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Participation in Research Involving Novel Sampling and Study Designs to Identify Acute HIV-1 Infection among Minority Men Who Have Sex with Men

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Abstract

HIV-1 infection disproportionately affects African American and Latino men who have sex with men (MSM) and their inclusion in biomedical and behavioral research is critical to understanding and addressing HIV vulnerability. Using focus groups, we sought to understand the perceptions related to participating in biomedical research of acute/recent HIV-1 infection (AHI) using complex sampling and data collection methods to reach this hidden group at highest risk of acquiring and transmitting HIV. Given the potential impact of AHI on transmission in MSM, it is important to understand this intersection for HIV prevention, care and treatment purposes. The aim of this study was to understand how recruitment and data collection methods affect AHI research participation willingness particularly among MSM of color. Findings suggest that major barriers to research participation with complex sampling to identify AHI and intensive risk behavior collection such as diary methods are lack of anonymity, partner disclosure, and study fatigue. The authors explore implications for future study designs and development based on these findings.

Keywords

MSM; HIV; Hidden Populations; Sampling; qualitative study

Introduction

Non-Hispanic black and Hispanic men who have sex with men (MSM) are diagnosed with HIV-1 disproportionately compared to their non-Hispanic white counterparts (37.5%, 32.2%, and 26.1%, respectively) (NYCDOHMH, 2008). In addition, racial and ethnic disparities in preventing and treating HIV persist (Gavin et al., 2009; Johnson et al., 2003). Understanding and resolving these issues require the participation of minorities, who tend to have lower research participation rates; and even when minorities do participate, they tend

to be less informed about the studies (Brown & Topcu, 2003; Newman et al., 2006; Sengupta et al., 2000; Shavers, Lynch, & Burmeister, 2002; Wendler et al., 2006). Study design, and data collection approaches to reach these populations may influence minority MSM research participation.

The Aaron Diamond AIDS Research Center identifies individuals during acute and recent HIV infection (AHI) for studies with implications for HIV prevention, care and treatment. Identifying AHI is challenging because of its short timeframe and (Pilcher, Eaton, Kalichman, Bisol, & de Souza Rda, 2006) signs and symptoms often go unrecognized as HIV (Schacker, Collier, Hughes, Shea, & Corey, 1996). MSM minorities are rarely identified during this HIV infection stage where transmission risk is high (MacKellar et al., 2007). Consequently, minority MSM are engaging in risk behaviors in contexts with higher background HIV prevalence and/or virus loads (Millet, Flores, Peterson, & Bakeman, 2007).

Gaining insight from minority participants on how study goals and design methods may influence study participation is not unfounded, but few studies have examined this issue. Studies of social networks using variants of snowball sampling have shown that the index or “seed” persons are more likely to refer their partners with whom they share drugs than their partners in a concurrent sex partnership (Castor et al., 2010). Furthermore, perspectives from minority MSM may lead to optimization of recruitment methodologies, questionnaire tools, communications about the research, and study retention.

We utilized qualitative methods among non-Hispanic black and Hispanic MSM in New York City study to: 1) understand if recruitment of sexual and drug-using partners in the context of possible HIV transmission posed a barrier to biomedical research participation; and 2) describe recruitment and data collection approaches for getting sex and drug use risk behavior prospectively to better assess HIV-1 transmission risks. This study fills a critical gap in the literature in understanding how our research design could pose as barriers or facilitators to minority MSM engagement in HIV research.

Methods

Recruitment / Sample

Potential participants were approached by trained recruiters visiting gay-identified venues frequented by minority men including bars, dance clubs, and circuit parties in New York City between June and August 2007. Recruiters distributed palm cards, discussed study details, posted flyers at venues and provided contact information for follow-up. A brief screening questionnaire on demographic information, sexual and drug use history, and initial study contact location was administered by telephone to potential participants. Eligible individuals were invited to participate in one of four focus group sessions. Eligibility criteria were: males age 18 years or older, sexual contact with at least one man during the previous month or drug use in the prior six months, and New York City residency. Of the 40 eligible respondents, 26 MSM were enrolled from all racial / ethnic backgrounds and disproportionately included minority MSM, for a 65% recruitment rate.

Design

Focus groups were conducted to explore the proposed aims. On average, seven individuals participated in each focus group. The racial and ethnic composition varied between group sessions. Two male facilitators—a main facilitator and the note taker / observer—conducted the focus group, each lasting between 1 to 1.5 hours. The facilitator utilized an open-ended questionnaire covering the following topic areas: barriers to HIV research participation, attitudes about participating in research; novel methods of survey research

(e.g. variants of snowball sampling and structured diary methodology to obtain “real-time” prospective HIV transmission risk data); approaches to reducing attrition and “study fatigue”; perceptions about the influence of one’s environment on their views and decision making about sexual behavior and drug activity. Ethical approval was obtained from the Rockefeller University Institutional Review Board.

Plan of Analysis

Focus group sessions were transcribed directly from the audiotapes by two transcribers to ensure inter-rater reliability. Inductive coding procedure was used to create initial codes. Subsequently, taxonomies were created by topic area in order to understand the hierarchical properties and relationships between emergent themes. A codebook was developed that outlined relevant themes across all topic areas. Thematic and content analysis was conducted iteratively by creating categories from the researcher-defined labels and participant specific terminology in order to define unifying and distinguishing concepts that emerged in the discussion. Summary reports were generated of response categories; levels of agreement, perceptions within and between the focus groups were coded and described in the pattern analysis. Indexing and coding was conducted in NVIVO.

Results

Socio-demographic factors

The race and ethnic compositions of focus groups 1 through 4 were comprised of 100%, 29%, 80% and 12.5% non-Hispanic blacks, and 0%, 83%, 0%, 38% of Hispanics. Additionally, 67%, 43%, 80%, and 62.5% of focus groups 1–4 respectively, were above age 35 years. Socio-demographic, sexual identity, and sexual risk behavior information are presented in table 1. The sample was mostly US-born (92%), attended some college or technical school (69%), considered themselves to be in at least good health (64%), and unemployed (68%). Fifty percent had been homeless at least once in their lifetime. In the past 3 months, participants reported having had sex with 6.5 partners on average. Non-Hispanic black men reported an average of 10 partners and all other non-Hispanic black men reported an average of 3 partners. Most did not have a steady partner. Less than one third of the men reported using condoms consistently. Fifty percent reported that their primary male sex partner was known to be HIV positive.

Contacting sexual and drug-using network partners in a research investigating HIV

A majority (75%) reported that this was their first time participating in a research study. Participants reported skepticism about participating in research. Half (53%) reported being comfortable referring either drug or sex network contacts in the structured interview. When asked about referring sexual or drug-using network partners, participants expressed concern about confidentiality, physical safety, and criminalization. Comfort with recruiting sex and drug contacts was contingent on protection from prosecution. Only one participant expressed the view that it was inappropriate to recruit contacts due to an invasion of privacy. Participants mentioned practical challenges that anonymous sexual contacts would pose for these types of studies. One participant stated, *“It’s hard for people to say ‘I’ve had sex with Jay, Mary, Jose, Antonio, Juan...’ Sometimes you have sex with people you don’t know... it’s very casual. You met them online, you go to their house, and that was it!”*

Transmitting information to network members about participating in a research study on HIV transmission

Focus group participants were asked to describe preferred methods to reach out to sexual and drug-using partners. Respondents in all four focus groups believed that an anonymous,

but official email, contact card, or phone call from a third party such as the research team would be most ideal to reach network members within a meaningful time frame. In addition to transmitting this correspondence, participants were concerned about how the information would be received. One participant stated, *“if you get an email and you’re sitting in there by yourself and thinking. All this stuff going through your head... If you’re sitting there next to someone and you’re getting the news, you don’t want to sit there facin’ them. You’re going through so [much]... you wanna be alone. Especially when it comes to HIV, you wanna be by yourself so you can think about it.”* In each focus group, a small fraction of participants expressed the belief that there should be direct contact between the index individual and their contacts in transmitting the information about the research study.

Views about information reporting

Across all FGDs, participants indicated that a short, structured, innocuous and secure data entry tool was absolutely necessary for documenting risk behavior prospectively. A small pocket check list of repetitive events with an open-ended space for special narratives was frequently suggested. One participant stated, *“I’m not in a relationship, so I’m dipping and dapping, I’m having sex with, you know, various people, so I’m not gonna write down each and every person I have sex with, okay?... Personally I wouldn’t put information through the mail [laughter] or the internet where God knows who and their mother can look at it...”* Another focus group member felt that face-face interaction was necessary, and a third said, *“I’m more for email actually... there’s more privacy”*. There was interest in reporting the context surrounding their sexual contact (e.g., physical attraction and emotional connection).

Data security emerged as a concern. In one focus group, electronic entries were preferred, *“Maybe even text it, like text this number or like that. That’d be cool, you’d never see it again”*. Another stated, *“I’d go for typing it in and keeping the diary locked and the password protected.”* To this, the entire group agreed. Lifestyle could pose a major challenge to diary keeping methods, as stated by one participant, *“That wouldn’t fit me... I start drinking on Thursdays... or whatever else I do. I mean, I go straight through it... I wouldn’t even think about picking it up and trying to fill out anything because I’d couldn’t see the paper, I wouldn’t see words on the paper.”* The issue of obtaining true contact information from casual and anonymous contacts was raised again.

Reducing study attrition

When asked about how they feel about participating in a research study with data collection and study visits to capture sex and drug use behavior in real time such as weekly or after each event, the participants suggested incentivized or reimbursed study visits, a convenient study site, and strong rapport between the research team and the participants as approaches to improve compliance and reduce attrition. Incentivized study visits were believed to be as important as the research setting and team. Establishing support and relationship building within the study was also viewed as key for intense HIV testing, *“build them up and nurture them and to, you know, inform them and to have support groups and stuff like that, that if you were to come back positive.”*

HIV serostatus and disclosure

Views on learning of one’s HIV positive status, and the subsequent need to disclose to sexual partners varied widely within the groups. Fear was identified as a barrier to participating in studies which would involve HIV testing and chain referral sampling. HIV-positive group members who self-disclosed mentioned privacy and rights, alcohol or drug use related disinhibition, assumption of HIV sero-concordance, and type and context of the sexual relationship as reasons for non-disclosure. One participant expressed concern about privacy and stigma associated with distinguishing HIV from other sexually transmitted

infections, *“Why invade someone’s life and tell them they have HIV? What about Hep C? What about syphilis? What about the other stuff out there? That’s worse than HIV. You don’t see it, but it’s there. We don’t talk about that. Just because you have this and this, then I am going to call your partner to say you have this and that. What about the rest? What makes HIV so special?”* Providing support on HIV self-disclosure, not just at the time of diagnosis but throughout follow-up was identified as an important aspect of establishing rapport between researchers and study participants, likely resulting in more valid reports of sexual activity and sexual contacts.

Discussion

In preparation for a larger prospective study on HIV transmission risk, this study was designed to explore barriers to research participation among minority MSM and to better understand approaches to addressing those challenges in larger scale HIV prevention, care and treatment studies. Specifically, we explored whether the study design including sampling methods in the context of HIV transmission and diagnosis might influence minority participation and looked at the influence of one’s social context on HIV risk behavior and research participation. While other qualitative and mixed methods studies have looked at other barriers and facilitators to minority research participation, to the best of our knowledge, the objectives of this research has not been addressed in prior publications, methodological issues that arise in reach hard-to-reach populations, particularly in the context of HIV transmission. The findings from the focus groups highlight key considerations in designing and implementing research studies using methods for hard to reach populations at the highest HIV risk.

Although focus group participants were unanimous in expressing their views about the importance and utility of HIV research, there was a high degree of hesitation about participating in research studies, specifically in participating in clinical trials. A majority of the participants had never participated in a research study before. Interestingly, participants were comfortable with referring both sexual and drug using network contacts to an HIV transmission study, but this was conditioned on a guarantee of anonymity and protection from prosecution. In addition to concerns about physical safety and privacy, criminalization as the index person was a concern expressed consistently. The feelings of fear of criminalization and partner violence expressed by the participants are not unfounded, and have been debated in the scientific, ethic and legal communities as well (Cameron, Burris, & Clayton, 2008; Kaye, Chibo, & Birch, 2009; Wainberg, 2008). For instance, biological measurements such as sequence data have been used in prosecuting individuals accused of criminal transmission of HIV, as well as identifying potential sources of HIV transmission (Albert, Wahlberg, Leitner, Escanilla, & Uhlen, 1994; Kaye et al., 2009; Leitner, Escanilla, Franzen, Uhlen, & Albert, 1996). While numerous cases of criminalization of HIV transmission have been documented in the lay press, arguments in the scientific and legal literature advocate for decriminalization of HIV transmission on the basis that these laws are stigmatizing and reduce likelihood of disclosure (Cameron et al., 2008). This issue is particularly acute for minority MSM who feel doubly stigmatized for being minority and MSM, and often are living in settings of high incarceration rates. Ensuring protection from criminalization and incorporating language about the nature of the participant’s confidential study data may be important in educating study participants, and obtaining valid reports and referrals to sexual contacts (Richard Woltiski, 2009).

Participant fatigue as a result of the level and detail of data that is often needed in HIV transmission studies was perceived to be a significant challenge. In addition, lifestyle / risk behavioral factors such as drug use patterns, frequency of anonymous sex partners emerged as very important considerations in the frequency, mode, quality and validity of diary data

obtained prospectively. Daily diaries have been used to obtain sex and drug use risk behaviors among MSM previously, but these investigations lasted a shorter time (30 days) than longer-term prospective studies that aim to identify AHI (Grov, Golub, Mustanski, & Parsons, 2010; B. Mustanski, 2008; B. S. Mustanski, 2007; Wilson, Cook, McGaskey, Rowe, & Dennis, 2008). Studies using diary methods and identifying AHI will be equipped to establish directionality between proximal risk behaviors and HIV transmission. Focus group participants indicated that long-term prospective data collection approaches, such as a daily diaries in conjunction with chain referral sampling, need to be “minimally invasive” to be consistently utilized by study participants. Several approaches described by participants, such as web- and text-based reporting, need to be piloted for data completeness, consistency and determination of the least amount of variables needed to ensure that it is minimally invasive and informative.

Identifying those at highest risk for HIV infection has important implications as the armamentarium for HIV prevention interventions for MSM have been expanded to include pre-exposure prophylaxis (PrEP) (CDC, 2011 ; Grant et al., 2010). Although this study was conducted before PrEP was shown to be effective, it was raised in several of the focus groups. A majority thought that PrEP would be utilized if made available and would influence participation in studies involving both referral sampling to identify AHI and recording daily diaries or sex and drug use risk behaviors over a longer term. With the recent success of the use of PrEP as a prevention method, it is imperative that information about this therapy is made available (Abdool Karim et al., 2010; Cohen et al., 2011; Grant et al., 2010). While our study did not focus on PEP or PrEP, the knowledge gap of the participants highlights the need to explore potential challenges and educate minority MSM on these interventions as they are implemented.

This study was limited by its sample size. It was designed as an exploratory study to better understand study design, logistical and contextual factors that may influence larger scale studies of HIV transmission, particular inferences made to minority MSM. Also, the mean age of the sample was 35 years, and the highest level of HIV incidence is among younger MSM of color, so these findings may not necessarily reflect younger men. However, one focus group was younger and different issues did not emerge in this session compared to the other three. In order to elicit specific responses, we used the term “diary” as an example to stimulate discussion. This could have inadvertently narrowed the range of responses about data collection. However, it provided deeper insight in the utility and unintended consequences of diary-based methods that are being used increasingly in HIV research.

Conclusion

Identifying the correlates of AHI and recent HIV would provide a more detailed picture of HIV transmission (Brenner et al., 2007; Castor et al., 2012; Cohen et al., 2011). Early HIV detection could help reduce forward transmission of the virus and thus overall HIV incidence. The burden of HIV in populations of minority MSM is great and it is important to understand barriers to participating in HIV-related research to address the concerns of these populations and improve recruitment and retention in studies. As implementation of PrEP advances, understanding patterns of HIV risk behaviors more proximal to HIV transmission (e.g. during AHI) may inform how PrEP can best be utilized in these populations.

Given the level of mistrust expressed by participants, unintended negative experiences from a study with a complex sampling and data collection approach could reinforce individual- and community-level mistrust of research studies. Building on the findings from this qualitative study, data collection tools were developed for a prospective follow-up pilot study exploring social, sexual and drug using network characteristics in the context of AHI

and changes in the characteristics before and up to one year after diagnosis. These findings have implications for effectively identifying, enrolling and retaining minority MSM in larger scale studies, and have implications for identifying these risk groups for service delivery of new prevention interventions like PrEP.

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Table 1

Demographic and risk characteristics of the sample (N=26).

Characteristic	Non-Hispanic Black (N=13)		Non-Black (N=13)		Total (N=26)	
	Mean	(±SD)	Mean	(±SD)	Mean	(±SD)
Age	37.9	8.12	33.7	6.13	35.8	7.37
Number of people you know who have taken PEP	2.2	6.67	0.67	2.31	1.3	4.62
Age of coming out	18.6	10.28	19.0	3.70	18.8	7.44
Sex partners in past 3 months						
Males	10.1	16.05	3.0	2.16	6.5	11.79
Females	0.23	0.60	-	-	0.12	0.431
	%	(N)	%	(N)	%	(N)
Employment						
Currently Full time/Part Time)	23.1	3	41.7	5	32.0	8
Unemployed / Student	76.9	10	58.3	7	68.0	17
Homelessness						
Never	46.1	6	53.8	7	50.0	13
Ever	53.8	7	46.1	6	50.0	13
First time study participant	83.3	10	66.7	8	75.0	18
Comfortable referring drug and sex contact to a network study	57.1	4	50.0	4	53.3	8
Exclusive condom use (%)						
Steady partner	40.0	2	12.5	1	23.1	3
Casual partners	33.3	4	22.2	2	28.6	6
Status of primary male partner						
HIV-Positive	40.0	2	55.6	5	50.0	7
HIV-Negative	20.0	1	44.4	4	35.7	5
Unknown	40.0	2	-	-	14.3	2
HIV infection						
Primary partner HIV positive	40.0	2	55.6	5	50.0	7
20%-50% of Personal network HIV-infected	15.4	2	-	-	7.7	2

Characteristic	Non-Hispanic Black (N=13)		Non-Black (N=13)		Total (N=26)	
	Mean	(±SD)	Mean	(±SD)	Mean	(±SD)
Have you ever taken prep						
No	88.9	8	92.3	12	90.9	20
Yes	11.1	1	7.7	1	9.1	2
Have you ever taken pep						
No	88.9	8	100	12	95.2	20
Yes	11.1	1	-	-	4.8	1

Sample sizes vary due to non-response.