


'I feel that I should decide on my own...': who should be involved in the decision-making process for adolescent involvement in HIV research?

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ABSTRACT

Introduction Efforts to improve health outcomes among adolescents and young adults living with HIV (ALHs) are hampered by limited adolescent engagement in HIV-related research. We sought to understand the views of adolescents, caregivers and healthcare workers (HCWs) about who should make decisions regarding ALHs' research participation.

Methods We conducted focus group discussions (FGDs) and in-depth interviews (IDIs) with ALHs (aged 14–24 years), caregivers of ALHs and HCWs from six HIV care clinics in Western Kenya. We used semi-structured guides to explore ALHs' involvement in research decisions. Transcripts were analysed using thematic analysis; perspectives were triangulated between groups.

Results We conducted 24 FGDs and 44 IDIs: 12 FGDs with ALHs, 12 with caregivers, and 44 IDIs with HCWs, involving 216 participants. HCWs often suggested that HIV research decision-making should involve caregivers and ALHs deciding together. In contrast, ALHs and parents generally thought decisions should be made individually, whether by HCWs/research teams (although this is likely ethically problematic), adolescents or caregivers. Caregiver and ALH preferences depended on ALHs' age, with younger ALHs requiring more support. A few caregivers felt that ALHs should consult with the research team/HCWs due to their greater knowledge of clinical care. ALHs emphasised that they should independently decide because they thought they had the right to do so and the capacity to consent. Poor communication and parental non-disclosure of HIV status influenced ALHs' views to exclude caregivers from decision-making. Regarding influences on research decision-making, ALHs were more willing to participate based on perceived contribution to science and less interested in participating in studies with potential risks, including loss of confidentiality.

Discussion While research teams and HCWs felt that adolescents and caregivers should jointly make research decisions, ALHs and caregivers generally felt individuals should make decisions. As ALHs sometimes find caregiver support lacking, improving family dynamics might enhance research engagement.

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Engaging adolescents and young people in designing and developing interventions improves their HIV prevention and treatment outcomes.
- ⇒ The existing literature acknowledges the importance of engaging caregivers and improving adolescent–caregiver communication to enhance adolescent participation in HIV research.

WHAT THIS STUDY ADDS

- ⇒ We identified two main decision-making approaches to adolescents' participation in HIV research: individual and joint decision-making.
- ⇒ The individualistic approach to decision-making favoured by adolescents and caregivers in our study contrasts with guidance promoting engagement of both adolescents and caregivers.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ There is a need to develop a shared decision-making framework to guide healthcare workers and research teams working with adolescents living with HIV and their caregivers to incorporate their values in decisions regarding participation in HIV research.

INTRODUCTION

Adolescents and young adults (AYAs—aged 10–24 years) represent a growing proportion of people living with HIV worldwide.¹ Compared with other populations, adolescents and young adults living with HIV (ALHs) have higher rates of HIV acquisition and low rates of viral suppression, antiretroviral therapy adherence and retention in care.^{2–5} Consequently, AYAs constitute a priority population for achieving goals to end HIV/AIDS by 2030.⁶ AYAs are unique, with distinct barriers to care, yet are rarely specifically prioritised in national HIV plans and programming efforts.⁷ Available

interventions and guidelines for AYAs are predominantly translated from adult populations.⁸ Given the physiological and developmental differences between AYAs and adults,⁹ interventions translated from adult settings may not adequately meet the needs of AYAs. Engaging AYAs in research may improve the development of interventions responsive to AYAs' needs and priorities.¹⁰

Although engaging AYAs in research may improve intervention fit with patient needs, several barriers limit AYAs' participation in biomedical and behavioural HIV research. Some studies have identified worries about potential side effects, concerns about privacy and potential stigma, and the inability or unwillingness of adolescents to participate if parental permission is required. There is also confusion generated by conflicts between guidelines and laws about when adolescents can consent for themselves without parental permission.^{11–14} One meta-analysis found that requirements for parental permission led to systematic biases in survey research with adolescents in the USA, including under-representation of males and older adolescents and decreased self-reporting of substance use.¹⁵ In clinical research, these barriers may prevent enrolment of AYAs who are most likely to benefit from the interventions under study and delay the collection of evidence to benefit AYAs at the population level.¹⁶

Although balancing adolescent autonomy and parental permission is recognised as a challenge,¹⁰ there is limited information on how best to balance these to engage adolescents in decision-making.¹⁰ Parents are generally recognised to have the authority to make decisions for children before they reach the age of majority.¹⁷ Adolescent decision-making capacity typically grows over time and depends on the individual's maturity, context and circumstances. Some adolescents may understand research as well as adults.¹⁸ While some scholars argue that adolescents should be the primary decision-makers for their involvement in HIV research,¹⁹ the perspectives of parents, healthcare providers and researchers are essential to consider.²⁰ Additionally, adolescent inclusion in research must be balanced with protection from risks. In response to these challenges, there are ongoing efforts to provide practical guidance to improve participation in HIV research involving adolescents in low-income and middle-income countries.²¹

Shared decision-making (SDM) has the potential to achieve a balance between adolescent inclusion in HIV research and their protection from research risks. However, SDM frameworks have paid limited attention to adolescents.²² Furthermore, existing legal frameworks vary widely regarding how and when adolescents can decide independently and when caregiver permission is required.²³ We sought to explore what interested parties thought about who should be involved in deciding whether AYAs participate in biomedical and behavioural HIV research. We further sought to understand factors influencing adolescent decisions regarding HIV-related research.²⁴

METHODS

Study setting

We conducted a qualitative analysis to identify decision-makers and critical influences on ALHs' research participation. A qualitative research approach was considered appropriate to capture expressive information about the beliefs, values, feelings, processes and motivations that underlie decision-making regarding the participation of ALHs in HIV-related research from interested parties, which are more challenging to capture with quantitative methods.²⁵ We conducted focus group discussions (FGDs) to allow study participants to build on each other's perspectives and in-depth interviews (IDIs) to highlight nuances regarding HIV research participation by ALHs.²⁶

Data for this analysis are part of the pretrial phase of the Data-informed Stepped Care (DiSC) Study,²⁷ a cluster randomised clinical trial that aims to improve adolescent HIV outcomes in Kenya by optimising the provision of clinical care. The DiSC pretrial phase required establishing an ALH cohort at six facilities in the Kisumu and Homa Bay counties in Western Kenya (Kisumu County Hospital, Kombewa, Ahero, Kendu, Oriang and Mbita), where HIV prevalence is highest nationally.²⁸ We conducted qualitative research with ALHs, caregivers of ALHs and healthcare providers from those six facilities to understand interested parties' views on adolescent decision-making, autonomy and support regarding HIV testing, care and research. Prospective participants provided written assent with parental or written informed consent before participating for those above 18 years. The prospective participants were also informed of the potential that some of the questions would be sensitive.

Study design

We used a qualitative research design including FGDs and IDIs to identify (1) who should be involved in deciding whether and how AYAs participate in HIV research and (2) key influences on decision-making about AYAs' research participation.

Population, sampling and data collection

We included ALHs aged 14–24 years, caregivers of ALHs and healthcare workers (HCWs) providing HIV-related health services to ALHs. ALHs and caregivers were identified via medical records by routine clinic staff and referred to the study team for consenting and enrolment. ALHs were eligible to participate if they knew their HIV status, were between the ages of 14 and 24 years, had an upcoming clinic visit and routinely attended one of the six study clinics. Caregivers were eligible if they provided care for an ALH between 10 and 17 years who routinely received care at one of the study clinics and had an upcoming visit. All HCWs from participating clinics who provide care to ALHs were eligible to participate. HCWs were informed of the study by the clinic in charge and referred to study staff if they were interested in participating.

ALHs and caregivers participated in FGDs, while HCWs participated in IDIs. FGDs and IDIs were conducted by two trained Kenyan social scientists with not less than five years of experience interviewing adolescents, caregivers, and healthcare providers about HIV care experiences. FGDs and IDIs were conducted in the participant's preferred language (English, Kiswahili, Dholuo or a mixture), and semi-structured guides were collaboratively developed by the research team based on literature reviews and personal experiences in research ethics and HIV research. Guides focused on understanding current practices versus best practices around ALHs' decision-making for medical treatment and research participation, including independent consent, parental involvement and support needs. This specific analysis focused only on questions related to research participation. FGD research participation questions asked ALH and caregiver participants to describe participation preferences based on hypothetical research scenarios, specifically: (1) clinical research involving blood draws or taking medication, and (2) behavioural research involving answering questions about sexual behaviours or HIV medications.

HCW research participation questions included who best supports adolescent decisions around research engagement and AYAs being part of research studies. Caregiver interview guides focused on eliciting the personal experiences of those involved in caring for ALHs centred on adolescent decision-making for HIV treatment and care and adolescent decision-making and participation in research. IDIs lasted between 20 and 30 min, while FGDs lasted between 69 and 117 min. As recommended by Simoni *et al*, detailed summaries in structured debrief reports were written by the interviewing team within 24–48 hours after each FGD.²⁹ All FGDs and IDIs were audio recorded, translated to English as necessary and transcribed verbatim by the interviewers.

Data analysis

Thematic analysis guided the coding and identification of key themes.³⁰ Transcripts were coded by a core team of four coders (KB-S, JN, HL and SKS) using ATLAS.ti software (V.8.4.24.0). An initial codebook was developed collaboratively by the coding team using an open-coding approach that included a subset of full transcripts and all debrief reports. The codebook was refined by reviewing additional transcripts against the existing codebook and reviewing code applications in team meetings and group discussions. Three coding team members (KB-S, HL and JN) independently coded the same three randomly selected transcripts using a final version of the codebook. A fourth member (SKS) assessed agreement with code application and interpretation. Following the agreement between coders, each transcript was independently coded by one member of the coding team and reviewed by a second team member to ensure an understanding of code application and interpretation. All disagreements in the code application were noted and resolved through group discussion.

FCM, KB-S and SKS used queries and code co-occurrence tables to draft and revise thematic memos to identify patterns within and across transcripts from the different participant groups and characterise the main themes.²⁹ The final themes were organised into conceptual diagrams to summarise, link and illustrate key patterns and influences on decision-making concerning AYAs' HIV research participation.³¹ Illustrative quotes are provided below. For each quote, we have noted the facility number, respondent type, respondent number and adolescent respondents' ages. We only represented the ages of the ALHs because their response reflected their positions of autonomous decision-making, their desire for SDM or responsibility shifting to other interested parties.

RESULTS

We conducted 24 FGDs and 44 IDIs: 12 FGDs with 86 ALHs, 12 FGDs with 86 caregivers, and IDIs with 44 HCWs. The breakdown of the participants is presented in online supplemental file 1.

The first level of our analysis focused on who the study participants thought should be involved in HIV research participation decision-making for ALHs. **Figure 1** illustrates who each group believed should make decisions and highlights a significant discrepancy between adolescent, caregiver and HCW beliefs. While HCWs felt adolescents and caregivers should decide together, adolescents and caregivers generally felt an individual should decide.

We then characterised key perceived benefits of individual versus joint decision-making with the factors influencing them based on the data collected (**figure 2**). Individual decision-making refers to one person selecting which way to proceed regarding HIV research participation for an ALH without engaging others. Joint decision-making involves two or more people determining whether an ALH should participate in research.

Individual decision-making

Autonomous adolescent decision-making

Many adolescents felt they should make independent decisions about participating in research without support from their caregivers or HCWs. Some ALHs suggested that they should have the *authority* to make decisions.

I can say that this is my life, not the doctor's [life]. So, for all decisions, I must be the one to make them all. If it is about my medication, I must consult if it is suitable before taking it. I cannot just take medication and answer questions blindly because the doctor has said so. (Facility 3; ALH; R6; 17 years)

I feel that it is I who should decide on my own whether to join the study or not because I am the one who will be getting any new information that is associated with it. Yes, so I should be able to decide on my own. (Facility 2; ALH; R4; 17 years)

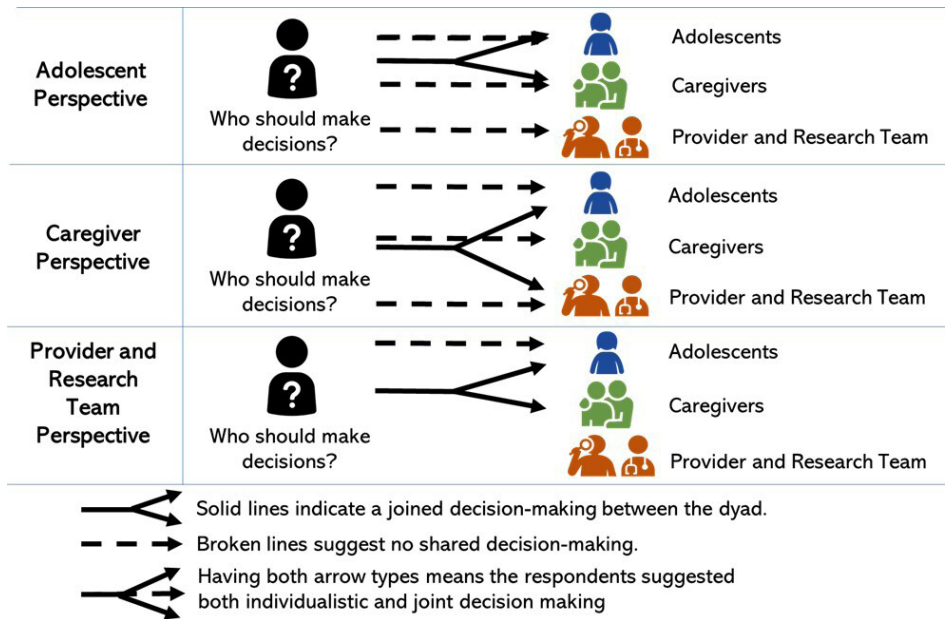


Figure 1 A representation of the participant’s preferred person to participate in research participation decision-making.

HCWs supported independent adolescent decision-making if adolescents could understand research and protect their interests by giving or withholding informed consent.

We have some 14-year-olds who are very smart and bright, and they know what is happening. So, if you have such adolescents, you only inform their caregivers on such a day; we would like your child to come for such a meeting. (Facility 1; HCW; R2)

Some caregivers also endorsed that adolescents should make their own decisions about research participation since they will be involved. Caregivers suggested that allowing adolescents to participate autonomously can foster independent decision-making as the adolescents move toward adulthood.

It is okay if he makes that decision independently because I want to introduce him to what adults do, so I

would allow him to make that decision on his own. (Facility 5; CG; R4)

I feel that at that age [16 years], she is the one who should be able to decide for herself because I do believe that she must have been taught and given all the information about that research. (Facility 3; CG; R6)

Similarly, some HCWs felt ALHs would be less willing to participate in HIV research if caregivers were involved:

We need to involve the adolescents directly because they are the adolescents we want to deal with, and we want to get everything from them. So, if you include the caregivers, sometimes they might partially be open to you. (Facility 1; HCW; R5)

So, depending on your age, you go on your own. You might not wish your parents to hear such stories [questions on sexual behavior] because they are always personal. (Facility 2; ALH; R4; 17 years)

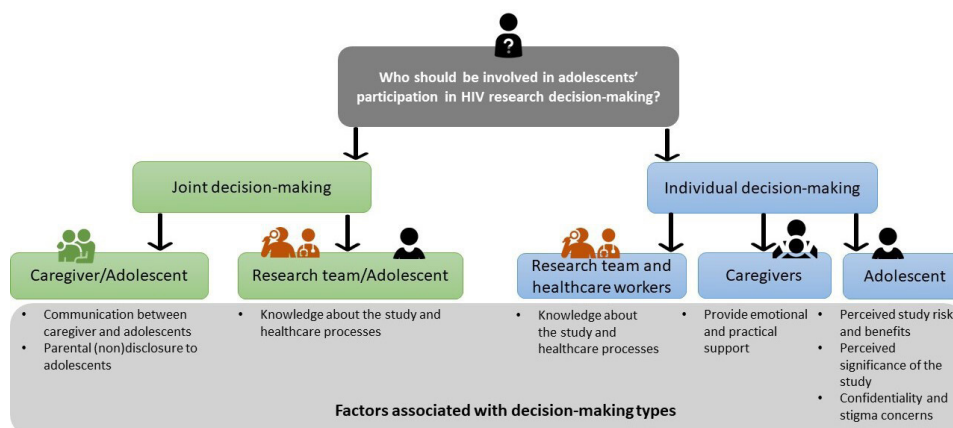


Figure 2 Thematic web illustrating benefits of joint or individual decision-making for ALHs’ participation in HIV research. ALHs, adolescents and young adults living with HIV.

Additionally, poor relationships between the ALH and their caregiver presented a potential opportunity for the ALH to autonomously decide on participating in HIV research without consulting with their caregivers. For example, one caregiver said:

Some parents are so hostile to their children that even the children are scared to discuss with them about anything. And sometimes, the child may not be taking their parents seriously, so they dismiss anything their parents say. (Facility 4; CG; R2)

A general observation was that most of the ALHs who suggested that they were most likely to decide on their participation in HIV research independently were between the ages of 16 and 17 years and that those who suggested including their caregivers were 15 years and below.

Caregivers deciding independently

Caregivers and adolescents felt that under some circumstances, caregivers could independently decide on the participation of their adolescent. Those who felt only caregivers should make research decisions focused on younger adolescents and their limited capacity for decision-making.

The caregiver should be able to decide for her [12 years old] because the child may not have the mind to think that he should join the research study with his peers. So, you must be the one to decide for him because you will better understand what the study is all about. (Facility 4; CG; R2)

Adolescents similarly emphasised that ALHs under 14 years should allow their parents to decide for them. ALHs suggested that they leave the decision for their caregiver to decide on their participation because of the possibility of side effects from participating in the study.

[A]s a child I cannot decide on taking out my blood without my parent's knowledge because taking out blood will have side effects, and the parents will observe those side effects and he/she will know you donated your blood...and therefore you will have many questions to answer. (Facility 6; ALH; R3; 14 years)

HCWs/researchers independently deciding

While some ALHs preferred that HCWs should decide about their participation in research, these ALHs still wanted to be part of the decision-making process. Some ALHs and caregivers preferred the HCWs/research team to play a significant role in their participation, stating that the HCWs were more knowledgeable about the research subject, the selection criteria and their abilities to participate in the study.

No, I cannot decide on my own. It is the Daktari [HCW-loosely applied to mean doctor] who must make that decision for me because he is the one who has more knowledge about that medication and how the questions are going to be beneficial to me. (Facility 3; ALH; R4; 15 years)

As a parent, I may be unable to decide for him because I may not know the research. So, you [Researchers] are the ones who know what the study is all about. (Facility 4; CG; R6; 56 years)

In support of the HCW/research team deciding, an ALH further suggested that their parents do not have the requisite knowledge to help them decide whether to participate in HIV research.

My parents can never decide for me because they may never know the benefits of the study, and again, they may be at home, so they may also not be aware of the study taking place and what it is all about. (Facility 6; ALH; R5; 17 years)

Joint decision-making

Caregivers alongside adolescents

While many adolescents suggested that they should independently decide to participate in HIV research, some alluded to consulting with their caregivers.

I think it's the parent [who should be involved in deciding] because if they say they [researchers] are giving you a drug, that drug might have an effect, and if you don't involve your parent in that decision-making, the parent may feel bad. (Facility 2; ALH; R3; 15 years)

While supporting the idea of having ALHs at the centre of the decision-making for HIV research, HCWs also wanted to include caregivers because of the perception that there may be risks or legal consequences if caregivers are not included.

I still believe no research should be done without the caregiver's consent. Because there are also, this caregiver might sue you, that why are you asking my child questions. (Facility 1; HCW; R7)

Some HCWs preferred to involve caregivers alongside adolescents based on their reflections on the potential consequences of not including them.

Research has its consequences, and it is not always 100% for the benefit of these participants. Is there a consequence with these adolescents participating here and still staying with their parents? What happens if the parents were uninvolved? (Facility 3; HCW; R4)

Many study participants reported that family dynamics and social support structures enhanced their research decision-making. For example, one of the ALHs suggested that 'It is easier for me [to consent] because I am close with my parents' (Facility 4; ALH; R1; 15 years). A caregiver added, "If he [ALH] tells me [about the research], then we will discuss it and see if he can go for the services – research study" (Facility 5; CG; R1; 42 years).

While a positive parent-ALH relationship is reported to favour caregiver engagement in HIV research, the contrary is held for rockier relationships.

R2: I never talk with her [caregiver] about that [sexual relations].

Moderator: And why is that?

R2: She can decide to cane [corporal punishment consisting of a number of hits] me about what I have shared with her. (Facility 3; ALH; R2; 17 years)

Similarly, another ALH described how a challenging relationship with their caregiver provided a less supportive environment for decision-making.

My grandmother has no time to sit down and talk with me because she is usually swamped. Again, she is very harsh, so I can never tell her anything she listens to. Sometimes, I can say something to her, and she will respond by telling me that I am making noise. So that usually makes me give up talking with her about anything. (Facility 4; ALH; R7; 16 years)

Some HCWs suggested that communication with ALHs was more accessible when parents fully disclosed their HIV status. For example, one ALH confirmed that parental disclosure facilitates HIV-related communication between the dyad.

There is nothing that I find hard talking with my parent because she disclosed to me quite early when I was still very young. Again, I made that decision because I now feel old enough. (Facility 3; ALH; R5; 17 years)

HCWs/research teams alongside adolescents

Some ALHs and caregivers agreed that ALHs should collaborate with HCWs and the research team because of their greater understanding of the subject matter.

They [ALH] should talk to the doctor because the doctors know what the research entails. (Facility 4; CG; R5; 38 years)

Because she [health care provider] is the one who has detailed information about that research, and yes, I believe that she will take her time to answer my questions, and I also believe that she is the only one who knows the benefits of the research. (Facility 6; ALH; R2; 15 years)

The ALHs and the caregivers typically focused on HCWs taking a consultative role because they were the most knowledgeable of the interested parties.

Influences on decision-making

When asked about influences on research decision-making, it emerged that ALHs' potential to contribute to science enhanced their willingness to participate in research. For example, one participant said, "I will be comfortable because I will share information" (Facility 4; ALH; R1; 15 years). Another said, "I can decide on my own because the study will benefit anyone from me" (Facility 6; ALH; R7; 16 years). Other ALHs were encouraged by the possibility of accessing new information through participation.

I decided on my own to join when she [HCW] called me and told me about it because, in my mind, I thought that through it, I would get new information that my peers could be having that I probably don't have... (Facility 6; ALH; R5; 17 years)

Risks were a deterrent to HIV research participation. However, transparency about risks was helpful. ALHs suggested that if the required information is provided, the ALH can decide whether to participate in the study.

They [study staff] must inform us prior about the study so that we have that in mind so that even if we get to decide on our own, we are already aware that such a procedure will take place. (Facility 5; ALH; R6; 17 years)

Confidentiality concerns also affected whether ALHs decided to participate in HIV research.

To be comfortable joining the study, I must first know the type of participants who will be in the study. Like are they all positive or negative, or are they all the same status? I may not be comfortable if others are negative and positive because the negative ones may tell others that I am [HIV] positive and taking HIV medication. (Facility 3; ALH; R6; 15 years)

Caregivers and HCWs felt stigma and losing confidentiality could deter ALHs' HIV research participation. HCWs and caregivers reflected on the challenges of stigma on HIV research participation.

Stigma is another big challenge for adolescents. You see, sometimes, they discover about themselves and feel that maybe they are different from others because they are taking drugs and others are not. So, because of stigma, they can disclose their status to others, and if they are not disclosing their [HIV] status, they may not participate in research. (Facility 4; HCW; R2)

The child could still suffer stigma, so deciding [to participate in research] may be hard for him. (Facility 3, CG; R6)

DISCUSSION

In this study, we explored the views of ALHs, caregivers, and HCWs about who should be involved in deciding whether adolescents participate in HIV research. Two main courses of decision-making were identified: individual decision-making and joint decision-making. With a few exceptions, ALHs and caregivers generally thought that the decision to participate in HIV research should be made by an individual, such as the ALH, caregiver or even an HCW/research team member. Additionally, given their knowledge and expertise, many suggested that the ALH must consult with the healthcare providers/research team. By contrast, HCWs and research teams viewed deciding to participate in HIV research as a joint exercise between the caregiver and the ALH. These findings have several implications.

First, the preference for individualistic decision-making was distinct from other research studies, and having HCWs or research team members make decisions for ALH research participation may raise ethical concerns about paternalism, conflicts of interest or exploitation that warrant further attention. Second, our findings suggest the need for further work to develop more explicit frameworks for SDM involving adolescents. Third, the

quality of caregiver–ALH communication influenced the possibility of collective decision-making, suggesting that improved family dynamics could enhance research engagement. Fourth, the capacity to consent was not necessarily the most essential factor in determining who should make decisions, particularly for older adolescents, and the authority to consent may be an underappreciated consideration for adolescent research decision-making. Finally, influences on adolescent willingness to participate in HIV research included perceived contribution to science, concerns about stigma and the study benefits/risks.

Perhaps our most striking finding was the individualistic approach to decision-making described by ALHs and caregivers in our study. Emphasis on individuals as decision-makers contrasts with existing ethical guidance promoting the engagement of adolescents and caregivers.³² Some of these differences may reflect the older age of participating ALHs (14–24 years old). While there has been recent literature highlighting reasons for adolescents to make decisions about HIV research participation for themselves, even these efforts often acknowledge the importance of finding ways to engage caregivers and improve adolescent–caregiver communication.³³ It was also surprising that some ALHs and caregivers are willing to cede decision-making authority to HCWs and the research team. Indeed, some ALHs and caregivers were open to allowing HCWs to decide for ALHs to engage in HIV research independently as they thought the HCWs were knowledgeable and could have valuable insights. While engaging HCWs and research teams can enhance the participation of ALHs,³⁴ allowing HCWs or research teams to decide on ALHs' research participation independently would raise ethical concerns. Making decisions on behalf of ALHs without their input would be paternalistic and unlikely to incorporate the values that matter most to ALHs and their caregivers. Additionally, researchers would have a conflict of interest, and such a process could make adolescents vulnerable to exploitation by exposing them to risks that they would not consent to otherwise.³⁵

Second, our findings illustrate contrasting preferences towards decision-making by the study respondents, suggesting that further research is needed to develop agreement on a framework (or perhaps on context-specific frameworks) to guide HCWs and research teams about working with ALHs and their caregivers. Rather than simply entrusting researchers or HCWs to make these decisions, an SDM approach for research participation might be more appropriate. SDM in clinical practice entails engaging in conversations with a patient to ensure the patient is well informed and that their preferences are incorporated into decisions regarding their illness and treatment. SDM primarily focuses on a dyadic interaction between patients and HCWs, with most conceptualisations and interventions failing to explicitly address the unique triad of caregivers, adolescents and HCWs.²⁶ The ethical justification for requiring parental permission

for children's research participation is grounded in respect for parental decision-making authority.¹⁷ Existing decision-making frameworks offer limited consideration of adolescents' unique developmental needs, especially in research decision-making.²⁷ Therefore, developing policies and guidelines and educating prospective research participants on the nature and their role in SDM can address some of the challenges around decision-making for HIV research participation.

Conceptually, paediatric SDM holds two important bioethical principles in tension—beneficence and respect for autonomy.³⁶ In other words, HCWs, research teams and caregivers should balance protecting ALHs' interests when they cannot do so themselves and respecting their autonomy when they can.³⁷ We found that HCWs and researchers sought to involve caregivers in ALHs' decision-making, irrespective of the adolescent's capacity and abilities to decide, because they put great weight on the need to protect adolescents and their perceptions of potential legal repercussions. The need to protect ALHs suggests that HCWs and researchers may benefit from more education regarding when a waiver of parental permission requirements is legally permitted and ethically acceptable. Researchers may also need to develop new ways of engaging caregivers that respect adolescents' concerns and protect their privacy. Finally, ethics review committees could provide clear guidance and support for researchers to understand when parental permission can be waived in their jurisdictions.³⁸

Sawyer and Rosenberg³⁹ suggest that researchers should also recognise that different families will share similar decisions in different ways based on their conception of relational autonomy. They further explain that varying degrees of sharing a decision could be acceptable and will depend on the potential risks and benefits, along with the values held by ALHs and caregivers.³⁹ Our findings add to this work, particularly as applied in the context of HIV, by suggesting that the HIV competency of their household also influences the willingness of ALHs to engage caregivers. Ideally, adolescents should be raised in an environment where they can be supported across the HIV care continuum.^{40 41} According to Masquillier *et al*,⁴¹ an individual whose HIV status is known in their household is more likely to receive sustainable support across the care continuum. To this end, ALHs who know their HIV status, primarily through parental disclosure, are more likely to participate in HIV treatment activities⁴² and, by extension, HIV-related research.⁴³ This implies that the household HIV environment and the caretaker–adolescent dyad relationship are crucial in decision-making for ALHs' consent to HIV research.⁴⁴ Therefore, interventions to improve parental to adolescent disclosure of HIV status and their communication about HIV may help enhance their participation in HIV-related research.

Third, our findings highlight the family environment's importance in fostering research decision-making. While having an HIV-competent household environment favours SDM between the ALH and their caregiver, a

challenging family environment may push ALHs towards independent decision-making. This finding corroborates findings from other studies. For example, one study conducted to explore the experiences of caregivers of ALHs found that they experience challenges related to family needs and psychological difficulties resulting from their own experiences during adolescence.⁴⁵ Additionally, a study conducted to explore the barriers and facilitators to participating in the Determined, Resilient, Empowered, AIDS-free, Mentored and Safe Study indicated that disagreements between the adolescent and their caregivers (grandmothers) hindered the adolescent's participation.⁴⁶ Interventions that improve family connectedness and communication, such as 'Family Talk'⁴⁷ and 'Family-Strengthening Intervention',⁴⁸ can improve family HIV competency and thereby enhance SDM between the ALHs and their caregivers. Further research may be needed for vulnerable subgroups of ALHs, particularly with male caregivers since evidence indicates that female caregivers provide better support to ALHs.⁴⁴

Fourth, an important area of contrast between our results and existing literature is that assessing adolescents' capacity to make decisions may not be the only relevant factor for determining when adolescents can independently consent for themselves.³⁷ While ALHs' autonomous decision-making is widely understood as dependent on their cognitive and psychosocial capacity,³⁸ our study identified that adolescents emphasised decision-making capacity and their perceived authority or a right to make decisions for themselves. This finding builds upon prior work by Shah *et al*,¹² showing that adolescents perceived parental consent requirements as an important barrier to their participation in HIV prevention research. We also found support from all groups, but primarily from ALHs and caregivers, for some adolescents to independently consent to participate in HIV research, particularly when caregiver involvement would be a barrier to engaging with adolescents. To address the confusion around who should be involved in the decision-making for adolescents' participation in HIV research, researchers should be aware that there may be significant disagreements about how best to engage adolescents in research. In the short term, this may mean greater community engagement and preparatory work may be necessary to develop a process that the relevant parties can agree upon. In the longer term, researchers should work to develop a context-specific SDM framework for ALHs' research participation by building consensus with the relevant parties.

Finally, our findings about barriers and facilitators to adolescent participation support the growing consensus around aspects of research that facilitate or deter participation. For example, other studies have similarly found that risks and social value are salient research features adolescents care about when deciding whether to participate.¹² There is growing evidence that although caregivers exhibit altruistic motives such as a desire to contribute to

medical knowledge, as we found among the ALHs, the most compelling motive for caregivers who enrol their child in clinical research is learning more about their child's illness, which was also highlighted by the ALHs.¹⁷

We also found that the participant's age could influence their views about their ability to participate in HIV research, with adolescents 16 years of age and older feeling more empowered to decide independently. There is no international consensus on the age at which an individual can decide to participate in research without parental involvement.⁴⁹ There are many exceptions to the general rule that minors cannot consent for themselves, including the concept of a mature minor—an adolescent below the age of majority who demonstrates the capacity to understand and make reasonable independent decisions about their well-being. Adolescents develop greater capacity and autonomy over time and potentially in different contexts,⁴⁹ necessitating flexible requirements for protection, participation and opportunity for autonomous decision-making among children and adolescents, particularly those who are older and/or of greater maturity, to provide valid informed consent.²⁷

Our findings also corroborate that confidentiality concerns and stigma remain essential barriers to research participation.⁵⁰ Accidental HIV disclosure and subsequent stigma were identified in a study as a risk to research participation, thus constituting a deterrent to research participation.⁵¹ Suggestions to implement privacy protections, consider recruitment locations carefully and develop supportive relationships with ALHs have been proposed to improve their possible participation in HIV research.⁵¹

LIMITATIONS

In our analysis, we combined responses from HCWs and researchers. We did this because before a research endeavour takes place, there is usually an agreement between the research team and the HCWs on how participants will be recruited. Furthermore, HCWs may be unlikely to recruit their patients for research unless they believe it is in equipoise or receive recruitment incentives, thereby providing some alignment between HCWs and researchers. These two groups also have more significant medical expertise than adolescents and parents. However, combining these parties' perspectives is a potential limitation of our findings, given the possible differences between these groups. For example, researchers may be more likely to be from other countries or be biased towards participation, and HCWs may have more of a trusted relationship with adolescents.

FGDs with ALHs were shorter than with caregivers and HCWs, suggesting that the data from caregivers and HCWs may have contributed more to our analysis than from adolescents. Nevertheless, in all the developed themes, we included the perspectives provided by the ALHs.

While qualitative research is inherently contextual, we did not directly analyse the decision-making authority and adolescent autonomy through a cultural lens. We recognise that culture plays an essential role in decision-making, especially regarding respect for elders, which can affect views on engaging adolescents in research in different contexts.^{52 53} Furthermore, different cultures may view ALHs' engagement in research very differently, so our findings may not generalise to other settings, and there may be a need to develop context-specific frameworks for SDM.^{52 53} While one strength of our study is that a large, multidisciplinary and international team interpreted the data, our team included members from urban settings in Kenya and the USA, and we may have missed nuances from participants with different cultural backgrounds in Kenya or from rural settings.

CONCLUSIONS

Engaging adolescents in HIV research is both critically important and challenging. Developing a robust consent process can ensure that adolescents make well-informed decisions that align with their interests but are not unduly deterred from research participation. Nevertheless, there is a limited understanding of who should decide about adolescent engagement in HIV-related research. We found that adolescents and caregivers tend to think decisions should be made independently, whether by adolescents, caregivers or HCWs/researchers. Developing, testing and disseminating an SDM framework for adolescent participation in HIV research, along with strategies to explore scenarios for individual consent and improve household HIV competency, should be further explored to enhance adolescent engagement in HIV research. Additionally, several factors influence adolescent decision-making about research, including concerns about risks and stigma. A deeper understanding of factors impacting ALHs' decisions about engaging in HIV research is essential for designing processes, systems, and guidelines and ultimately improving HIV prevention and treatment for ALHs.

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