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Adolescent Barriers to HIV Prevention Research: Are parental consent requirements the biggest obstacle?

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Globally, individuals ages 15-24 make up one third of all new HIV infections.¹ Risk factors for HIV infection, especially drug use and unprotected sex, often first present during adolescence.² In South Africa (S.A.), young women in relationships with older men are at increased risk,³ and young women and girls aged 15-24 are four times more vulnerable to HIV infection than their male peers.⁴ In parts of the U.S., adolescents remain at high risk for HIV, particularly young men who have sex with men (MSM).⁵

This heightened risk for HIV infection makes adolescents a critical target for HIV prevention interventions.⁶ Because adolescents and adults differ in many respects, including pharmacokinetics of antiretrovirals,⁷ immune responses to vaccines,⁸ and sexual behaviors,⁹ it is essential to enroll adolescents in HIV prevention research. It is therefore important to identify and address barriers to adolescent participation in such research.

Prior assessments have identified several potential barriers, such as reporting requirements regarding abuse/neglect or under-age sex,¹⁰ social pressure not to participate,¹¹ and—critically—requirements for parental consent (or, more precisely, “permission”).¹² International and national laws generally require that one or both parents give permission for their children (typically individuals younger than 18) to participate in research, though

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waivers of parental permission are allowed in specific circumstances.¹² Concern has been expressed that parental permission requirements may deter adolescents from research participation. This might occur by at least three different mechanisms. Adolescents may not want their parents to know about their risk behavior or sexual activity or orientation, they may worry about negative consequences if their parents learn about these,¹³ and some adolescents may be unable to rely on their parents to make the effort to provide permission.

Previous studies examining barriers to adolescent enrollment have typically involved qualitative methods, and have rarely focused on HIV prevention research,¹⁴¹⁵¹⁶¹⁷¹⁸¹⁹²⁰²¹²² with the exception of a few studies focused on sexual and gender minority youth in the U.S.²³²⁴ Also, previous studies have not asked adolescents to rank barriers to their enrollment, making it unclear whether efforts to increase adolescent enrollment in prevention research should focus on parental permission or elsewhere. Finally, research on adolescent views of HIV prevention research has primarily been conducted in the U.S., and attitudes may differ in countries with higher HIV prevalence in adolescents.

AIMS AND METHODS

We assessed whether parental permission is regarded as an important barrier in the U.S. and S.A., and how it compares to other potential barriers. Parental permission could be a barrier for at least three reasons. Adolescents might decline to participate in research that requires parental permission out of concern that it might lead to their parents learning about their behavior. Others might be concerned that their parents might impose consequences for participation if they learned about it, including physical harm. Finally, some adolescents might decline to participate based on the assumption that their parents would not be willing to make the time and effort to consent. Accordingly, we asked adolescents about three potential barriers related to parental consent: (1) that their parents would suspect drug use or sexual activity, (2) the fact that their parents would have to consent, and (3) that their parents would be upset upon learning they wanted to participate in an HIV prevention study. We also identified other potential deterrents, including concerns about mandatory reporting for abuse or research risks.

Sample

In South Africa, we enrolled adolescent females ages 14-17 (adolescent males are at much lower risk of HIV infection) from the Sweetwaters region in KwaZulu-Natal. KwaZulu-Natal has the highest HIV prevalence in South Africa, which bears 40% of the global burden of HIV,²⁵ and incidence rates for young black South African women are among the highest for any population globally.²⁶ In the U.S., we enrolled males and females ages 14-17 seeking STI testing/treatment or family planning services at the Children's Hospital of Aurora, Colorado. We also asked participants to inform their partners about possible study participation if of interest. In Colorado in 2016, 13-19 year olds accounted for 3% of the total HIV diagnoses.²⁷ The Denver metro area has both the largest concentration of new STIs and the highest HIV prevalence rates in Colorado, and this site was one of the highest enrolling sites for a recent pre-exposure prophylaxis (PrEP) HIV prevention trial in adolescents, enrolling a relatively diverse population of participants.

Recruitment strategies differed in the two sites, though both relied upon convenience sampling. In Sweetwaters, S.A., potential participants were approached through schools. Permission to approach adolescents was first obtained from educational gatekeepers, and research staff approached adolescents during specified classes. Contact information for parents was provided by the adolescents, and staff contacted the parent/guardian telephonically to schedule an appointment for informed consent and adolescent assent at their home or at another suitable venue. In Colorado, U.S., staff at a family planning clinic housed in Adolescent Medicine reviewed records to determine potential eligibility and approached adolescents in the clinic. We used snowball sampling, but did not track how many participants referred others, so we were unable to provide a response rate. Staff were trained to approach all eligible adolescents while in the clinic and follow up on all referrals to avoid introducing bias.

Measurements

Our survey instrument was developed in consultation with the University of Wisconsin Survey Center and with expert input. The final instruments were refined based on cognitive pretesting with 8 adolescents in each site. In the South African site, the survey (Appendix 1) was translated into isiZulu. Smartphones or tablets were used for data collection at both sites.

The survey included a vignette about a hypothetical, year-long PrEP trial which required trial participants to take a pill daily, answer survey questions about sexual behavior, and give small amounts of blood. Parental permission was required to enroll in the hypothetical trial. The possible side effects of PrEP were described as: upset stomach, loss of appetite, and headache. The less common side effects mentioned were changes in how the kidney works or in bone thickness. Respondents were informed that they could benefit from this study by learning more about their HIV risk, having easier access to health clinics, and learning where to seek health care. Payment for the hypothetical study was also described (\$25 in U.S. and R150.00 ZAR in SA per visit). (Appendix 2)

After reading the vignette, adolescents were asked to rank the importance of specific barriers: “*How important are the following things that you might not like about the study, or reasons not to be in the study?*” Answer options were: very important, somewhat important, only a little important, not at all important. Of the barriers that were identified as “very important”, respondents were asked to indicate which one would be the most important in deciding whether to enroll in the trial (Appendix 1). Adolescents were also given show cards to illustrate key details of the trial to ensure accurate recall when answering questions (Appendix 2). Survey domains included the following: (1) sociodemographics, (2) relationships with parents or guardians (3) understanding of research, (4) perception of role in decision-making process, (5) comfort in providing independent consent to HIV prevention research, (6) perception of risk for HIV infection, (7) barriers to participation in HIV prevention research, and (8) motivators for participation in HIV prevention research. The present study reports the results regarding barriers to participation.

Approvals

We obtained Institutional Review Board (IRB) approval from the University of Colorado, with reliance agreements from the National Institutes of Health and the University of Wisconsin. We obtained ethical approval from the Human Sciences Research Council (HSRC) Research Ethics Committee (REC) in South Africa, and the University of KwaZulu-Natal Human and Social Sciences REC granted reciprocity of ethics approval. The University of Colorado IRB granted a waiver of parental permission for this study, but the South Africa site could not complete a community engagement process required for a parental permission waiver in time (see Limitations, below, for more information). As a result, all adolescents enrolled in Colorado gave their own consent to participate, while adolescents in KwaZulu-Natal gave their assent and a parent/guardian provided permission.

Statistics

Based on existing data, we hypothesized that approximately 40% of adolescents would regard parental permission as the most important barrier to HIV prevention research, approximately 10% would be most concerned about risks,¹³²¹ and the remaining 50% would consider another barrier to be most important. This suggested that a sample size of 54 per study site would be enough to show that difference in proportions statistically significant with 80% power, and $n=71$ for 90% power. We planned to conduct sub-analyses with the U.S. and S.A. samples, and therefore aimed for 75 participants in each region to have over 90% power to answer the primary objective.

Descriptive statistics were calculated for all variables. To test for statistically significant differences, 2-sample tests for equality of proportions with continuity correction were performed using the R statistical software package. Differences with a p-value of less than 0.05 were considered statistically significant. Multivariate analyses were conducted to look at differences based on the site from which participants were drawn, whether adolescents lived with their parents, and knowledge of HIV, and are reported where significant.

RESULTS

Sample

We enrolled 150 adolescents aged 14-17 from the two sites. Most respondents were females (80%). In S.A. only one participant identified as gender non-conforming and there were 74 female participants. In the U.S., the majority of the 75 participants were female (61%) (Table 1). The mean age was slightly higher in Colorado than in KwaZulu-Natal (16.3 v. 15.3).

Most of the participants from the U.S. identified as Hispanic (52%), with just over 30% identifying as white, 16% identifying as African-American, and 7% identifying as Native American. Most of the participants in S.A. identified as African (95%), with the rest identifying as “colored” or choosing multiple categories, which accurately reflects the demographics of the community.

Sixty-five percent of respondents did not live with both of their parents (44% in Colorado and 86% in KwaZulu-Natal). Of those who did not live with both parents, 56% (67% in Colorado, 50% in KwaZulu-Natal) lived with their mothers. Twenty-two percent did not live with either parent (18% Colorado, 45% KwaZulu-Natal). Most respondents in both settings (80% in Colorado, 68% in KwaZulu-Natal) had never participated in research before.

Adolescent barriers to HIV prevention research

When we asked adolescents how important each barrier was independently of the others, approximately half of all adolescents thought that ten of the potential barriers were “very” or “somewhat” important (Table 2). The two barriers that the most adolescents identified as “very” or “somewhat” important were: (1) side effects (77% of adolescents) and (2) that parents would have to consent (69% of adolescents). Fewer than a third of adolescents considered worries about stigma, dislike of research participation by a sexual partner, conflicts with school, boredom, or if one’s friends were not participating to be “very” or “somewhat” important. More South African adolescents than U.S. adolescents considered the fact that their parents would have to consent “very” or “somewhat” important (13% vs. 2.7%; $p=0.03$). The importance of other barriers did not differ significantly between the sites. As will be discussed further in the limitations section below, however, there are several differences between the two sites that make it difficult to compare responses across sites.

When asked to rank different barriers against each other, no single barrier was ranked most important by a majority, but the three barriers related to parental consent requirements collectively formed the most important barrier for the largest group of adolescents (29.5%) (Table 3, in purple). Of the barriers related to parental consent requirements, most adolescents indicated the most important reason not to participate was that their parents might think they were sexually active or using drugs (17.4%), followed by the fact that their parents would have to consent (8.1%). A smaller proportion indicated the most important barrier was that their parents might be upset (4%) (Table 3).

If the researchers did not have to obtain parental permission, 26.6% ($n=40$) of adolescents said they would be much more likely to be participate, and an additional 20% ($n=30$) said they would be a little more likely to participate, with comparable numbers in each site. However, 8% ($n=12$) said that they would be a lot less likely to participate if the researchers did not involve their parents.

These barriers differed for adolescents in S.A. and the U.S. For 37% of S.A. adolescents, barriers related to parental permission requirements were the most important (see Table 3, in purple). The fact that their parents might think they were sexually active or using drugs was the individual barrier ranked most important by the largest proportion of adolescents in S.A. (21.3%)—ranked higher than side effects. By contrast, for U.S. adolescents, 30% were concerned most about side effects and 22% considered barriers related to parental permission requirements to be most important. Additionally, in SA, approximately 5% of adolescents thought stigma was the most important barrier (others seeing them at the research site), though no adolescents in the U.S. did. (Table 3)

Several barriers were identified by only a few participants as most important. Few adolescents chose conflicts with school, boredom, transportation issues, child care, or that their sexual partners might find out as most important. Moreover, few selected the possibility of mandatory reporting of suspected abuse.

The survey also asked adolescents why they ranked a barrier as the most important and coded their open-ended explanations. We received 133 brief responses (inputted through tablets). Many adolescents expressed concern that their parents would think they were engaging in risky behaviors or had been infected with HIV if they were eligible for research. For example, one adolescent responded: “*My parents can think bad things about me, they can think I’m involving myself into sexual activities*” (SA). Along similar lines, one adolescent said: “*My parents may interpret the study as me having HIV.*” (U.S.), and another adolescent indicated: “*My parents think I am a perfect child and I don’t want them to think otherwise*” (U.S.).

Adolescents who felt parental consent itself was a barrier gave a variety of reasons. One adolescent was troubled by the idea of having parents make the decision, stating: “*[T]his is important because I have the right to choose what I do in my life and I have the mental capacity to learn about this on my own.*” (U.S.). One adolescent noted that parental consent was “*very important because whatever happened in my life without my parents’ permission won’t [sic] work...*” (S.A.), and a few others indicated their parents or the adult they were living with would not give permission. Finally, one adolescent worried about their parents being upset said: “*I don’t think they will know how to take it*” (U.S.). Others indicated their parents would be upset after finding out that they are sexually active (S.A.).

A few adolescents were worried about being experimented upon, with one adolescent from S.A. indicating this was the biggest barrier “*[b]ecause no one wants to feel like a test bunny to help others.*” (SA).

Whether parental consent was the most important barrier was not associated with adolescents’ knowledge about HIV, age, or whether they lived with their parents. All adolescents who reported poor relationships with their parents (5%, n=8) reported that parental consent was a very important barrier.

Finally, 44% of adolescents said there was a “high chance” they would decide to participate in the hypothetical study, while 18% chose a “somewhat high chance”, 18% chose a “somewhat low chance”, and 4% indicated there was no chance they would participate. Most (71%, n=106) adolescents indicated that if parental permission was not required, they would want to talk with someone else about the study, such as a trusted adult in the community who knows about medical research. Indeed, all of the adolescents who indicated that “parents having to consent” was the biggest barrier said they would want to talk to someone else about the study. These numbers were higher in S.A. than in the U.S., with 93% (n=70) of S.A. adolescents desiring extra support from another adult, as compared with only 49% (n=36) of American adolescents.

DISCUSSION

This study was designed to quantitatively explore whether parental permission requirements are the most important barrier for adolescent participation in HIV prevention research and whether this differs between the U.S. and S.A., which has the world's highest burden of HIV infections. Our results suggest four important lessons.

First, a parental permission requirement is one important barrier to enrollment in HIV prevention research by adolescents, though it is not necessarily the most important barrier. We found, in line with prior research with young MSM in the U.S.,²⁴ that most adolescents considered parental permission to be a somewhat or very important barrier to research participation. Parental permission was a more important barrier for S.A. versus U.S. adolescents. While U.S. adolescents ranked it second only to risks, when adolescents were asked to rank parental permission requirements, other barriers were of similar importance. This suggests a need to address a requirement for parental permission in addition to other barriers to enrollment. There are legally and ethically acceptable ways to conduct adolescent HIV prevention research without parental permission, however, laws permitting waivers of parental permission are often complicated or confusing to apply to research,²⁸²⁹ and legal reform is needed. Meanwhile, additional scholarship to clarify existing legal flexibility in different contexts could help researchers secure waivers where possible. Additionally, researchers should engage community stakeholders to build trust in the concept of parental waivers which may require building in extra time and funding. Researchers should also engage REC/IRBs to identify their concerns and requirements.³⁰ Researchers could also identify sites with prior success in obtaining parental waivers, provided data from these sites remains representative of the target population.

Relatedly, respondents were most concerned about parental permission due to the parents finding out about their risky behaviors, suggesting that requiring parental permission may have the effect of excluding higher-risk adolescents from such studies. Other studies have similarly identified parental permission requirements as a barrier for high-risk adolescents,³¹³² and that parents with conservative attitudes about sexuality less often grant permission for their adolescents to enroll.³³ Where researchers cannot obtain IRB/REC approval for waivers, then, they should design adolescent studies (where possible) to ensure sensitive information about individual adolescents is not shared with their parents, and explain this to adolescents and parents during the consent process.¹⁰ Researchers could provide counseling to adolescents about how to talk with their parents about their risky behaviors. Finally, researchers should recognize the limitations of the data from studies in which parental permission is required.

Second, researchers should consider support for adolescent decision-making such as 'opt-in' involvement of trusted adults. In our study, a sizeable minority of adolescents reported their parents *should* decide whether they enroll in research, in line with prior findings.²⁰²²³⁴ This suggests that even when researchers are able to secure waivers, researchers should not prohibit parental involvement for adolescents who want it. In our study, most adolescents indicated that if parental permission was not required, they would want to talk with someone else about the study, such as a trusted adult in the community

who knows about medical research, particularly in S.A. The need to involve parents or consult with a trusted adult may depend on the cultural context or individual needs. Nevertheless, making such protections available may help to fulfill regulatory requirements permitting parental permission to be waived “provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.”³⁵

Third, adolescents are also concerned about side effects or risks in HIV prevention research. Adolescent concerns about side effects have been reported in other studies.³⁵ These data may allay concern that adolescents have more limited capacity than adults to appreciate long-term risks.³⁶ Additionally, these results suggest that researchers should ensure that adolescent participants accurately understand risks and risk mitigation strategies and develop and test strategies to educate adolescents about risks so that any concerns are based on an accurate evaluation of risks.³⁷

Finally, certain barriers to adolescent research participation may be less important than previously thought. One surprising finding is that few SA adolescents were concerned about being experimented on, despite widespread concern about perceptions of exploitation of participants from lower-income countries.³⁸ Strikingly, most adolescents did not select whether one’s friends were participating as most important, which seems to contradict concerns that adolescents are vulnerable to peer pressure.³⁹ Few adolescents thought reporting to authorities of suspected abuse was the most important barrier, though a majority thought it was important when asked about it independently. This suggests that several barriers discussed extensively in the literature may deserve less attention, particularly compared to parental permission requirements or worries about risk.

LIMITATIONS

Views about a hypothetical study vignette may not reflect the actual decisions adolescents would make. We had limited ability to directly compare responses across contexts because of large differences in demographic features, recruitment approaches, HIV risk levels, gender, and parental consent requirements. Some of these differences also limit the generalizability of our findings. For instance, S.A. participants were predominantly female, with one gender non-conforming participant, whereas U.S. adolescents included some males. Parental consent for SA adolescents may have inadvertently skewed enrolment into our study. The fact that parental permission was required for SA adolescents, along with differences in sampling and participant demographics, may at least in part account for the finding that that parental permission was a more important barrier. Since US participants did not need parental permission for this study, they may have perceived it as a less important barrier. Conversely, however, the fact that all SA adolescents were able to participate even with a parental permission requirement for the survey makes it striking that they perceived parental permission as an important barrier for the hypothetical study.

South African adolescents were considered at relatively high risk of HIV infection because they were young females in a high prevalence setting. U.S. participants were considered at elevated risk of HIV infection due to behavior (presenting at clinics for diagnosis and treatment of STIs). Nonetheless, we likely did not reach adolescents at highest risk who tend

to avoid healthcare-settings or the education system altogether. We were unable to collect information about potential participants who declined, so we cannot provide a response rate. By asking participants to refer others for interviews, we may have limited the generalizability of our findings in that the participants we identified were likely to refer people similar to them. Further research is needed to determine whether our results would hold across various settings and populations. Such research should endeavor to engage hard-to-reach adolescents resembling the target populations for HIV prevention research and implementation.

CONCLUSION

Our findings add quantitative data to the growing evidence base that adolescents perceive parental consent as a barrier to their participation in HIV prevention research and are reluctant for their parents to know about their behavior. More research is needed on the relative importance of parental permission requirements in different contexts, and other barriers, such as concerns about risks, are also important. These data suggest that legal reform and scholarship could help expand the use of parental waivers under appropriate conditions. Where waivers are being implemented, more research is needed into ways to provide adolescents with sufficient protections, such as additional counseling and decisional supports. More research is needed to explore “opt-in” parental involvement, as many adolescents desired parental involvement, e.g. intergenerational communication interventions for difficult topics⁴⁰ or the involvement of other trusted adults. It is important that innovative ethically and legally appropriate ways to conduct adolescent HIV prevention research with parental permission waivers are explored, and supported, while maintaining flexibility for adolescents who desire parental involvement, to have greater, ethically appropriate inclusion of this critical and vulnerable group.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Implications & Contribution

Findings demonstrate that adolescents perceive parental consent as an important barrier to their participation in HIV prevention research, along with several other barriers (including side effects). Although waivers of parental permission may be important to increase adolescent enrollment, some adolescents may still require decision-making support.

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Table 1

Demographics

	All - % (N)	USA - % (N)	SA - % (N)
Male	20.1% (30)	39% (29)	0
Female	79.8% (119)	61% (46)	99% (74)
Gender non-conforming	1% (1)	0	1% (1)
14	15.4% (23)	3% (2)	28% (21)
15	26.2% (39)	21% (16)	31% (23)
16	24.8% (37)	21% (16)	28% (21)
17	34.2% (51)	55% (41)	13% (10)
Live with both parents	34.2% (51)	55% (41)	13% (10)
Prior research experience	27% (40)	22% (16)	32% (24)
Hispanic	26.2% (39)	52% (39)	0
Non-Hispanic	24.2% (36)	48% (36)	0
White	15.4% (23)	33% (23)	0
African American	7.4% (11)	16% (11)	0
Native American	3.3% (5)	7% (5)	0
Asian American	1% (1)	1% (1)	0
Other	8.7% (13)	19% (13)	0
African	47.7% (71)	0	95% (71)
Colored	4% (3)	0	4% (3)
Multi-racial	12.1% (18)	24% (17)	1% (1)

Table 2:

Barriers to HIV research independently assessed as “very or somewhat important”

Barrier	Adolescents describing it as “very” or “somewhat” important
Side effects	77%
Parental consent requirement	69%
Being experimented on	67%
Time commitments	65%
Having to answer personal questions	62%
That researchers have to report abuse	57%
Having to get transportation	56%
Parents might find out about drug use/sexual activity	53%
Parents will be upset	45%
The need for child care	47%
That others will see adolescent at research site	29%
Sexual partner won't like it	28%
Conflicts with school	28%
Participation will be boring	20%
Friends not participating	12%

Table 3:

Relatively ranked barriers to HIV prevention research adolescents said were most important

Barriers	All	USA	SA
The possibility of having the side effects mentioned	25% (37)	30% (22)	20% (15)
Your parents might think that you are sexually active or using drugs *	17% (25)	14% (9)	21% (16)
The amount of time it would take	9% (13)	8% (6)	9% (7)
The fact that your parents have to consent *	8% (12)	3% (2)	13% (10)
You might be experimented on	8% (12)	12% (9)	4% (3)
Your parents might be upset *	4% (6)	5% (4)	3% (2)
The need to get transportation to the study site	3% (5)	4% (3)	3% (2)
None of your friends are participating	3% (4)	1% (1)	4% (3)
Having to answer personal questions	3% (4)	0% (0)	5% (4)
You don't want other people to see you at the HIV research site	3% (4)	0% (0)	5% (4)
Conflicts with school or other activities	3% (4)	5% (4)	0% (0)
Your sexual partner or partners won't like you being in research	2% (3)	3% (2)	1% (1)
It might be boring	2% (3)	4% (3)	0%
Other	2% (3)	4% (3)	0%
The researchers might report suspected abuse	1% (2)	0%	3% (2)
It would be difficult to find someone to care for your child	1% (1)	0% (0)	1% (1)

* barriers related to parental permission requirements (in purple)