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Adolescent decision making about participation in a hypothetical HIV vaccine trial

Andreia B. Alexander[a,*], **Mary A. Ott**[a], **Michelle A. Lally**[b], **Kevin Sniecinski**[c], **Alyne Baker**[d], **Gregory D. Zimet**[a], and **the Adolescent Trials Network for HIV/AIDS Interventions**

Andreia B. Alexander: andreia.alexander@gmail.com; Mary A. Ott: maott@iu.edu; Michelle A. Lally: Michelle_Lally_MD@brown.edu; Kevin Sniecinski: sniecinskisf@aol.com; Alyne Baker: abaker4@tulane.edu; Gregory D. Zimet: gzimet@iu.edu

[a]Section of Adolescent Medicine, Department of Pediatrics, Indiana University School of Medicine, 410 West 10th Street, HS 1001, Indianapolis, IN 46202, United States

[b]Department of Medicine, Alpert Medical School of Brown University, Box G-A1, Providence, RI 02912, United States

[c]Department of Pediatrics, University of California, 505 Parnassus Avenue M696, Box 0110, San Francisco, CA 94143, United States

[d]Section of Adolescent Medicine, Department of Pediatrics, Tulane University School of Medicine, 1440 Canal Street, TW-42, New Orleans, LA 70112, United States

Abstract

Purpose—The purpose of this study was to examine the process of adolescent decision-making about participation in an HIV vaccine clinical trial, comparing it to adult models of informed consent with attention to developmental differences.

Methods—As part of a larger study of preventive misconception in adolescent HIV vaccine trials, we interviewed 33 male and female 16–19-year-olds who have sex with men. Participants underwent a simulated HIV vaccine trial consent process, and then completed a semistructured interview about their decision making process when deciding whether or not to enroll in and HIV vaccine trial. An ethnographic content analysis approach was utilized.

Results—Twelve concepts related to adolescents' decision-making about participation in an HIV vaccine trial were identified and mapped onto Appelbaum and Grisso's four components of decision making capacity including understanding of vaccines and how they work, the purpose of the study, trial procedures, and perceived trial risks and benefits, an appreciation of their own situation, the discussion and weighing of risks and benefits, discussing the need to consult with others about participation, motivations for participation, and their choice to participate.

Conclusion—The results of this study suggest that most adolescents at high risk for HIV demonstrate the key abilities needed to make meaningful decisions about HIV vaccine clinical trial participation.

[*]Corresponding author at: Department of Emergency Medicine, Rutgers – New Jersey Medical School, 30 Bergen Street, Newark, NJ 07101, United States. Tel.: +1 973 972 9261; fax: +1 973 972 9268.

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Keywords

HIV vaccine trial; Decision making; Adolescent; Qualitative research

1. Introduction

Adolescents and young adults aged 13–24 accounted for 26% of new HIV infections in the United States in 2010 [1], and are therefore an important target for prevention. For legal and ethical reasons, HIV vaccine trials have predominantly enrolled adults [2,3]. However, inclusion of adolescents is essential in order for an efficacious vaccine to have an indication for use for minor adolescents. Enrolling minors in an HIV vaccine clinical trial poses a number of challenges, due to developmental, ethical and regulatory issues. Adolescents differ from adults in dimensions important to HIV [4], including relationship characteristics, sexual practices, needs for confidentiality, and family involvement [4–9]. Adolescence is a time of rapid development in cognitive capacity, with relevant differences from adults [10,11]. Other aspects of research decision-making in which adolescents may differ from adults include risk perception, willingness to accept risk, and decision making experience [12–15].

Because minors are considered a vulnerable population, adolescent HIV vaccine research presents complex regulatory challenges [16,17]. A core protection for all trial participants, particularly for research on sensitive topics [18], is informed consent. U.S. Federal regulations [19,20] typically use a parental permission/adolescent assent approach for minors who meet the definition of “children”, which is based largely on the assumption that parents will act in their children's best interests [16,21,22]. For research on sensitive topics, such as HIV, however, parental permission may introduce risk of harm, such as inadvertent disclosure of an adolescent's sexual orientation or HIV risk behaviors. In lower risk research on sensitive topics, best practice guidelines from the Society for Adolescent Health and Medicine recommend adolescent self-consent as an alternative to parental permission; for higher risk research, these guidelines recommend that investigators consider individual adolescents' capacity to consent [23].

The few existing data on adolescent clinical trial decision-making paint a mixed picture. One study found that some adolescents had difficulty with more complex trial concepts, such as randomization and false-positive tests [24]. Our own research showed that, generally, adolescents understood concepts such as placebo and clinical trial, but had more difficulty with the concept of randomization [25]. These studies focused on the outcome, rather than the process of the decision. The purpose of this study was to examine the *process* of adolescent decision-making about participation in an HIV vaccine clinical trial.

2. Methods

2.1. Participants and procedures

As part of a larger IRB approved study, we conducted qualitative interviews to elicit adolescents' understanding of an HIV vaccine clinical trial. Adolescents were recruited from four urban U.S. sites that were part of the Adolescent Medicine Trials Network for HIV/

AIDS Interventions (ATN). Recruitment venues included youth groups, health clinics, and community events. Participants were sexually active 16–19 year old males (MSM) or females who had sex with males, were HIV-negative, and indicated a possible willingness to participate in an HIV vaccine trial. For the qualitative interviews, each site recruited 6–9 participants from the larger quantitative study [26]. Informed consent was obtained from each participant, and parental consent was waived.

Participants underwent a simulated adolescent HIV vaccine trial consent process adapted from adult HIV vaccine trials. Adolescent participants were asked to read through the simulated HIV vaccine trial consent form, and then research staff walked participants through the information on purpose, procedures, risks, benefits and compensation, as if the participants were going to participate in an actual HIV vaccine trial. As part of the standard consent process, participants were given the opportunity to ask questions about the trial. Procedures were conducted by experienced ATN research staff – the very individuals who obtain consent for actual adolescent biomedical prevention trials. Following the consent process, all participants completed surveys, and a subset participated in qualitative interviews. This analysis focuses on the qualitative interviews.

2.2. Interviews

Semi-structured one-on-one interviews lasting 30–60 min were conducted by trained staff. Questions addressed the decision to participate in HIV vaccine trials, such as, “If an HIV vaccine clinical trial were available, would you participate? Why or why not?” Additional questions assessed the involvement of others in the decision-making process, risks and benefits of participation, and how risks and benefits played a role in the decision to participate (Fig. 1).

2.3. Analysis

Interviews were audio-recorded and transcribed. Data were analyzed using ethnographic content analysis [27], informed by a model of research decision-making from Applebaum and Grisso, that identifies four key tasks: (1) understanding relevant information about procedures, risks and benefits; (2) appreciating one's own situation and potential consequences of participation; (3) reasoning about options; and (4) communicating a choice [28–30]. This model has been used to inform assessments of capacity to consent among adults with psychiatric illnesses [31] and adults participating in HIV research [32].

Two researchers read transcripts, identifying codes surrounding the decision-making process used by adolescents. Data were analyzed using ethnographic content analysis, in which new codes were allowed to emerge from data during analysis, coding was iterative, and a consensus-based processes was used to resolve differences between coders. A preliminary model was created, and then tested and adjusted as subsequent transcripts were read, in an iterative manner. Disagreement between researchers was resolved through discussion. Detailed accounts of this coding process and the rationale behind each decision made were documented in a field journal.

3. Results

3.1. Participants and overview of decision-making model

Thirty-three interviews were available for analysis. Demographics are in Table 1. We identified 12 concepts related to adolescents' decision-making about participation in an HIV vaccine trial. These concepts largely mapped onto Appelbaum and Grisso's four components of decision-making capacity [28,29], as depicted in Fig. 2. A complete list of model components and representative quotes can be found in Table 2.

3.2. Understanding relevant information

Most participants understood the purpose of the trial, procedures, risks and benefits (Fig. 2, Box 1). They demonstrated a range of understanding about the concept of a vaccine as preventative (see Table 2). Furthermore, we observed that understanding improved across the research interview, as adolescents reconsidered initial perceptions and understanding, and asked interviewers for additional information:

> I: How do you come to that decision after you said before that maybe I wouldn't, but now I will, take it [the vaccine]?
>
> A: Because based on how I think about vaccines and how I [thought] that they actually give you the [HIV] virus, and after reading about it and talking about it and being told that it won't give you that [the HIV virus], then I'm okay with it. (Male, 16, Site 4)

Adolescents discussed three categories of perceived risks: effects of the vaccine, trial procedures, and stigma (see “Appreciate Own Situation” below). The most frequently discussed effects of the vaccine were physical side effects, followed by receiving a vaccine-caused positive HIV test result if tested using an antibody test (the standard HIV screening test), and the potential for a breach of confidentiality. The possibility of testing positive for HIV outside of the research facility was highlighted in the simulated consent forms, and was a recurring point of discussion throughout the interviews. Many participants were unclear about what this positive result meant and how it would affect them, but most resolved this ambiguity through discussion with the interviewer. Although almost every participant mentioned the possibility of a positive test result, only six (out of 33) identified it as a concern specifically for themselves, citing psychological and emotional stress and the effects on romantic relationships and family members if they found out about the positive test results. Three adolescents were concerned with breach of confidentiality, but all stated they would participate in the HIV vaccine trial if it were available that day and would discuss participation with their mothers.

The only perceived risk related to trial procedures was receiving a shot, mentioned by two adolescents who reported being afraid of needles. A list of representative quotes can be found in Table 2, Section 1. Some trial procedures, such as the high number of visits (20 visits) and the trial length (5 years) were considered inconveniences, but not risks. Older, male adolescents cited more time/commitment concerns, noting that they were at a point of transition in their lives and could not commit to something for 5 years because they did not know where they were going to be 5 years from now.

Participants discussed both benefits to self (see “Appreciate Own Situation”), and benefits to others. The most frequently discussed benefit to others was helping others. For example, one adolescent stated,

> “I think the benefits are, HIV is globally a big problem. I think we need to step towards vaccine. I think it's globally benefiting, not just benefiting me (Female, 17, Site 3).”

Another identified a contribution to the development of a possible HIV vaccine and saving lives.

3.3. Appreciate own situation (Fig. 2, Box 2 and Table 2, Section 2)

Most adolescents understood that participation in an HIV vaccine trial was research, not prevention (i.e., it was being done to learn something, rather than to give them early access to a vaccine). Additionally, most understood that they may not receive the actual vaccine as part of the trial and that it was not a treatment for HIV. A more detailed discussion of participants' understanding of the research concept of ‘experiment’ can be found elsewhere [25].

Personal risks and benefits showed more variation than risks and benefits specific to trial participation. It was evident that when discussing personal risks and benefits adolescents were actively considering their own situation and how the trial would affect them. The most commonly discussed personal risks specific to adolescent trial participation were the potential for a positive initial HIV test and stigma.

Two adolescents discussed the potential for a true positive HIV test results during the screening blood draw (i.e. finding out that they were already infected before the start of the trial) as a potential emotional risk for trial participation. Both of these adolescents were 19 year old males who felt they were at an increased risk for acquiring HIV and knew people who were HIV positive.

The majority of adolescents discussed aspects of stigma as personal risks of trial participation, which included family suspicion that they were already HIV positive and discrimination on the job. For example, one adolescent stated:

> “If your information got leaked that you were in the study, somebody might assume that you have HIV, so it's possible you can lose a job or your family could, I don't know how to put it, but your family might not agree with it, or they might treat you different as far as thinking that you have something (Female, 19, Site 1).”

Several adolescents were concerned about partner acceptance of their participation in the trial, indicating that their (potential) partners might not understand the positive HIV test result if they were to go with them to get tested at a facility outside of the trial facility. They felt their partners would think they either had HIV or were doing things that made them more likely to get HIV.

The most frequently discussed personal benefits were gaining information on HIV/AIDS followed by monetary compensation, access to a vaccine for HIV/AIDS prevention, and free

HIV testing. As a whole, adolescent participants stated they would still participate in the vaccine trial even if there were no monetary compensation. However, they did not believe other adolescents would participate without monetary compensation.

Adolescents who discussed monetary compensation as a benefit to trial participation tended to state their reason for participation without compensation was to prevent themselves from getting HIV. Those who did not state monetary compensation as a benefit tended to state 'helping others' as their reason for participation without compensation. A list of personal benefits and example quotes can be found in Table 2, Section 2.

3.4. Reasoning about options (Fig. 2, Box 3 and Table 2, Section 3)

Most participants reported that they would discuss participation in an HIV vaccine trial with someone who could advise them on decision-making. The categories of individuals included (in order of decreasing frequency) were: peers, health care workers, family, and other adults. Only one participant stated that he would not talk to anyone before making the decision. Nine participants stated that even though they would talk to someone about the trial, that person's opinion was advisory only because they 'make their own decisions.' For example, when this adolescent was asked what role others would play in his decision, he stated,

> "Just their opinion, that's it, because it's up to me if I'm going to decide to do it or not, just their opinion. (Male, 17, Site 3)"

The remaining 23 adolescent participants would involve at least one individual they identified as providing decision-making support (see "mother" in Table 2 Section 3).

While participants identified peers as the individuals they would most frequently talk to about joining the trial, health care providers were identified as the most influential, the most likely to sway their decision one way or the other. "My doctor" was the most frequently mentioned health care worker; reasons included (in decreasing frequency): (1) to make sure they were healthy enough to participate, (2) they trust their doctors, and (3) their doctors would be able to provide facts about HIV and HIV vaccines.

Mothers were identified as the most frequently consulted family members. Most of the adolescents who stated they would talk to their mother about an HIV vaccine trial were female and felt they would do so because they valued her opinion as their mother. Other reasons included the mother's knowledge of the medical field and because she has to drive them to appointments. A subset would talk to their mother out of respect, but that her opinion would not necessarily influence their decision. Of the adolescents who did not state they would discuss this decision with their mother, three specifically stated they would not consult their mother. Two of these adolescents were MSM and felt their mother would not understand why they wanted to participate in an HIV vaccine trial. The last was female and felt her mother had too much to worry about right then.

Six adolescents stated they would talk to an adult outside of their family and health care providers. Each of these adolescents was a young MSM, and none of them would have talked to a family member about the trial. Reasons for only consulting adults outside of the family included concerns that their family would not understand, might think they have

HIV, or would disapprove. See Table 2, Section 3 for individuals consulted and representative quotes.

3.5. Choice (Fig. 2, Box 4 and Table 2, Section 4)

All participants felt that the choice was theirs to make, and felt capable of making a choice. Consultation with peers, family and health care providers were characterized as useful for input, but not for the final decision regarding participation. The large majority of participants stated they would participate in an HIV vaccine clinical trial if one were available to them with fewer stating they were unsure or would not participate. Reasons for participation were consistent with the perceived benefits. Five adolescents were unsure if they would participate, citing concern about stigma, life being too unstable to make the commitment, and potential side effects. At the same time, these undecided adolescents still viewed participation as a way to 'help others.' Three said they would not participate in an HIV vaccine trial. Two of these participants felt the vaccine would not benefit them directly, while the other was concerned about unknown side effects.

4. Discussion

Among adolescents participating in a simulated consent process for participating in an HIV vaccine trial, we observed that most participants were able to comprehend relevant information about trial participation. Understanding trial purpose and procedures is a necessary component for informed consent [28,33]. Understanding was a process, and we observed that many adolescents who started the interview with a lower understanding level were able to resolve much of this misunderstanding through discussion with the interviewer [25]. Best practices for recruitment of adolescents will likely require an interactive process of assessing understanding and addressing misperceptions. Similar to previous research on adolescent capacity to consent to research [34,35], participants demonstrated to the interviewer that they were able to appreciate their own situation, logically manipulate information, and make a choice.

We found that adolescents were willing and interested in consulting with others about research participation, and placed particular trust in parents and health professionals. Even those that were planning on making their decisions on their own would consider the perspectives of trusted others. These findings are consistent with adolescent development. Adolescents are embedded in peer groups and families, are in a socially less powerful position compared to adults in their lives, and actively use role models and mentors in learning.

Finally, adolescent participants identified several issues related to HIV biomedical prevention trials that posed specific or increased risks to adolescents. The first was the distress related to a new HIV diagnosis made during baseline HIV testing. While a new diagnosis of HIV is distressing for individuals at any age, adolescents are particularly vulnerable because they have less access to health care and other resources, and heightened confidentiality concerns. The second was the high level of concern about stigma related to just participating in an HIV vaccine trial. Adolescents' vulnerabilities [36,37], including their financial and legal dependence upon families, increased confidentiality concerns. Their

position in society (in school, in entry-leveljobs) is more tenuous and dependent, putting them at increased likelihood of experiencing stigma. These vulnerabilities are heightened among adolescents at high risk for HIV, which include young MSM and adolescents in high poverty, low resource communities.

4.1. Limitations

While small sample sizes are necessary in qualitative research to gather information in sufficient detail, they also limit transferability of results to similar groups of adolescents. We recruited from the ATN as these are the adolescents that will most likely be recruited into a U.S.-based HIV vaccine clinical trial when one becomes available to them. A second limitation is that this interview was not a formal capacity assessment and should not be interpreted as such; instead it was a broader interview into the process of, and influences on, adolescent clinical trial decision-making.

The results of this study suggest that most members of this sample of adolescents at risk for HIV demonstrate the key abilities needed to make meaningful decisions about HIV vaccine clinical trial participation. These include the ability to understand the basic information provided to them, appreciate their own situation, consider information about risks and benefits of participation, consult with outside individuals and make a logical choice. These abilities can be supported through additional protections, such as additional efforts by HIV prevention researchers to assess adolescent understanding and address misperceptions, the judicious involvement of trusted adults selected by the adolescent to support them in the decision-making process, and attention to adolescents' situations, which may amplify concerns such as confidentiality and stigma.

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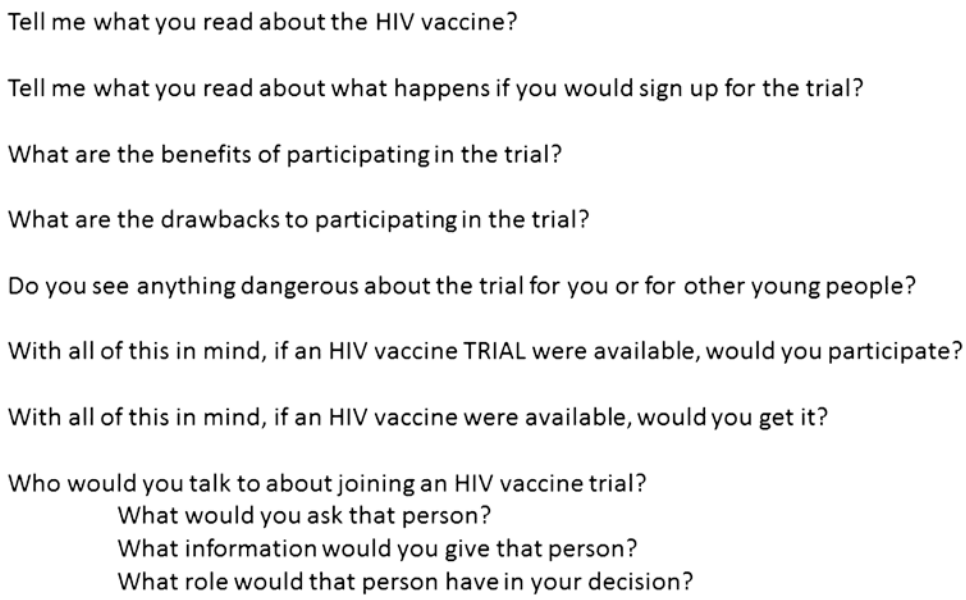

Fig. 1.

Main questions from interview guide used for analysis of decision making among adolescents regarding participation in a hypothetical HIV vaccine trial.

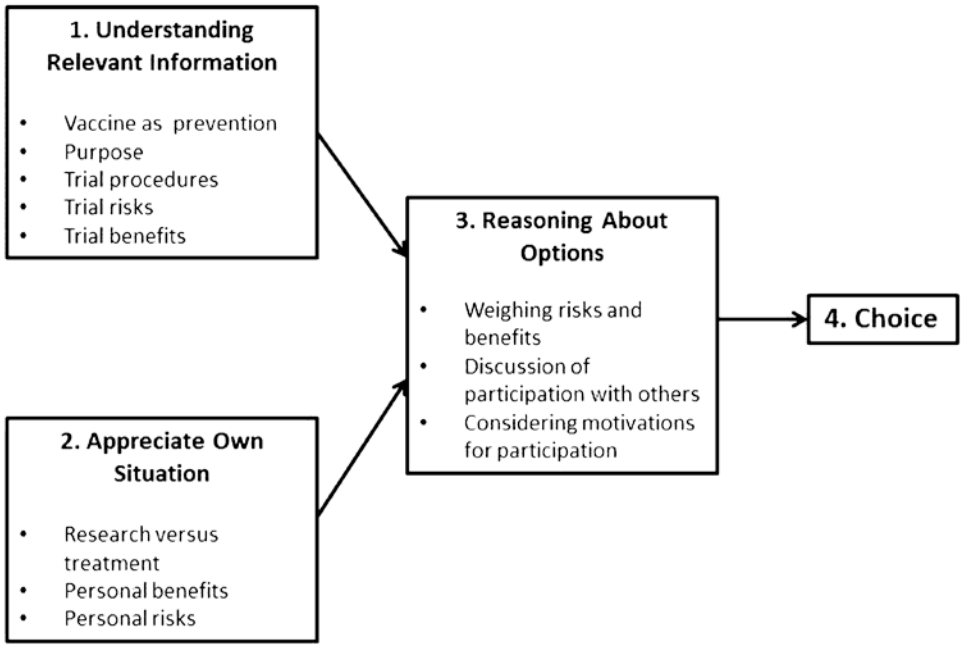

Fig. 2.

Model of decision making among adolescents regarding participation in a hypothetical HIV vaccine trial.

Table 1

Demographics.

Characteristic	***N* (%)**
Age	
16–17 years	18 (54.5%)
18–19 years	15 (45.5%)
Race/ethnicity	
White, non-Hispanic	4 (11.1%)
African American, non-Hispanic	21 (58.3%)
Latino/Hispanic	4 (11.1%)
Other	7 (19.4%)
Gender	
Male	19 (57.6%) – includes 1 transgender M → F
Female	14 (42.4%)
ATN site	
Site 1	9 (27.3%)
Site 2	9 (27.3%)
Site 3	9 (27.3%)
Site 4	6 (18.2%)
Recruitment venue	
Clinic	12 (36.4%)
Community organization	12 (36.4%)
Othervenue	9 (27.2%
Total	33 (100%)

Table 2

Quotes representing components of decision making model.

Concept	Quote
1. Understanding relevant information	
Vaccine as prevention	Limited understanding: Interviewer (I): Would you get an HIV vaccine if it were available? Adolescent (A): No, because I'm not HIV positive. (Female 16, Site 1) Good understanding: A: Not the ones who are already infected with HIV, already. It won't help them but it will help people that don't have HIV, protect them from getting the virus. (Female 18, Site 3)
Purpose	I read that it was a basic, trial and error kind of thing to see if it will have a positive or negative effect on your body, to see whether or not they can use that as a possible HIV prevention in the future. (Male 19, Site 4)
Trial procedures	Well, all your information is kept in to yourself. Everything is pretty much private, since you have - if you sign up for the research and stuff, it's pretty much you're helping to see - to find a vaccine for it, the HIV prevention. So, when you sign up for it, everything, you're just going to your appointments and stuff like that, to make sure everything's okay… You have like a 50–50 chance. One group will get it and the other group will not. One will get the placebo, one will get the vaccine. So it's like the flip of a coin. You really don't know who will get it. It's not decided amongst the doctors, or you can't decide if you're gonna be in group A or group B. It's like the flip of a coin. It could be heads or tails. (Male 18, Site 3)
Trial risks	Well, a lot of stuff like I said, it's an experimental vaccine. So what actually happens to the human body when they give it to you, they're not 100% sure on what exactly it will do, whether it will make things better or worse. Whether it will prevent HIV or make chance of getting it higher. In the long run I could be screwing myself over. (Male 16, Site 1)
Trial benefits	It could help. They could find some results off it and eventually come up with a vaccine for HIV that's open to the public, that maybe one day in the future somebody could go to a doctor who has HIV and get a vaccine for it. (Male 16, Site 1)
2. Appreciate own situation	
Research versus treatment	What I read about the HIV vaccine? I read about it was basically it's a vaccine; it's a research study. In the research study, you'll receive a placebo or the real thing, from what group you're in I guess. (Male 16, Site 1)
Personal risks Stigma	Well, some people would question because they're just people. Why would you do something like that or do you have HIV or something (Female 18, Site 3)?
Testing positive	There is that thought that you can possibly go to another HIV site and get tested and you can – your results could come back positive. That can be mind-blowing because who wants to be infected with HIV? Nobody… you wouldn't have it, but you would get a positive read if you were to go get tested somewhere else. Nine times out of ten, you'd get a positive read and that's the part of –you thinking, okay, well, I have HIV. (Male 17, Site 3)
Personal benefits Information on HIV Monetary compensation	You learn more about it, of how to prevent HIV, to prevent from AIDS, everything, so that's why I'm looking at. (Female 17, Site 3) Also, another good thing is you're paid 75 dollars as well for your, I think for each visit if I remember. (Female 16, Site 2)
3. Reasoning about options	
Weighing of risks and benefits	I feel like the consent form laid out very clearly what the pros and cons were. The main reason, motivation, why you participate in this study, as in finding a vaccine that prevents HIV, I think that's really important, and I'm really happy that that's there, that the study is there. I feel like that because you cannot get HIV through the vaccine, and the side effects seem relatively low or minimum, that it is really – yeah, that I consider the pros and cons, like the time that it would take, the health impact or not, and whether I could give HIV to other people or not, and it seems a safe study and well monitored as well. There are a lot of commitments that the subject needs to make, and I think that is really important to keep the study consistent but also the person, subject, safe. And then even though it may be a little bit of a hassle, the blood test, I feel like that it's really helpful to find out more information but also to make sure that the subjects stay safe. And so all those aspects together, I feel like I wanted to consider the study. (Male 17, Site 2)
Discussion of participation with others	
Friends/family Doctor	It would just be her opinion and I would take it into consideration out of respect…I make my own decisions. (Female 19, Site 1) A big one because of his status and his being educated about it, I think he could speak more off of facts instead of what he thinks than more statistics. I think by telling him the information that was provided to me, and then knowing his background information from his personal experience, that would help me with my decision a little bit more. (Female 17, Site 1)

Concept	Quote
Mother	Yes, because she's a big part of my life. She's a big influence in my life so if she was to tell me no, I would listen to her and see why she's saying no and if it's for some of the same reasons, then I probably wouldn't. (Female 19, Site 4)
Considering motivations	
Altruism Financial	INT: What if there were no money involved in the trial. How would that affect the benefits to you? R: I think I would still do it. I like helping people, so if participating in it would help to see if it really does work in the future, then I'd still do it. (Female 16, Site 1)
Medical benefit	A: I would – I would say because of the fact that I'm one of those guys that's very sexually active and I think that would be something that's important for me to do. I: So you would get the HIV vaccine so that you can continue your sexual activity? A: Well not to just continue. Try to be on the safe side and, yeah. (Male 19, Site 3)
4. Choice	
Yes	Oh, because it would inform me – it would show me that while I participate, just because like I said, about me knowing that maybe I have a part in actually finding HIV vaccine one day, and to inform other young adults that unprotected isn't okay, or whatever. And it informs us that just because we have this vaccine, that they're experimenting on this vaccine, don't go out and have unprotected sex, because it's not guaranteed that you wouldn't contract the HIV virus. (Male 16, Site 3)
Unsure	Well, if I wanted, I would do it. Seeing how like I already read through a lot of the information and I've seen a lot of the risks and stuff, I'd most likely be willing to do it, but that's only if I wanted to – I still have mixed feelings about it…since there is a life-threatening allergic reaction that could happen, there might be other – they said there were unknown – other unknown side effects. (Female 17, Site 2) I think there's a lot more factors that might contribute to whether or not I would or not. Would I be interested? Certainly but I'll go back to me being a youth and how unstable my life is right now. I wouldn't want to enroll in it if I didn't know if two months from now if I would still be able to do it. And I would like to but there's a lot of things contributing to whether or not I would do it, mostly with how unstable my life is and so I'd be very hesitant to do it. (Male 19, Site 2)
No	I think I don't want to try the study because I don't want to have to go through all ofthe symptoms and you know, the risk of – you know, you never know what the pill or the shot will do to your body, but I'd just rather stay out of it, you know, because I don't want to pop up and it may be life threatening, you know? (Female 19, Site 3)