations which utilize local researchers for data collection should consider employing staff who are fluent in local languages and culturally competent, yet not from the community where the study is conducted.

Although most of our interviewees correctly interpreted the study risks as low, it was concerning that so few study participants could identify *any* risks two months later. In a study specifically focused on ethics and informed consent, we expected a much higher retention and recall of the informed consent process (Afolabi et al., 2018), particularly as participants so clearly remembered the details of the incentives. This raises an important ethical question. Our participants appear to have a somewhat inflated perception of study benefits, and an under-appreciated view of study-related risks. What should be done about this, since these views may undermine the quality of informed assent? To address this

imbalance, as recommended by the recent guidance specific to adolescent participation in HIV and SRH research (NASCOP and KEMRI 2015), extra attention needs to be paid in the assent process with this population, emphasizing what benefits are truly study-related (and what is not offered), as well as key risks of participation. This may be challenging, given that the risk/benefit perceptions of adolescents may be strongly shaped by their socio-economic circumstances. However, promising interventions to improve informed consent, such as enhanced consent procedures and extended discussions, have been found to improve comprehension of risks and benefits of research in a variety of settings and populations (Kass et al. 2015; Nishimura et al., 2013; Addissee et al., 2016). Guideline developers should consider including these interventions in guidance documents.

This study provokes a discussion of the extent to which Kenyan youth join studies voluntarily and whether decisions to join are based on adequate information and assessment of study risks and benefits (Rennie et al., 2017). Our data suggest that study participation by youth may likely be a result of encouragement by supportive adults in the community and shared decision-making. We did not find indication that adolescents felt unduly influenced or regretted their decision. Additionally, adolescents in our study seemed to confound the difference between research and health care provision. Thus, researchers should educate potential adolescent research participants regarding this distinction, so they can make more informed choices regarding research participation in the future.

13. Limitations

This analysis has several limitations that could be addressed through further study. First, we intentionally sampled high HIV prevalence communities to detect effect sizes for other study outcomes; thus, the sample is not representative of all of Kenya, sub-Saharan Africa, or otherwise. Second, the overall HIV prevalence in our sample was low. Post-study qualitative focus groups to share our data with key stakeholders in Kenya revealed disbelief in the low prevalence. It could be that the face of HIV in Kenya is changing, or that individuals with suspicion (but not confirmation) that they are HIV-positive did not join our study. Third, we intentionally attempted to interview all individuals who had an HIV + or inconclusive HIV test result at baseline. It is very possible that these test results further enhanced the desire for privacy and confidentiality. Fourth, although study participants did not recall risks at the two-month follow-up interview, this does not necessarily mean they did not understand them at the time of enrolment; it is possible their understanding was acceptable to give an informed consent at enrolment. Finally, protocols were sufficiently flexible to allow interviewers the ability to probe on questions where they sensed a participant had more to say. Conversely, not all participants were asked every follow up question, rendering qualitative counts more general than specific.

14. Conclusion

As clinical trials with adolescents increase, particularly in sub-Saharan African countries, there is a greater need to explore how they understand HIV research studies. Our study helps situate adolescents as similar, but not identical to adults in terms of their motivations to join an HIV-risk study. Documenting youth experiences within a study remain an important

aspect of ethical research. It is clear from our work that the study was memorable for its confidentiality and 'teachings.' Youth are hungry for HIV-related information. Future work could identify ways in which study participation changes overall understanding of disease transmission as well as risk reduction behavior over time. In addition, policymakers, researchers and ethics review board members need to be aware that adolescents may underestimate research risks and overestimate benefits to a greater degree than adults. Policymakers could add to current guidelines a requirement for enhanced consenting procedures and extended discussions to improve comprehension of risks and benefits among adolescents participating in HIV-related research. Researchers could include community awareness activities for local stakeholders in their study protocols, not only to facilitate recruitment, but to also enhance research literacy among key adults in the community. Future work could explore whether community awareness activities with key adult stakeholders is a feasible and effective approach to further increase adolescent understanding of research-related risks and benefits without undermining their recruitment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Demographics of 2-Month Follow Up Participants.

	HIV-positive (n = 15)	HIV-Negative (n = 47)	Indeterminate (n = 20)	Total
Age				
Younger adolescents (15–17 years)	7 (47%)	33 (70%)	16 (80%)	56 (69%)
Older adolescents (18–19 years)	8 (53%)	14 (30%)	4 (20%)	26 (32%)
Gender				
Male	4 (27%)	26 (55%)	11 (55%)	41 (50%)
Female	11 (73%)	21 (45%)	9 (45%)	41 (50%)
Site				
Site l	6 (40%)	13 (28%)	2 (10%)	21 (26%)
Site 2	8 (53%)	20 (42%)	13 (65%)	41 (50%)
Site 3	1 (7%)	14 (30%)	5 (25%)	20 (24%)
Study Arm				
Clinic	10 (67%)	26 (55%)	13 (65%)	49 (60%)
Home	5 (33%)	21 (45%)	7 (35%)	33 (40%)