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ORIGINAL RESEARCH ARTICLE

A qualitative assessment of perspectives on the inclusion of adolescents in HIV vaccine trials in South Africa

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Summary: Adolescents are at high risk for HIV acquisition, and thus need to be included in HIV vaccine trials. In preparation for inclusion of adolescents in HIV vaccine trials in an urban community in Cape Town with a high antenatal HIV prevalence, the study assessed the attitudes towards the inclusion of adolescents in HIV vaccine trials. A total of 18 focus group discussions were conducted using a semistructured interview guide. The participants ($n = 200$) were adolescents, young adults, parents and other key informants. Participants from all groups welcomed the inclusion of adolescents in HIV vaccine trials due to their high-risk status. There were, however, concerns about sexual disinhibition, fear of side-effects, fear of HIV testing and disclosure of HIV status, mistrust of nurses and clinics. The study highlighted a number of ethical and social issues that need to be addressed before the trials.

Keywords: HIV vaccine trials, adolescents, community consultation, South Africa

INTRODUCTION

The number of sub-Saharan Africans living with HIV continues to grow, especially among people under 25 years, often due to their engagement in risky sex.[1–6] An HIV vaccine is our best hope for halting the spread of AIDS. Adolescents prior to sexual debut are an important target for vaccination, yet no HIV vaccine trials have included adolescents thus far. Inclusion of adolescents in HIV vaccine trials is complex due to the perceived vulnerability and risk-taking that characterize this population, thus posing social, ethical and legal challenges.[7,8] This study was launched as a preparatory phase to assess the inclusion of adolescents in future HIV vaccine trials in an urban community in Cape Town, South Africa. Its aim was to inform the inclusion of adolescents from a high-risk community by obtaining a clear understanding of youth culture and motivations; issues around parental consent; adolescent, parental, and greater community fears and stigmas around HIV and vaccines; adolescent health needs; and community adolescent resources and support structures.

METHODS

Study participants

Eighteen focus group (FG) discussions were conducted with a total of 200 participants. Participants included 34 adolescents (14–17 years), 24 young adults (18–35 years), 27 parents with adolescent children who were not linked to the adolescent participants, 23 youth from church-based organizations, 26 teachers from local high schools, 22 members of community-based organizations (CBOs) working with HIV-positive people, 16 HIV/AIDS counsellors from local clinics and 28 members of the adolescent and adult HIV vaccine trial community advisory boards (CABs). There were a mean of 11 persons per group (range 5–23). Participants were recruited by the community educators through community-based education campaigns from local high schools, youth clubs, clinics, churches, CAB and other CBO. The majority of the FGs were confined to a single sex and age group. In order to generate varied responses, some FGs contained members of both genders (parents, adolescents and youth) (Table 1). The study was approved by the University of Cape Town's Research Ethics Committee. Prior to the FGs, informed consent was obtained from all participants over the age of 18 years in a group setting. For adolescents under the age of 18 years, we sought consent from their parents and assent from the adolescents themselves.

Study setting

The study was conducted in a well-established Xhosa-speaking community in one of the Cape Metropole districts. The district is formed by six large townships where the antenatal HIV prevalence is 29%.[9] Throughout the district there is diverse socioeconomic status and housing is both formal and informal. HIV vaccine trial related activities have been established by the Desmond Tutu HIV Centre since 2004. These include outreach and community education programmes and phase II HIV vaccine trials. FGs were conducted in various accessible

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Table 1 **Demographics of FGD participants**

	Number of groups	Gender	Age range (years)
Adolescents	2	Male	14–17
Adolescents	1	Mixed	14–17
Youth	1	Male	18–30
Youth	1	Mixed	18–30
Teachers	1	Mixed	35–55
Teachers	2	Female	29–55
HIV counsellors	1	Mixed	Not collected (adults)
Community-based organization employees	1	Female	Not collected (adults)
Parents	1	Mixed	45–65
Mothers	1	Female	25–60
Fathers	1	Male	45–65
Church youth group members	1	Mixed	18–24
Adolescent CAB members	1	Mixed	14–18
Adult CAB (mixed)	1	Mixed	20–59
Adult plus adolescent CAB members	1	Mixed	16–50
Home-based carers	1	Female	18–56
Home-based carers	1	Mixed	29–39

FGD = focus group discussion; CAB = community advisory boards

venues around the community. These included community halls, churches, offices, schools, clinics and homes.

Study instrument

The study instrument used was a semistructured FG guide and the FGs were conducted by a Xhosa-speaking researcher. The guide included topics such as attitudes towards HIV vaccine trials, attitudes towards adolescent inclusion in HIV vaccine trials, the potential influences on adolescent's decisions about taking part in the HIV vaccine study, parents' opinions about allowing or refusing their adolescents to take part in HIV vaccine trials, issues around parental consent and parent access to study results (including HIV, pregnancy, sexually transmitted infections [STIs] and illegal sexual activities).[10] Although the interview guide was the same for all FGs (except that of the adolescents role-plays), not all topics were broached with every group.

Data collection and analysis

FGs were conducted in the participants' home language (Xhosa) and were tape recorded with their permission. FGs with adolescents were conducted using role-plays and scenarios where adolescents watched staff members discussing HIV vaccine trials and were asked to add and comment on the discussions and were also given possible scenarios of adolescents involved in HIV vaccine trials and asked to comment. These were introduced to encourage maximum participation from adolescents. Every attempt was made to avoid bias naturally introduced by role-plays. Data were transcribed and then translated into English. FG scripts were read by five individuals from the research team using thematic analysis.[11] FG questions were used to group data, and each individual extracted similarities and differences and these were constantly compared with central themes. New codes were added for the second set of data.

RESULTS

There was some variation between the levels of understanding of HIV vaccine trials between the groups, and for some, the facilitator had to provide a brief introduction. Due to the nature of CABs, both the adolescent and adult CAB members were far more sophisticated in their knowledge. In general, the facilitator found the non-CAB adolescent groups had trouble following the discussion, but that the youth groups, CBO members and teachers understood far better. The results of the FGs showed that despite the support for the inclusion of adolescents in future HIV vaccine trials, there are also challenges. Major themes emerged around community involvement in health research, knowledge and attitudes towards HIV vaccine trials and adolescent inclusion. The prospects of including adolescents in HIV vaccine trials were influenced by recognition of high HIV risk among adolescents and early sexual debut, access benefits such as adolescent friendly voluntary counselling and testing (VCT) and altruism. Perceived challenges were centred around concerns about sexual disinhibition, fear of side-effects, mistrust of nurses and negative experiences in clinics, fear of HIV testing and disclosure of HIV status, and parental access to study test results and sensitive information. Insightful suggestions to overcome the challenges were made.

Community involvement in research

Adult participants regarded this research project as part of a participatory process of gaining community consent for vaccine trial research, and they expressed appreciation for being consulted and involved in decisions around vaccine research – 'these days research is accessible to people, understand! Because previously, things were done and we didn't have any idea of what's going on about them' (female parent). In particular, they appreciated being consulted by researchers who spoke their own language, with whom they could identify, and whom they trusted to represent their interests. This was in contrast to their previous experiences of research conducted by people with whom they could not communicate, and therefore felt they could not trust.

However, there was an element of skepticism towards medical research among teachers – 'people like to do research and use people … and not think about the effects it will have on the people …' (female educator). They wanted to know the rationale behind choosing their communities as study sites and the diversity of the research across other races in South Africa. One teacher indicated that – 'this might have unintended outcomes where people might feel that they are used, understand, … unfortunately we have a long history of apartheid where blacks were exploited' (male educator).

Knowledge of and attitudes towards HIV vaccine trials

Although some participants did not have specific knowledge of HIV vaccines, they had general vaccine knowledge, which made it easy to conceptualize HIV vaccines. There were positive and negative perceptions about HIV vaccines. Parents were most welcoming of HIV vaccine trials with the hope or belief that a successful vaccine or the research itself will provide some protection for their children – 'it is going to protect

them against the one thing that they fear most (HIV)' (mother). Teachers were also quite knowledgeable and welcoming of HIV vaccines – 'I see it as a right thing to test the vaccine in humans because it cannot be tested in something else as it is affecting humans' (female educator).

Attitudes towards adolescent inclusion

Adolescent inclusion in HIV vaccine trials was supported, especially due to the current lack of hope for future generations – 'this vaccine is needed because we have buried our children, do you get me!' (father). Teachers understood the need to test vaccine efficacy in adolescents – 'you need to do that now and not wait until the vaccine is successful and only give it to them then, what if at that stage you find out that it's not right for them and then it would be too late' (female educator). Adolescents also welcomed their inclusion in future HIV vaccine trials – 'I don't see anything wrong with testing the vaccine on us … it's us who are dying of AIDS' (female adolescent).

However, there was some hesitation expressed, especially among parents, probably due to lack of understanding of trial concepts – 'it's very difficult to allow your child to go and participate in something that you even yourself (as a parent) have no idea of what's going on' (mother). This issue was also emphasized by the CABs – 'if the parent is not well informed he/she will not allow their child to be part of the research' (male adult CAB).

Perceived facilitating factors

Recognition of high HIV risk among adolescents and early sexual debut

Parents expressed a great amount of concern about today's youth's risky behaviours – 'we cannot run away from the fact that these children are highly sexual active' (female CBO). Thus they welcomed the inclusion of adolescents in HIV vaccine trials – 'They are fortunate that at least there is a possibility that something might come up, to protect them. Because really these children, they need it' (mother). Today's youth sexual risk behaviour was perceived as a result of the pressure emanating from social norms that promote early sex (media, peer pressure) and the limits of parental influence and control over children. Teachers agreed with parents – 'they are the ones who are mostly exposed to these things that are happening out there seeing that the values in our communities have dropped' (female educator). Also the perception that sexual debut among adolescents occurs at a very early age served as a motivator for adolescent inclusion in HIV vaccine trials. HIV counsellors were also supportive of adolescent inclusion in HIV vaccine trials – 'I think this is a very good idea as these children at the age of 12 are sexually active, they are at risk' (male HIV counsellor). Adolescents themselves agreed that they are at high risk for HIV: 'it's us young people who are after these things, most of us have sex even at the age of 14' (male adolescent).

Adolescent-friendly VCT and other counselling

VCT is a successful HIV prevention intervention.[12] However, there are many barriers for VCT uptake among adolescents. Adolescents saw participating in a vaccine trial as an enabler for them to undergo VCT, and thus know their HIV statuses – 'I'm saying they should be part so that they can be informed and also be aware of their status' (female adolescent). Members of the CAB identified adolescent-tailored counselling as a possible motivator for adolescent participation – 'I think it's good to participate in HIV vaccine trials because of certain benefits that you might get, like … for us black people we don't have those services where you have access to counseling, perhaps for a person to go to therapist' (male adult CAB).

Altruism

Altruism was expressed by both adolescents and parents – 'They [adolescents] can help others as they will be helping with the process of finding a vaccine that works' (mother). According to parents, one of the reasons that adolescents would want to participate in vaccine trials is so that they 'can help others as they will be helping with the process of finding a vaccine that works' (mother). Adolescents saw participating in a vaccine trial as a constructive way of spending their time, – 'I think my friends will be interested … we like to be involved in these things to keep ourselves busy' (female adolescent).

Perceived challenges of adolescent inclusion in HIV vaccine trials

Concerns around sexual disinhibition and lack of understanding about efficacy

Parents felt that if they encouraged their children to participate in HIV vaccine trials, they might be misinterpreted as encouraging their children to have sex – 'if we tell our children about this vaccine thing, it might seem as if we are encouraging them to go out and jol [party]' (mother). A male parent agreed with this point – 'yes, they will just behave in whatever manner they want because they know that they are safe' (father). Adolescents also admitted to this – 'like let's say … I get this cherrie [girlfriend], then I would know that I am safe and that the vaccine will help me' (male adolescent). When asked if their friends would be interested in participating, one said – 'mine would be interested in anything that might protect them against HIV, so that they won't have to worry for condoms' (male adolescent). This was seen as having a potential of encouraging multiple-sexual partners – 'so now they might have more girls and know that they took the vaccine so whatever they do they are protected' (female adolescent). These were unfortunate misperceptions about the degree of protection an experimental HIV vaccine would provide. Teacher viewed HIV vaccine trials as challenging their efforts of promoting condom use among adolescents as they are promoting abstinence, faithfulness and condom use. They felt that the introduction of an effective post-licensure HIV vaccine might discourage adolescents from using condoms and therefore increase their risk for other STIs and pregnancy which will not be protected by an HIV vaccine – 'this vaccine thing is going to contradict us because at the moment we are still preaching safe sex and the use of condoms. When we talk to the kids we tell them that a condom is not only protecting against HIV/AIDS … but also for other things, like pregnancy and STDs' (female educator).

Fear of side-effects

For some of the parents, the potential for side-effects was a very big concern – 'Eish, I will not allow my child to be part of the study!

You see, what makes me to refuse is this issue with side-effects. When you see your child suffering from them, you will end up regretting to ever let her be part of the study in the first place' (mother).

Similar sentiments were expressed by some adolescents – 'I think people might be scared of these things that are tested, thinking that as time goes by, they might become sick, you see' (female adolescent). In other FGs, participants raised questions like – 'will vaccine trials have the power to detect less prevalent side-effects?' (male educator). '. . .after vaccine trials I develop a disability or something. So I want to know what will happen to me after that incident' (female CBO). 'What if it could kill people?' (male youth).

Mistrust of nurses and negative experiences in clinics

This view was mainly shared by adolescents because of the negative experience either they or their friends had in the public clinics – '. . . the nurses are very rude in those clinics' (female adolescent). The adolescents repeatedly argued that the clinic environment is not conducive for them due to the negative attitudes of the nurses and counsellors; lack of confidentiality; lack of privacy; fear of being stigmatized as well as clinic administrative issues such as long queues and inconvenient operating hours. 'These counsellors they even talk in the passages, perhaps the counsellor is walking down the passage to her room with the results and responds "hey 3 are positive and 2 are negative" . . . So everybody now knows' (female adolescent CAB member).

However, clinic staff members had an opposite view – 'Sometimes they [adolescents] are lying' (male HIV counsellor). When asked how they feel about adolescent use of services, one counsellor said – 'You feel discouraged because seeming she didn't utilize the information you've given her' (female HIV counsellor).

Fear of HIV testing and disclosure of HIV status

Although some thought the access to HIV testing was an advantage of trial participation, others, especially adolescents and the people from CBOs working with HIV-positive people, were concerned about the requirement for HIV testing, disclosure of positive study results and the potential stigma associated with those – 'for me it would be easy if there were no tests first' (male adolescent); 'most people do not want to get tested, they are still afraid to test. We cannot force people to go for VCT' (female CBO member). This concern was also shared by some of the youth: – 'no, I won't get tested myself . . . because the position that I'm in right now, I don't think if I could be diagnosed HIV positive I would be able to accept it, I would rather commit suicide' (male youth).

Parental access to study test results and sensitive information

Participant's attitudes toward parental access to study test results was perceived as a possible barrier. Although adolescents reported that parents should consent to their participation in vaccine trials,[10] they expressed concern about lack of control over access to their study results – 'but what about confidentiality, that's my business not hers [her mother's]' (female adolescent).[10]

DISCUSSION

The effects of HIV/AIDS as well as the potential benefits of an HIV vaccine for adolescents were clear to all participants. As was the case with other studies in South Africa and abroad, we found the perceived adolescent risk of HIV infection was the most important motivator of acceptance of adolescent HIV vaccine trials.[13–15] The history of apartheid in South Africa may have left behind additional challenges for some populations to wholly accept HIV vaccine research without skepticism.[16] Researchers need to be sensitive in their approach to recruitment of study participants.

It is important to include adolescents in HIV vaccine trials to ensure development of an adolescent-suitable vaccine, as adolescents and children may be physiologically and immunologically different from adults, and this therefore may affect the safety and efficacy of vaccines.[17] However extra precautions should be taken due to their vulnerability, and the developmental changes that occur during this phase of life.[18] Similar to other studies conducted in developing countries, eminent barriers to participation were fear of vaccine side-effects and confusion about how HIV vaccines work.[8,19,20] There was also a concern that availability of an HIV vaccine might discourage the use of condoms which protect against pregnancy and other STIs. It is important to address all these concerns about the social implications of participating in a vaccine trial beforehand.[8] Researchers need to understand influences on adolescent's understanding and develop methods to assess understanding prior to their participation in research.[20] This would guard against adolescent sexual disinhibition within the trial.

This community supports the inclusion of adolescents in future HIV vaccine trials driven largely by the recognized susceptibility of adolescents to HIV. The results of this study highlight issues that need to be addressed by clinical trial site staff. Privacy and confidentiality should be negotiated before participation. Counselling should be appropriate for adolescent social and emotional development.[21] Trial site staff must provide a supportive health-care infrastructure and study setting that balances the need to be 'adolescent friendly' with the needs of parents, and should support both disclosure by adolescents when required, or manage parents' expectations when not. Extensive education needs to be conducted and these issues addressed before the commencement of vaccine trials.

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