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ORIGINAL PAPER

Parents' Perspectives About Adolescent Boys' Involvement in Biomedical HIV Prevention Research

Brian Mustanski[1] · Kathryn Macapagal[1] · Matthew Thomann[1,2] · Brian A. Feinstein[1] · Michael E. Newcomb[1] · Darnell Motley[3] · Celia B. Fisher[4]

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Abstract Research on the use of pre-exposure prophylaxis (PrEP) among adolescents at high risk for HIV is urgently needed, and parents' perspectives on these studies are essential for guiding the responsible conduct of adolescent PrEP research. We conducted interviews with 30 parents of adolescent boys (50% known/presumed heterosexual; 50% sexual minority) to understand their views of research risks and benefits and parental permission regarding their son's involvement in a hypothetical PrEP adherence trial. Parents identified several health and educational benefits of the study and expressed that waiving parental permission would overcome barriers to accessing PrEP, particularly for youth who may benefit most. Among their concerns were medication non-adherence and risk compensation. Parents provided suggestions to facilitate informed, rational, and voluntary participation decisions and protect youth's safety if parental permission was waived. These findings can inform ways to increase parental trust in PrEP research and create adequate protections for adolescent participants.

Keywords HIV prevention · Pre-exposure prophylaxis · Parents · Adolescents · Men who have sex with men

✉ Brian Mustanski
brian@northwestern.edu

[1] Department of Medical Social Sciences, Institute for Sexual and Gender Minority Health and Wellbeing, Northwestern University, 625 N. Michigan Avenue, Suite 2700, Chicago, IL 60611, USA

[2] Department of Anthropology and Sociology, Kalamazoo College, Kalamazoo, MI, USA

[3] Psychology Service, Edward Hines, Jr. VA Medical Center, Hines, IL, USA

[4] Department of Psychology, Center for Ethics Education, Fordham University, Bronx, NY, USA

Introduction

Adolescents in the U.S. are disproportionately affected by HIV. In 2014, adolescent males had a four times higher rate of diagnoses than adolescent females, and adolescent men who have sex with men (AMSM) accounted for 92% of new HIV diagnoses among male adolescents (Centers for Disease Control and Prevention [CDC], 2016). Despite this disproportionality, there is a dearth of HIV prevention research focused on AMSM. Scholars have observed substantial barriers to conducting adolescent HIV prevention and sexual health studies, such as difficulty obtaining institutional review board (IRB) approval due to beliefs that research risks outweigh benefits, parental permission requirements that deter youth enrollment, and IRBs' concerns about parents' negative reactions if parental permission is waived (Fisher, Arbeit, Dumont, Macapagal, & Mustanski, 2016; Miller, Forte, Wilson, & Greene, 2006; Mustanski, 2011; Mustanski & Fisher, 2016).

Adolescent HIV prevention research is especially critical as the prevention landscape is changing rapidly. Combination approaches—such as using condoms in tandem with pre-exposure prophylaxis (PrEP), a highly effective HIV prevention medication (Grant et al., 2010)—are high priorities for HIV prevention in at-risk adults (White House Office of National AIDS Policy, 2015), and there is great interest in PrEP for adolescent populations. One U.S.-based study has examined the safety, acceptability, and feasibility of PrEP among AMSM under age 18 who self-consented to the study (Gilbert et al., 2015). Ethical questions regarding minor adolescents' involvement in PrEP research with and without parental permission, and how their parents feel about this research in general, remain unanswered (Knopf et al., 2016). As more PrEP studies with adolescents are likely on the horizon (Pace, Siberry, Hazra, & Kapogiannis, 2013), this study seeks to give voice to par-

ents' perspectives on the responsible conduct of adolescent PrEP research.

In an attempt to give adolescents agency in research decisions that affect their health and well-being (United Nations General Assembly, 1989), most empirical ethics research on HIV among adolescents has described teens' own views of study participation, risks and benefits, and parental permission. A series of qualitative studies with 14- to 17-year-old sexual and gender minority (SGM) adolescents demonstrated that, across three different types of studies (sexual health survey/focus group, HIV behavioral surveillance with testing, PrEP adherence), youth overwhelmingly felt that the benefits of being involved (e.g., emotional/psychological benefits, preventing HIV, learning one's HIV status, learning about sexual health, contributing to the SGM community) far outweighed the risks (e.g., emotional or physical discomfort, privacy/confidentiality concerns; Fisher et al., 2016; Macapagal, Coventry, Arbeit, Fisher, & Mustanski, 2017; Mustanski, Coventry, Macapagal, Arbeit, & Fisher, 2017). However, teens were substantially less likely to participate if their parents' permission was required, citing pursuant risks of revealing sensitive information about their sexual orientation, gender identity, and same-sex sexual activity to parents who held negative attitudes toward adolescent sexual behavior and SGM identities.

IRBs and investigators have struggled with decisions to involve adolescents in biomedical HIV prevention research and the extent to which parents should be involved (Gilbert et al., 2015; Knopf et al., 2016; Mustanski & Fisher, 2016). On the one hand, parents are assumed to have the best interests of their child in mind, and as such, parental permission is a tool for protecting children from emotional, psychological, or physical harm arising from research. On the other hand, requiring some youth to obtain their parents' permission may not be feasible (e.g., if the youth is homeless) or actually increase the risk of harm (e.g., if the youth identifies as SGM, if youth's parents disapprove of their adolescents' behavior). In such cases, IRBs are permitted to waive parental permission provided that adequate substitute protections exist (Department of Health and Human Services, 2009). Yet while adolescents may show that they can make informed, rational, and voluntary decisions about biomedical HIV prevention research participation without parental involvement and are willing to participate when research benefits are perceived to outweigh risks (Fisher et al., 2016), their parents may have differing views on the matter. For instance, a study of parent–adolescent dyads presented with a hypothetical microbicide trial for adolescent STI/HIV prevention found that parents wanted to be more involved in the research (e.g., by granting permission, learning about test results and risk behaviors) than their adolescent would have liked (Rosenthal et al., 2016). Moreover, while parents recognized the importance of adolescent participation and waivers of parental permission for this study, parents tended to express more concerns about research risks such as side effects, medication safety, and physical discomfort than did the teenagers (Chavez et al., 2016).

Parents' openness to adolescent participation in sexual health and HIV prevention research and their perspectives on risks, benefits, and parental permission likely varies according to parent and child characteristics. For instance, parents who have positive attitudes toward sexuality and science, believe the study is being conducted ethically (Moilanen, 2015, 2016), and see potential benefits and limited risks of study participation (Moilanen, 2016; Ott, Rosenberger, & Fortenberry, 2010) may be more inclined to give permission for adolescent sexual health research. In addition, parents may be more open to adolescent research participation if their teen is already having sex or at risk for STIs/HIV (Moilanen, 2015; Ott et al., 2010). Among parents of sexual and gender minority children, one study found that nearly 75% of parents believed parent permission should not be required for minor adolescents to participate in an HIV behavioral surveillance study (Newcomb, Clifford, Greene, & Mustanski, 2016). This percent increased as parents considered situations in which obtaining consent would be difficult or more dangerous (e.g., adolescent was not out). In addition, many expressed concern about the external validity of research findings if parent permission was required, and the possibility that teens who asked for parental permission may face negative consequences. Taken together, these studies suggest that parents may be open to adolescent involvement in sexual health and HIV research, and in some cases without parent permission. However, these studies examined parental perspectives on self-report and behavioral studies that likely would meet the criteria for minimal risk research and involve procedures for which IRBs are more likely to waive the requirement for parental permission. In addition, it is possible that parents' perspectives on adolescent involvement in more intensive biomedical HIV research protocols (e.g., multiple study visits, blood draws, adherence to study drug) may differ from their views on one-time self-report or behavioral studies.

Biomedical HIV prevention research on adolescents at high risk for HIV is urgently needed to stem the tide of infections in this group, and the voices of parents can inform policies and procedures for adolescent participation in these studies. To this end, we interviewed parents of heterosexual, gay, and bisexual teenage boys about their views on research risks and benefits and parental permission for a hypothetical PrEP adherence trial. Parents of sexual minority boys were included due to the high incidence of HIV among AMSM (CDC, 2016; Garofalo, Hotton, Kuhns, Gratzer, & Mustanski, 2016). Because child disclosure of an SGM identity may be related to HIV risk (Garofalo, Mustanski, & Donenberg, 2008; Mustanski, Swann, Newcomb, & Prachand, 2017; Thoma & Huebner, 2014), ideally a study of parents would include those whose sons are out and not out. However, recruiting parents whose sexual minority adolescent sons are not out to them is impractical, and as such for this study parents of heterosexual sons

were included to avoid the bias that may result with only hearing perspectives from parents who have sons who are out as gay/bisexual. We also explored potential differences in parent attitudes by their son's sexual orientation.

Method

Participants

Participants were 30 parents of adolescent boys recruited nationally through multiple sources, including paid Facebook advertisements targeting parents of teenagers (70%), a database of parents of SGM teenagers who had participated in our previous research (20%), and word of mouth (i.e., peer-to-peer recruitment, email advertisements; 10%). Advertisements described a university study that aimed to better understand health issues affecting teenage boys. Advertising strategies sought to recruit parents with diverse viewpoints, backgrounds, and sons of different sexual orientation identities. Facebook advertisements were targeted to individuals over age 18 who identified themselves as parents of teenagers and/or whose Facebook interests reflected that they were parents (e.g., parentteacher organizations, parenting websites). Advertisements depicted images of parent–child dyads and ad copy such as: "Being the [parent/mom/dad] of a teen is not always easy, especially when it comes to helping them learn to make safe and healthy choices for themselves. We want to hear from [parents/moms/dads] on how to help teens make safe decisions about participating in HIV prevention studies. Click here to find out if you're eligible." Additionally, advertisements specific to parents of sexual minority boys either specified that the study team was looking for parents of gay or bisexual adolescent boys and/or included more overt references to the gay community in the ad copy or images (e.g., rainbow flag).

Ads aimed at parents of heterosexual boys routed interested parties to an online eligibility survey with the university logo, while the eligibility survey for parents of sexual minority boys also included the logo of the sexual and gender minority research institute hosting the study. Individuals who screened as eligible were contacted via email with additional information about the study and a copy of the consent form and then had a brief phone call with a research assistant to address any questions they had about the study and to complete the consent process. Parents then were sent a link to a pre-interview survey and scheduled for a 30- to 45-min interview.

All interviews were conducted over the phone between July and September 2016. Eligibility criteria were that participants were parents of a cisgender male (i.e., assigned male at birth, current male gender identity) adolescent between the ages of 13 and 17 and that they spoke English. Further, half of the interviews were conducted with parents of adolescent boys whose parents were aware they identified as gay, bisexual, or queer. This study was approved by the IRB at Northwestern University, and participants were paid $30 for their time.

Measures

Before the interviews, participants completed survey items assessing sociodemographic characteristics (e.g., age, race/ethnicity, sexual orientation) and the age and sexual orientation of their son (i.e., gay, bisexual, straight/heterosexual, questioning/unsure, don't know). Additional measures were included to examine parents' experiences and perspectives relevant to sexual health and social and political issues. Participants were asked to rate their views on foreign policy, social, and economic issues on a 7-point scale (1 = very liberal; 7 = very conservative); higher scores indicated more political conservatism (Pratto, Sidanius, Stallworth, & Malle, 1994). Only the item on social conservatism was used for the purpose of characterizing the sample. In addition, participants also completed a six-item measure assessing whether they had ever talked to their child about various sexual health topics (e.g., when to start having sex, condoms, HIV/AIDS, choosing their sex partners; Miller, Kotchick, Dorsey, Forehand, & Ham, 1998).

Semi-structured Interview

Three trained staff members (two doctoral-level clinical psychologists and one doctoral student) conducted the interviews, which lasted approximately 30–45 min. The interview contained two parts (see Appendix). In Part 1, participants were read a vignette that described a randomized controlled trial of a text message-based PrEP adherence study for adolescent boys. The hypothetical study included the following components: HIV testing and self-report questionnaires every three months for one year, contact with medical providers at all study visits to assess safety of the drug, and randomization to receive daily text message reminders to take PrEP or no text message reminders (Fisher et al., 2016). After describing the study, interviewers asked parents about how their son and other teens could benefit from taking part in the study, their concerns about their son's participation in the study, potential barriers to their son's understanding the risks and benefits of the study, and what researchers should do to protect teens in the study. Next, we described the conditions under which IRBs would choose to waive requirements of parent permission for minor participation in research (i.e., when minor is legally allowed to consent to procedures involved in the study, or when study is minimal risk and it is unreasonable for the minor to obtain parental permission). Then, parents were asked about perceived benefits and concerns related to study participation if parental permission was waived, and what researchers should do to protect teens participating under a parental permission waiver.

In Part 2 of the interview, we aimed to understand more about teenage boys' decision-making capacities as they related to

research. Interviewers first asked parents to describe a time their teen had to make an important decision during which they thought their child made a good decision, and a time when they thought their child did not make a good decision. Following this, interviewers asked whether and how their sons would apply these decision-making strategies to the decision to participate in a research study on PrEP, what might get in the way of their child's ability to make a good decision about study participation, and what researchers can do to help teens make the best decision for themselves about participating in a study on PrEP. Interviewers used open-ended probes in response to participants' answers to elicit more detailed responses.

Coding and Analysis

Individual transcripts were imported into Dedoose (2015) mixed-methods software for analyses. We coded both deductively, based on our research questions, and inductively, which enabled themes to emerge throughout the analysis. We began with the following broad codes, which were directly related to questions posed to participants: (1) Benefits to teen involvement in a study with and without parental permission, (2) Concerns around teen involvement with and without parental permission, (3) Attitudes toward waiver of parental permission, and (4) Desired protections for teens involved in a study without parental permission. Broad codes were applied to each transcript to identify excerpts broadly representing each key topic covered during the interviews, with subcodes developed to represent themes that emerged from the transcripts. Themes were identified using the constant comparison method (Glaser & Strauss, 1967). Two team members applied thematic codes to the transcripts, and reliability was tested on 25% of the transcripts. The coders achieved a kappa score of .81, indicating strong reliability (Hruschka et al., 2004). Participant quotes are presented verbatim with the exception of minor edits to utterances, spelling, and grammar to facilitate readability.

Results

Demographic characteristics of the sample are presented in Table 1. Most parents were female, White, heterosexual, and socially liberal. The average parent age was 45.5 (SD = 6.6 years, range 33–56 years), and the average son's age was 15.3 (SD = 1.5 years, range 13–17). Most parents reported having talked with their sons about sex and sexual health issues. At the beginning of the interview, parents were asked if they had heard of PrEP to provide the interviewer with context regarding their baseline knowledge of the medication. Most parents had not heard of PrEP, and of those who had ($n = 7$), most did not know much about it. Parents who had heard of PrEP all identified as female and liberal, were mostly White ($n = 5$). Parents of heterosexual sons and parents of SGM sons did not systematically differ in how frequently they endorsed

Table 1 Demographic characteristics of the sample ($N = 30$)

Demographic characteristic	Mean (SD) or *n* (%)
Parent age (in years)	45.54 (6.61)
Parent gender	
Female	26 (86.7%)
Male	4 (13.3%)
Parent race/ethnicity	
White	21 (70.0%)
Black or African American	5 (16.7%)
Latino	2 (6.7%)
Asian	1 (3.3%)
Other	1 (3.3%)
Parent sexual orientation	
Straight or heterosexual	27 (90.0%)
Gay	1 (3.3%)
Bisexual	1 (3.3%)
I don't want to answer	1 (3.3%)
Social conservatism	2.23 (1.63)
Very liberal	15 (50.0%)
Liberal	6 (20.0%)
Slightly liberal	1 (3.3%)
Middle of the road	5 (16.7%)
Slightly conservative	2 (6.7%)
Conservative	0 (0.0%)
Very conservative	1 (3.3%)
Parent talked to son about sexual health topics	
When to start having sex	25 (83.3%)
Condoms	27 (90.0%)
HIV/AIDS	28 (93.3%)
Pressure to have sex	27 (90.0%)
Choosing sexual partners	25 (83.3%)
Sex between men[a]	10 (66.7%)
PrEP knowledge at baseline	
Knew about PrEP	7 (23.3%)
Did not know about PrEP	23 (76.7%)
Child age (in years)	15.37 (1.45)
Child sexual orientation	
Straight/heterosexual	14 (46.7%)
Gay	7 (23.3%)
Bisexual	6 (20.0%)
Questioning/unsure	2 (6.7%)
I don't know (presumed heterosexual)	1 (3.3%)

All participants who reported a Latino ethnicity were coded as Latino for race/ethnicity regardless of their race; $n = 24$ for parent age, because six parents did not report their age; parent age ranged from 33 to 56; child age ranged from 13 to 17; social conservatism ranged from 1 to 7 (1 = very liberal to 7 = very conservative)

[a] This item was only asked of the 15 parents who indicated their son was gay, bisexual, questioning, or unsure of their sexual orientation

themes. Three members of the researcher team independently read transcripts separately for the parents of sexual minority and then heterosexual sons to see whether there were nuanced differences in the way parents discussed these issues that may not have been detected by differences in the counts of code applications. Each researcher independently arrived at the conclusion that there were not nuanced differences in the descriptions. As such, results for both groups of parents are reported together.

Benefits of Participation in PrEP Studies

After describing a hypothetical PrEP study, parents were asked how their teen and other teens could benefit from the study. The majority of parents ($n = 26$; 87%) perceived potential benefits of their sons participating in the PrEP adherence study (including HIV protection, increased awareness of risk behavior and PrEP as prevention, and sexual health education). Four parents (13%) stated that there would be no benefits, and their comments reflected a general distaste for preventive medications or the belief that their teen was not engaging in sexual risk behavior.

HIV Protection

Fifteen of the parents (50%) noted that being in a PrEP study would help teens remain HIV-negative. For example, a mother of a gay 17-year-old said: "…if it's something that can prevent HIV…and for him to understand that there's something that is tested and could prevent him in case he screws up and has unprotected sex…that would be a huge benefit for him…" Some parents also said it could protect their teen's sexual partners, the gay community, and the general population. For instance, a mother of a heterosexual 17-year-old said: "It could prevent him from getting infected with AIDS, HIV" and "It could protect any sexual partners from HIV infections." Additionally, a mother of a gay 17-year-old said, "Anybody who's sexually active, especially gay teenagers, this study is huge if it can prevent an entire upcoming generation from having to worry constantly about becoming HIV positive because they made a mistake…"

Increased Awareness of Risk Behavior and PrEP as Prevention

Thirteen of the parents (43%) also noted that being in a PrEP study would increase teens' awareness of the riskiness of their sexual behavior and the availability of a medication to help prevent HIV. A father of a heterosexual 5-year-old described this as: "I think that going to an appointment every three months would raise his paying attention to and awareness of the risk and what counts as risky behavior…" Similarly, a mother of a gay 16-year-old said: "I think that kids as a general rule feel invincible…and we can talk condoms all we want, but they're not necessarily going to use them, and just to be aware that there's another option [for HIV prevention]…it's great…"

Sexual Health Education

Thirteen of the parents (43%) expressed that participation in a PrEP study could provide teens with education about sexual health in general, which the parents may not have the appropriate knowledge to do themselves. Some parents also noted that even teens who were not in the study could benefit, because those who were in the study could share what they learn with friends. For example, a mother of a bisexual 17-year-old said:

> …I think it would be really good and beneficial if he could take that information back to his circle and say, "…you guys need to go talk to your moms and see about going on this PrEP stuff, and if you're already having sex and you realize you didn't use a condom, there's this other stuff called PEP that you can use," or, "Talk to your doctor and you don't have to tell your mom you know that you talked to your doctor," that kind of stuff. You know, just empower them a little bit more and give them more control of their sexual health…

Concerns About Participation in PrEP Studies

Parents were asked what concerns they would have if their teen was in a PrEP study. Parents described three concerns: medication risks, increased risk behavior, and medication non-adherence.

Medication Risks

Most parents ($n = 21$; 70%) expressed concern about the short- and long-term side effects of PrEP, especially given the preventive nature of the medication. Parents' concerns about side effects related, in part, to their teen's developmental stage. A mother of a gay 16-year-old said: "…I would worry about the effects of the medicine on someone that's developing still and growing…" Parents also expressed concerns about potential drug interactions with medications that their teen was already taking.

Some parents' concerns depended on their perception of whether or not their teen was engaging in risk behavior. For instance, a father of a heterosexual 14-year-old said: "If I thought that he was sexually active and at high risk, then I would probably feel differently, I'd think it would be a good thing that would help him, but I don't think at this point it's something that he would benefit from…" Some parents went as far as to say that they did not think anyone should take preventive medication. A mother of a heterosexual 17-year-old said: "Taking a pill when you're negative…I just don't think you need it, even if you're at risk. I think once you become positive you take it, but if you're just at risk I don't think it's a good thing to be taking something when you don't have something."

Increased Risk Behavior

Another common concern expressed by parents was that their teen would be less likely to use condoms if they were taking PrEP ($n = 14$; 47%). A mother of a heterosexual 14-year-old stated: "…he may not always [take the pill] and he could encounter the risky behavior and think he's okay because he's on this, but he hasn't taken it [consistently] so he might be exposing himself." Similarly, a mother of a gay 17-year-old said: "…I wonder if it would increase unsafe sex because you thought you were protected. Because these are boys who don't know; their brain is not formed yet…" Other parents expressed their concerns more bluntly, for instance: "…the PrEP drug could encourage him to be more promiscuous" (mother of a heterosexual 17-year-old) and "…there's a subtext there of, 'oh now you can engage in this risky behavior'…[PrEP] doesn't prevent everything—it doesn't prevent pregnancy, other STDs…" (father of a heterosexual 15-year-old).

Medication Non-adherence

Seven of the parents (23%) raised concern about whether or not their teen would be able to adhere to a daily medication without their help. A mother of a bisexual 16-year-old said: "I don't know if he's mature enough to really keep track every day by taking a pill." For some parents, this concern was based on previous experience with their teen. A mother of a gay 14-year-old said: "Well, I can tell you that he is on meds right now, and the kid does forget. We always have to remind him." Of note, a father of a heterosexual 15-year-old expressed that his concern about medication non-adherence could be alleviated if he was involved in the study: "If we had given him permission…his mother and I would make it our job to make sure he took it every day." Although several parents expressed this concern, a father of a heterosexual 14-year-old thought it could promote responsibility: "…it could teach him a responsibility of protecting himself and taking his medication on a regular basis."

Attitudes About Participation in PrEP Studies with Parental Permission Waiver

Parents were then asked about their attitudes toward their teen's participation in PrEP studies with a waiver of parental permission. Parents were specifically asked to describe both the potential benefits and concerns they would have if their teens were participating in such a study without their permission.

Twenty-seven parents commented on their general feelings about their teen's participation in the PrEP study under a parental permission waiver. Of these, fifteen (56%) stated that they would not be comfortable with a waiver of parental permission, eight (26%) said that they would not feel any differently, and four (15%) expressed conflicted or mixed feelings. We then asked all parents to elaborate on the specific benefits and concerns about their teen's participation in the study with a parental permission waiver.

Benefit of PrEP Study with Parental Permission Waiver

Twenty-eight parents answered the question about potential benefits of parental permission waivers. The only benefit they identified was increased comfort with participation ($n = 12$; 43%). These parents often made comments supporting their teen's autonomy over their sexuality and health and saw the waiver of parental permission as a means to reinforce that autonomy. A mother of a gay 17-year-old stated: "So at 17, he's certainly afforded his own level of privacy and liberty, and so he would be able to maintain that. Also if he had questions and wanted to talk about it, he could come to me with it in his own way versus walking past me every day going 'oh my god she knows'."

Parents often noted that the benefits of a permission waiver may be greater for certain groups of teens, such as sexual minority youth or youth of color. For example, a mother of a gay 17-year-old explained: "There are some teens whose parents might not necessarily have an open perspective…so they would be able to participate without their parents' permission if their parent wasn't supportive of their lifestyle." In addition, a mother of a Black, gay 17-year-old gay said: "There's a history of African-Americans and other minorities not wanting to participate in research because they have this fear of what's going to happen, so if you have children who are not out to their parents…or whose parents just have a fundamental opposition to research in general or have a huge distrust of the medical community, then they would participate without worrying about their parents."

Finally, other parents stated that waiving parental permission would lead to increased comfort with participation and thus facilitate youth's access to PrEP. This could benefit teens engaged in risky sexual behavior who were not willing to tell their parents as well as the community by creating a lower-risk pool of sexual partners. A mother of a gay 16-year-old explained: "…kids that are participating in unprotected sex would then have this layer of potential protection for them that they wouldn't get [if] the parents had to be informed because their parents might not let them."

Concerns About PrEP Study with Parental Permission Waiver

Twenty-six parents responded to the questions regarding concerns about parental waiver. While three (12%) expressed that they would have no concerns, most excerpts reflected parents' belief in the value of parental monitoring during biomedical research study participation. Fourteen parents stated that they would have heightened concerns about medication side effects if their permission was not required ($n = 14$; 54%). A mother of a bisexual 14-year-old explained it this way: "Some medications have long-term side effects…and I would just be concerned about not knowing that they were taking a certain medication and if they were having a reaction to the medication…"

Six parents (23%) perceived their sons to be too immature to decide about PrEP research or adhere to PrEP on their own. For example, a mother of a heterosexual 17-year-old explained that her teen would have difficulty weighing the pros and cons of PrEP use, particularly as she perceived him to be at low risk and expressed concern that research staff would not provide adequate information for him to make that decision. She explained: "[I'd be concerned] that he wasn't objectively informed of the risks and benefits. And that risks and benefits to him were not fully assessed…I would like to weigh that out with him and say, 'These are the risks, these are the benefits, the benefits to you personally are extremely small, they're bigger to the wider community.'" A mother of a gay 17-year-old felt that her teen should not be allowed to initiate use of a medication because he was not capable of thinking through the implications: "I don't know that he is mature enough to think about possible implications of being in a drug study." Finally, a mother of a bisexual 16-year-old stated: "I would be more concerned about his ability to take it every day…I know that with his other medications that he takes I remind him or I always ask or check that he's taking it every day. And he doesn't always remember, so if I'm there checking then it's fine, it works out."

Protections for Teens Involved in PrEP Study Without Parental Permission

Parents were asked what protections they would like to see in place should their teen be involved in a study without parental permission. Parents described three sets of protections: access to medical professionals, access to mental health professionals and general research protections that should be in place for any study.

Access to Medical Professionals

Nine (33%) of the 27 participants who responded to the questions about necessary protections for teens stated that they would want medical professionals available should their teen self-consent to a PrEP study. After stating that she would want her son to be monitored carefully for side effects, a mother of a bisexual 14-year-old stated:

> If you're asking about side effects and things like that it should probably be some sort of a medical personnel… somebody with some clinical background who could say "oh that actually is a side effect of this medication" or "that's not a side effect of this medication" or "okay that's a side effect but we don't need to worry about it" or "it might be a side effect that we do need to worry about."

A father of a heterosexual 14-year-old explained that he would expect medical professionals to also contribute to his son's adherence: "I would hope that they would…make sure that he's definitely following the instructions and taking the medication the way he's supposed to be."

Access to Mental Health Professionals

Five (19%) of the participants stated that they would want their teen to have access to mental health professionals as well. A mother of a heterosexual 17-year-old felt a counselor should be present in order to ensure that her son was being provided objective information about their involvement in the study, explaining: "[I would want] a lot of counseling, to be sure that they do objectively understand all the things in consideration… To help decide whether, whether the study is really informing him objectively, recruiting him objectively."

General Research Protections

Twenty (74%) of the respondents desired protections for their teens that represent standard procedures for any IRB-approved study. Most of these parents described the importance of providing developmentally appropriate information during the consent process, ensuring that teens comprehend the study procedures, and providing teens with information about PrEP. For example, a mother of a heterosexual 17-year-old said: "Make sure [he] understands clearly what is going on, what's happening, what he is taking…the pill that you're going to give him, how much has that been researched, what are the side effects of everything…is this an experimental thing or is it something that's been used before and they know is gonna work?" Some parents simply stated that "confidentiality" was important. One mother of a bisexual 17-year-old indicated that researchers should ensure that teens "feel that their questions and their feelings are valid" during the study. Finally, although a youth advocate is often suggested by IRBs as an adequate substitute protection for minor participants when the parental permission requirement is waived, no parents spontaneously suggested this option; in fact, when participants were asked if they had a particular type of person in mind who could help their teen through the consent process, parents simply reiterated their desire to have a doctor or mental health professional available.

Teen Decision-making Experiences Applied to Research

Finally, parents were asked about the decision-making strategies that their sons use in their everyday lives and how those strategies relate to their ability to decide whether or not to participate in a research study. In general, parents indicated that the decision-making strategies their sons use in everyday life would apply to decision making about research participation (e.g., consulting with parents, peers, other trusted people; making a list of pros and cons). For example, one mother of a bisexual 14-year-old said, "Well I would say gathering as much information from the researcher, probably doing some research

online about HIV on his own and also the medications, PrEP… statistics [about] contracting HIV and passing it on to your partner, and by putting all of those together deciding whether it was something he connected with and was important enough in his life to be in the study." Similarly, parents cited that certain personality traits (e.g., impulsivity, being easily persuaded) and not using rational decision-making skills (e.g., not thinking things through carefully) would be barriers to good decision making in both a research study and in everyday situations. The mother of a heterosexual 17-year-old explained, "If he ended up making a bad decision about study participation, I would guess it would be because he didn't…pay attention to all the information that was given to him, or went straight to his friends and asked only their opinion and went with that without thinking about it."

When asked to reflect on how researchers could help teens leverage their inherent decision-making skills in the research context, parents provided several suggestions that can help ensure that teens make informed, voluntary, and rational decisions about study participation. Echoing sentiments from the "general research protections" section, nearly all parents advocated for giving teens ample information about the study, especially its risks and benefits; one mother of a gay 17-year-old suggested having a "list of questions that a person should ask themselves…'When you're thinking about your decision, think about these things…Do you feel comfortable committing to take a pill every day? Do you take other medication that you might be on regularly, or do you miss days?'" Moreover, parents suggested that researchers could encourage participants to take time between learning about the study and deciding to participate to facilitate more deliberative decision making. For example, a mother of a heterosexual 14-year-old said:

> Having a very non-pressured approach, potentially even a waiting period before enrolling in a study might be helpful…Maybe there's a consent process and then a waiting period…where you do some education, you make sure he's absorbing the information, and before a study drug is introduced, or before tough questions about sexual activity or drug activity or whatever are introduced, he has some time to get to know the researcher or a point person on the research team and be able to develop that rapport and feel like, "Okay, I definitely want to continue in this study, I don't feel pressured, I don't feel like I've made a hurried decision."

In addition, some suggested allowing teens to consult with someone outside of the study team, like a sibling, friend, former participant, or counselor during the consent process. Parents also suggested that the researchers provide links to videos, websites, and information so that teenagers could determine whether the study was trustworthy. For instance, a father of a heterosexual 15-year-old said: "It would be…helpful to be able to tell him, 'You can go to this website to find out about the study,' to see that it's affiliated with this university, 'If you have concerns to call this number,' to help him feel that it's a legitimate operation."

Discussion

Research studies examining attitudes about youth participation in sexual health survey research have demonstrated that parents generally consider participation worthwhile (Moilanen, 2015). This is particularly the case when parents consider the potential benefits of participation in the research as sufficient and the risks minimal (Moilanen, 2016; Ott et al., 2010). Findings from the present study demonstrate that parents of both heterosexual boys and AMSM critically consider if and how they want their adolescent sons to take part in biomedical HIV prevention research. Further, parents of heterosexual boys and parents of AMSM did not differ in the themes which manifested in their interviews. It must be noted though that the parents represented in the study were unique, in that they tended to endorse having spoken with their sons about sex and presumed to know the sexual orientations of their sons. Accordingly, findings must be understood within that context.

Parents identified several benefits of their son's participation in a hypothetical PrEP adherence study. Consistent with previous research on parental motivators for consenting to adolescent participation in sexual health research (Moilanen, 2016), parents described gaining sexual health information as a benefit of participation. Further, parents stated that participation in this study would heighten their son's awareness of what constitutes risky behavior while also alerting them to the availability of PrEP to reduce HIV risk. It is interesting to note that some parents' narratives regarding their son's participation in sex seemed to assume that adolescent sex was necessarily predictive of poor outcomes or indicative of irresponsibility. While the perspective that adolescent sex is irresponsible or a risk behavior in and of itself is not atypical for parents or even researchers (Harden, 2014), it may limit adolescent participation in biomedical HIV research in multiple ways. These parents may be particularly reluctant to allow their sons to participate in such research if the study is construed as endorsing adolescent sexual behavior. This may reflect the incorrect belief that answering research questions about sex may make teens more likely to engage in sexual behavior (Santelli et al., 2003). Further, their sons may perceive participation in such a study as violating parental expectations and therefore potentiating a negative outcome (e.g., punishment from parents). As such, it may be important for studies to consider how they encourage healthy sexual behaviors for adolescents while avoiding being misunderstood as encouraging adolescent participation in sex.

Parents' most frequently cited concerns about the hypothetical PrEP adherence study were about medication side effects. These

were similar in nature to concerns voiced by youth in other studies (Fisher et al., 2016; King et al., 2014) such as drug interactions, impacts of PrEP on developing adolescent bodies, and other unforeseen outcomes of taking the medication. IRB regulations require the disclosure of potential intervention side effects, and our findings suggest that providing detailed information about what is and is not known about PrEP, along with ample opportunities to ask questions, will be an important aspect of facilitating parents' permission for adolescent PrEP research.

Some parents also expressed concern about risk compensation when receiving PrEP—that their sons would be less likely to use a condom when having sex or would increase how often they engaged in condomless sex. Parents noted that PrEP does not prevent pregnancy or other STIs besides HIV, and therefore if taking PrEP was associated with an increase in condomless sex it could increase the risk of these other outcomes.

Parents also noted concern about whether their sons would be able to adhere to the medication without their assistance. Parents often cited their son's maturity and ability to be responsible as causes for concern in this area. This was similar to concerns communicated by youth assessing whether they would participate in a hypothetical PrEP study (Fisher et al., 2016). This demonstrates that parents and youth are assessing the potential risks of study participation in similar ways.

When asked their attitudes about their teen's participation in a PrEP study without parental permission, parents demonstrated a wider range of perspectives. Similar to research examining other sexual health research with teens (Flicker & Guta, 2008), some parents indicated no difference from their attitudes about participation with permission while others demonstrated varying levels of discomfort about such participation. A small group of parents described feeling conflicted about whether their sons were sufficiently able to make decisions about their health on their own. Though these parents ultimately indicated that they would be supportive of their sons participating in research without their explicit consent, this demonstrates the potential need to develop and utilize tools to assess consent preparedness in adolescents. Such tools would need to examine factors like ability to assess risks and benefits, understand requirements of study participation, and research design aspects (e.g., random assignment; Fisher et al., 2016). More than half of parents stated that they would not be comfortable with their sons participating in a PrEP study without their permission, citing concerns related to medication side effects, adherence, and potential increased risk behavior. That parental concerns about waivers were primarily tied to these potential risks, rather than inherent beliefs about parental rights, suggests that study designs that could remove or reduce these risks would likely increase parental acceptance of their child participating in a study without their permission. Further, most parents in the study indicated that they had not known much about PrEP before their participation in the study. Accordingly, it is not explicitly clear whether some of their stated concerns might abate over time or with greater knowledge about PrEP. This raises the question as to whether increased public knowledge about the risks and benefits of PrEP might also increase parental acceptance of their child participating in a PrEP study without explicit parental permission.

While parents varied in whether they would support their teen's participation in a PrEP study without their permission, some parents were able to identify utility for a waiver of permission given that some adolescent men cannot safely reveal same-sex desire or behavior to their parents. This is consistent with the findings of previous research indicating that parents were supportive of waivers when youth had difficult relationships with their parents (Newcomb et al., 2016). Further, it is consistent with current practice when obtaining parental permission is not a reasonable requirement for protecting the child (Department of Health and Human Services, 2009). Parents also stated that they believed that a waiver of consent would benefit teenagers who are interested in participating in a PrEP study, but whose parents may distrust research or the medical establishment. Accordingly, the waiver of parental permission was perceived to increase the validity of PrEP study data and reduce obstacles to participation by facilitating access to research to teenagers who may otherwise be unable or unwilling to participate.

Parents described a number of actions they believed researchers could take in order to ensure the safety of teens taking part in research without parental permission. Access to medical and mental health professionals appeared to be an important factor for increasing parents' comfort with their sons participating in biomedical research. Parents described these professionals as necessary for answering questions, ensuring the child's health was consistently assessed, and to provide any support needed, given the gravity of sexual health and sexual health discussions. As such, researchers should provide youth with access to such professionals when possible, or well trained staff with similar skills, in order to increase parent comfort. In addition, parents voiced a desire for research protections that are standard practice in any IRB-approved study, suggesting that parents appreciate and are supportive of currently used participant protections for adolescents. These protections included measures to protect confidentiality, obtaining informed consent, and providing health resources and education to support healthy behaviors during study participation.

Parents offered examples of teens making good decisions in everyday life (data not presented) and drew connections to how those skills could apply to making decisions about research participation (e.g., searching online for more information about the study, consulting with others). They also described examples when they believe their son did not make a good decision and offered suggestions for how researchers

could prevent that from occurring when a teen is making a decision about being involved in a research study. In addition to the suggestions described above, in this section of the interview the parents also suggested that study protocols could set aside time for the adolescent to think about their study participation to prevent a rash decision and give opportunities to get to know the research team.

Limitations

The findings of this study must be understood with consideration of its limitations. First, the sample size was relatively small. However, there have been very few studies of parents of gay/bisexual teen boys and methods for larger-scale recruitment of these parents are still in development (Mustanski, 2015). Second, the participants were parents who were willing to participate in a study related to attitudes about children's participation in research, half of whom were comfortable sharing that their child identified as a sexual minority, and most tended to be more socially liberal and had previously talked with their sons about various sexual health issues. Parents who were unwilling to participate in this research or were unable to be reached by our recruitment methods may have different perspectives on adolescent research participation. It may be particularly useful in future research to interview parents with other political orientations. More specifically, parents with a libertarian orientation may be more likely to support adolescents consenting to research participation (Jago & Bailey, 2001), but they may also have different perspectives on how that should best be done. Further, parents with a more conservative orientation may have perspectives that differ in multiple ways (e.g., support for participation, concerns related to participation, protections needed for adolescent participants) from the parents in the present study. Third, parents reported their beliefs about the sexual orientation of their child and many believed their sons had never had sex, and some may be incorrect. Given findings suggesting that perception of risk impacts parents' perspectives on study participation (Pasternak, Geller, Parrish, & Cheng, 2006), it is worth considering how the perspectives of parents might change if their son disclosed same-sex attractions or that they were sexually active and not using condoms. The fact that we found no substantial differences in the perspectives of parents with sexual minority or heterosexual sons partially ameliorates this concern. Fourth, the sample was mostly White and therefore may not reflect attitudes of parents of color. Finally, this study focused specifically on the perspectives of parents whose sons are cisgender. As such, the findings of this study do not represent the attitudes of parents of transgender adolescents. These parents may perceive risk somewhat differently than the parents of cisgender boys, given the additional medical complexity of transgender youth receiving gender-affirming medical care.

Conclusion

Recognition of the urgent need for empirically validated HIV prevention strategies for at-risk youth raises ethical challenges for investigators and IRB members who often need to interpret broadly written federal regulations by drawing on their own moral compass to determine acceptable risk–benefit ratios and the extent to which waiver of parent permission provides adequate protection of youth's rights and welfare. Parent perspectives on these critical decisions are an untapped resource for identifying contextually sensitive and age-appropriate participant protections. Our findings illustrate how engagement of parents in discussion of ethically relevant issues can inform the responsible design and implementation of urgently needed HIV prevention research involving AMSM. Parental views reflected the value of guardian involvement in PrEP research participation as well as an appreciation for reasons why guardian permission benefits could be outweighed by the possibility that failure to waive such permission would result in inadequate representation of sexual minority male youth most in need of evidence-based HIV prevention strategies. On the one hand, our respondents noted that parents could play an important role in PrEP intervention studies through reinforcing medication adherence and providing support in case of an adverse event or side effect. This perspective echoed the opinions of SGM youth who were out to and had supportive relationships with their parents (Fisher et al., 2016). On the other hand, recognizing that for some sexual minority males guardian permission requirements could result in family rejection or punishment, respondents recommended that when permission was waived investigators should ensure youth had access to medical and mental health professionals and that strict confidentiality procedures were in place to protect against disclosures to parents that might place the youth in jeopardy. Within the context of guardian permission waivers, parents also provided guidance for best practices for ensuring informed and voluntary youth self-consent. For example, they recommended enhanced discussion of PrEP risks and benefits, use of age-appropriate information delivery formats (e.g., multimedia), built in time for youth to consider their participation decision, and decision supports (e.g., providing in advance of the first study appointment information about the research and a list of suggested issues to consider in making a participation choice). As our study illustrates, understanding the hopes and concerns of parents can help investigators and their IRBs maximize benefits and minimize risk in adolescent PrEP research and create conditions for youth self-consent that reflect parental values and merit their trust.

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Appendix: Interview Script

Description of PrEP Adherence Study

We'll be discussing a study that involves taking a medication called PrEP, which stands for pre-exposure prophylaxis. Have you heard of PrEP before?

Interviewer Note: Get a Sense of Parent's Knowledge About PrEP Before Continuing

PrEP is a medication that prevents people from getting HIV. It is a pill that is taken the same time each day. PrEP is very effective when taken daily, but like any medication there are short-term side effects, like upset stomach, loss of appetite, or mild headache, and possible long-term side effects that are no worse than daily aspirin use. It has been approved for adults by the U.S. FDA (Food and Drug Administration), and studies testing PrEP in teenagers are underway.

Now I'll tell you about a hypothetical study that researchers at a university might do with teenagers and PrEP. I'll ask you what you think about the study, its potential benefits, and what researchers can do to make sure [teen's name] is safe while he participates. Please keep these things in mind as I tell you more about the study.

The purpose of this study would be to see whether getting daily text message reminders would help your son remember to take PrEP every day. First, [teen's name] would have to get your permission to participate. Assuming you agree, to make sure [teen's name] doesn't have HIV, researchers would give him an HIV test at the beginning of the study. If his test showed he had HIV, he wouldn't be able to participate, but the researchers would connect him with a doctor for HIV treatment. If he did not have HIV, a study doctor would give him PrEP pills and a counselor would talk to him about safer sex.

The study would last a year. [Teen's name] would be randomly assigned to one of two groups—one group that gets daily text message reminders to take PrEP, and the other group that gets reminders every 3 months during check ins with the researchers. Everyone has the same 50/50 chance of being in each group. To make sure the study is fair, the teens and researchers don't choose who would get to be in which group.

After [teen's name] enrolled in the study, he would take the pill every day. Every 3 months, all participants would have a check in with the study counselor where they receive another HIV test, talk about safe sex, how many days he didn't take PrEP, and a reminder to take PrEP. The text message group would get reminders every day.

Once the study is over, researchers will know whether or not getting daily text messages improved teens' ability to take the PrEP pills daily. This will help doctors in the future decide whether to offer text messaging as part of HIV prevention treatment.

Now I'm going to ask you some questions about what I just told you. Let's assume [name of teen] wanted to participate in the study and that you gave him permission to do so.

1. How could he benefit from being in a study like this? How might *other* teens benefit from this study taking place?
2. What would your concerns be if [name of teen] were in this study?
3. What might get in the way of [name of teen] being able to understand the risks and benefits of this study?
4. What do researchers need to do in order to ensure the safety and well-being of [name of teen] if he was in this study?

Parental Permission Waiver for PrEP Study

Now, imagine that this study didn't require your permission to participate

1. How might you feel differently if [name of teen] did NOT need your permission to participate in this study?
2. What would your concerns be if [name of teen] were in a study on PrEP and your permission was NOT required?
3. What would be the benefits to [name of teen] if your permission was not required for the PrEP study? How might *other* teens benefit?
4. If [name of teen] did not need your permission to participate in this study, what do researchers need to do in order to ensure his safety and well-being?

Questions About Teen Decision-making Strategies and Application to Research Consent

In this next set of questions, we'd like to know more about how [name of teen] makes decisions and how those strategies might be applied to his decisions to participate in research studies.

Tell me about a time [name of teen] had to make an important decision and you think he made a good decision. What skills did they draw from? Tell me what strategies he used.

Now I'm going to ask a question about how this could apply to a hypothetical study.

1. How could [name of teen] use that same approach you just described when making a decision about participating in a research study on PrEP?

Now tell us about a time [name of teen] had to make an important decision and you think he did not make a good decision. What strategies did they (fail to) use? What got in the way if the decision being a good one?

Now like before, I'm going to ask about how this decision-making strategy could apply to a hypothetical study.

1. How might [name of teen's] process for making the bad decision you described get in the way of [name of teen]'s ability to make a good decision about participating in a PrEP research study?
2. What do you think could have prevented him from making the bad decision you just described? Are there similar things that the researchers can do for [teen's name] that might help him make the best decision for himself about participating in a PrEP research study?

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