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Community perspectives on the ethical issues surrounding adolescent HIV vaccine trials in South Africa

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Abstract

Summary—Adolescents globally are at high risk for HIV acquisition and are the targets of HIV prevention interventions such as HIV vaccines. In order to understand stakeholders' attitudes towards the ethical issues of adolescent involvement in HIV vaccine trials, we conducted focus group discussions with key members of a semi-urban, informal Cape Town community with high HIV prevalence in which HIV vaccine trials are taking place. Themes were identified from focus group transcripts by four researchers, and included necessity of guardian consent, age of independent consent, and confidentiality of in-trial medical results. In general, ethical adolescent HIV vaccine trials will be feasible in this community.

Keywords

Adolescents; HIV vaccine trials; community; ethics

Introduction

Youth worldwide are the fastest growing group of HIV-infected individuals [1], and this risk primarily involves females. Thus, HIV prevention efforts, including HIV vaccines and microbicides, should target this group. Despite over 15 years of HIV vaccine trials, to date no HIV vaccine trial has enrolled adolescents [2]. This is due to the need to enroll potentially vulnerable participants in research for whom individual benefits and risks of participation are undefined. The personal benefits for an adolescent taking part in a trial of a vaccine with unknown risks and without known efficacy may include indirect benefits such as HIV testing

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and counseling and easier access to health care. It is clear that societal benefits of adolescent inclusion in HIV vaccine trials exist. In fact, not including adolescents in HIV vaccine research at an early time point and delaying access of this high risk age group to the benefits of a successful vaccine is unethical. Therefore, there is a need to enroll adolescents in HIV vaccine trials whilst protecting individual vulnerable participants

There are many ethical complexities associated with enrolling adolescents in HIV prevention research trials [3-5]. Most centre on the need to balance an adolescent's emerging autonomy with ethical-legal protections which aim at reducing their vulnerability. All international research must adhere to the International Conference for Harmonisation (ICH) [6], and in some instances, local laws and guidelines additionally regulate research, such the US Code of Federal Regulations (Reviewed in [4]). Until recently, no specific legislation regulated research involving children or adolescents in South Africa, and guidance has been provided through the ICH [6], as well as local ethical guidance [7]. Using this approach, it has generally been held that consent for research involving children or adolescents should be obtained from participants or their proxy and that children are entitled to privacy regarding research participation [8]. Soon, a comprehensive ethical-legal framework for health research will be operationalised by the National Health Act [9], introducing three major changes; firstly, written consent must be obtained in all circumstances, secondly, minors (persons under 18) may not provide independent consent for research in any circumstances, and thirdly, consent for child research must be obtained from a parent or legal guardian and not any other caregiver. In addition to adhering to the law, any research involving minors will also need to be ethical, it must be relevant to minors, and have acceptable risk standards that are outweighed by benefits[10]. This is somewhat in line with international norms [4]. The research must also respect the participant; particularly relevant in this case is respect for their privacy. However, the rights of adolescents to confidentiality become complicated by provision of proxy consent. There are no data addressing these and other complexities within HIV vaccine research involving adolescents.

HIV vaccine trials are enrolling adults at multiple sites in South Africa. One such site is in Cape Town, in an informal community, where the antenatal HIV prevalence is approximately 28%. Throughout the district there is diverse socio-economic status and housing is both formal and informal. HIV vaccine trials started in this community in 2005 and were preceded by a widespread education campaign around HIV vaccine research. In this paper, we explore the community perspectives on the major ethical issue of consent and confidentiality pertaining to adolescent involvement in HIV vaccine trials, as these issues emerged strongly from the focus group discussion and have been previously identified conceptually important [3,5,8].

Materials and methods

The study instrument used was a semi-structured focus group guide. The guide included topics such as attitudes towards HIV vaccine trials, and adolescent inclusion in such trials, reasons for parents allowing or refusing their adolescents to take part in HIV vaccine trials, and parental access to study results (table 1). For the few participants who had never previously heard of HIV vaccine trials, a brief overview was given before the focus group.

A total of 200 participants were included in 18 focus groups. An audit of relevant community stakeholders was performed, and groups working with adolescents on HIV/AIDS related issues were identified. Teachers were chosen who actively participated in HIV/ AIDS awareness at their respective schools. Parents, youth and adolescents were recruited via community outreach activities at community meetings and clinics. Focus groups were conducted in Xhosa, and were tape recorded with participants' permission. Focus groups with adolescents were conducted in the form of role-plays and scenarios to encourage maximum participation. Groups were held

separately with adolescents (two groups), youth aged 18 to 30 years (three, including one church-based youth group), parents (three groups), teachers (three groups), community based organizations (four, including one group of home-based carers, one group of HIV counselors, one woman's group, and another HIV non-governmental organisation), one adult and one adolescent HIV vaccine community advisory board (CAB) group, and one mixed adult and adolescent CAB group. Church youth groups are groups of church members aged 18 to 24 years that have formed a social network. Some participants were acquainted prior to the meetings; however, this was not true for the parent and adolescent groups. There were a mean of 11 persons per group (range 5 to 23) and the length of each session was approximately two hours.

Data were transcribed and translated into English. The method of analysis used was "thematic analysis"[11]. Focus group transcripts were read by four individuals from the research team to avoid bias. The focus group discussion facilitator also participated in the analysis. In order to enable comparison across and between participant groups (e.g. adolescent versus adult), a stratified analysis was undertaken. First, transcripts were read and coded by participant type. Each individual extracted similarities and differences and these were constantly compared with central themes. Thereafter, themes were compared across participant types.

The study was approved by the University of Cape Town's Research Ethics Committee. Prior to the focus groups, informed consent was obtained from all participants over 18 years and from parents of participants under 18 years; assent was obtained from participants under 18 years. All responses were confidential, including those of the adolescents.

Results

Throughout the focus group discussions, it was clear that there was varied understanding of the concept of HIV vaccine trials and therefore the discussion was tailored to the level of knowledge of the group. Several themes arose around the concept of consent for study participation and parental access to adolescent participants' HIV, pregnancy and STI test results.

1. Consent

1.1 Who should consent?

There were diverse opinions about whether parental consent for adolescent participation is necessary. There were participants of all ages who felt that informed consent from a parent or guardian for adolescent involvement in HIV vaccine trials is necessary.

"We should be able to give permission; these are our kids." (Mother)

Most adolescents felt the same way:

"We want our parents to consent for us." (Adolescent CAB member)

The most common reasons given for requiring the consent of a parent or guardian were that such research involves risks.

"...the person should be accompanied by a guardian at the end of the day who will act there as the child's legal wise." (Church youth - female)

However, the emphasis was less on the need for parental involvement to make informed decisions about participation, and more on the need for parental support during the trial:

"Parents should be involved so that should something bad happen, your parents know." (Male adolescent)

Both adults and adolescents acknowledged that the benefits of involving parents or guardians are numerous and include better retention within the study. The adolescents themselves recognised that as an age group, they could potentially be unreliable:

“At least if your mom knows, she will remind you.” (Female adolescent CAB member)

“A 14 year old child is not reliable, she will always choose the other things” (Female adolescent CAB member)

However, some adolescent participants felt adolescents are mature enough to make decisions for themselves:

“There is that saying that “umntu yinkosi ukuzazi” (you know yourself best).” (Female adolescent CAB member)

A common justification for independent adolescent consent was that children in South Africa have to face situations and responsibilities that generations before have not had to face and are therefore maturing much faster:

“When you look at the things that are happening outside, these kids mature at very early ages and ...by the age of 18 they ... know everything. So the law doesn't really match what is happening in our communities.” (Female teacher)

“These days a 14 year-old is very mature. The environment we live in makes them be so.” (Female adolescent CAB member)

There were various reasons given for why parents should not consent for adolescents. Firstly, many adolescents are not living with their parents, or their parents are uninvolved or unsupportive:

“There are those parents who won't sign the consent form for their children ...they are busy in the shebeens (bars).” (Male youth)

“But what about those parents who don't support their children.” (Male youth)

Secondly, parents are not always the best people to consent, as often other family members are taking care of the adolescents, due to cultural norms, parental neglect or social circumstances. In this case, participants suggested that other family members should be better equipped to provide consent:

“If the parent doesn't care about the child's wellbeing, how about you ask the child to come with a family member who is a person close to the child?” (Female adult CAB member)

There were even advocates for community consent for adolescent participation in HIV vaccine research.

1.2 Age of independent consent

There were varied opinions as to the age that adolescents should be able to give independent consent. Some adolescents felt that they should be able to consent for themselves from the age of 14 years. However, few youth or adults agreed. Participants in all groups suggested that at the age of 16 years, an adolescent should be able to consent for themselves:

“[Before 16] a parent is needed to be part of the research because ... deep in his/her heart the child cannot differentiate between a right thing and the wrong one...” (Male adult CAB member).

“I think this should start at 16, because at that age we are able to make our own decisions without our parents.” (Adolescent CAB Member)

Some mothers felt that the current independent consent age of 18 years was appropriate. Some participants felt that parental consent has less to do with age, and more to do with individual maturity, which was closely linked to financial independence:

“There are some people who, even though they are 18, still act as if they are 13 ... they still depend entirely on their parents to make decisions for them.” (Female adolescent CAB member)

“Even if you are 21 years old, if you are still staying under your parent’s care, it is their responsibility to bury you when you die.” (Male HIV counselor)

“...because you are still under your mother’s roof, you still depend on her, she still tells you what to do”(Female adolescent)

1.3 True understanding of the consent and trial process

There was concern expressed over whether younger adolescents would truly understand the consent process and the complexities of HIV vaccine trials:

“At that age they cannot think broadly like 18 and 25 year-olds would.” (Female church youth)

The majority of concerns about potential lack of understanding lay around disinhibition of sexual behaviour:

“Children would be reckless because they would have hopes to get a vaccine after all.” (Male church youth)

“These 14 – 17 year-olds, won’t there be misinterpretations of the intentions of the vaccine trial and they get false hopes?” (Male teacher)

Participants recommended extensive age-appropriate education for both parents and adolescents about the process, in order to ensure true understanding, particularly with the use of visual tools and the media:

“I would like to ask whether you have videos because children of that age group, when they see something from the television they pay lots of attention, more than when you are telling them personally.” (Male church youth)

Recommendations were also made for assessing true understanding, which mainly involved testing of the participant and then clarification of the misunderstandings identified.

2. Confidentiality

2.1 Medical test results within the research

The majority of adolescents and youth thought that adolescents are entitled to privacy regarding tests conducted during the trial:

“We shouldn’t be forced.” (Adolescent CAB member)

“They cannot be given access. Seriously, the issue of HIV results is very confidential.”(Male church youth)

“Maybe you didn’t yet want to disclose your results and that is your decision ... they should get them from me when I’m ready” (Male adolescent)

Furthermore many parents and other adults agreed that the child has a right to decide whether parents or guardians should have access to results:

“That would depend on the type of... relationship the parent has with her child.” (Adult CAB member)

“It is her right to tell me; I cannot force her.” (Father)

“I think you should leave that decision to the children as they are the one who know their parents better than us” (Female Educator)

Some felt that there should be differing degrees of confidentiality for HIV versus pregnancy test results. Participants suggested that because STI's are easily treated, there is no need to inform parents or guardians. However, since HIV was permanent and potentially fatal, parents should have access to these results:

“At least an STI wouldn't require the child to be taken care of like HIV, so a child would keep it confidential if he/she wants to. It is totally different with HIV because at the end of the day when this child gets sick, you will be the one taking care of her.” (Female NGO staff member)

Pregnancy test results were also controversial:

“With pregnancy and HIV it's different. But with STI's you can cure them and people won't have to know.” (Female adolescent CAB member)

“With abortion, it is only between her and her God and Satan. It doesn't concern us parents at all.” (Female NGO staff member)

Concern was expressed that parents perhaps would not maintain confidentiality:

“It's because I know that my mother won't support me; instead she will go and tell the neighbour what a whore I am when I have an STI or HIV.” (Adolescent CAB member)

“Maybe the mother is drinking and she won't keep her status confidential.” (HIV counselor)

Concerns were also raised, particularly by the teachers, that disclosing confidential information may not be in the best interest of the minor. It was feared that some parents would be unsupportive or even verbally abusive:

“Sometimes telling a parent these things might not help these children.” (Female teacher)

There were many concerns, not only from the adolescents themselves, but also from teachers and parents, about the possibility of physical abuse by parents:

“If you insist on telling the parent, that child might end up being a victim at home and you won't be there to protect that child.” (Female teacher)

On the other hand, there were many participants, even adolescent ones, who felt that parents should have access to test results:

“They must give permission for their children to be tested and again not have the results of their children? This is really not fair.” (Female teacher)

“S/he is my child and whatever happens to him/her is my responsibility.” (Male youth)

Reasons for parental access to results included the need for parents to be able to offer appropriate emotional support and care:

“...no matter what, parents should have that information so that they are able to give their children support should it be necessary...” (Female teacher)

“They need to know, for instance, if you are HIV-positive, in order for them to take care of you.” (Female adolescent)

Finally, varied opinions were expressed as to who should be responsible for disclosure of results to parents and how it should be done. Whatever the process, it was agreed that it should be made clear to participants and their parents at the start of the trial.

“There would be an understanding before the child participates that the parent would be entitled to certain information and the parent needs to know very clearly how this study will be done or that some of the results might be confidential.” (Female HIV counselor)

Some thought it should be up to the adolescent to divulge their confidential information. However, other participants, particularly adolescent ones, felt more comfortable with the researchers passing on the adolescents’ confidential information.

“Only when you are ready and you want your parents to know, you can ask the researcher to tell them.” (Adolescent CAB member)

Participants made many constructive suggestions regarding access to test results, summarized in Table 2.

2.2 Could degree of confidentiality impact study design and recruitment?

Young adults perceptively raised concerns that informing adolescents that their parents would have access to test results could impact on the risk group that would be recruited, which would bias results, and would impede recruitment:

“[If parents have access to results] the kind of a person who will go there (enroll) will be the one who knows he/she...has nothing to hide. So this will ... impact of the kind of people/children you want to recruit for your study.” (Female church youth)

“When you tell children that you will grant their parents permission to their results, I really think you will lose too many children.” (Male church youth).

Discussion

To our knowledge, this is the first in-depth exploration into community perspectives on adolescent inclusion in HIV vaccine trials in South Africa, and elsewhere. There have similar studies amongst adults in other settings [12], and some quantitative studies of willingness to participate in HIV vaccine trials in Africa [13,14]. Our study explored in-depth perceptions around the two major ethical aspects of adolescent HIV vaccine trials, consent and confidentiality, amongst a broad selection of community stakeholders.

These focus groups confirm that the South African ethical and legal principles [7,9,15], and that of many other countries [4] regarding consent are generally acceptable to this community for vaccine research. Most participants agreed that adolescents should not be enrolled in an HIV vaccine trial without consent from a parent or guardian. However, where they disagreed with the law was with regard to the age at which such a protection should fall away. The majority felt that at the age of 16 years, instead of 18 years, adolescents should be able to consent independently to research. Regardless of the age of independent consent, participants recommended that procedures be put in place to ensure true understanding. Participants also deviated from the law with regards to who should give consent for an adolescent. The consensus appears that the law does not take into account current cultural norms and perceptions of family, where a broader range of persons are responsible for adolescents, rather than only parents or legal guardians. It was felt that this larger family should have the authority to provide consent for participation in research.

Section 13 of the South African Children’s Act [15] provides that every child has the right to privacy regarding their “health status”. However, this right may be limited where maintaining

confidentiality is not in the best interests of the child (s13(1)(d)). Section 133 of the Act also specifically provides that no person may disclose a child's HIV status without consent unless they are required to do so by law. In the USA, the Health Insurance Portability and Accountability Act (HIPAA) provides protection for health care information for adolescents, which applies to research. With regard to privacy, participants recognized many of the complexities regarding an adolescent's right to privacy within research. They stated that different aspects of a trial should be treated differently, and that where test results would have a significant impact on a child's life, children should be encouraged to disclose to their families in order to access support. Participants also identified the need for additional social support for adolescents as in many cases adolescents could face abuse rather than support if they disclosed, for example, their HIV status. Finally, participants agreed that reporting of child abuse may not always be in the best interest of the adolescent.

Participants recommended that disclosure support be offered to both adolescents and their parents or guardians. Furthermore, participants felt that adolescents themselves were best placed, if need be, to identify a responsible adult other than their parents who would be able to provide more appropriate support. This is in keeping with the broader definition of family in this culture.

In addition to providing in depth attitudes toward HIV vaccine trials involving adolescents, these focus groups provided valuable insight into the hardships faced by adolescents in this and other communities in South Africa. Frequent concerns about lack of parental support, parental neglect and alcohol abuse, and sexual abuse were expressed. Researchers will need to be cognizant of these added vulnerabilities of the adolescents with whom they work.

These focus groups have provided valuable insights and recommendations for researchers who plan to conduct HIV vaccine trials involving adolescents. It is clear that enrolling adolescents will take more time and resources than their adult counterparts. Although some ethical incongruencies in the current framework exist, in general from a community perspective, adolescent enrolment within this structure appears acceptable and feasible.

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Table 1

Sample focus group discussion prompts

Group	Sample prompt
Adolescents	Role play: The interviewer is accompanied by two educators, and one would act as the researcher and one as the parent who comes to the clinic and wants to know her child's HIV test results. Adolescent participants would be asked to comment on whether that parent has the right to do that, what should happen, what should the researcher do etc?
Parents	"Should parents/guardians need to give consent or adolescents should be able to participate without your consent?"*
Teachers	"Do you think adolescents should/should not be included in HIV vaccine research?"*
Counsellors	"How do you feel about HIV and sexual risk in adolescents?"*

* Many of the same prompts were used for all groups except for the role play.

Table 2
Participant recommendations regarding access to sensitive information within
adolescent HIV vaccine trials

Support for disclosure should be provided to both the adolescent and their parent or guardian
Education sessions should be provided to adolescents and parents about HIV, STI, abuse etc
Adolescents should be able to identify a responsible adult to whom they can turn to for support should their parent not be appropriate
The rights to or limits of confidentiality should be made clear upfront to both adolescent and guardian
Ultimately, the approach to disclosure of confidential information should be individualised