



Where are the BROTHERS

A Report on Retention Strategy Recommendations for HPTN-061

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Section 1. Acknowledgments

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Planning and Logistical Support

The logistics of the retreat would not have been possible if not for the organizational support of the wonderful individuals at Family Health International, Inc., (Kathy Hinson, Sarah Artis, and Jonathan Lucas). Thank you to the retreat participants (HPTN-061 Black Caucus members and special guest) for your willingness to convene and work so hard over a holiday period (See the Retention Retreat Participants section for a full list of the participants). Finally HPTN 061 is supported by an award from the National Institute of Allergy and Infectious Diseases (Grant # U01AI068619), National Institute of Drug Abuse, and the National Institute of Mental Health and we want to thank them for their support.

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Section 2. Retention Retreat Participants

The participants of the retention retreat consisted of most of the members of the HPTN-061 Black Caucus and a few invited guests. In all a total of 18 individuals participated in the retreat. Below you will find a list of the participants in alphabetical order by last name.

Table 1: Retention Retreat Participants

Name / Credentials	Title / Location	061 Site / Affiliation
Michael P. Arnold , PhD	Director of Population Health and Health Disparities HIV Research Section, San Francisco Department of Public Health San Francisco, CA	San Francisco
Lawrence Bryant , PhD, MPH, BSW, RRT	Assistant Professor, Division of Respiratory Therapy, Georgia State University Atlanta, GA	Atlanta
Chadwick K. Campbell , BA	Project Director Center for Research on Gender and Sexuality San Francisco State University San Francisco, CA	Invited guest / Consultant
Rudolph H. Carn , BS	Founder & CEO – NAESM, Inc. Atlanta, GA	Atlanta
Jamaal Clue , AB	Nicholas A. Rango Fellow, Racial and Ethnic Health Disparities, National Alliance of State and Territorial AIDS Directors Washington, DC	Invited guest / Consultant
Sheldon D. Fields , PhD, RN, FNP-BC, AACRN, DPNAP, FAANP	Associate Professor of Nursing and in the Center for Community Health, University of Rochester Rochester, NY	Black Caucus Chair
Christopher Hucks-Ortiz , MPH	Project Manager, Department of Family Medicine University of California Los Angeles Las Angeles, CA	Los Angeles
Craig Hutchinson , MPH	Research Counselor, New York Blood Center/Project Achieve New York, NY	New York (Blood Center)
Yovannys Kenney	Research Associate/Peer Health Navigator, Fenway Health Boston, MA	Boston
Jonathan Paul Lucas , MPH	Community Program Manager, Family Health International Durham, NC	HPTN Core / FHI
LaRon E. Nelson , PhD, RN, NP	Assistant Professor, University of Toronto & Vice Chair, Black Gay Research Group Toronto, ON (Canada)	HPTN Scholar Invited guest / Consultant

Borris Powell, MHS	Community Engagement Officer, Office of HIV/AIDS Network Coordination (HANC), Fred Hutchinson Cancer Research Center, Seattle, WA	HVTN Legacy Project
Gregory D. Victorianne, BA	Research / Administrative Coordinator, David Geffen School of Medicine at UCLA Department of Family Medicine University of California Los Angeles, CA	Los Angeles
S. Wakefield, BS	Director Community Relations HIV Vaccine Trials Network, Fred Hutchinson Cancer Research Center Seattle, WA	HVTN Legacy Project HPTN 061 Protocol Team Member
Jermel L. Wallace, MHS	Senior Research Project Coordinator, Emory University Atlanta, GA	Atlanta
Christopher Chauncey Watson, BS	Research Field Supervisor, George Washington University School of Public Health and Health Services Washington, DC	Washington, DC
Darrell P. Wheeler, PhD, MPH, ACSW	Associate Dean for Research & Community Partnerships and Associate Professor, Hunter College School of Social Work New York, NY	HPTN-061 Co-PI
Leo Wilton, PhD	Associate Professor of Human Development and Africana Studies Binghamton University College of Community and Public Affairs Binghamton, NY	Qualitative Working Group lead

Section 3. HPTN-061 Background

HPTN-061 Background and Schema

HPTN 061 is a feasibility study that is focusing on Black MSM, a population that represents a quarter of the new HIV infections each year in the United States and for which few interventions are available. HPTN 061 will collect information about recruitment and the uptake of intervention components and will facilitate design of a full interventional trial. HPTN 061 will use participant samples, behavioral data, and HIV test results from this study to improve laboratory methods for determining HIV incidence from cross-sectional surveys.

HPTN 061 Schema

Title: A Feasibility Study of a Community-Level, Multi-Component Intervention for Black Men Who Have Sex with Men

Purpose: To determine the feasibility and acceptability of a multifaceted intervention among Black men who have sex with men (MSM), to prepare for a community-level randomized trial to test the efficacy of the intervention in reducing HIV incidence among Black MSM.

Design: A multi-site, community-level feasibility study, with longitudinal data collected for the majority of participants and only baseline cross-sectional data collected for a minority of participants. A subset of participants will also be recruited for qualitative interviews and focus groups.

Population: Sexually active Black MSM living in select cities in the United States (US).

Study Size: Approximately 2418 participants (403 per site at each of six sites)

- Men enrolling for this study will be recruited in one of two ways—either directly from the community (“community recruited” participants) or as sexual network partners referred by participants (“referred” participants).
- Enrollment of certain sub-categories of community-recruited participants will be limited according to criteria detailed in the protocol. Enrollment of community-

recruited participants at a site will cease when 250 community-recruited participants who agree to HIV testing have been enrolled.

- A subset of community-recruited and referred participants will be considered “index” participants. Index participants are those who are newly identified with HIV infection, those with previously diagnosed HIV infection who are not receiving HIV care, and a random sample of HIV-negative participants. Index participants will be asked to refer sexual partners.
- There will be no cap on the number of referred participants enrolled into the study, however enrollment of referred participants will stop two months after closure of enrollment of community-recruited participants.

A subset of participants will be recruited from the main study to participate in focus groups (approximately 18-24 participants per site, or 108-134 participants overall) and qualitative interviews (up to 30 participants at each site, or 180 participants overall).

Intervention: The intervention components provided to participants include:

- Referral of up to five sexual partners by index participants for enrollment into the study.
- HIV risk reduction counseling, testing, and referral for care
- STI testing and referral for care.
- Screening for substance use, mental health issues, partner and/or homophobic violence, and (if indicated) provision of counseling and referral for care.
- Engagement with peer health care system navigators (PHNs) to facilitate uptake of health care and other services.

Study Duration: The total duration of the study will be two years. This timeline includes 12 months for participant accrual and up to 12 months of follow-up for each participant.

Primary Objective: To obtain the information needed to design a full, community-wide randomized trial. Specific areas of interest include:

- Recruitment of Black MSM.
- Uptake of the intervention components by Black MSM, including the proportion of enrolled participants who:

- Agree to HIV testing.
- Agree to STI testing.
- Use peer navigation.
- Estimating the following in the course of the study:
 - Proportion of participants who are newly diagnosed with HIV at enrollment.
 - Increase in condom use from enrollment to week 52.
 - Decrease in viral load at week 52 among HIV infected participants who initiate HAART during their study participation.
 - Decrease in prevalence of STIs from enrollment to week 52.
- Satisfaction of Black MSM with intervention components

Secondary Objectives:

- To collect samples, behavioral data, and HIV test results to improve laboratory measures of HIV incidence in cross-sectional surveys.
- To estimate the HIV incidence rate under intervention conditions.
- To estimate the effect of the intervention on HIV incidence through mathematical modeling.
- To describe the social and sexual networks of Black MSM based on individually self-reported network data.
- To describe risk behaviors of sexual network members of Black MSM, especially of those who are newly diagnosed with HIV infection, or previously diagnosed but not in care.
- To assess attitudes of Black MSM toward other HIV prevention interventions.
- To use qualitative research methods to:
 - Examine individual, interpersonal, cultural, institutional, and geographic-specific processes that influence study participation and uptake of intervention components.

Understand how and to what extent stigma and discrimination (and other emergent themes) influence HIV testing and access to care by geographic region.

Charge to the HPTN 061 Black Caucus

The retreat was held at the National Conference Center in Leesburg, Virginia from the evening of Friday December 3, 2010 – Sunday December 5, 2010. We had full participation from most of the sites. There was no representation from the Harlem New York site and the representative from the San Francisco site was only present for the Sunday morning meeting. The group engaged in a very dynamic and in-depth process in which a plethora of issues and concerns regarding retention were discussed. The planning team for the retreat consisted of Jonathan P. Lucas, Dr. Sheldon D. Fields, Benjamin D. Perkins, Gregory D. Victorianna and Christopher Chauncey Watson. ***The charge that was given to the Caucus was to assess the current retention trends of the study to identify barriers and other issues and to come up with recommendations to improve the retention of participants in the study.***

Section 4. Methodology/ Process

The process of conducting the retention retreat started during the regularly scheduled HPTN 061 Black Caucus conference calls with the identification of the need to hold a face-to-face meeting. Once the idea of conducting a retention-focused retreat was approved by the HPTN 061 leadership team an agenda (See Appendix A for a copy of the agenda) was set up for the meeting and the logistics of the meeting were put into place by Family Health International (FHI). As chair of the Black Caucus, Dr. Sheldon D. Fields served as the facilitator of the retreat. The retreat was organized in a manner that would facilitate open dialogue, and the stimulation of ideas using a working group model to draw on the collective wisdom of those assembled. The agenda and research articles on the issue of retention were e-mailed to participants to read in preparation for the retreat (Corbie-Smith, 2004; Magnus et al., 2010; & Silvestre, et al., 2006).

Day One: Friday December 3, 2010

The retreat began with opening remarks and introductions of those in attendance followed by a group discussion of the ground rules for how the retreat would proceed. The group collectively established 7 ground rules. The agenda was reviewed and approved by the group. This was followed by brief power point presentations done by each site that focused on their successes and challenges related to retention efforts for 061 (See Appendix B for copies of presentations). Christopher C. Watson from the Washington, DC site then provided the group with a presentation of up to date 061 participant data. This presentation allowed for the identification of aggregate retention trends in the 061 study across all of the sites. All of the presentations further helped to lay a foundation for a discussion using the research literature on retention studies (Corbie-Smith, 2004), as well as behavioral studies in order to identify common themes/issues specifically related to the retention of Black MSM. It is to be noted that Dr. Wheeler one of the 061 study co-principal investigators was present by telephone for a majority of this discussion.

Day Two: Saturday December 4, 2010

Day two of the retreat began with a recap of the day one activities and a review of the agenda for day two. Next, the group was led in an exercise using the information and initial ideas from day one to stimulate a discussion about barriers for retention in the current study. Once this was done the group collectively combined the identified barriers into the three focus areas of:

- (1) Burden/benefit analysis**
- (2) Intervention delivery**
- (3) Community engagement**

Each retreat participant was then asked to self select which focus area they would like to work more closely on. This process resulted in five participants being assigned to each work group. Each group identified a group lead who would be primarily responsible for moving the group along throughout the rest of the day, a scribe who would use an electronic work plan to record the group's recommendations, and a

recorder would be responsible for manning the recording device used in each group. See table two for a list of those assigned to each work group.

Table 2: Assigned Workgroup and Responsibilities

Focus Area	Assigned Responsibilities
Burden/Benefit Analysis Work Group	Group Lead: Jamaal Clue Scribe: Dr. LaRon E. Nelson Recorder: Christopher Chauncey Watson Member: Mr. Rudolph H. Carn Member: Dr. Leo Wilton
Intervention Delivery Work Group	Group Lead: Christopher Hucks-Ortiz Scribe: Jermel L. Wallace Recorder: Craig Hutchinson Member: S. Wakefield Member: Borris Powell
Community Engagement Work Group	Group Lead: Gregory D. Victorianne Scribe: Jonathan Paul Lucas Recorder: Dr. Lawrence Bryant Member: Yovannys Kenney Member: Chadwick K. Campbell

Each work group was assigned a separate room to work in for the remainder of the afternoon as they developed their lists of recommendations. Dr. Fields as the moderator spent time with each group and monitored the time for each of them. At the end of this day each group was tasked with reporting back their work to the whole group. Dr. Wheeler joined the group once again via telephone at this point in order to hear the report back of the preliminary retention strategies that each group came up with and to render his own comments. Each group's leader was then tasked to prioritize the recommendations and forward via email to Dr. Fields an updated work plan. All three work plans of the prioritized preliminary strategies were forwarded to Dr. Wheeler via email so that he could read them in preparation for day three.

Day Three: Sunday December 5, 2010

Day three commenced with a recap of the busy events of day two and a review of the agenda for day three. Each work group then reconvened with the task of reviewing their work plan in order to finalize their recommendations and to attach time

lines to any action items for follow-up (See Appendix C, D, E). Following this process the group came back together one final time and a member from each group gave an overview of their action items for all to comment on. Again Dr. Wheeler joined the group via telephone to hear the final summary report-out and to offer any last comments. The group was dismissed at the conclusion of this exercise with final comments from Dr. Fields on a job well done.

Section 5. Results / Recommendations

The issues and concerns that emerged from the group process were collapsed into three major areas of focus: (1) Burden/Benefit Analysis, (2) Intervention Delivery, and (3) Community Engagement. Specific recommendations to address the various retention issues stem directly from these three key over-arching focus areas (See Appendix C, D, and E for focus area attachments’).

Focus Area 1: Burden/Benefit Analysis

Four major retention recommendations emerged in the area of burden/benefit analysis which will be presented in order of possible implementation from immediate to future. The first overarching recommendation in this area is:

- **Increase flexibility around how we engage people in the study so that we can be more accommodating to their dynamic social circumstances** (Zook, et al, 2010).

“When investigators take more innovative actions...these efforts have been more successful” (Corbie-Smith, 2004, pg. 386).

The work group had to get a handle on how each site was actually implementing the follow-up visit process as the discussion quickly revealed that there was a great deal of variation across the clinical sites in terms of things like: visit length, clinic hours, lab hours, transportation assistance, availability of other services, and the role of peer health navigators (PHNs). The group developed the “**HPTN Black Caucus Barrier Identification Tool**’ that each clinic site filled out that assisted with the identification of

barriers (See Appendix C for copy of this tool). The bottom line is that the benefits of participating in the study must be in balance with, and in a majority of cases be greater than, the logistical burden of participating in the study (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999). Five concluding strategies for retention emerged under this major recommendation and are included in Appendix C:

1. *Streamline the follow-up visit process: Assess and Implement the Harlem Model*
2. *Implement universal, opt-out PHN services and standardize PHN implementation across sites*
3. *Expand windows of opportunity for follow up visits*
4. *Implement a mechanism of interim engagement for participants*
5. *Location of Study Site: Transportation reimbursement or Incentives* (Brown, Basen-Engquist, & Tortolero-Luna, 2000; Woods, Mayo, Catley, Scheibmeir, & Ahluwalia, 2002).

In terms of streamlining the visit process (strategy #1) the work group recommends using the Harlem clinical site model as they have the shortest follow-up visit times and the highest retention rate of any site. Strategy#2 involves utilizing PHNs to assist participants with other life issues that they bring up during the course of the study. In some cases these life issues are seen as more pressing than being involved in this study; however, addressing these higher-order issues may allow the participant to be more available to participate in the study. Additionally, an expanded PHN case management service would be an added “benefit” to being in the study that would help balance the burden of the study visits. Implementing a universal PHN opt-out option and standardizing how this is done across the sites may also allow us to capitalize on the positive correlations between PHN engagement and retention that has been noted across all sites. In terms of expanding opportunities to do the follow-up visits (strategy #3) it is recommended that each clinical site make it possible to conduct visits during alternative times such as weekends and evenings. To do this would mean that serious attention will need to be given to adjusting current clinic and lab hours as well. Since each site is contracted with a national lab this task should be achievable.

Strategy #4 deals with ways to increase interim engagement of participants between visits using multiple methods of contact such as monthly check-in calls from study staff, and the use of monthly social events like those being conducted at the Boston site in collaboration with their local CBO partner. Strategy #5 under this recommendation deals with the location, transportation, and incentives used. The immediate implementation of a reimbursement measure for transportation in the form of gas cards, metro/train passes is seen as key. Locating primary or satellite clinical sites in the neighborhoods most convenient to and accessible by participants is something that is recommended to be seriously considered for future studies.

The second overarching recommendation in the burden/benefit analysis area is:

- **Identify ways to make the follow-up sessions shorter? Split up the follow-up visits so that folks have two pleasant experiences versus one frustrating experience**

The burden, especially in terms of the amount of time it takes to conduct the follow-up visits, was reported as a barrier across all sites. The recommendation here is to develop a standard operating procedure (SOP) that would allow for split follow-up visits. A two-day model is being proposed based on what is being considered at the Washington, DC clinical site (Appendix C). On day one the critical measures that need to be collected such as the case report forms and blood draws would be done along with the risk reduction components. The day two visit would include the ACASI and social sexual network follow-ups. It is noted that these visits should occur within seven days of each other. The option of split visits should be considered if: (A) the participant expresses time constraints (for any reason), (B) discusses length of visit is too much/too long or (C) when there is a staff shortage or inability to perform all duties needed for the follow up visit.

The third overarching recommendation in the burden/benefit analysis area is:

- **Identify and address the parallels between staff and participant attrition; provide cultural competency training to all study personnel (site, protocol, coordinating center)**

At the heart of this recommendation is the issue of cultural competence and how it has impacted the retention issues in the study. The work group recommends assessing the staff regarding their experience of burnout and psychological fatigue and identifying expert trainers in cultural sensitivity. This strategy is most likely one for future consideration as it is a larger issue that needs to be addressed by HPTN with the assistance of the Black Caucus. Nonetheless the work group does lay out specific steps that might be undertaken to address these issues that can be found in the table in Appendix C.

The fourth overarching recommendation in the burden/benefit analysis area is:

- **Provide participants with a cell phone that will allow us to reach them, and that will allow us to re-fill phones with minutes on a regularly scheduled basis, if needed**

The ability to find and communicate with participants emerged as a major barrier for retention. In this age of modern technology and wide spread use of cell phones the work group highly recommend that future studies seriously consider including a cell phone component similar to the one proposed for use at the Washington, DC site. As aforementioned, many of the men in the study live under very “dynamic” circumstances. By “dynamic”, the work group refers to the complicated ways in which the cultural debris of institutionalized and structural racism have caused many Black men to live under very unstable, transient situations. Imprisonment, homelessness, unemployment, poverty, and lack of access to resources are part of this “dynamic”; Black MSM are not removed from this reality. In fact, analysis of participants enrolled in the study indicate the complete opposite. Moving forward, in order to effectively engage Black MSM and other marginalized groups, fruitful engagement of communication strategizing is imperative. It may also include a re-evaluation and examination of the problematic conceptualization of “*coercion*” and what it means for communities of color. Cell phones even when not used for talking, per se, can also be used to send text messages to participants which is also currently a very popular way in which participants are communicating in their everyday lives. The use of cell phones in the study may not be feasible for sites at this time but other communication tools such as retrieving email

addresses along with contact information for one professional contact (social worker, case manager, pastor, medical providers) is also recommended. Email is also currently a popular way that participants communicate and a large majority of participants have at least one email address. Participant's email address should be updated at each visit. Collecting contact information, especially for those transitionally housed, would allow for another potential way to find participants who do not actively follow-up. The use of information sharing arrangements in line with HIPPA regulations in some cases would have to be put into place to facilitate such sharing of contact information.

Focus Area 2: Intervention Delivery

Four major retention recommendations emerged in the area of intervention delivery which will be presented in order of possible implementation from immediate to future (Appendix D). The first overarching recommendation in this area is

- **Cultural Competency: Increase cultural competency at site levels that will maximize retention efforts**

The members of the intervention delivery group focused a great of their time discussing the issue of cultural competency and its affect on retention of participants. The caucus recommends the four following retention strategies:

1. *Assess what has been learned about cultural competency since the beginning of the project (incl. what it means; definition).*
 - a. *Discussion should explain what clinical coordinators and PI have learned or experienced in regards to dealing with the target population. Staff feasibility retention retreat (i.e. Who we enrolled, where we enrolled, etc)*
2. *Principal investigators and Study Coordinators should maximize engagement and presence in the areas of retention and cultural competency.*
3. *Site Teams should consider the barriers associated with recruiting and retaining the target population.*

4. *Site teams should review roles/responsibilities for disparate burden of retention activities.*

The primary focus in this area should be placed on this first area of concern dealing with overall cultural competency. Assessing and increasing cultural considerations for this work across all clinical sites would provide a strong foundation for affecting retention as well as staff morale. In order to do this there has to be a mechanism set up to gather, assess and report issues related to cultural competency at the clinic sites in a way that allows staff to disclose issues in a confidential and safe manner. These cultural competency issues have been found to relate to race, ethnicity, culture, gender identity, sexual orientation, and sexual preference. To this extent we recommend the use of the newly created “***Clinical Research Site Cultural Competency Report Form***” (Appendix D). We envision this 9-question form being put up electronically on a site like survey monkey with a link to it being sent to clinical site staff. Data received would be analyzed and summarized by site and then used to plan with the site administrators strategies to best address the concerns. These strategies most likely will include training opportunities, rewards for program success, identification of cultural factors that address specific barriers, and the identification of the role(s) that all staff might play in the retention success of the study. Retention after all starts at enrollment.

The second overarching recommendation in the intervention delivery area is:

- **Racial and Sexual Identity of Staff / Staff Gender: Increase acceptability and functionality of staff**

The racial/ethnic, sexual identity and gender identification of the staff at each site was another area of discussion. It has been noted that in a study that is targeting Black MSM that the staff they interact with at the clinical sites have an impact on their retention in the study. The caucus recommends the three following retention strategies:

1. *Identify study staff capacity to address participant’s needs at each site based on sexual orientation, race, gender, and class.*

2. *Formulate questions to participants that will allow sites to better understand what and or who the participant wants to see or hear from at various parts of the study visit.*
3. *Have sites identify levels of continuity by presenting best practices*

The study participants need to feel a connection to study staff on some level and that can be enhanced by assuring that clinical sites have a **range of staff** that reflect the racial/ethnic, sexual identity, and sexual preference of those being enrolled. Ideally this includes making sure that there are self-identified out Black MSM staff members at each clinical site at all levels. We recommend that each site assign someone the task of reviewing the SCHARP data report summaries about who is actually enrolled at their site to ensure and maintain a compassionate connection to those enrolled. We also recommend operationalizing a way to ask participants who they may prefer in terms of staff members handle their follow-up visits as a way to do a bit of individualizing retention plans for participants. Every attempt to accommodate the participants request within reason should be made and if not able to then arrange a follow up discussion with the participant as to the limitations of the available staff to ascertain other possible solutions. This process of honoring participant's wishes we believe would be most beneficial. Lastly since retention does begin at enrollment we recommend using recruitment staff that first encounter the participants subsequently be used to conduct retention activities as well allowing for a sense of continuity in the study for the participants.

The third overarching recommendation in the intervention delivery area is:

- **Clinical Site Capacity: Ensure and increase capacity for retention through considerations of participant need**

Various issues related to site capacity emerged in the discussion of retention as well. Capacity in this case was conceptualized as site specific things that might impact retention through consideration of identified participant needs. To this extent the caucus recommends the nine following retention strategies:

1. *Identify on a per participant/ per site basis barriers associated with hours of operations and service access.*
2. *Identify innovative approaches to retention. Consider remote study visits.*
3. *In what capacity can we utilize mobility to reach out to the target population?*
4. *How do sites improve their representation in the community by investing in community based organizations planned social events.*
5. *Provide staff time to community based organizations to assist with true partnerships and collaborations.*
6. *Educate community based organizations on the research being conducted.*
7. *Incorporate 061 retention in recruitment plans for co-studies at sites.*
8. *Improve organization capacity to support Black MSM staff and initiatives.*
9. *Educate IRB members/staff about the particular needs of 061 participant populations.*

Retention strategy activities in this area range from implementing flexible clinic site hours (evenings, early mornings, weekends), providing transportation vouchers (cab services, tokens, bus passes), conducting home and virtual visits, setting up community and/or mobile satellite sites, using local club promoters to conduct retention events for participants, supporting the work of local CBO partners with staff for resources for events (Balls, Black AIDS Awareness Day, Pride Events), increasing the education given to CBO partners about the research being conducted and the identified barriers to retention of Black MSM. Other activities to consider are developing flyers and other print materials to use as outreach material for co-studies that are being conducted that also target Black MSM. Improving each clinical sites capacity to support Black MSM staff (internal support groups, workshops, mental health wellness check-ins, micro-aggression discussions) should also be implemented at each site. Lastly there appears to be some need to educate institutional review boards (IRBs) about the particular retention needs of the Black MSM participants enrolled in HPTN-061 (Yancey, Ortega, & Kumanyika, 2006). This could be done with the use of the literature, and this retention report with a goal of possibly helping the IRB to better understand some of the novel, innovative retention

strategies that need to be utilized with this population so that protocol study changes are not delayed at the individual IRB site level.

The fourth overarching recommendation in the intervention delivery area is:

- **Clinical Research Collaboration: Decrease competition for services by collaborating with community resources**

The group began a discussion about some clinical research collaboration issues that most likely will have to be implemented at a later time or in a future study. The caucus recommends the following one retention strategy in this sub-area

1. *Set local retention goals based on current enrollment, literature, etc*

This recommendation stems from the fact that each clinical site is unique in the characteristic makeup of the Black MSM sub-populations enrolled. So much so that it raises the question at least of setting retention goals locally as opposed to a uniformed overall benchmark goal for which we could not find support for in the literature specific to the Black MSM.

Focus Area 3: Community Engagement

The goals of the community engagement group were multi-faceted; 1) to promote long term community relations, 2) to improve community perception, and 3) to promote trust among researchers conducting HIV prevention trials. **Four** major retention recommendations emerged in the area of community engagement which will be presented in order of possible implementation from immediate to future (Appendix E).

The first overarching recommendation in this area is:

- **The HPTN 061 Black Caucus will develop a standard locator form to be used by each clinical research site participating in the BROTHERS study**

The group's discussion regarding locator information concluded that establishing a standardized locator form will ensure that each site is collecting as much locator information as possible. The caucus recommends the following retention activity:

1. *Creating an improved locator form to be used across all clinic sites*

To achieve this goal locator forms currently in use were collected from each site and assessed. What emerged from this process is a new improved updated “**HPTN 061 Locator Form**” (Appendix E). The caucus recommends that this form be adapted for use in the study immediately.

The second overarching recommendation in the community engagement area is:

- **Clinical research sites participating in HPTN 061 will ensure that there is adequate staff dedicated solely to retention activities and that those staff members receive appropriate support**

There was much discussion around staff utilization, particularly staff who are assigned to conduct retention activities. It was discovered that not all clinical sites have designated HPTN-061 retention staff, for those sites that do, the time spent on retention activities varies widely (Silvestre, et al., 2006). The caucus therefore recommends the two following retention activities:

1. *Increase staff output and morale*
2. *Increase the efficient use of project resources*
 - A. *Designated staff solely for project retention*
 - B. *Designated or re-directed resources for retention activities*

We believe these activities can be accomplished by collecting and assessing data (Black Caucus in conjunction with FHI) from each clinical research site related to retention staff distribution and responsibilities. Based on this data overall recommendations will be made to the HPTN-061 principal investigators for the reallocation of existing staff and responsibilities. We then recommend that the principal investigators meet with the clinical site leaders to make final site specific suggestions for the reallocation of staff or the hiring of adequate retention staff as soon as possible. We believe that these activities can be conducted quickly once approved by the study leadership.

The third overarching recommendation in the community engagement area is:

- **Clinical research sites participating in HPTN 061 will initiate monthly communications with study participants to build rapport and ensure that locator information is updated on a regular basis**

The need to engage the participants more frequently and in a consistent manner was a theme that emanated across all sites. Minority communities have a low level of trust in researchers and building rapport through positive interactions may improve retention of study participants. The caucus therefore recommends the two following retention activities:

1. *Regularly updating the locator information*
2. *Finding ways to Improve rapport with study participants*

These activities can be achieved by establishing with each study participant a regular consistent communication plan using their preferred communication channel. We recommend that sites establish a minimum monthly communication pattern for each participant. We also recommend the use of the “**HPTN-061 Contact Log**” (Appendix E) to track and document contact attempts along with the “**Locating Hard-to-Reach Participants**”, and the “**Home Visit Contact Log**” forms (Appendix E). Regularly updating the locator form will of course assist with this process along with adding to the issue of monthly communications as a follow-up item on the regularly scheduled protocol team call for feedback.

The fourth and final overarching recommendation in the community engagement area is:

- **Clinical research sites participating in HPTN 061 will solicit staff input related to participant retention on a weekly basis and ensure that recommendations for novel approaches to retention activities are given serious consideration**

Considering that HPTN is a dynamic and fluid study, the group discussed the most efficient way to solicit insight and ideas from those on the ground level regarding improving retention. Additionally, we feel that this feedback should be as close to

“real time” as possible. The caucus therefore recommends the two following retention activities:

1. *Increasing communication among staff and upper management*
2. *Increasing staff capacity for direct input*

These strategies are meant to **empower** the front line staff directly and to be able to respond quickly to ideas, and innovations that might impact retention as close to real time as possible. To accomplish this we recommend that each clinical research site immediately implement **weekly retention meetings** to solicit ongoing staff ideas, in addition to appointing a **lead staff retention person**. Good ideas should not have to wait, windows of opportunity need to be taken advantage of whenever possible. The Black caucus should also add this item to its monthly call as well as a check-in.

Other Results / Issues for Consideration

There were a few other issues that came up during the group’s discussion that did not fit per se into the three main areas identified above. Although standard retention rates were strictly applied to Black MSM in this study, we did not find any scientifically evidenced based body of work to support the use of the 95% and 90% percent retention benchmark at 26 and 52 weeks among Black MSM. While we acknowledge the use of these gold standard benchmarks in clinical research among other groups, the lack of evidence supporting its applicability in studies specifically enrolling Black MSM in clinical trials is questionable. One overarching concern is whether or not these standard benchmarks can be relegated to this population, given the many extenuating life factors this group deals with. One recommendation would be to use this pilot study as a means to establish a more meaningful set of benchmarks based on a final retention analysis at the end to this current study. This solution seems applicable given the fact that until now there just has not been this type of study conducted specifically targeting Black MSM. An obvious concern is the assessment of the success of this study in terms of retention and its implications for future studies involving Black MSM. The work group further

recommends an ongoing discussion of this issue of an appropriate, more feasible and achievable retention benchmarks for Black MSM that for the first time will have some evidence to support them.

Another issue that emerged that appears to be impacting retention in HPTN-061 seems to be occurring at sites and in locations **where both HPTN-061 and HVTN-505** are being conducted simultaneously. We ascertained that in some cases there has been a shift from retention in HPTN-061 to recruitment for HVTN-505 especially at sites that are utilizing the same staff resources to conduct both study activities. The work group recommends that this situation be dealt with immediately as it has implications for not only HPTN-061 but for HVTN-505 as well if staffs are indeed feeling overwhelmed by the demands of both studies. The recommendation above of having specific dedicated HPTN-061 retention staff would help mitigate this situation.

Discussion / Limitations

In research, successfully engaging and retaining participants is essential for achieving the study objectives. Identifying factors related to missed visits and deactivations are the initial step in recognizing the potential at-risk participants and can enable the design of targeted strategies to retain participants (Zook, et al., 2010). This is the essence of what we are attempting to do in regards to retention in HPTN-061. The work group identified any number of factors that are impacting retention and have noted some concerns about the original design of 061 and the benchmarks that have been set. The recommendations highlight just how essential the contextual realities of the Black MSM participants are. The reality is that Black MSM by and large don't organize their lives around a research study or protocol. The interjection of a protocol is artificial in many ways and the study team and leaders must understand this at the project inception. Future studies should involve Black MSM and community organizations, from project design to future sustainability efforts.

The importance of the success of this study can't be over stated. That said, we want to underscore the absolute necessity for research on Black MSM to continue. The

success of HPTN-061 has been greatly enhanced by the Black Caucus and we also want to advocate for the inclusion of Black MSM at every step and level of this and future studies.

This process is not without its limitations. The lack of evidenced based literature was a limitation. Crafting recommendations for an ongoing study so that things can be implemented realistically was a limitation as well. Not every recommendation is applicable to every clinical site. That being said, I want to also once again acknowledge the great expert contributions of the members of the HPTN-061 Black Caucus.

Conclusions

The issue of participant retention in the HPTN-061 (BROTHERS) study is multi-faceted and complex with not just one factor that needs to be considered. The Black Caucus retention retreat to study this issued concluded that most of the issues could be grouped into three major areas of (1) Burden/Benefit analysis, (2) Intervention delivery, and (3) Community Engagement. Within these three areas of focus emerged several overarching and many sub-level retention strategy activities to address the identified issues. Some of the recommendations can and should be implemented immediately and others have long term implications for future son of 061 studies.

Next Steps

In order to implement these recommendations the Black Caucus will add the retention retreat to its work plan for monthly follow-up. It will also be added as a standing agenda item for our monthly conference call. We also recommend that the retention retreat be added as a standing agenda item for the overall protocol team's monthly call. The Black caucus will also be available for ongoing consultation.

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