“You guide them but ultimately they make decisions”: Insights into moving beyond the ethical dilemmas of adolescent consent to HIV care and research by stakeholders in Kenya

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Abstract

“You guide them but ultimately they make decisions”: Insights into moving beyond the ethical dilemmas of adolescent consent to HIV care and research by stakeholders in Kenya

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Objectives: To identify best practices of performing and obtaining consent for HIV care and research involving adolescents, and strategies to promote representative participation of adolescents in HIV care and research in Kenya.

Design: Qualitative interviews were conducted with stakeholders with expertise in ethical, legal, and social issues (ELSI) in Kenya.

Methods: 18 semi-structured individual interviews were conducted with ELSI stakeholders recruited through professional network, public databases, and other in-country resources. The interviews were conducted in English by Kenyan social scientists, audio recorded and transcribed verbatim. A qualitative analysis using a conventional content analysis approach and thematic network analysis techniques was performed to elucidate common themes around adolescent decision-making, autonomy, and consent practices regarding HIV care and research.

Results: Three major themes emerged related to adolescent decision-making and consent practices in HIV care and research. First, ELSI stakeholders relied heavily on the risk/benefit ratio when evaluating when adolescents should be given autonomy to make independent decisions. Secondly, adults should involve adolescents in decision-making to empower and build adolescent capacities. Thirdly, Consent processes in HIV care and research involving adolescents should respond to changing circumstances in Kenya.2) adults shall empower and involve adolescents in decision-making ; and 3) current policies shall adjust to changing realities.

Conclusion: Revisions to current policies and guidelines around consent practices in HIV care and research involving adolescents should consider replacing the requirement for parental consent with a shared consent model that emphasizes the importance of adolescent empowerment and receiving guidance supportive adult figures.

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Introduction

Adolescents (ages 10-19) represent a growing percentage of people living with HIV and account for 40% of new HIV infections worldwide.[1, 2] Of the estimated 1.8 million adolescents living with HIV (ALHIV), 84% are living in sub-Saharan Africa.[3, 4] Kenya has an HIV overall HIV prevalence of 4.9% among adults (age 15 and above), while the prevalence among adolescents, especially in Western Kenya, is 10.4%.[5-7] According to UNAIDS 2019 HIV Estimates, as of 2018, an estimated 7,300 adolescents were newly infected with HIV in Kenya, mostly through sexual intercourse.[4, 7] Although Kenya has made tremendous progress in reducing the annual number of new HIV infections and HIV-related deaths, and in improving the quality of life of people living with HIV, not all age groups experience such progress equitably.

Compared to adults, adolescents in African countries are less likely to know their status, have lower retention, adherence to ART, and poorer clinical outcomes.[8-12] Loss to follow-up among adolescents within the first 12 months of ART ranges from 15% to 83%.[11, 13, 14] Poor ART adherence is common, with adolescents and young adults having significantly lower rates of viral suppression (range: 73%-93%) after ART initiation compared with adults (range: 88%-97%).[15-17] Suboptimal ART adherence increases risks of virologic rebound after initial suppression, virologic failure, and drug-resistance-related mutations and leads to faster disease progression, HIV transmission, and high mortality.[8, 9, 18, 19] In Kenya, only 61.4% (95%CI: 43.8%-79.1%) of adolescents on ART are virally suppressed, as compared to 71.6% (95%CI: 68.8%-74.4%) of adults.[5] Adolescents who fail on first-line ART regimens need to initiate second-line regimens, resulting in higher costs to both the individual and the national ART program, which are challenging in resource-limited settings like Kenya.[20, 21]

Kenya is strongly committed to attaining the UNAIDS 95-95-95 goals and to ending AIDS by 2030 and has identified adolescents as a key population to achieve these ambitious goals.[5, 7] However, previous studies suggest that adolescents' HIV care linkage, care retention, and the optimal ART regimen remain poorly understood and evaluated.[18, 22-24] Adolescents have distinct physiological, psychological, and developmental needs, and are exposed to different sexual and reproductive health risks when compared to adult or child populations.[1, 19, 22, 23, 25, 26] These distinctions in needs and risks render medical and social HIV-related tools and interventions proven effective in adult populations less relevant to adolescents. For instance, the WHO's criteria for immunological failure showed an alarmingly low sensitivity of 14% in adolescents, indicating an urgent need to develop clinical tools specifically for this age group.[18] Designing and implementing effective drug regimens and social interventions require representative participation of adolescents in HIV care and research, which implies complex legal and ethical considerations.

Though Kenya has adopted the WHO definition for adolescents (age 10-19), an ethical dilemma arises from the lack of a legal definition for the word "adolescent" in Kenyan laws encompassing HIV care and research. Based on the Children Act in Kenya, an individual is assigned with a legal status of either "child" or "adult". Therefore, all individuals (except for emancipated or mature minors) below the age of the majority (age 18) are recognized in the legal framework as children, seen as vulnerable, and enjoy only diminished autonomy.[27] Protection of adolescents in HIV care and research is typically reflected in the requirement of parental consent, assuming that parents naturally make decisions in adolescents' best interests. Though adolescents age 15 and above can independently consent to an HIV test, they need to identify a primary caregiver when they are enrolling in care and initiating medical treatment.[28] While parents are a reliable source of support, they are also a key barrier to HIV testing and care among adolescents, as indicated by previous studies.[29, 30] Insisting on parental involvement and requiring parental consent for HIV testing and care, when adolescents are not fully prepared for the disclosure of their sexual activities and HIV status, may result in abrupt disclosure, increased stress for adolescents, loss-to-follow-up, delayed treatment initiation, poor ART adherence, and poor quality of life of ALHIV.[20, 25, 30]

HIV research implies even more layers of ethical, social, and legal complexities than HIV care. While occasional enrolment of adolescents in HIV care without parental consent can be easily justified by the urgency and proven clinical benefits of ART, some HIV research is not therapeutic in nature or may not be directly beneficial to a given individual and are therefore harder to justify including adolescents in research without involving their parents. The decision to limit adolescent autonomy to give independent consent usually centers around an adolescents' ability to understand the basic premises of the research, and whether they can rationally weigh the research premises against their values and interests.[31, 32] Western scholars in ethics suggest that adolescents should be granted authority over their decisions if they develop similar capacity to make decisions as that of competent adults.[31, 33] Previous research in Western societies demonstrated that adolescents aged 11 years have the neurological capacity to make autonomous decisions if given favourable environmental factors, and adolescents aged 14-15 years have similar decision-making capacity with adults related to medical treatment using hypothetical treatment dilemmas.[34] However, younger adolescents may need more time and support during the consent process to avoid misconceptions of the research premises. In addition, adolescents who possess lower social and/or emotional maturity, despite the neurological capacity to make autonomous decisions, may be influenced by third parties and make decisions that are not in their best interests.

The majority of the studies investigating adolescents' decision-making capacities have presented results related to Western societies. Scholars have not reached a consensus on the age cut-off at which adolescents are mature enough both neurologically and emotionally to make autonomous decisions in clinical or research settings. Hence, scholars generally suggest limited adolescent involvement in non-therapeutic medical research and parental involvement in medical treatment. In Kenya, adolescents generally do not have the legal capacity to consent to research participation. However, the Kenyan guideline on adolescent research participation also states that adolescents should be involved in the consent process and should only participate when they have demonstrated active willingness to be involved in research.[35]

Nonetheless, the different conceptions of autonomy influence how we approach the ethical decision-making of adolescents. Autonomy can be relational, instead of building on the conceptions of Western individualism and the rational human. The individualistic approach to autonomy emphasizes that an autonomous individual should be self-sufficient, self-reliant, and self-realizing. One makes rational decisions to maximize personal gains and avoid being overly influenced by others.[36, 37] Adolescents are deemed not capable of making such self-sufficient, rational decisions without the influence or support of peers and adult figures around them, and thus do not qualify for the legal status of autonomous agency.[37]

Relational autonomy, by contrast, questions isolated individualism, holding that persons are embedded in social contexts, and there is a social dimension to selfhood. It implies that interpersonal relationships and mutual dependencies are integral to an autonomous agent's fundamental value commitments. The line between the interests of self and significant others is ambiguous.[36, 39] Hence, involving significant others and valuing their input in the decision-making process is not viewed as an intrusion to one's autonomy. Instead, it is an essential aspect of making critical decisions and helps autonomy flourish. ALHIV in Kenya reported that supportive relationships between them and their significant adult figures, not limited to parents or adults who hold a formal position to support adolescents, helped them cope with their HIV status and adhere to treatment. When adolescents received support from healthcare workers and family members during the consent process of research, they also felt reassured that research participation would be meaningful and that the benefits would outweigh the risks.[30, 40, 41]

Data-informed Stepped Care (DiSC) to Improve Adolescent HIV Outcomes is a formative study based in Kenya to inform future intervention development and efficient use of clinical prediction tools among ALHIV. The study aims to identify strategies to promote adolescent retention in HIV care and representative participation of adolescents in HIV research in two counties in Western Kenya, Kisumu and Homo Bay, where the gaps between HIV testing and care are the largest in the country.[7] The qualitative aim of DiSC is to understand stakeholders' view on adolescent decision-making, autonomy, and support regarding HIV testing, care, and research, and to identify best practices in obtaining and performing consent. This specific subset of the qualitative analysis focuses on the perspectives of ethical, legal, and policy-maker stakeholders who have experience with adolescent decision-making in Kenya.

Methods

Study Design and Population

In-depth, one-on-one interviews were used to collect qualitative data on beliefs about adolescent autonomy and consent practices in HIV testing, care and research from Ethical, Legal and Social Issues (ELSI) stakeholders in Kenya. ELSI stakeholders were defined as those involved in public or school administrative office, serving on ethical review committees, or employed as a lawyer within the Kenya Bar Association. Purposive sampling was used to recruit participants representing a broad range of professional expertise (see *Table 1* for specific eligibility criteria of ELSI stakeholders). Potential participants were initially identified through professional networks, public databases and other in-country resources. Individuals who satisfied the eligibility criteria were contacted by a study staff, taken through the consent process, and enrolled in the study.

Data Collection

Semi-structured interviews were conducted between October 2019 and March 2020 using a discussion guide to probe experiences with and beliefs about 4 primary domains: 1) considerations for adolescent and young adults' (AYA) decision-making, 2) laws and regulations encompassing AYA decision-making for HIV testing, care and research; 3) optimal support for AYA decision-making; and 4) AYA participation and autonomous consent in research (see *Appendix 1* for the complete interview guide). The interview guide was piloted with study staff prior to being finalized to allow for optimal phrasing, timing and ordering of questions.

Prior to each interview, study staff collected basic demographic information, including age, sex, educational level, occupation and years of experience. Interviews were conducted in English by two trained Kenyan social scientists. All interviews were audio recorded and transcribed verbatim. In addition, each interviewer summarized their impression of the interview and the participant's perspectives in a structured debrief report completed immediately following each interview. Interviews ranged between 21 and 67 minutes in length.

Data Analysis

Qualitative data analysis was performed by a core team of four coders (KB, SS, EH and HL) using *ATLAS.ti* software (version 8.4.24.0, ATLAS.ti, Berlin, Germany: Scientific Software Development GmbH). The coders performed a conventional content analysis using the constant comparison method to produce a description of key concepts and themes arising within and between the individual primary categories represented in the interview guide.[42] Of the 18 interviews conducted, three were excluded from full transcript data analysis due to damage of the audio recordings.

An initial structured codebook was developed using open coding, by two coders (HL and EH), after reviewing the full set of debrief reports and a subset of transcripts. The codebook development was guided by published literature on adolescent autonomy and consent, as well as a previous codebook used to analyze qualitative data from other stakeholders (adolescents, caregivers, and healthcare workers) within DiSC. The initial codebook was refined through an iterative process of reviewing additional transcripts against the existing codebook, reviewing code application in team meetings, and refining based on team feedback.

A final version of the codebook was used to code all transcripts. Three coders (KB, EH, and HL) each independently coded a randomly selected subset of transcripts. All coded transcripts were then reviewed by a second member of the coding team ((KB, EH, HL, SS) to assess consistency in code application and interpretation. Disagreements in code application were resolved through group discussions until consensus was reached. The analysis team drafted and revised thematic memos throughout the qualitative analysis process, which were used to identify patterns within and across transcripts, and informed initial queries and themes. Themes were further refined by running queries and evaluating code co-occurrence tables to compare and contrast key factors impacting adolescent decision-making and best practices to perform and obtain consent in HIV care and research between transcripts. Thematic network analysis techniques were used to characterize and map the network of related themes regarding the main domains investigated.[43, 44]

Ethical Considerations

This study was reviewed and approved by the Masneo Ethical Review Committee in Kenya and University of Washington Institutional Review Board. All participants provided written informed consent to participate in the study.

Results

A total of 18 ELSI stakeholders participated in interviews and represented IRB/ERC members (N=3), lawyers (N=5), policymakers (N=6), and school administrators/teachers (N=4). The median age of participants was 41 years and the majority were female (61%), Eight participants reported currently having at least one adolescent child. All participants had university level education, and the majority (78%) had a certificate or professional training related to health education, adolescent counselling, or bioethics. The majority of participants (83.3%) reported being familiar with policies on adolescent autonomy, and 14 participants (78%) reported having previously participated in a research study themselves.

Three major themes emerged the analysis related to adolescent decision-making and consent practices in HIV care and research: 1) perceived risk/benefit ratio influenced adolescent decision-making; 2) adults should empower and involve adolescents in decision-making ; and 3) current policies shall adjust to changing realities.

Perceived risk/benefit ratio influenced decision-making

All participants agreed that adolescents were frequently involved in decision-making processes, though independent decisions were largely limited to experiences at school, for example, which class to take, what activities to participate, and so forth. School administrator and teacher participants frequently referenced school practices like class assemblies and peer counsellors, as a way of empowering and supporting adolescents and building adolescent capacity to cope with later life events.

The majority of participants believed adolescents could also make independent decisions related to their health, noting that health problems are personal, and that the urgency of needing to treat a health problem outweighed potential risks.

"[W]hen it gets to health issues, health issues are going to be very personal and if you are going to have an adolescent who has already decided on what they want especially when they are going to utilize a particular health product which has been researched on and approved either internationally and at the national level and that has been found to be working and has been rolled out and the adolescents really want to utilize it. I think at that point they have…they can be allowed to make their own decision…" - [Participant 8, School Administrator/Teacher]

When evaluating HIV testing, HIV care, and HIV prevention, most participants generally supported independent adolescent decision-making only when risks and benefits were fully assessed for the individual, and many still preferred having a caregiver to be involved. Risks considered during assessment included health risks, emotional risks (e.g. adolescents not having appropriate support to cope with their status after testing positive for HIV), and social risks (e.g. conflicts between caregiver/parent and adolescents).

“This adolescent can consent, and be tested for HIV but from my own discussions with them and my assessment I need to involve their care taker and get the opinion or get their care taker also assent to what is before the service provided…..” – [Participant 5, Policymaker]

When compared with HIV care and PrEP for HIV prevention, participants felt that adolescents independently asking to test for HIV could be more easily justified based on the direct health benefits of knowing their status.

“We do encourage them to go for a test because: one we tell that we don’t whether the parents were okay, and therefore it’s good for you to get a chance and go and just be tested .It will give you an opportunity to make your life better .So what we wish is that they decide on their own whether to go for the test.” – [DiSC-ELSI-02, School Administrator/ Teacher]

When assessing the ability of an adolescent to provide independent consent for health services, common characteristics considered included age, level of maturity, and the family or social environment. Age was frequently seen as a proximal factor for the cognitive development of adolescents, though it did not always reflect adolescents’ level of maturity.

“You know the mental faculty increases with age, yes somebody who is still very young would not be able to make certain decisions, so age is important and even exposure.” – [Participant 1, School Administrator/Teacher]

“If they are mature enough because you know for you to make a decision that you will be taking medication, it is maturity because you need to know why you will be taking these drugs because normally ARVs are life long.” – [Participant 4, Policymaker]

“So for me from where am seated as the director in charge of preventive and promotive, this thing depend on maturity and people don't mature the same way, you can find an adolescent who is 12 and is well developed in the brain but you find one who is 15 but he is still not very mature…” – [Participant 7, Policymaker]

Many participants felt that adolescent participation in research entailed more layers of consideration, as the direct health benefits to adolescents are less certain. Because the risk/benefit ratio of adolescent participation in research was less favorable when compared to known health services, participants were less inclined to support independent adolescent consent for research participation. Participants described needing to evaluate specific aspects of the research, including study design, IRB approval, and the necessity of involving adolescents in research when evaluating which studies might be appropriate for independent adolescent consent.

“It depends on the content of the study; what the study is up to, if it is something that is geared towards the adolescents then when they become part of that study then I think they will move forward to gaining from that study, and then maybe they can even use the aspects from that study to help.” – [Participant 3, School Administrator/Teacher]

“But the risks are usually most likely set; psychological risks, emotional risks, physical risks, the risk of intimate partner violence and things like that, so now because of that, involving adolescents in research is not necessarily the same kind of risk when they come for care.” – [Participant 10, ERC Member]

Adults should empower and involve adolescents in decision-making

While agreeing that adolescents were frequently involved in decision-making processes, some participants expressed concerns that adolescents might make wrong decisions due to lack of experience or in response to coercive adult figures, peers, or the internet.

"They might be swayed easily and in that, that might expose them easily to the predators you see and because their mind is not mature enough I might fear that one also, so there are only two things one is that age that they might have not developed their brain to stand firm now they get to it, number two because their brains are not easily developed they might forget the counselling and say no now this pain is more than, you see maybe they see another person suffering maybe from TV or from Cyber, whatever source they might try, they might drop whatever the decision because they don't know what it takes to live safe or whatever it takes to drop the maybe drug that you are given, yeah." – [Participant 7, Policymaker]

Other participants believed that adolescents should be given the opportunity to make their own decisions, allowing them a deeper level of investment in the decision and subsequent outcomes, believing that learning would occur through the process of making independent decisions. However, they were often not given the opportunity.

"[I]ts necessary that the adolescents be given an opportunity to make decisions because when an adolescent is given an opportunity to make a decision then they own up the process of decision making because they are part of it, but many times that is not what happens under most circumstances." – [Participant 3, School Administrator/Teacher]

"[Y]ou see, they can make very ridiculous decisions, and in their own imagination or in their own opinion, that is the best decision that they can do and it can be a very wrong one, but so if it is a wrong decision you have just to tell them, yes this is how you did it, this was not the right way and you could have done it this other way. You try to help them understand you don't just give them a no and then you don't explain your no, sometimes you are even

able to give them an option and tell them the consequences and then from there they are able to pick and agree." – [Participant 8, School Administrator/Teacher]

Parent/caregivers were commonly seen by participants as the primary sources of support for adolescents, especially for younger adolescents (<15 years) and for decisions related to health. Parents were expected to provide counselling, guidance, options, and logistical support (for example, paying tuition and rides to clinics, taking care of nutritional needs, etc.) to support adolescent decision-making.

"At the end of the day the parent has to know coz the parent now will be forced to come in and support nutritionally, in adherence, psychosocial support, clinic days, in school and that's why maybe there is…the policy was bringing about now if you want to test this person." – [Participant 6, Policymaker]

All participants agreed that when the primary caregivers or parents were absent or abusive, other trusted figures could step-in and provide similar support for adolescent decision-making. Participants suggested that other relatives of the adolescent, teachers, healthcare workers, and church affiliates would all be appropriate alternative support figures for adolescents. Beyond this list, some participants were more liberal, suggesting that any person within the community, either physical or virtual, or a social institution that adolescent trusted, could provide alternative support for adolescent decisions. The key consideration was the level of trust the adolescent placed in the alternative support option.

"Wow! it varies, it could be a health care worker it could be a parent, it could be a sibling. I don't think I have a direct answer to that but you can put it to in the context of the person within, it should be someone that the adolescent is completely comfortable with and they relate well together and not someone who have coercive power over them. I think for me that would be the determining factor, is it someone that you easily relate with, is it someone that you easily work with and they are able to get along." – [Participant 14, Lawyer]

Compared with HIV testing and care, more emphasis was placed on information provision, and performing and obtaining consent in helping adolescents make informed decisions related to research participation.

"Yes if they have the information and they understand what the study is about and where this study is going to be taken, is their identity going to be protected, my fear would be what if the study is to exploit them?" – [DiSC-ELSI-11, Lawyer]

Some participants insisted on the importance of involving parents in the consent process of research participation, while others suggested that parental consent could be waived if the research involved sensitive topics to adolescents, such as research related to sexual and reproductive health. They were worried that adolescents might not reveal themselves once they knew their parents would be notified their participation in research about sensitive topics like sexual and reproductive health, which might hinder opportunities to advance health services and interventions provided to adolescents.

Consent processes should be responsive to changing circumstances

Most participants believed that current policies regarding consent practices in HIV care and other sexual and reproductive health services should be periodically reviewed and adjusted in response to changing cultures and technologies.

"Who is it helping? Is the policy in place for us to feel right and religious and moral or isn't the policy in place to protect and to work for our adolescents? So for me I just feel the policies need to completely change; even the laws need to change to reflect current society." – [DiSC-ELSI-11, Lawyer]

One particular participant suggested that the reviews to current policies and guidelines should be based on robust evidence from studies in similar populations.

“[T]he best way is to have solid evidence through research that is robustly done and properly disseminated, have stakeholders review that information and look at what it means and let them chat their ways about how to you know to ensure that they change the system through policy…” – [DiSC-ELSI-10, Policymaker]

Many other participants suggested that reviews to current policies and guidelines should be done with broad involvement of multiple stakeholders, including the adolescents, their parents/caregivers, and healthcare workers directly serving adolescents.

“*[N]ormally…when policies are normally being made they are normally from up coming down, so normally understanding them becomes a problem*.” – [DiSC-ELSI-04, Policymaker]

“[I]t has to be based on a lot of consultations so that nobody is left behind, nobody says no, they never seek for our opinion, they don’t value our opinion, they don’t like think we can provide this kind of information so include everybody on board.” – [DiSC-ELSI-08, School Administrator/Teacher]

Some participants expressed concerns over policies developed primarily around age, which might not reflect the level of maturity of adolescents and denies adolescents’ access to certain health services and opportunities to build capacities and life skills. However, if required to set an age threshold to consent practices for health services, many participants suggested that 15 or 16 could be the best age cut-off for providing independent consent.

“I’m just looking at the maturity or maybe the exposure of an adolescent who has reached 15 years maybe in terms of the knowledge that they have so I would say that a 15 year old probably would be in a better position maybe to participate in those kind of research compared to an adolescent who is still maybe younger than 15 years.” – [DiSC-ELSI-05,

Policymaker]

For research involving adolescents, participants referenced the importance of IRB regulation, in addition to age guidelines, to ensure the studies and especially the consent process, were ethically designed and implemented, and that adolescents were not exploited by researchers.

"[T]he reserves that could be found for adolescents that could be extrapolated from the 14 years and above who are likely to be a bit more mature and that is the kind of thinking that would go on in my mind but I would leave it to the IRB to decide." – [DiSC-ELSI-10, Policymaker]

Discussion

This qualitative study identified key factors influencing adolescent decision-making and primary support adolescents need regarding HIV testing, care and research participation in Kenya. By understanding personal accounts of ELSI stakeholders on best practices for supporting and building adolescent decision-making capacity, we identified several strategies to move beyond the ethical dilemmas of how best to involve adolescents in HIV care and research. Similar to previous studies, stakeholders valued parental support and consent for HIV care and research despite acknowledging that some caregivers/parents may be non-supportive, absent or abusive, and that adolescents could receive support from alternative trusted figures within the community.[45] Our study identifies risk/benefit ratio, either at individual- or population-level, as a determining factor in deciding the necessity and extent of parental involvement in decisions. Results from this study demonstrate the importance of a participatory approach to national policy and guideline revision, and the potential of adolescent informed consent with guidance from a trusted figure or social institution to promote equitable and representative participation of adolescents in HIV care and research in Kenya.

Many participants, particularly participants who served on IRB or as policymaker, valued parents/caregivers as the primary source of support for adolescents in HIV care and research. However, there were concerns over non-supportive parents being a barrier to adolescent utilization of health services, especially sexual and reproductive health services, which are viewed as sensitive topics in Kenya. This is in line with previous studies showing that key social relationships (adolescent relationships with parents, partners, or healthcare workers) played a critical role in adolescent uptake of HIV testing services in Kenya.[40]

The concern that requiring parental consent might be a barrier to adolescent involvement was more evident in adolescent research participation as compared with HIV testing and care. While participants commonly preferred parental involvement in the consent process of research involving adolescents, they also acknowledged that parents were at times a barrier to involving adolescents in research and therefore advancing interventions targeting ALHIV. This involves a delicate balance between the risk/benefit ratio of research participation of an adolescent and that of adolescents as a group. This concern has long been recorded in literature discussing barriers to and ethical dilemmas in adolescent participation in non-therapeutic health research, the scientific validity of which is often compromised by low enrolment rate or selection bias. [31, 32]

A previous study investigating PrEP use among uninfected members of HIV serodiscordant couples in Kenya suggested that the emphasis of male partners' involvement in the consent process of pregnant women's participation in research be placed on providing support, instead of compromising pregnant women's autonomy. [46] Similarly, our participants emphasized parents' presence in the consent process as a source of support for adolescents to make informed decisions and cope with unknown situations during or after research, rather than insisting on the ultimate power of parents to make decisions for adolescents. Consequently, a guided informed consent process, instead of required parental consent, for adolescent research participation was identified by our participants as an acceptable and appropriate alternative that supported adolescent autonomy as well as the critical role parents/caregivers fill in providing support.

We also found that solely setting an age cut-off to consent practices in HIV care and research limits healthcare workers' service provision to adolescents. Healthcare workers were often left with the responsibility to assess adolescents decision-making capacity, to educate adolescents about risks and benefits of sexual and reproductive health services, and to navigate personal complexities on an individual basis, adding to their over-stretching responsibilities. Most participants felt that current adolescents in Kenya mature faster than previous generations given broad dissemination of information through the Internet, and that not all adolescents mature at the same pace. Policies around consent practices in HIV care and research should be reviewed periodically with contribution from all stakeholders and collaboration of multiple sectors to address changes in culture and technologies between generations.

Our study has a few limitations. All stakeholders participated in the study were recruited to represent policy, legal and ethical decision makers in Kenya, and their accounts do not necessarily represent perspectives of other stakeholder groups. The length of each interview also varied considerably, ranging from 21 minutes to 67 minutes. This is largely because many participants were providing essential services in Kenya, which limited their availability to participant in the study and respond to the interview guide to the same level of details as other participants.

Conclusions

Future revisions to national policies and guidelines around HIV care and research involving adolescents in Kenya should consider the perspectives and concerns of ELSI stakeholders. Optimizing drug regimens and social interventions targeting ALHIV and promoting representative participation of adolescents in HIV care and research require moving beyond age as the primary cut-off for consent practices. Adolescents making informed decisions with supportive guidance from a trusted adult figure can help to protect adolescents’ rights while avoiding the potential negative consequences. As ALHIV continue to represent a significant proportion of people living with HIV and remain a high-impact target for ending the AIDS epidemic in Kenya, adopting alternative decision-making policies that promote equitable access to HIV services and research should be prioritized.

Reference List

1. Kim, S.H., et al., *Adherence to antiretroviral therapy in adolescents living with HIV: systematic review and meta-analysis.* AIDS, 2014. **28**(13): p. 1945-56.
2. Kasedde, S., et al., *Reducing HIV and AIDS in adolescents: opportunities and challenges.* Curr HIV/AIDS Rep, 2013. **10**(2): p. 159-68.
3. UNAIDS, *On the Fast-Track to end AIDS by 2030: Focus on location and population.* . 2015: Geneva, Switzertand.
4. UNAIDS, *UNAIDS 2019 HIV Estimates*. 2019.
5. (NASCOP), N.A.a.S.C.P., *Preliminary KENPHIA 2018 Report*. 2020, NASCOP: Nairobi.
6. *Kenya HIV Estimates Report 2018*, M.o. Health, Editor. 2018: Republic of Kenya.
7. *Kenya Fast-track Plan to End HIV and AIDS Among Adolescents and Young People.* , M.o. Health, Editor. 2015: Republic of Kenya.
8. Murray, K.R., et al., *Improving retention in HIV care among adolescents and adults in low- and middle-income countries: A systematic review of the literature.* PLoS ONE 2017. **12**(9).
9. Nachega, J.B., et al., *Antiretroviral therapy adherence, virologic and immunologic outcomes in adolescents compared with adults in southern Africa.* J Acquir Immune Defic Syndr, 2009. **51**(1): p. 65-71.
10. Lamb, M.R., et al., *High attrition before and after ART initiation among youth (15-24 years of age) enrolled in HIV care.* AIDS, 2014. **28**: p. 559-568.
11. Idele, P., et al., *Epidemiology of HIV and AIDS among adolescents: current status, inequities, and data gaps.* J Acquir Immune Defic Syndr, 2014. **66**: p. S144-S153.
12. Koech, E., et al., *Characteristics and outcomes of HIV-infected youth and young adolescents enrolled in HIV care in Kenya.* AIDS, 2014. **28**(18): p. 2729-38.
13. Ojwang, V.O., et al., *Loss to follow-up among youth accessing outpatient HIV care and treatment services in Kisumu, Kenya.* AIDS Care, 2016. **28**(4): p. 500-7.
14. Zanoni, B.C., et al., *Systematic review and meta-analysis of the adolescent HIV continuum of care in South Africa: the Cresting Wave.* BMJ Glob Health, 2016. **1**(3): p. e000004.
15. Barth, R.E., et al., *Effectiveness of highly active antiretroviral therapy administered by general practitioners in rural South Africa.* Eur J Clin Microbiol Infect Dis, 2008. **27**(10): p. 977-84.
16. Evans, D., et al., *Treatment outcomes of HIV-infected adolescents attending public-sector HIV clinics across Gauteng and Mpumalanga, South Africa.* AIDS Res Hum Retroviruses, 2013. **29**(6): p. 892-900.
17. Mutevedzi, P.C., et al., *Association of age with mortality and virological and immunological response to antiretroviral therapy in rural South African adults.* PLoS One, 2011. **6**(7): p. e21795.
18. Muri, L., et al., *Development of HIV drug resistance and therapeutic failure in children and adolescents in rural Tanzania: an emerging public health concern.* AIDS, 2017. **31**(1): p. 61-70.
19. Attia, S., et al., *Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis.* AIDS, 2009. **23**(11): p. 1397-404.
20. Nabukeera-Barungi, N., et al., *Adherence to antiretroviral therapy and retention in care for adolescents living with HIV from 10 districts in Uganda.* BMC Infect Dis, 2015. **15**: p.

520.

21. Ekstrand, M.L., et al., *Suboptimal adherence associated with virological failure and resistance mutations to first-line highly active antiretroviral therapy (HAART) in Bangalore, India.* Int Health, 2011. **3**(1): p. 27-34.
22. Grimsrud, A., et al., *Implementation and Operational Research: Community-Based Adherence Clubs for the Management of Stable Antiretroviral Therapy Patients in Cape Town, South Africa: A Cohort Study.* J Acquir Immune Defic Syndr, 2016. **71**(1): p. e16-23.
23. MacPherson, P., et al., *Service delivery interventions to improve adolescents' linkage, retention and adherence to antiretroviral therapy and HIV care.* Trop Med Int Health, 2015. **20**(8): p. 1015-32.
24. Govindasamy, D., et al., *Interventions to improve or facilitate linkage to or retention in pre-ART (HIV) care and initiation of ART in low- and middle-income settings--a systematic review.* J Int AIDS Soc, 2014. **17**: p. 19032.
25. Enane, L.A., R.C. Vreeman, and C. Foster, *Retention and adherence: global challenges for the long-term care of adolescents and young adults living with HIV.* Curr Opin HIV AIDS, 2018. **13**(3): p. 212-219.
26. Reisner, S., et al., *A review of HIV antiretroviral adherence and intervention studies among HIV-infected youth.* Topics in HIV Medicine, 2009. **17**(1): p. 14-25.
27. *Chapter 141. Children Act*, L.o. Kenya, Editor. 2001: Nairobi.
28. Programme, N.A.a.S.C., *Guidelines for HIV Testing Services in Kenya*, K.D.o. Health, Editor. 2015: Nairobi.
29. Denison, J.A., et al., *The HIV testing experiences of adolescents in Ndola, Zambia: do families and friends matter?* AIDS Care, 2008. **20**(1): p. 101-105.
30. Wolf, H.T., et al., *"It is all about the fear of being discriminated [against]...the person suffering from HIV will not be accepted": a qualitative study exploring the reasons for loss to follow-up among HIV-positive youth in Kisumu, Kenya.* BMC Public Health, 2014. **14**: p. 1154.
31. Moore, Q.L., et al., *Legal Barriers to Adolescent Participation in Research About HIV and Other Sexually Transmitted Infections. .* Am J Public Health, 2016. **106**: p. 40-44.
32. Fisher, C.B., et al., *Self-Consent for HIV Prevention Research Involving Sexual and Gender Minority Youth: Reducing Barriers Through Evidence-Based Ethics.* Journal of Empirical Research on Human Research Ethics, 2016. **11**(1): p. 3-14.
33. Jaspan, H.B., et al., *Community perspectives on the ethical issues surrounding adolescent HIV vaccine trials in South Africa.* Vaccine, 2008. **26**(45): p. 5679-83.
34. *Guidelines for Conducting Adolescent HIV Sexual and Reproductive Health Research in Kenya*, M.o. Health, Editor. 2015: Republic of Kenya.
35. Weithorn, L.A. and S.B. Campbell, *The competency of children and adolescents to make informed treatment decisions.* Child Development, 1982. 53(6): p. 1589-1598.
36. Walter, J.K. and L.F. Ross, *Relational Autonomy: Moving Beyond the Limits of Isolated Individualism.* Pediatrics, 2014. **133**(S1): p. S16-S23.
37. Code, L., *Second Persons*, in *What Can She Know? Feminist Theory and the Construction of Knowledge.* 1991, Cornell University Press: Ithaca. p. 71-109.
38. Feinberg, J., *Autonomy*, in *Harm to Self. The Moral Limits of the Criminal Law*. 1989, Oxford University Press: New York.

39. Mackenzie, C. and N. Stoljar, *Introduction: Autonomy Refigured*, in *Relational Autonomy: Feminist Perspective on Autonomy, Agency, and the Social Self.*, C. Mackenzie and N. Stoljar, Editors. 2000, Oxford University Press: New York. p. 3-32.

40. Wilson, K.S., et al., *"At our age, we would like to do things the way we want: " a qualitative study of adolescent HIV testing services in Kenya.* AIDS, 2017. **31 Suppl 3**: p. S213-S220.

41. Beima-Sofie, K., et al., *Using health provider insights to inform pediatric HIV disclosure: a qualitative study and practice framework from Kenya.* AIDS Patient Care STDS, 2014. **28**(10): p. 555-64.

42. Hsieh, H.F. and S.E. Shannon, *Three approaches to qualitative content analysis.* Qual Health Res, 2005. **15**(9): p. 1277-88.

43. Attride-Stirling, J., *Thematic networks: an analytic tool for qualitative research.* Qualitative Research, 2001. **1**(3): p. 385-405.

44. Ryan, G. and H.R. Bernard, *Techniques to Identify Themes.* Field Methods, 2003. **15**(1): p. 85-109.

45. Fisher, H. et al. *Barriers and enablers to adolescent self-consent for vaccination: A mixed-methods evidence synthesis.* Vaccine, 2019. 37(3): p. 417-429.

46. Ngure, K. et al. *The role of male partners in women's participation in research during pregnancy: a case study from the partners demonstration project.* Reproductive Health, 2017. 14(S3): 160.

Table 1. Eligibility Criteria of ELSI Stakeholders

Stakeholder Type	**Criteria**
Policy Makers	1) 18 years-old or above; and 2) Employed currently or in the past at a national- or county-level public office.
Ethics Committee Members	1) 18 years-old or above; and 2) Serves or previously served on a research ethics committee in Kenya.
Lawyers	1) 18 years-old or above; and 2) Licensed attorney in Kenya; and 3) Has experience with laws related to adolescents, or consent for care and research.
Other Relevant Stakeholder	1) 18 years-old or above; and 2) Has relevant experience with adolescent, such as teachers and school administrators.

Table 2. Characteristics of ELSI Stakeholders

Characteristic	**Missing**	**N=18**	**100%**
	n	**n**	**%**
Gender			
Female		11	61
Male		7	39
Occupation			
IRB/ERC Member		3	17
Lawyer		5	28
Policymaker		6	33
Other		4	22
Currently have adolescent children	4		
Yes		8	57
Ever had adolescent children	4		
Yes		9	64
Know any policies informing adolescent autonomy			
Yes		15	83
Ever participated in research studies			
Yes		14	77

Appendix 1. ELSI Stakeholder In-Depth Interview Guide

Interviewer Instructions: Copies of the informed consent form should be provided to the participant and read aloud for the benefit of those who cannot read. Participants should be provided an opportunity to ask any questions. Verbal agreement to participate should be taped.

The following set of questions is a guide. Try to ask all the questions below in the order given, but it is more important to maintain the flow of discussion. Suggested probes have been included.

Welcome and Introductions

Before turning on the recorder, start with the following introductory script:

Hi, my name is ____________. Thank you for agreeing to talk to me today. As mentioned earlier, I am a researcher and I am trying to learn more about current practices for providing services for HIV-infected adolescents. I am especially interested in how to balance adolescent's developing autonomy with providing appropriate support when adolescents are making medical and research decisions. We hope that the information you tell us can help improve the process of getting medical care for adolescents and young people with HIV.

This project is funded by the US National Institutes of Health.

Thank you for allowing us to spend time with you today.

Before we begin talking with you about your experiences, we want to learn a little bit more about who you are by asking a few short questions.

Ask and complete demographic survey now.

Thank you. We are now ready to begin our longer discussion. During this conversation, I am interested in understanding all of your thoughts, experiences and opinions. I will ask you questions that you are free to answer in any way you wish. Your opinion is very important to us. You do not have to answer any question that you are not comfortable with. If you want to stop the interview at any time, just tell me and we can stop.

There is no right or wrong answer to anything that I ask. If a question is unclear to you, please feel free to ask me to explain it.

The research team may take short sections of what you say and share them with non-study members. The research team will take information about your age, education, and experience and combine this information with others participating in these interviews.

I would like to record the interview so I don't miss anything that you say. I will not include your full name in the recording. Your name will not be on any study documents. Your answers will be kept confidential.

Is it okay if I record our discussion? [Wait for the participant to give verbal consent to recording; those who decline at this stage will be asked to leave the group and not participate]

I am turning on the recorder now.

Before beginning interview questions, please read the following script for the recording:

Today is [day of week], [month, day, year] and it is now [time of day]. I am speaking with participant [participant ID].

Can you confirm for me again, by stating yes or no, that you are willing to participate in the conversation today?Also, can you confirm if you agree to be audio-recorded?

You are now ready to begin asking the questions outlined below.

Semi-Structured Interview Questions

First, I would like to learn more about your involvement with adolescents. Please tell me a little bit about your professional role and how it relates to adolescents with HIV.

Can you tell me more about how your professional role involves thinking about adolescent decision-making?

- In what types of situations do you think about adolescents being involved in the decision-making process?
- In what situations do you think about adolescents being able to give consent for themselves to participate?
- In your professional role, what policies govern adolescent decision-making abilities?

Who are the best people to help support adolescent decisions about medical care?

- What is the role of a parent or guardian in helping adolescents make decisions?
- Who else might help support adolescents?
    - Under what circumstances can these supportive people step in if parents aren't available?
    - Is there a role for peers in supporting young people with their decisions? What might that role look like? Why?
    - Is there a role for other adults (not a caregiver or guardian) in supporting young people with their decisions? What might that role look like? Why?

Do you think adolescents should be able to make independent decisions to get an HIV test? Why?

- Under what circumstances is this acceptable? [For example:Does it depend on age, gender, maturity, education,behavior, fear of parental involvement, region of the country?]
- In what circumstances is this unacceptable?

Do you think adolescents should be able to make independent decisions to get HIV care? Why?

- Under what circumstances is this acceptable?[For example: Does it depend on age, gender, maturity, education, behavior, fear of parental involvement, region of the country?]
- In what circumstances is this unacceptable?

Do you think adolescents should be able to make independent decisions to get HIV prevention (PrEP)? Why?

- Under what circumstances is this acceptable? [For example: Does it depend on age, gender, maturity, education, behavior, fear of parental involvement, region of the country?]
- In what circumstances is this unacceptable?

Do you think adolescents should be able to make independent decisions to enroll in research studies? Why?

- Under what circumstances is this acceptable?[For example: Does it depend on age, gender, maturity, education, behavior, fear of parental involvement, region of the country?]
- Does the type of research activity matter?
    - What about participating in surveys?
    - What about participating in interventional studies?
- In what circumstances is this unacceptable?

What types of factors to you consider most frequently when thinking about adolescent autonomy and decision-making? Why?

Do you think that if an adolescent was determined to be mature and able to understand the research, it is ok for them to participate without their parents or anyone else helping them make decisions?

Do you think that if an adolescent was assessed and supported by a trusted adult(not parent or caregiver) in making a decision (e.g., by helping the adolescent think about longer term consequences, or resist peer pressure), that they could make a decision without parental support?

In your field, what are the best ways to change policies about when adolescents are considered able to make autonomous decisions?
Do you think current policies should change? Why?

Today, we talked about adolescent autonomy and who helps adolescents make different types of decisions about their HIV care, testing for HIV, HIV prevention and involvement in research studies.

Before we end, is there anything else you would like to add?

Do you have any questions for me before we end our conversation today?

Thank you very much for your time and for all the helpful information you have provided!