

UCLA

UCLA Previously Published Works

Title

Engaging, Recruiting, and Retaining Black Men Who Have Sex With Men in Research Studies

Permalink

<https://escholarship.org/uc/item/6g69d6rg>

Journal

Journal of Public Health Management and Practice, 20(6)

ISSN

1078-4659

Authors

Magnus, Manya

Franks, Julie

Griffith, Sam

et al.

Publication Date

2014-11-01

DOI

10.1097/phh.0000000000000025

Copyright Information

This work is made available under the terms of a Creative Commons Attribution-NonCommercial-NoDerivatives License, available at

<https://creativecommons.org/licenses/by-nc-nd/4.0/>

Peer reviewed



Published in final edited form as:

J Public Health Manag Pract. 2014 ; 20(6): E1–E9. doi:10.1097/PHH.0000000000000025.

Engaging, Recruiting, and Retaining Black Men Who Have Sex With Men in Research Studies: Don't Underestimate the Importance of Staffing—Lessons Learned From HPTN 061, the BROTHERS Study

Dr. Manya Magnus, PhD, MPH,

Department of Epidemiology and Biostatistics, The George Washington University School of Public Health and Health Services, Washington, District of Columbia

Dr. Julie Franks, PhD,

ICAP, Mailman School of Public Health, Columbia University, New York, New York

Mr. Sam Griffith, MAT,

FHI 360, Research Triangle Park, North Carolina

Dr. Michael P. Arnold, PhD,

San Francisco Department of Public Health, San Francisco, California. Fred Hutchinson Cancer Research Center, Seattle, Washington

Ms. Krista Goodman, MA, MPH, and

Project ACHIEVE/New York Blood Center, New York, New York. Gilead Sciences, Foster City, California

Dr. Darrell P. Wheeler, PhD, MPH

Loyola University, Chicago, Illinois

for the HPTN 061 Study Group

Abstract

Context—HIV/AIDS in the United States continues to primarily impact men who have sex with men (MSM), with disproportionately high rates among black MSM.

Objective—The purpose of this study was to identify factors that may influence engagement and retention of black MSM in HIV research.

Copyright © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins

Correspondence: Manya Magnus, PhD, MPH, Department of Epidemiology and Biostatistics, The George Washington University School of Public Health and Health Services, 2100-W Pennsylvania Ave, NW, 8th Floor, Washington, DC 20037 (manyadm@gwu.edu).

The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.JPHMP.com).

All coauthors have reviewed and approved of the final draft. The content of this publication does not necessarily reflect the views or policies of NIH/NIAID/HPTN, and the responsibility for the content rests solely with the authors.

Design and Participants—This was a qualitative evaluation of study implementation within a multisite, prospective, observational study (HIV Prevention Trials Network 061, *BROTHERS*) that enrolled 1553 black MSM in 6 cities throughout the United States. Data collection for this evaluation included a written, structured survey collected from each of the sites describing site characteristics including staff and organizational structure, reviews of site standard operating procedures, and work plans; semistructured key informant interviews were conducted with site coordinators to characterize staffing, site-level factors facilitating or impeding effective community engagement, study recruitment, and retention. Data from completed surveys and site standard operating procedures were collated, and notes from key informant interviews were thematically coded for content by 2 independent reviewers.

Results—Several key themes emerged from the data, including the importance of inclusion of members of the community being studied as staff, institutional hiring practices that support inclusive staffing, cultivating a supportive working environment for study implementation, and ongoing relationships between research institutions and community.

Conclusions—This study underscores the importance of staffing in implementing research with black MSM. Investigators should consider how staffing and organizational structures affect implementation during study design and when preparing to initiate study activities. Ongoing monitoring of community engagement can inform and improve methods for engagement and ensure cultural relevance while removing barriers for participation.

Keywords

black MSM; community; HIV/AIDS prevention; recruitment; retention

As we enter the fourth decade of the epidemic, HIV/AIDS in the United States continues to primarily impact men who have sex with men (MSM), with disproportionately high rates of infection among black MSM as compared with other racial or ethnic groups.^{1–3} Despite the urgent need for prevention efforts responsive to this population, few evidence-based prevention interventions for black MSM have been developed, disseminated, or widely adopted.^{4,5} This gap in the national prevention armamentarium not only neglects a critically important population but also undermines the broader public health mission to halt the spread of HIV. A clear example is the few black MSM enrolled in the recent iPrEX trial of preexposure prophylaxis: of 2499 participants, only 9% overall identified as black.⁴ The small proportion of black participants in one of the primary preexposure prophylaxis trials among MSM to date limits generalizability of this important HIV prevention intervention. The promise of recent advances in biomedical approaches to HIV prevention such as preexposure prophylaxis and treatment as prevention^{6–9} can be accomplished only if the populations and communities most impacted by HIV are actively engaged in the development and implementation of strategies to optimize the use of both behavioral and biomedical prevention interventions.^{10–12}

In 2008, the Domestic Working Group HIV Prevention Trials Network (HPTN) sought to address the epidemic among black MSM with a novel prospective cohort study, *HPTN 061, a Feasibility Study of a Community-Level, Multi-Component Intervention for Black Men Who Have Sex With Men*, also known as the “BROTHERS Study” (*Broadening the Reach of*

Testing, Health Education, Resources and Services for Black Men Who Have Sex With Men [www.hptn.org]).¹³ A primary aim of the study was to assess the feasibility of recruiting and engaging large numbers of black MSM in prospective HIV prevention studies.¹³ The study was conducted at sites in 6 US cities and enrolled over 1500 black MSM between July 2009 and October 2010, the largest cohort of black MSM to be followed prospectively in the United States.¹⁴ The HIV risk behavior among the group was substantial, with 26% reporting unprotected receptive anal intercourse with HIV-infected partners or partners of unknown status and 31% reported 5 or more sexual partners in the 6 months preceding enrollment.¹⁴ Recognizing the need to identify salient factors affecting the engagement and retention of large samples of black MSM in prospective prevention studies,^{15,16} the network and investigators approved a qualitative substudy of factors affecting sites' experience with recruitment, enrollment, and retention of HPTN 061 participants. The substudy focused on the community and organizational contexts in which the intervention was delivered, 2 domains that have been identified as critical to the implementation of innovative health interventions.^{17,18} Because the sites operated in distinct community and organizational settings, each site approached community engagement, outreach, recruitment, and retention in unique ways. The purpose of this study was to characterize each site's approach to engagement of the study population, including outreach, recruitment, and retention of study participants and to better understand the community-and organizational-level factors associated with engaging and retaining black MSM in HIV prevention research. The overarching study goal was to better inform cultural competence to implement prevention research in this critical population.

Methods

Parent study methods

HPTN 061 was a multisite study to determine the feasibility and acceptability of a multicomponent intervention for black MSM. The study was conducted in Atlanta, Boston, Los Angeles, New York City, San Francisco, and Washington, District of Columbia; Atlanta and New York City each had 2 physical sites. The institutional review boards at all participating institutions approved the study. Between July 2009 and October 2010, black MSM were recruited from the community and as sexual network partners. Men were eligible to participate in the study if they self-identified as a man or male at birth and as black, African American, Caribbean black, or multiethnic black; were at least 18 years old; reported at least 1 instance of unprotected receptive or insertive anal intercourse with a man in the past 6 months; resided in the metropolitan area and did not plan to move away during the time of study participation; and provided informed consent for the study. Each site worked extensively with its local community advisory board to develop locally appropriate recruitment methods. Recruitment methods included nonrandom venue-based recruitment, community outreach, engagement of key informants and local community-based groups, peer- and provider-referral, advertising, and use of online strategies including the placement of banner advertisements, text advertisements, chat room outreach, and social networking sites.¹⁹

At the enrollment visit, written informed consent was obtained and eligibility was confirmed. Participants provided locator information as well as demographic information to an interviewer and then completed a behavioral assessment using audio computer-assisted self-interview technology. Following completion of the audio computer-assisted self-interview assessment, a social and sexual network questionnaire was completed with an interviewer. All participants received HIV/sexually transmitted infections (STI) prevention risk-reduction counseling and HIV and bacterial STI testing. Participants with HIV infection had CD4 cell count testing and HIV viral load testing performed. All participants testing positive for any infection were referred for treatment and medical and social services. A study-driven multicomponent intervention was implemented and comprised sexual network member referral, HIV and STI testing/counseling, referral for mental health or other services, and the opportunity to work with a peer health navigator. Peer health navigator conducted assessments of participants' health care history; unmet social, medical, and mental health service needs and barriers to health care; developed an action plan with the participant to address those needs; and then met with participants over time to implement the action plan. Retention methods included regular calls, institutional review board–approved e-mails or texts, home visits, birthday cards, and other site-specific retention activities.

Substudy methods

The goal of this substudy was to characterize staffing, organizational, and community-level factors perceived as facilitating or impeding effective community outreach, recruitment, and retention at each HPTN 061 site. A team of investigators from 3 sites and FHI 360, the study-coordinating center, designed the substudy with input from site personnel and faculty at all sites. Data were collected from 3 sources:

1. Study coordinators at each site completed a written, structured survey characterizing funding, staff composition, organizational, and other barriers related to recruiting and hiring, training, and retaining staff, challenges in community engagement, integration of study into other site activities, and external barriers and facilitators related to study implementation. These questions were informed by investigators with expertise in research among this population as well as field staff working with the population, many of whom were also members of the population.
2. An in-depth, semistructured individual interview was conducted with the study coordinators. This interview guide covered the domains addressed in the site survey and addressed sites' experience organizationally with regard to staffing, implementation, community engagement, and recruitment. Three substudy investigators (MM, MA, and JF) conducted interviews in pairs, with 1 taking notes and the other moderating. To enhance respondents' candor, detailed notes were taken during each session, but the conversations were not voice recorded.
3. Site-specific standard operating procedures prescribing community outreach, recruitment, and retention at baseline were evaluated.

All sites responded to the survey forms and study coordinators from each site were interviewed. (Although the parent study was conducted at 8 physical sites, the 2 sites in Atlanta were managed as a single unit.) During in-depth interviews, coordinators identified

factors that they perceived facilitated or hindered the implementation of all phases of HPTN 061, particularly around constituting and sustaining staff who could effectively engage study populations.

Data from the site survey and standard operating procedure evaluation were summarized and tabulated. Content analysis of in-depth interview texts used a coding paradigm²⁰ in which the data were examined to understand: how site coordinators defined study recruitment and retention goals; contextual and structural conditions perceived to impact on those goals; processes and strategies employed in recruitment and retention; and perceived consequences of their recruitment and retention efforts. Variables and categories derived from the interview guide served as deductive codes applied to the data, and additional inductive codes emerged directly from close reading of the texts.²¹ Two substudy researchers (MM and JF) independently conducted deductive and inductive coding of interview texts, compared findings, and reviewed discrepant coding until consensus was achieved. Inductive codes were applied iteratively to all interview data. Axial coding was conducted to determine relationships among codes and to identify dominant themes that linked coded data.^{21,22} The substudy was approved by the HPTN and The George Washington University Institutional Review Board.

Results

Staff characteristics

There was considerable variability in the staffing patterns in all facets of study implementation and organizational makeup, including the number of staff, their professional backgrounds, experience with black MSM, and the communities with which they identified, as shown in Table 1. While no site reported having a black transgender staff member, all sites reported at least 1 black MSM staff member. In addition, all sites had multiple staff members with experience working with the black MSM community and some staff persons who had experience working with transgender communities.

Table 2 (Supplemental Digital Content, available at <http://links.lww.com/JPHMP/A62>) presents quotes illustrating codes that were related to aspects of study implementation salient to the interviewees, within domains identified in the interview guide. As shown in Table 2 and extracts below, coordinators highly valued having a diverse study staff, that is, staff including black MSM but not exclusively black MSM. While affirming the importance of ensuring that black MSM were part of protocol implementation, coordinators observed that ethnic, sexual, and cultural diversity within the study staff allowed for responsiveness to participant needs. For example, coordinators perceived that some participants preferred to work with women or nonblack men to reduce fear of disclosure in more insular social networks.

Staff should reflect the population but diversity is also really important . . . We intentionally wanted a diverse group on the study, to appeal to all potential participants—some Black MSM are more comfortable with members of their community, that is with Black MSM, others will be more comfortable with non-community members, someone who is a bit outside.

Black MSM [may have a] concern about being “outed” by the staff. African Americans (AA) that are Muslim may not be comfortable having a PHN or research counselor that is AA or Muslim. This is one of the downsides. [We] have to know/understand the whole culture in terms of the staff and site leadership, and how can [we] make sure that the participants are given someone that they are comfortable with.

Cultural competence—comfort with and ability to work effectively with the study population—was perceived as the overarching characteristic necessary for staff. Study coordinators emphasized the importance of staff members who were personally committed to the study goal of engaging black MSM in HIV prevention research, describing them as “passionate,” “committed,” and “eager.”

Staffing models

Several sites had individual staff members dedicated entirely to recruitment, retention, or providing peer health navigation, while other sites cross-trained staff so that a single staff person recruited, conducted data collection, delivered peer health navigation, and performed other duties. No one model emerged as preferable with respect to recruitment, engagement with the community, or retention: site coordinators tended to find benefits in and advocate for their selected staffing model and voiced being pleased overall with their results.

Five of the sites conducted HPTN 061 concurrently with other HIV-related studies, and the majority of them did not find it difficult to incorporate HPTN 061 into the site’s workload. However, 2 coordinators acknowledged particular challenges around managing staff on multiple concurrent studies:

At first, with everyone assigned to two studies, staff got burnt out. After they were split into individual study teams, everything went smoother.

Initially staff was dedicated to [two studies] and that caused problems related to coordinating efforts, schedules, resources for both studies.

Irrespective of their staffing model, however, many sites expressed a need for increased resources dedicated to community engagement.

There were institutional limitations; community engagement should be a bigger part of the budget for studies, there should be dedicated resources and it should be built into the study design, and the timeline, because it takes time. If this study had its own community engagement staff they could have continued efforts that initially the research staff was doing, and then when they got so busy with enrollment [and] data management . . . they did not have time to maintain those community linkages.

This indicates that although community engagement and outreach were recognized by the study team as critical components of study implementation, insufficient resources were perceived to be available to perform these activities at the site level.

One site noted the overall benefits of sharing recruiters with other studies in terms of resource allocation and streamlining study functions; however, within this model, staff indicated that they faced some challenges with recruiters being less attuned to cultural

considerations of potential HPTN 061 participants since they were used for several diverse studies:

There are a couple of limitations [of sharing recruitment staff across studies]—depending on the study it might help to have more recruiters who represent the population. The recruiters we have are diverse, but say if they are recruiting African-American transwomen, you would want that type of recruiter, which we currently do not have. But for the most part works very well.

While all sites identified unique challenges and strengths related to their organizational structure, no one framework was viewed as the ideal to engage, recruit, or retain participants.

We talk about relationship-building with communities as part of engagement [recruitment] but there is also relationship building within the organization that has to happen for that to be possible—this has to be part of the system to if we are going to implement studies like this one.

Where site staff were not representative of particular subgroups (particularly for the transgender population), this was referenced as a challenge and a barrier to reaching that population.

Facilitators and barriers to staff recruitment and retention

Factors that impacted creating and sustaining cohesive study teams are displayed in Table 2 (Supplemental Digital Content, available at <http://links.lww.com/JPHMP/A62>); the number of occasions in which factors were mentioned within and across interviews is provided in Table 3. These barriers and facilitators were identified in a staffing context in which coordinators had a primary goal of having staff members who represented the study population. The intention was that this would facilitate recruitment and retention of study participants and overall engagement with the local communities.

We wanted to hire people who would be acceptable to the community and who had a connection to the community. This was important in terms of reaching participants but also to strengthen community partnerships.

One challenge for several sites was being unable to hire otherwise qualified applicants for staff positions—representative of the target population and/or having the requisite skill sets—because they did not meet the employment criteria of the site’s parent institution:

One person wasn’t eligible to be on staff due to not meeting [institutional] educational requirements. There are some staff that . . . didn’t have a BA, . . . but would have been qualified based on what they could do and what they know about the community.

More broadly, some coordinators noted that creating and retaining a staff that reflected the study population could present challenges to the organizational context in which the study was conducted. This is especially true when the population itself has myriad needs and comprises not just 1 “type” of participant but rather a highly diverse group of individuals.

The organizational culture . . . can be barrier to getting study like this off the ground. An environment where the staff is not used to working with a lot of Black people or whatever the group is can lead to staffing issues and problems. [The institution] had a learning curve.

Several coordinators noted that support from local study and institutional leadership was important for building and maintaining a cohesive study team.

I have a very strong support system from the PI level. That has helped out a great deal.

Relationship building within the organization has to . . . model characteristics about how to interact with participants, as well as with fellow staff.

Study coordinators also cited the importance of training and ongoing mentoring of staff members to ensure that they engaged the study population effectively and maintained professional boundaries. One coordinator observed that while on-the-job capacity building was essential to the creation of a culturally responsive and competent study team, it required effort and time that had not been anticipated:

We were committed to the idea of hiring young men from the community, which probably made a difference . . . but they needed increased monitoring and supervision The intensive coaching and advising did pay off in terms of delivering the intervention but it required intensive follow up on my part.

Staff turnover was present and was identified as one challenge to ongoing engagement of the study population, especially with regard to delays of recruitment, effect on retention activities, and costs (both direct and indirect) of hiring and training new staff. No uniform cause for turnover was elucidated, and it did not seem to be a result of overarching hiring or management practices.

One coordinator noted that some of the challenges of retaining staff were not dissimilar to those of participants, and supervisors needed to be attentive to staff needs:

A lot of the issues you see in your population are included in your staff. Such as substance use, etc. It is important to keep my antenna up and be mindful of these things and humanize it. We are all fucked up in different ways.

Several sites identified novel approaches to staff retention that involved not only team incentives but also communicating the importance of staff continuity from the beginning of the hiring process:

In looking for staff that will stay for a long time, [it's] important that they understand their contribution and impact to the community, the project, their achievements, and what they can get from it.

Discussion/Lessons Learned

Lessons learned from this substudy underscore the importance of culturally appropriate staffing to successful implementation of research among black MSM in the US.²³ Successful study implementation may be challenged by institutional policies and practices

that do not support the hiring, training, and retention of appropriate staff, whereas the presence of supportive institutional policies and practices—or the willingness to develop them—will support the development and implementation of research among black MSM.¹⁵

For site coordinators in HPTN 061, community outreach and recruitment were intrinsically linked. Coordinators argued that where community outreach was successful, so too was recruitment. Conversely, they cited resource constraints, limited access to the community, too few representative staff, and other barriers to outreach as responsible for gaps in recruitment. A primary example is with regard to transwomen, who in most locations were recruited incidentally to MSM recruitment activities, rather than as a result of active community outreach. In addition, the heterogeneity of black MSM created challenges in outreach and recruitment: subpopulations such as homeless black MSM were perceived as easier to reach than were more affluent black MSM, for whom the study activities (eg, length of study visits) may have created barriers to participation.

Facilitators to participant retention were identified in relation to organizational constructs. The sites where staff conducted all facets of the study (from recruitment to retention) and those that had separate duties for each staff member both harnessed the strengths of their staff and were viewed positively by interviewees. Participants getting to know the staff and working with them in a continuous way were a considerable strength at those sites adopting this model. The unique skill sets of staff experienced in working with diverse populations were crucial study implementation. These enabled staff to connect with and perform community in-reach and access persons with barriers to participation.

Previous research echoes our findings regarding the need for intensive training, supervision, and mentoring of community-grounded staff^{24,25} and for adequately funded, targeted outreach activities^{15,26} to support the engagement of racial and ethnic minority populations in HIV research.²⁷ While several studies and policy statements have highlighted the benefits to study recruitment and implementation when communities under study are engaged in staffing and recruitment strategies,^{15,23,26,28–32} the processes for creating effective, culturally grounded teams have not been widely studied.^{15,33} This study explores several key areas to prioritize for more systematic study in implementation research and scale-up of novel programs for black MSM, namely, the hiring and retention of study staff and the development of targeted, community-based recruitment plans.

This study had several limitations and challenges. One key limitation is the use of staff respondents who may be biased with regard to the relative strengths and weaknesses of their own sites, specifically with regard to their own study activities and their own perceptions of recruitment and retention successes. Our data suggest that they were candid about each of these and able to provide an accurate impression of site-level characteristics impacting implementation. However, this study intentionally utilized a purposive sampling strategy to engage experts at each site rather than an “objective” review of the site staff by an external evaluator, for example. The nature of qualitative research and purposive sampling should be taken into account. Another challenge is that staff and faculty affiliated with the project—although at different sites—participated in the design, data collection, and analysis of interview and survey data. All data were validated independently by at least 1 other member

of the substudy team, but there is the possibility of bias despite our attempts to minimize it. As with all convenience samples and with those using purposive sampling strategies as in this study, it is challenging to generalize findings to a larger population; for the purposes of this study, this limits our ability to generalize to other studies of black MSM. Although this study found saturation of theme and convergence on results from each of the sites, we cannot determine whether this is a function of the study group, the network, or the unique nature of each site. Similarly, we cannot conduct hypothesis testing on the data and assess the relationship of our findings to chance.

Despite these limitations, this study also has several strengths. With the HIV/AIDS epidemic increasingly affecting black MSM in the United States, this study provides important information about how to better implement studies that are culturally appropriate and can gather meaningful data. Enrollment and retention are imperative to research that can inform intervention development; learning directly what works and what does not offers insight into how we can better serve this population through research. Our data offer a unique perspective into the question of how sites working with black MSM in the US might be able to enhance community engagement, study accrual, and retention. This study also suggests the value that could be gained by systematically collecting site-level process measures when conducting a trial with a marginalized population, especially if these metrics could be collected, analyzed, and made available to sites in real-time or near-real-time for refinement of their implementation approach. Valuable data to collect in future studies might include priority recruitment sites, perception of community engagement, quantification of facilitators and barriers to recruitment and retention, and local perception of the study among nonparticipants in the community. Detailed data about persons who were screened as eligible but declined to enroll, as well as those in the community not screened but were potentially eligible would deepen our understanding of subpopulations not represented in the research, enhance our ability to generalize study findings, and help identify ways to improve local study implementation.

Conclusions

Although research has the potential to be a decisive factor in slowing the HIV/AIDS epidemic, its ability to do so depends on the success with which we engage and learn from those most affected by it. In general, public health researchers in the US have encountered challenges in enrolling minorities and, in particular, black MSM into research in numbers proportionate to their burden of disease because of myriad barriers described by other investigators. HPTN 061 effectively demonstrated the feasibility of enrolling and retaining more than 1500 black MSM in a longitudinal HIV study. This substudy of HPTN 061 provides a foundation for future research among black MSM, allowing a deeper recognition that how we implement studies to support research among black MSM will necessarily affect our accrual and retention of participants, and, ultimately, our ability to leverage findings to improve public health. Our findings underscore the importance of integrating staff representative of the target population on the study teams and as investigators. It also demonstrates that a critical element of success in reaching people often missing from clinical trials and observational studies includes hiring staff who are experienced in working with the community and can interface with the community in an ongoing and meaningful way.

Participation of black MSM in clinical trials and other studies among black MSM will be supported by their integration in study implementation; this likely reflects a similar need to include members of the target population in every phase of research from idea and protocol development and instrumentation to implementation, analysis, and dissemination. Study coordinators interviewed here emphasized the importance of culturally competent, diverse staff able to work effectively with each local community and of institutional practices supportive of hiring and retaining such staff. In addition, devotion of ample resources to support community outreach and to measure its impact would improve our ability to work with those most at risk for HIV/AIDS. As we expand our armamentarium of prevention modalities to include biomedical as well as behavioral interventions, increased understanding of ways to remove barriers to participation in research by black MSM has become increasingly crucial.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The study HPTN 061 was funded by the National Institute of Allergy and Infectious Disease (NIAID), National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) under Cooperative Agreement # UM1 AI068619. All coauthors have reviewed and approved of the final draft. The content of this publication does not necessarily reflect the views or policies of NIH/NIAID/HPTN, and the responsibility for the content rests solely with the authors.

HPTN 061 grant support was provided by NIAID, NIDA, and NIMH: Cooperative Agreements UM1 AI068619, UM1 AI068617, and UM1 AI068613. Additional site funding—Fenway Institute CRS: Harvard University CFAR (P30 AI060354) and CTU for HIV Prevention and Microbicide Research (UM1 AI069480); The George Washington University CRS: District of Columbia Developmental CFAR (P30 AI087714); Harlem Prevention Center CRS and NY Blood Center/Union Square CRS: Columbia University CTU (5U01 AI069466) and ARRA funding (3U01 AI069466-03S1); Hope Clinic of the Emory Vaccine Center CRS and The Ponce de Leon Center CRS: Emory University HIV/AIDS CTU (5U01 AI069418), CFAR (P30 AI050409), and CTSA (UL1 RR025008); San Francisco Vaccine and Prevention CRS: ARRA funding (3U01 AI069496-03S1, 3U01 AI069496-03S2); UCLA Vine Street CRS: UCLA Department of Medicine, Division of Infectious Diseases CTU (U01 AI069424).

The authors thank Kenneth Mayer, Beryl Koblin, and the HPTN 061 site investigators and staff for their assistance and expertise, including Benjamin Perkins, Kelvin Powell, and Benny Vega; Alan E. Greenberg, Jeanne Jordan, Irene Kuo, Gregory Phillips II, and Christopher Chauncey Watson; Sharon Mannheimer and Avelino Loquere Jr; Hong Van Tieu; Susan P. Buchbinder, Chadwick Campbell, and Mathew Sanchez; Steven J. Shoptaw and Christopher Hucks-Ortiz; Erica Hamilton, LaShawn Jones, Georgette King, Jonathan Paul Lucas, and Teresa Nelson; Jane Bupp and Vanessa Elharrar; Sheldon Fields, and Steven Wakefield; Leo Wilton. We also acknowledge the participants in HPTN 061, whose collaboration made the study possible. Benjamin Perkins, Kelvin Powell, and Benny Vega; The George Washington University School of Public Health and Health Services: Alan E. Greenberg, Jeanne Jordan, Irene Kuo, Gregory Phillips II, and Christopher Chauncey Watson; Harlem Prevention Center: Sharon Mannheimer and Avelino Loquere Jr; New York Blood Center: Beryl Koblin and Hong Van Tieu; San Francisco Department of Public Health: Susan P. Buchbinder, Chadwick Campbell, and Mathew Sanchez; University of California Los Angeles (UCLA): Steven J. Shoptaw and Christopher Hucks-Ortiz; HPTN Coordinating and Operations Center (CORE); FHI 360: Erica Hamilton, LaShawn Jones, Georgette King, Jonathan Paul Lucas, and Teresa Nelson; HPTN Network Laboratory, Johns Hopkins Medical Institute: Sue Eshleman and Vanessa Cummings; HPTN Statistical and Data Management Center, Statistical Center for HIV/AIDS Research and Prevention: Lei Wang, Corey Kelly, and Ting-Yuan Liu; Division of AIDS (DAIDS) at the US National Institutes of Health (NIH): Jane Bupp and Vanessa Elharrar; HPTN 061 Protocol Team Members: Sheldon Fields, Kaijson Noilmar, and Steven Wakefield; Other HPTN 061 Contributors: Black Gay Research Group, Kate MacQueen, and Leo Wilton.

References

1. Finlayson TJ, Le B, Smith A, et al. HIV risk, prevention, and testing behaviors among men who have sex with men—National HIV Behavioral Surveillance System, 21 U.S. cities, United States, 2008 [published online ahead of print October 28, 2011]. *Morb Mortal Wkly Rep Surveill Summ.* 2011; 60(14):1–34.
2. National Center for HIV/AIDS VH, STD & TB Prevention, Division of HIV/AIDS Prevention. [Accessed October 9, 2013] HIV Surveillance in Men Who Have Sex with Men (MSM). 2012. http://www.cdc.gov/hiv/pdf/statistics_surveillance_MSM.pdf
3. Maulsby C, Millett G, Lindsey K, et al. HIV among black men who have sex with men (MSM) in the United States: a review of the literature. *AIDS Behav.* 2013;10.1007/s10461-013-0476-2
4. Wilton L, Herbst JH, Coury-Doniger P, et al. Efficacy of an HIV/STI prevention intervention for black men who have sex with men: findings from the Many Men, Many Voices (3MV) project [published online ahead of print March 10, 2009]. *AIDS Behav.* 2009; 13(3):532–544.10.1007/s10461-009-9529-y [PubMed: 19267264]
5. Maulsby C, Millett G, Lindsey K, et al. A systematic review of HIV interventions for black men who have sex with men (MSM). *BMC Public Health.* 2013; 13(1):625.10.1186/1471-2458-13-625 [PubMed: 23819660]
6. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men [published online ahead of print November 26, 2010]. *N Engl J Med.* 2010; 363(27):2587–2599.10.1056/NEJMoa1011205 [PubMed: 21091279]
7. Curran K, Baeten JM, Coates TJ, Kurth A, Mugo NR, Celum C. HIV-1 prevention for HIV-1 serodiscordant couples [published online ahead of print March 15, 2012]. *Curr HIV/AIDS Rep.* 2012; 9(2):160–170.10.1007/s11904-012-0114-z [PubMed: 22415473]
8. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy [published online ahead of print July 20, 2011]. *N Engl J Med.* 2011; 365(6):493–505.10.1056/NEJMoa1105243 [PubMed: 21767103]
9. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med.* 2012; 367(5):399–410.10.1056/NEJMoa1108524 [PubMed: 22784037]
10. Institute of Medicine. *Methodological Challenges in Biomedical HIV Prevention Trials.* Washington, DC: Institute of Medicine; 2008.
11. Mayer KH, Wheeler DP, Bekker LG, et al. Overcoming biological, behavioral, and structural vulnerabilities: new directions in research to decrease HIV transmission in men who have sex with men. *J Acquir Immune Defic Syndr.* 2013; 63(suppl 2):S161–S167.10.1097/QAI.0b013e318298700e [PubMed: 23764630]
12. Celum C, Baeten JM. Antiretroviral-based HIV-1 prevention: antiretroviral treatment and pre-exposure prophylaxis. *Antivir Ther.* 2012; 17(8):1483–1493.10.3851/IMP2492 [PubMed: 23221365]
13. Vermund SH, Hodder SL, Justman JE, et al. Addressing research priorities for prevention of HIV infection in the United States [published online ahead of print April 20, 2010]. *Clin Infect Dis.* 2010; 50(suppl 3):S149–S155.10.1086/651485 [PubMed: 20397942]
14. Koblin BA, Mayer KH, Eshleman SH, et al. Correlates of HIV acquisition in a cohort of black men who have sex with men in the United States: HIV Prevention Trials Network (HPTN) 061. *PloS One.* 2013; 8(7):e70413.10.1371/journal.pone.0070413 [PubMed: 23922989]
15. Wilson PA, Moore TE. Public health responses to the HIV epidemic among black men who have sex with men: a qualitative study of US health departments and communities [published online ahead of print April 18, 2009]. *Am J Public Health.* 2009; 99(6):1013–1022.10.2105/AJPH.2008.140681 [PubMed: 19372516]
16. Millett GA, Peterson JL. The known hidden epidemic HIV/AIDS among black men who have sex with men in the United States. *Am J Prev Med.* 2007; 32(4 suppl):S31–S33.10.1016/j.amepre.2006.12.028 [PubMed: 17386333]
17. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training

- challenges [published online ahead of print December 24, 2008]. *Adm Policy Ment Health*. 2009; 36(1):24–34.10.1007/s10488-008-0197-4 [PubMed: 19104929]
18. Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation [published online ahead of print March 7, 2008]. *Am J Community Psychol*. 2008; 41(3–4):327–350.10.1007/s10464-008-9165-0 [PubMed: 18322790]
 19. Arnold, MP.; del Rio, C.; Griffith, S., et al. Identifying effective recruitment strategies to engage black MSM in HIV prevention research: screening data from HPTN 061-A feasibility study of a community-level, multi-component intervention for black men who have sex with men. Paper presented at: 18th Conference on Retroviruses and Opportunistic Infections; February 27, 2012 to March 2, 2012; Boston, MA.
 20. Strauss, A.; Corbin, J. *Grounded Theory Procedures and Techniques*. 2. Thousand Oaks, CA: Sage publications; 1998. *Basics of qualitative research*.
 21. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis [published online ahead of print October 6, 2005]. *Qual Health Res*. 2005; 15(9):1277–1288.10.1177/1049732305276687 [PubMed: 16204405]
 22. Downe-Wamboldt B. Content analysis: method, applications, and issues [published online ahead of print July 1, 1992]. *Health Care Women Int*. 1992; 13(3):313–321.10.1080/07399339209516006 [PubMed: 1399871]
 23. Malebranche DJ. Black men who have sex with men and the HIV epidemic: next steps for public health. *Am J Public Health*. 2003; 93(6):862–865. [PubMed: 12773340]
 24. Raja S, Teti M, Knauz R, et al. Implementing peer-based interventions in clinic-based settings: lessons from a multi-site HIV prevention with positives initiative. *J HIV/AIDS Soc Serv*. 2008; 7(1):7–24.10.1080/15381500802093092
 25. Cupples JB, Zukoski AP, Dierwechter T. Reaching young men: lessons learned in the recruitment, training, and utilization of male peer sexual health educators. *Health Promot Pract*. 2010; 11(3 suppl):19S–25S.10.1177/1524839909358847 [PubMed: 20488965]
 26. Alvarez RA, Vasquez E, Mayorga CC, Feaster DJ, Mitrani VB. Increasing minority research participation through community organization outreach. *West J Nurs Res*. 2006; 28(5):541–560. discussion 61–63. 10.1177/0193945906287215 [PubMed: 16829637]
 27. Gwadz M, Cleland CM, Leonard NR, et al. Predictors of screening for AIDS clinical trials among African-Americans and Latino/Hispanics enrolled in an efficacious peer-driven intervention: uncovering socio-demographic, health, and substance use-related factors that promote or impede screening. *AIDS Behav*. 2013; 17(2):801–812.10.1007/s10461-012-0194-1 [PubMed: 22638865]
 28. Wei C, McFarland W, Colfax GN, Fuqua V, Raymond HF. Reaching black men who have sex with men: a comparison between respondent-driven sampling and time-location sampling. *Sex Transm Infect*. 2012; 88(8):622–626.10.1136/sextrans-2012-050619 [PubMed: 22750886]
 29. Barresi P, Husnik M, Camacho M, et al. Recruitment of men who have sex with men for large HIV intervention trials: analysis of the EXPLORE Study recruitment effort. *AIDS Educ Prev*. 2010; 22(1):28–36.10.1521/aeap.2010.22.1.28 [PubMed: 20166785]
 30. Centers for Disease Control and Prevention. *Principles of Community Engagement*. 2. Washington, DC: Government Printing Office; 1997. *Principles of Community Engagement*. 1997. Report No. Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement.
 31. Leonard NR, Banfield A, Riedel M, et al. Description of an efficacious behavioral peer-driven intervention to reduce racial/ethnic disparities in AIDS clinical trials. *Health Educ Res*. 2013; 28(4):574–590.10.1093/her/cyt052 [PubMed: 23669214]
 32. Vargo S, Agronick G, O'Donnell L, Stueve A. Using peer recruitment and OraSure to increase HIV testing. *Am J Public Health*. 2004; 94(1):29–31. [PubMed: 14713690]
 33. Ahmed SM, Palermo AG. Community engagement in research: frameworks for education and peer review. *Am J Public Health*. 2010; 100(8):1380–1387.10.2105/AJPH.2009.178137 [PubMed: 20558798]

TABLE 1**Organizational Characteristics of HPTN 061 Sites (N = 7)**

Question	Median (IQR)
Number of individuals who contribute at least 0.5 FTE as paid staff for HPTN 061 at each site	11 (9–12)
Of the total staff members, how many	
were black MSM?	4 (2–7)
were black transgender?	0 (0–0)
had more than 1 year of experience working with black MSM prior to HPTN 061?	6 (4–7)
had more than 1 year of experience working with black transgender people prior to HPTN 061?	3 (1–5)
Distribution of staff in each activity area (each staff may have more than 1 responsibility)	
Outreach and recruitment	3 (2–9)
Participant screening	7 (6–8)
Counseling and testing	4 (4–7)
Peer health navigation/health services navigation	3 (3–6)
Clinical and laboratory activities	4 (2–7)
Administrative and regulatory activities	2 (1–6)
Study management/leadership	2 (2–3)
Turnover (as of the beginning of year 2 of the study)	
Number of people left staff	2 (1–3)
Number of people joined staff	3 (0–5)
Out of 7 sites	
Any other study conducted at the site with intended or recruited MSM or transgender populations	5
If yes, ease of coordination	
Very easy	2
Somewhat easy	2
Somewhat difficult	1
Very difficult	0

Abbreviations: FTE, full time equivalent; IQR, interquartile range; MSM, men who have sex with men.

TABLE 3

Common Themes

Critical Aspects of Study Implementation Identified in Interviews	Number of References in Interviews
Access to community/external resources	30
Organizational adaptability/capacity to build study team reflective of participant population	22
Access to organizational/internal resources	21
Study team reflective of participant population	14
Connections between team and community	14
Collaboration among team members	6
Responsiveness to participants	5