



“Where Did This [PrEP] Come From?” African American Mother/Daughter Perceptions Related to Adolescent Preexposure Prophylaxis (PrEP) Utilization and Clinical Trial Participation

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Abstract

Despite the demonstrated effectiveness of preexposure prophylaxis (PrEP) to reduce incident HIV infections, PrEP's potential as an HIV prevention strategy for adolescent populations is unknown. This study assessed perceptions of adolescent PrEP use and clinical trial participation among African American women and their adolescent daughters. We conducted focus group discussions with 15 African American mother/daughter pairs ($N = 30$). Findings suggest a general lack of PrEP awareness, favorable attitudes toward adolescent PrEP use, altruistic attitudes regarding research participation among daughters, and less favorable attitudes toward adolescent clinical trial participation among mothers. Study findings have the potential to inform strategies that provide equitable access to HIV scientific advances among African American women and girls and promote informed parent–child research decision making.

Keywords

African American women and female adolescents, preexposure prophylaxis (PrEP), clinical trial participation, informed parent–child research decision making

Introduction

There is an urgent need for effective HIV prevention tools for African American female adolescents who are disproportionately affected by HIV and adverse sexual health outcomes due to inequities in the uptake of HIV care, prevention, and treatment services (Centers for Disease Control and Prevention [CDC], 2014a). The rate of HIV for African Americans girls ages 13 to 24 years is 20 times higher than that of their White counterparts and approximately 6 times higher than that of Hispanics (38.4 per 100,000, 1.9 per 100,000, and 6.4 per 100,000, respectively; CDC, 2012, 2014a), highlighting the need to reduce HIV incidence among African American adolescent girls. Individual-level factors that heighten young women's vulnerability to HIV include a lack of awareness regarding safe sexual practices, existence of other sexually transmitted infections (STIs), cultural and gender barriers to assert male partner condom use, early onset of puberty, and psychosexual maturation (CDC, 2014a). Ecological risk barriers to sexual health services include HIV/AIDS stigma and discrimination within the African American community, social marginalization, neighborhood disadvantage, high viral

load neighborhoods, rates of untreated STIs, and inadequate access to health information and preventive services (Adimora & Schoenbach, 2002, 2013; CDC, 2017a; Kerr & Jackson, 2016). The multiple individual and ecological factors that increase HIV vulnerability for African American adolescent girls underscores the need to implement evidence-based and population-sensitive HIV prevention methods that are “discrete, reliable, and woman-controlled” (Seidman & Weber, 2016) to attenuate the cumulative impact of these factors (Bradley, DiClemente, Sales, Rose, & Davis, 2015; Cáceres et al., 2015; Pace, Siberry, Hazra, & Kapogiannis, 2013).

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Approved by the Food and Drug Administration (FDA) in 2012 for use by uninfected adult populations, preexposure prophylaxis (PrEP) is a promising biomedical prevention strategy that has the potential to alleviate HIV/AIDS-related disparities among African American female youth by equipping them with greater control and agency over their sexual lives (PEPFAR, 2016). However, PrEP efficacy is highly dependent on consistent daily use for women in pill form (Baeten et al., 2012; Baeten, Haberer, Liu, & Sista, 2013; Collins, 2016; Grant et al., 2010; Marrazzo et al., 2015; Okwundu, Uthman, & Okoromah, 2012; Thigpen et al., 2012; Van Damme et al., 2012), for whom near perfect adherence is required (i.e., six to seven doses per week) to achieve optimal protection in the female genital tract (Cottrell et al., 2016). Thus, clinical trials are currently underway to evaluate other forms of PrEP delivery, including vaginal rings, microbicides, and injectables.

Recent studies indicate that PrEP is acceptable to women (Auerbach & Hoppe, 2015; Auerbach, Kinsky, Brown, & Charles, 2015; Marrazzo et al., 2013; Van Damme et al., 2012) and that women are more likely to adhere if (Bekker et al., 2015) PrEP delivery is sensitive to the sociocultural, structural, and behavioral barriers to uptake and adherence (Pettifor et al., 2015; Strathdee, Wechsberg, Kerrigan, & Patterson, 2013). However, PrEP's potential as an HIV prevention strategy for African American adolescent girls is unknown. Furthermore, little is known about African American mothers' knowledge of, and attitudes and beliefs toward, their daughters' use of HIV preventive medications, especially within experimental contexts. Adolescents generally are not proportionally included in studies of biomedical and combination prevention due to multiple barriers, including regulatory and parental permission-related issues, an inadequate understanding of the clinical research process, inability to access clinical trial sites, parental and adolescent mistrust of scientific research, forced adolescent disclosure of sexual behavior or sexual orientation, and concerns about adherence and stigma associated with participation (Abdool Karim & Dellar, 2014; Bekker, Slack, Lee, Shah, & Kapogiannis, 2014; DiClemente, Ruiz, & Sales, 2010; Knopf et al., 2017). Given the disproportionate rates of HIV among adolescent populations, it is critical to examine the social, behavioral, and ethical complexities surrounding adolescent participation in HIV prevention trials to inform the construction and implementation of population-sensitive research protections (Fisher, 2014).

Strategically engaging African American female youth and their mothers in the development of tailored PrEP prevention strategies to optimize PrEP as a real-world strategy is of great importance. The goal of the present study was to assess perceptions of adolescent PrEP use and clinical trial participation among African American women and their adolescent daughters. Study findings have the potential to inform strategies to provide equitable access to scientific advances and promote parent-child informed decision

making among a population disproportionately affected by the HIV epidemic.

Method

Setting and Study Sample

Participants in this research study consisted of African American mother/daughter dyads residing in the Chicago area who were recruited from a two-arm randomized controlled trial. Participants were recruited through community-based settings (i.e., churches, youth events, health fairs, nail salons). The experimental arm of the parent study IMARA (Informed, Motivated, Aware, and Responsible about AIDS) blends three CDC-demonstrated evidence-based interventions, Sisters Informing Sisters about Topics on AIDS (SISTA); Sisters Informing Healing Living and Empowering (SiHLE); Strengthening Today's Youth Life Experiences (STYLE), to create a culturally relevant, multilevel, integrated, family-based, HIV and mental health prevention program that simultaneously targets African American women and their daughters (L. K. Brown et al., 2014; DiClemente et al., 2004; Whithers, 2007). Despite IMARA's focus on HIV/STI prevention, PrEP was not introduced to participants in the IMARA research workshops. Mothers and daughters randomly assigned to the health promotion control arm, FUEL, participated in a 2-day workshop identical in length and intensity to IMARA. FUEL focused on healthy activities such as good nutrition, exercise, and informed consumer behavior. In contrast to IMARA, FUEL did not directly address HIV/STI prevention.

IMARA and FUEL arm participants were invited to take part in the current study if they formally agreed to be contacted for future research studies. Mothers and daughters met the following eligibility criteria if girls (a) self-identified as African American, (b) lived with a female caregiver above age 18 years, and (c) provided baseline data for the parent study. Women and their daughters each received US\$35 to participate, and women received US\$10 for transportation costs. The Institutional Review Board of University of Illinois at Chicago reviewed and approved the research protocol.

Procedure

Focus groups were conducted with mother/daughter dyads between July and August 2015. Mother and daughter groups were conducted concurrently in separate rooms (i.e., four groups with mothers, four groups with daughters), so that both groups could speak freely without familial influence or coercion. Focus groups were held at the University of Illinois at Chicago School of Public Health and lasted up to 120 min. Focus group format and content included a 15-min

Table 1. Health Belief Model and Focus Group Questions.

Construct	Daughter questions	Mother questions
PrEP awareness	Have you heard of PrEP before today? If so, what have you heard about it?	Have you heard of PrEP before today? If so, what have you heard about it?
Attitudes toward PrEP use	How would you feel about taking PrEP? (Probe: pills, vaginal rings, gels injectables?)	How would you feel about your daughter taking PrEP to prevent from getting HIV? (Probe: pills, vaginal rings, gels injectables?)
Barriers	What would be the reasons you <i>would not</i> participate in a PrEP clinical trial?	What would be the reasons you <i>would not</i> allow your daughter to participate in a PrEP clinical trial?
Perceived benefits	What would be your reasons for participating in a PrEP clinical trial?	What would be your reasons for allowing your daughter to participate in a PrEP clinical trial?
Perceived susceptibility/risks	If you were participating in a PrEP clinical trial, would you be concerned that you would have sex with fewer people, more people, or about the same number of people?	If your daughter were participating in a PrEP clinical trial, would you be concerned that she would have sex with fewer people, more people, or about the same number of people?

Note. PrEP = pre-exposure prophylaxis.

PrEP educational module informed by two local community advisory boards. The educational video included facts about (a) HIV and how PrEP worked to prevent acquisition, (b) PrEP side effects (i.e., nausea, diarrhea, rare bone weakness), (c) different types of PrEP delivery (i.e., daily pills, vaginal rings, microbicide gels, injectables) and adherence requirements (i.e., daily pill intake, insertion of rings, duration of injection effectiveness), and (d) description of a hypothetical clinical trial for female adolescents comparing the effectiveness of a vaginal ring with PrEP medication versus placebo vaginal ring. Participants were also informed that due to limited data available on efficacy, acceptability, and safety, PrEP is not yet approved for adolescents younger than 18 years (Knopf et al., 2017).

After participants provided consent, the focus group discussion commenced. Women and girls selected pseudonyms to use throughout the focus group discussion to maintain anonymity. The first and fourth authors facilitated the group discussions. Both authors are formally trained in focus group facilitation techniques and shared self-identified racial and gender characteristics with the target population. Two graduate research assistants served as comoderators, with the primary responsibility of documenting verbal and nonverbal cues during the groups in an effort to enhance the analysis.

The Health Belief Model (HBM) informed the educational video and focus group discussion guide (Table 1). As a value expectancy theory, the overarching principle of the HBM is that health behaviors are primarily determined by perceptions and beliefs about a disease, one's vulnerability to the disease, and the available resources and strategies to decrease the likelihood of disease occurrence (Hayden, 2013; Verheggen, Nieman, & Jonkers, 1998). The HBM is especially appropriate for this study given its emphasis on health-related beliefs and practices, which can be influenced heavily by race/ethnicity, age, and gender (Ashing-Giwa, 1999; Glanz &

Rimer, 1997; Glanz, Rimer, & Viswanath, 2008). HBM provides a useful framework for understanding (a) how attitudes toward PrEP use and youth involvement in PrEP research studies are influenced by mothers' and daughters' perceptions of youth susceptibility to and severity of contracting HIV, (b) the efficacy of PrEP as a way of reducing HIV risk, and (c) the extent to which individual, interpersonal, and institutional factors are perceived as barriers or facilitators in helping girls take action against HIV acquisition.

Analysis

The study team de-identified and transcribed focus group audio recordings. Two coders used inductive and deductive methods to analyze interview transcripts independently. The study team developed an initial codebook using information obtained from a preliminary focus group debriefing session, a literature review, the focus group interview guide, and their understanding of the project's focus. After further analysis of the audio recordings and transcript text, coders used the HBM as a framework to categorize qualitative responses into perceived barriers, and facilitators related to adolescent PrEP utilization and clinical trial participation among both mothers and daughters. Differences in coding were resolved through consensus among the coders; all coders agreed the final identified themes best represented the major findings and tone of the focus groups. All qualitative data were analyzed using NVivo 11.1.1. Demographic data were analyzed using SPSS 16.0 for Windows.

Results

Fifteen mother/daughter dyads completed the study ($N = 30$) during eight focus groups. All study participants self-identified as African American (100%). As in many African American family units, aside from biological mothers, other

Table 2. Demographic and Sexual Health Characteristics.

Characteristic	n (%)
Maternal age, <i>M</i> (<i>SD</i>)	43.4 (13.4)
Maternal race	
African American	15 (100.0)
Maternal education level	
Less than high school	2 (13.3)
High school	3 (20.0)
Some college/vocational school	6 (40.0)
College degree or higher	4 (26.7)
Household income	
Less than US\$10,000	6 (40.0)
US\$10,000-US\$19,999	2 (13.3)
US\$20,000-US\$29,999	2 (13.3)
US\$30,000-US\$39,999	3 (20.0)
US\$40,000-US\$49,999	1 (6.7)
US\$50,000-US\$59,999	1 (6.7)
Relationship to adolescent	
Biological mother	10 (66.7)
Grandmother	3 (20.0)
Aunt	2 (13.3)
Daughter age, <i>M</i> (<i>SD</i>)	14.8 (0.6)
Daughter race	
African American	15 (100.0)
Daughter current grade level	
Seventh grade	3 (20.0)
Eighth grade	5 (33.3)
Ninth grade	5 (33.3)
10th grade	2 (13.3)
Daughter sexually active	
Yes	4 (26.7)
No	11 (73.7)
Daughter age of sexual initiation, <i>M</i> (<i>SD</i>)	14.0 (0.8)
Daughter history of positive STI test	
Yes	3 (20.0)
No	12 (80.0)
Daughter birth control use (last 6 months)	
Yes	11 (73.7)
No	4 (26.7)

Note. STI = sexually transmitted infection.

female guardians (e.g., aunts, grandmothers) serve as the primary caregivers and mother children. Hence, we refer to all guardians as “mothers” throughout this article. The mean age (*SD*) was 43.4 years (13.4) for mothers and 14.8 years (0.6) for daughters; 66.7% of the guardians were the adolescent’s biological mother; 40.0% of mothers reported an annual income of less than US\$10,000, with 53.3% currently employed and 66.7% having completed some college or higher. The mean age (*SD*) of sexual initiation for daughters was 14.0 years (0.8), with 20% of daughters reporting a previous positive STI result (Table 2). Major themes relating to PrEP use for adolescent HIV risk

reduction and participation in an adolescent HIV research trial are described below.

Qualitative Results

Lack of available health information regarding PrEP. Participants in focus group discussions across both generations believed that reducing HIV risk was a priority for sexually active African American youth. Mothers and daughters were both surprised and disappointed that they had not heard of PrEP prior to focus groups. Mothers, especially, were alarmed that information about PrEP was not disseminated to them, particularly, given the increased prevalence of HIV in their communities. Their comments suggested that a lack of information was indicative of underlying biases by both the government and pharmaceutical companies, and ultimately prevented African American communities from receiving pertinent and potentially life-saving information in a timely manner. As these two mothers passionately asserted,

Being approved by the FDA. And it’s [PrEP] not widely known. You know, that is kind of baffling. Statistically our teenagers, our Black teenagers, male and female, are susceptible for HIV more than any other race. (Mother focus group)

Think about the lives that could have been saved if it [PrEP for HIV prevention] was already like, marketed the way HIV medications are marketed on these billboards. (Mother focus group)

Cautious acceptance of PrEP as an effective means to reduce HIV risk. Both mothers and daughters recognized HIV as a serious condition that placed youth who did not engage in safe sexual practices at risk. Once informed of PrEP, both mothers and daughters expressed favorable attitudes toward its use for sexually active adolescents to prevent HIV acquisition. As one daughter stated,

I feel okay with using it [PrEP] because it’s like helping you not to get—it’s protecting you from not getting any type of HIV. (Daughter focus group)

Although parents desired abstinence for their daughters, they recognized that long-term sexual abstinence was not likely; thus, mothers believed that PrEP offered a viable HIV prevention method for adolescents. One mother stated,

Well, me, you know, I go back into my fairyland thinking of wanting my granddaughter to be abstinent. And I know that’s not going to happen. So in order to protect her from getting HIV, I would have to say yes [to PrEP]. (Mother focus group)

Mothers were realistic about the benefits and limitations of PrEP related to protecting their daughters. Many mothers emphasized that PrEP should be used as a “back-up” method to the condom for optimal protection. As one mother asserted,

I'm pushing the condoms. But, you know, those can fail. And then they [adolescents] got something to fall back on and that's the PrEP. (Mother focus group)

Beliefs about adolescents' ability to effectively use PrEP. Although most mothers and daughters expressed favorable attitudes toward adolescent PrEP use, as illustrated in the above comments, they described various concerns that reflected skepticism toward adolescents' ability to adhere to PrEP regimens, given observed adolescent adherence challenges with other drugs.

I'm on medication, also. So that's why I'm pretty much, like, I don't know about taking the pill [PrEP] because I don't know how it's going to affect my body or affect the way the medication I already take during the day, you know, together and mixed up together and how it's going to make me feel. (Daughter focus group)

I hear it all the time in the clinic [from teenagers]. I can't take the pills. I can't remember it. And this and that. (Mother focus group)

Interestingly, some mothers were also concerned that teenagers might share their PrEP prescriptions with other teenagers and improperly take PrEP (i.e., take immediately before sex). One mother noted,

They [teenagers] can think that, oh, take this pill [PrEP], you know, one night, and it's not enough [PrEP] in their system not to contract the disease. And then they think, oh, yeah, go ahead and take this. It'll stop you from, you know [from getting HIV]. (Mother focus group)

Beliefs about which PrEP delivery tools are most effective. We highlighted different forms of PrEP delivery such as pills, vaginal rings, microbicide gels, and injectables. Because taking pills as prescribed was a major concern, many mothers felt that adolescents might benefit from alternative forms of PrEP delivery such as injectables that did not require daily attention. One mother stated, "Injectables seem more plausible than the gel; I am not fond of the vaginal ring." Although most mothers were aware that an HIV vaccine had not yet been developed, an HIV vaccine similar to the human papillomavirus (HPV) vaccine emerged as a strong preference among group members. One mother described the HPV vaccination as a promising preventive approach because the vaccination incurred long-term protection against HPV and ultimately prevented cervical cancer. Furthermore, because sexual intercourse was not a prerequisite for vaccination use, in comparison with PrEP, mothers expressed greater support for the development of an HIV vaccine.

My thing was back to the HPV, you don't have to be sexually active. Like, you don't have to be getting pap smears. But we caught ourselves guarding you [our children] from possibly

when you get up in age or whatever when cervical cancers come into play. (Mother focus group)

Although mothers desired protection for their daughters from both HIV and cervical cancer, for some, an HIV vaccine risked their daughter being subject to greater community stigma than the HPV vaccine. As one mother stated,

I guess I think of cervical cancer disease or something, it's a little more different from HIV, yes. I would want my daughter to be protected from HIV. But it's so much that goes with that HIV. (Mother focus group)

Mothers and daughters' beliefs about the health benefits of participating in an adolescent HIV prevention trial. Fears of medical and scientific exploitation of communities of color and concerns about unknown side effects and social stigma were pervasive beliefs surrounding clinical trial participation. At the same time, both generations believed that there were societal benefits that could result from clinical trial involvement. Perceived benefits included trials educating communities about HIV prevention, making drugs available to HIV vulnerable populations, increased teenage awareness of PrEP, creating resources to aid individuals in making better choices, helping to reduce HIV/AIDS stigma, and aiding in disclosure of HIV status.

Experimental mistrust. Compared with daughters, mothers expressed less favorable attitudes toward clinical trial participation rooted in the legacy of abuse of African American populations by the medical scientific establishment. Along with their belief that the heightened HIV rates in the Black community represented a serious health problem, mothers were especially concerned that "at-risk" communities would be targeted exclusively for PrEP "drug experimentation." As these participants expressed,

Is this research just for African Americans only? Is the Caucasian, anybody else taking these drugs? (Mother focus group)

We (daughter and I) could wait on the testing. I want to watch everybody else. I wouldn't want my daughter to be in the test [PrEP clinical trial]. (Mother focus group)

Among mothers, in particular, a general fear of experimentation appeared to be heightened by a lack of PrEP knowledge and awareness in the community as well as unknown long-term medication risks for adolescents. As one mother noted,

And by not having knowledge you can just be like, oh, they're experimenting and then throw it to the side. (Mother focus group)

Unknown long-term side effects and social stigma as barriers to PrEP use. Given the paucity of long-term PrEP data for adolescents, both mother and daughters perceived unknown side effects as a barrier to participation in PrEP research. Daughters, in particular, highlighted the potential for weight gain, bowel movements, and vaginal bleeding. As one mother stated,

For me it's always about the side effects of the drugs and the long-term. I always look at the long-term. With the clinical trials you don't know until years later what the harmful effects will be to their health. (Mother focus group)

However, some mothers felt that the protection offered by PrEP could outweigh the risks of possible side effects:

I am on the fence because of the side effects but I'm definitely all for PrEP because they're [teenagers] going to do what they're going to do. (Mother focus group)

Mothers, in particular, expressed concerns that unknown effectiveness of pills might increase HIV risk:

Oh [teenagers in a PrEP study will think they] can sleep with whoever they want to because I got these AIDS pills, and then they honestly don't work and then what? You're HIV positive and you have nothing, you know, no way you can deal with it. (Mother focus group)

Regarding the stigma and embarrassment surrounding PrEP use, some youth expressed concerns about PrEP's potential to give them a bad reputation and stigma imposed by members of the community, particularly adolescent boys. As these two girls expressed,

They [young boys] want attention or make everything positive and uplifting seem like a negative factor to make you feel bad; it's really not funny when half our generation is walking around with HIV and AIDS. (Daughter focus group)

Say you tell someone that you're doing a study to help prevent, like, HIV. Some people might take it a different way and, like, spread rumors that you have it [HIV] because you're taking the test, and it ends up affecting you. It makes you, like, some people just take that as peer pressure and it makes you stop [drug and/or study participation]. (Daughter focus group)

Perspectives on potential risks and benefits HIV prevention trial participation. Daughters expressed favorable attitudes toward adolescent clinical trial participation and described both individual- and societal-level benefits associated with potential participation. Girls believed that clinical trial participation would offer them resources such as education, HIV testing, and compensation as well as the opportunity to reduce HIV/AIDS among their peers, communities, and society. As one daughter noted,

Because it's really, like, us young, black women, we catch it [HIV] very easily because we don't know. These dudes would not let you know if they have AIDS or HIV or anything. But we should reach out to our peers and try to get them to do something like this because they can also learn what we are learning, also, to help, you know, whoever in their community. (Daughter focus group)

Another participant expressed,

There is no reason to not participate—if it [PrEP] could protect you, why not? (Daughter focus group)

Mothers, however, remained skeptical as illustrated in this comment:

I wouldn't want my daughter to participate, but I think it's a great idea if it helped others. (Mother focus group)

Some girls were additionally concerned that PrEP clinical trials would force them to have uncomfortable discussions with their mothers about sex given the nature of the drug. One daughter asserted,

I feel like my mom she's supportive, but then again she might be like, "You're having sex. You're doing this." (Daughter focus group)

An additional concern expressed by one young woman was increased HIV risk resulting from assignment to the placebo group in a research trial:

Because what if, like, someone's thinking, "I got the actual medicine" but they actually have a placebo. Like they're doing risky things. Like, there's always the chance that okay maybe I'm not actually getting what I signed up for. (Daughter focus group)

Despite their concerns, most daughters believed that their mothers would be supportive of their participation in a PrEP clinical trial. Many girls highlighted that their mothers were generally supportive and would trust their judgment even if they had concerns about the experimental nature of the study. As one participant expressed,

She trusts me enough to understand that what I'm doing is something I want to do and not just something that was pushed on to me. So as long as I want to [participate in clinical trial] and I put my all into it, it's fine. (Daughter focus group)

Mothers and daughters' beliefs about guardian permission to participate in HIV prevention trials. The extent to which guardian permission is a barrier or facilitator toward adolescent research participation continues to arouse heated ethical debate (DiClemente et al., 2010; Fisher, 2003;

Fisher, Arbeit, Dumont, Macapagal, & Mustanski, 2016; Fisher et al., 2013, p. 11-12; Fisher & Mustanski, 2014; Fisher & Wallace, 2000; Macapagal, Coventry, Arbeit, Fisher, & Mustanski, 2017). Most mothers were not supportive of guardian permission waivers for PrEP studies involving adolescents, and agreed that they would want to know whether their daughters were enrolled in a PrEP clinical trial or taking PrEP. Most daughters also saw maternal involvement in research participation as promoting their health and welfare. Mothers strongly communicated the important role they should play in monitoring whether their daughters were taking pills correctly and to evaluate potential side effects of PrEP. One mother commented, "I would make sure that she took the pill." Although group members understood the rationale for protecting teenagers' rights to receive sexual health services in research and clinical practice, many participants, like the grandmother quoted below, believed that parental involvement is needed in PrEP clinical trials, particularly, to promote drug adherence and to monitor their daughter's health.

My granddaughter had a STD. Twice I had to have her take those pills. She said, "They leave a taste in my mouth, Grandma. I don't like to take them. I feel okay." But then she's complaining to me about her stomach hurting. Because, I mean, she's not taking the preventive measure so that she's not going to get an STD. But when she get one [STD], she don't take the pills. (Mother focus group)

Another mother noted,

She's [Daughter] is not really mindful of her body and the changes in her body and what she should be looking for. I check everything, so I need to know if she looks a little glassy eyed or, you know, tired, more fatigued or something. I'm able to talk to her about it, tell her what to tell the doctor to look for so I can help. (Mother focus group)

Despite their overall desire to be informed with clinical trials involving their daughters, mothers recognized that daughters needed to make their own decisions, including decisions about their sexual health.

They got to have an opinion. And they got to be able to make a decision on their own. Because all too often when we force them to do things, it just don't quite work out that way. (Mother focus group)

Daughters desired their mothers' involvement in clinical trials, primarily to remind them to take their medications and monitor drug side effects. In general, daughters placed high importance on the relationships that they had with their mothers, which extended to issues related to their sexual health, including PrEP.

I wouldn't like it at all because, like, your parents should know what you are doing at ages 17, 16, 15, you should automatically have your parents' permission [to participate in clinical trials]. (Daughter focus group)

To this end, many girls stated that even if they participated in a trial that did not require parental permission, they would still inform their mothers of their participation. General comments included the following: "We have an honest relationship—I tell her everything anyway"; "I don't want to keep secrets"; "If you don't tell her, she'll think something's wrong"; "What would you do to treat possible side effects if she doesn't know what's going on?"

Discussion

The advent of PrEP represents a promising approach to attenuate persistent HIV/AIDS disparities. Compared with other groups of women, African American women and girls are disproportionately affected by the HIV/AIDS epidemic (CDC, 2012, 2014b). Thus, there is a need for effective HIV prevention strategies for African American women and girls to achieve health equity. PrEP has the potential to equip HIV vulnerable women with the tools to assert agency or control over their sexual lives in a manner that is independent of partner influence (Auerbach & Hoppe, 2015). However, awareness and utilization of PrEP is especially low among African American women (Auerbach et al., 2015; Bush et al., 2016; Flash et al., 2014), which has implications for access, acceptability, and uptake.

Findings from our study demonstrate a lack of PrEP awareness among both African American mothers and daughters. Mothers, in particular, questioned why information about PrEP had not been disseminated to them, particularly, given the increased prevalence of HIV in their communities. Once informed of PrEP, both mothers and daughters expressed favorable attitudes toward PrEP adolescent utilization. Auerbach and colleagues reported similar findings among African American women who initially expressed frustration and anger because they had not heard of PrEP, but perceived PrEP as an attractive option, once informed (Auerbach et al., 2015).

These findings support the need to expand targeted use of effective combinations of evidence-based HIV prevention approaches for African American female adolescents. In addition, there is a need for PrEP educational efforts and strategies tailored to the needs of key populations, with a strong emphasis on HIV-stigma reduction, which continues to undermine HIV/AIDS prevention, testing, and treatment (L. Brown, Macintyre, & Trujillo, 2003; Chesney & Smith, 1999; Kerr et al., 2014; Mahajan et al., 2008).

Although mothers were open to adolescents taking PrEP once FDA approved for adolescents, they expressed less

favorable attitudes toward adolescent clinical trial participation primarily due to concerns surrounding medical exploitation and a lack of available evidence related to the long-term effects of PrEP for adolescents. Daughters, in contrast, expressed altruistic attitudes regarding research participation. Due to the history of medical research exploitation in the United States, African American men and women have expressed skepticism toward research participation and reluctance to access new scientific advances (Alsan & Wanamaker, 2016; Gamble, 1997; Reverby, 2010; Scharff et al., 2010). Thomas and Quinn argue that the history of slavery and racism in the United States has contributed to conspiracy theories, which have affected the promotion of condom distribution programs, clean needle exchange programs, and antiretroviral therapy (ART) usage aimed to reduce the spread of HIV (Thomas & Quinn, 1991, 1993). Thus, further research is necessary to examine the role of institutional racism and research exploitation on attitudes toward PrEP use and research participation intergenerationally.

Fisher and Wallace (2000) found that African American adolescents and parents held similar conspiracy theories, mistrust, and fears of exploitation in response to questions regarding participation in research on adolescent risk behaviors. Consequently, attitudes toward the medical and research enterprise held by African American mothers, in particular, may influence willingness to allow their adolescent daughters to participate in PrEP research studies, especially given the controversial nature of an HIV prevention pill. Despite such views, other evidence suggests that restricted access and availability to research and information may have a greater influence on racial/ethnic minority populations' participation decisions (Wendler et al., 2006). Thus, engaging African American communities in the research process represents an important step in promoting informed decision making and equity related to PrEP use and clinical trial participation. Drawing from a community-engaged framework, the impacted community members should identify future research and intervention strategies to address the community's structural realities (Minkler, 2005).

Both mothers and daughters identified potential barriers to adolescent PrEP use and clinical trial participation. Pervasive concerns included short- and long-term side effects of PrEP, HIV stigmatization, group assignment, increased STI risk in the absence of condom use, and adherence failures. In addition to barriers to PrEP use and clinical trial participation, we described to mothers and daughters that guardian permission has emerged as a barrier to adolescent participation in HIV research. As a result, parental permission waivers have been granted to enhance recruitment, retention, and alleviate stigmatization related to sexual orientation and HIV status. Mothers in our study expressed a desire to be involved with their daughters' PrEP use and clinical trial participation; daughters similarly expressed a desire for their mothers to be involved. These findings are

consistent with those indicating that many sexually active lesbian, gay, bisexual, and transgender (LGBT) youth whose parents are supportive of their sexual orientation also perceive guardian permission as an important means of protecting their health when participating in HIV prevention trials (Fisher, 2014).

Future clinical trials and programs for adolescents should address both patient- and provider-level barriers to PrEP use. At the patient level, trials must be culturally and developmentally tailored and account for the cost of long-term usage to facilitate proper adherence and address adolescent-specific barriers. Increased provider awareness about PrEP is necessary to increase comfort with prescribing it to adolescents and to clarify uncertainty about legal and confidentiality issues. Furthermore, given the intersections of race, gender, and age among African American adolescent females and the potential for marginalization, health care provider training is key to reduce biases and disparities in prescribing PrEP and potential judgment surrounding sexual behavior (Calabrese, Earnshaw, Underhill, Hansen, & Dovidio, 2014; Flash et al., 2014).

Best Practices

Although youth ages 13 to 24 account for 22% of all new HIV infections, with the burden disproportionately falling on minority youth (CDC, 2017b), PrEP is not FDA approved for use by adolescents younger than 18 years. There are unique psychosocial, physiological, and ethical considerations related to adolescent HIV prevention trials and potential PrEP use. Thus, "risks and benefits of PrEP for adolescents should be weighed carefully in the context of local laws and regulations about autonomy in health care decision-making by minors" (CDC, 2014b). Furthermore, Rudy and colleagues (2010, p.12) highlight the importance of "conducting preparatory studies that include safety, feasibility and acceptability among youth if we are to facilitate their inclusion in large scale biomedical prevention trials so that concurrent product licensure can be achieved with those of adult indications."

Designing ethically responsible studies for HIV vulnerable adolescent populations requires attention to the contextual challenges, social concerns, and the myriad of vulnerabilities experienced by such groups. PrEP adolescent studies such as Adolescent Trials Network for HIV/AIDS Interventions 082 serve as a framework to inform the development of future effectiveness studies among high-risk young men who have sex with men ("Evaluating the Acceptability, Safety and Use," 2014; Fisher, 2014; "An Open Label Demonstration," 2013). Relatedly, studies focused on African American female youth are needed to ultimately inform targeted strategies to increase PrEP

uptake, adherence, and culturally sensitive modes of application. Seidman and Weber emphasize that successful implementation of PrEP requires due consideration to women's preferences and the particular social forces that influence the daily realities of women and ultimately decisions surrounding PrEP uptake and adherence (Seidman et al., 2016).

Educational Implications

Our findings suggest that reluctance and concerns about PrEP were largely related to a lack of information, evidence, and testing about PrEP, and not merely based on fear of medical experimentation and health care system distrust. Both mothers and daughters recognized the importance of PrEP research; teenagers, in particular, demonstrated altruistic perceptions related to PrEP clinical trial participation. As such, it is critical to engage African American female youth, African American caregivers, and community stakeholders to assess potential barriers to participation in HIV prevention trials and ideas about adolescent PrEP use in a real-world context. Stakeholders should be included in all research phases to ensure the ethically sound development of studies that are sensitive to the sociocultural, structural, and medical needs of the affected individuals and communities.

Limitations and Research Agenda

To our knowledge, this study is the first to examine perceptions related to adolescent PrEP use and clinical trial participation among African American women and their adolescent daughters. Study findings provide important considerations for the development of future interventions involving PrEP and African American youth. Findings also suggest that engaging community stakeholders in the construction and evaluation of population-sensitive research protections to inform ethical practice and policies for HIV prevention science offers great promise (Fisher, 2014). The limitations of this study suggest fruitful avenues for future research. First, we sampled African American mothers and daughters in Chicago, Illinois, who were already participating in a family-based two-arm randomized control trial. Additional research is necessary to determine the extent to which participants' views reflect those of female African American youth who did not enroll in a family-based program designed to strengthen mother–daughter sexual health communication. Second, our study examines mother–daughter attitudes toward a hypothetical PrEP study; future research should determine how expressed attitudes and beliefs influence participation in actual trials or uptake of PrEP. Finally, as with all focus group research, the need to keep group membership small to facilitate discussion, the unique community history of participants, and the

interactive nature of focus group designs does not lend to generalization beyond the particular discussants. Rather, this study provides an analysis of African American mother/daughter perspectives that can inform current ways of thinking about self-consent and point to new directions of scientific inquiry (Fisher & Wallace, 2000). As one daughter stated,

We should try to help our generation as much as we can so that when our generation grow up or the next generation that's coming up behind us, we can also feed them the stuff that we already know. (Daughter focus group)

Authors' Note

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Drug Abuse, National Institute of Child Health and Human Development, National Institutes of Health Office of Research on Women's Health, National Institute on Minority Health and Health Disparities or the National Institutes of Health.

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