SUPPORTING STATEMENT A:

Evaluating Locally-Developed HIV Prevention Interventions for African-American MSM in Los Angeles

New OMB Application

OMB No. 0920-New

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention requests approval for a term of 3 years for a new data collection called "Evaluating Locally-Developed HIV Prevention Interventions for African-American MSM in Los Angeles". The primary purpose of the project is to implement and rigorously evaluate a HIV prevention intervention, which was developed by In the Meantime Men's Group (ITMT), a community-based organization (CBO) in Los Angeles with substantial input from the served community, to reduce sexual risk for HIV infection and transmission among young high risk African-American men who have sex with men (MSM). The secondary purpose is to study factors associated with sexual risk among sexually-active MSM. The study site will implement and test their intervention with the goal of determining efficacy of the intervention.

Data on HIV cases reported in 33 U.S. states with HIV reporting indicate the burden of HIV/AIDS is most concentrated in the African American population compared to other racial/ethnic groups [1]. Of the 49,704 African American males diagnosed with HIV between 2001 and 2004, 54% of these cases were among men who have sex with men (MSM). In Los Angeles County (LAC), the proportion of HIV/AIDS cases among African American males attributable to male-to-male sexual transmission is even greater (75%) [2]. In the absence of an effective vaccine, behavioral interventions represent one of the few methods for reducing high HIV incidence among African American MSM (AAMSM). Unfortunately, in the third decade of the epidemic, very few of the available HIV-prevention interventions for African American populations have been designed specifically for MSM. In fact, until very recently [3] none of CDC's evidence-based, HIV-prevention interventions had been specifically tested for efficacy in reducing HIV transmission among MSM of color [4].

While a number of individual- and group-level HIV interventions have been created by and for a variety of AAMSM organizations across the U.S., evaluation data to document the efficacy of these programs are practically non-existent. Factors that hinder minority-run, gay organizations from conducting routine outcome evaluations include lack of financial resources, high staff turn-over, inadequate technical assistance, and cultural differences that make collaborations with academic researchers a challenge. Such factors may also preclude the consistent implementation of essential intervention components in these same community-based settings.

Given the conspicuous absence of 1) evidence-based HIV interventions and 2) outcome evaluations of existing AAMSM interventions, our collaborative team intends to address a glaring research gap by implementing a best-practices model of comprehensive program evaluation. The intervention is a 3-session, group-level intervention that will provide participants with the information, motivation, and skills necessary to reduce their risk of transmitting or acquiring HIV. The purpose of this study, therefore, is to pair an outcome evaluation using an experimental study design with methods to identify intervention elements needed to produce positive outcomes in a real-world setting.

In this study, we will test the hypothesis that participants of the MyLife MyStyle program (MLMS) will report a 15% absolute decrease in frequency of unprotected anal sex with male partners at three and six months post-intervention. To test our research hypothesis, we will implement a randomized controlled trial for a minimum of 528 AAMSM, ages 18-29 years, to measure the efficacy of MLMS to reduce unprotected anal sex with male partners at three and six months post-intervention compared with a wait-list control condition. In addition to testing our main hypothesis, we will conduct a comprehensive program evaluation to identify the critical elements of a successful HIV risk-reduction intervention designed for young AAMSM at risk of HIV acquisition and transmission.

The data to be collected for this study will be used to establish the preliminary efficacy of a homegrown intervention and will provide important information about sexual risk behaviors and the context in which they occur. These data are essential for identifying effective homegrown HIV/AIDS prevention interventions for young at-risk African American MSM and for improving the quality of HIV prevention services the CBO delivers in their community. The findings from this study will be shared with Division of HIV/AIDS Prevention leadership and the scientific community through publication in peer-review journals and presentations at national conferences. In addition, this funding opportunity can potentially increase the number of evidence-based interventions (EBIs) for young African-American MSM at high risk for acquiring or transmitting HIV. Ultimately, the beneficiary of this data collection will be young African-American MSM who are at risk for HIV.

The project is in alignment with several goals outlined in the National HIV/AIDS strategy:

- Goal 1- 1.2.1 Prevent HIV among gay and bisexual men and transgender individuals
- Goal 1- 1.2.2 Prevent HIV among Black men and women
- Goal 1- 2.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV in high risk communities
- Goal 1 – 2.4 Expand prevention with HIV-positive individuals
- Goal 1 – 3.2 Promote age-appropriate HIV and STI prevention education for all Americans
- Goal 3 – 2.1 Establish pilot programs that utilize community models

The study also supports several objectives of the Division of HIV/AIDS Prevention Strategic Plan. For Short-Term Milestone 1 (By 2010, decrease by at least 10% the number of persons in the United States at high risk for acquiring or transmitting HIV infection by delivering targeted, sustained and evidence-based HIV prevention interventions.), Objective 2 is *Among men who have sex with men (MSM), increase the proportion who consistently engage in behaviors that reduce risk for transmission of HIV.* Under the same Milestone, Objective 2a is *Increase the number of proven effective behavioral prevention interventions for African Americans and other racial and ethnic groups disproportionately affected by HIV/AIDS,* and Objective 3a is *Increase the number of proven effective behavioral prevention interventions for MSM.*

The following section of the U.S. Federal Code (**Attachment 1**) is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of

"research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man."

Privacy Impact Assessment

Overview of the Data Collection System

This study will use a randomized controlled trial (RCT) study design to test whether delivery of a three-session, group intervention implemented over approximately three-weeks —MyLife MyStyle—reduces HIV sexual-risk behaviors among 18- to 29-year-old African American men who have sex with men. All data will be collected and maintained by the Grantees. The data collection system involves screenings, limited locator information, participant contact information, baseline questionnaire, client satisfaction surveys, 3-month follow-up questionnaire, 6-month follow-up questionnaire, and success case study interviews (see **Attachment 3a** for Data Collection Flow chart). An estimated 700 men will be screened for eligibility using the Outreach Recruitment Assessment (**Attachment 3d**); this process is estimated to take 5 minutes per respondent. Data collection for eligibility screening will occur through a brief interview conducted either face-to-face or over the phone. Participants will be recruited through active venue-based outreach and passive internet recruitment.

For men meeting eligibility criteria, MLMS project staff will use the limited locator information form (**Attachment 3c**) to collect contact information (e.g., name, email, telephone number). Limited locator information will be used to contact men to set up appointments to complete the informed consent process and up to a 1-hour Baseline Questionnaire (**Attachment 3d**) via ACASI at a mutually convenient place and time. Enrolled participants will provide more extensive locator information on the Participant Contact Information Form (**Attachment 3e**). This information will be used to contact participants to remind them of intervention sessions and follow-up visits. After participants complete the baseline questionnaire, they will receive their random assignment to the experimental or control condition. Individuals assigned to the experimental group will be told the specific date and time to appear for the first session. After each intervention session, participants will be asked to complete a client satisfaction survey (**Attachment 3f**). After experimental group receives the intervention, all participants (experimental and control groups) will be asked to complete 3-month and 6-month follow-up questionnaires (**Attachments 3g**). The research team will also conduct qualitative, in-depth interviews with a subset of 36 randomly selected participants assigned to the intervention group for the "Success Case Study" interviews using a semi-structured interview guide (**Attachment 3h**).

The site will collect information in identifiable form for all participants so that they may track individuals longitudinally. Each study participant will be given a unique identifier, which will appear with the study data. In order to prevent inadvertent linkage of research-related data with participant names, signed consent forms will be labeled with a Study ID number. Signed consent forms affixed with the Study ID will be stored in locked filing cabinets initially at ITMT and ultimately at Los Angeles County Department of Public Health HIV Epidemiology Program (HEP). The Study ID numbers that label the informed consent forms will be marked out or

removed by the HEP Project Epidemiologist after the follow-up questionnaires are complete so that there is no detectable linkage between a participant's consent form signature and his unique Study ID. An additional password-protected Excel spreadsheet located on a double password-protected data network will be maintained by HEP's Project Epidemiologist to provide an electronic linkage between participants' identities and their unique Study ID. Participant names or other personal identifiers will not be stored with any electronic questionnaire files (e.g., baseline, follow-up measurements) that are associated with the project. Identifying information will not be included with study data and will not be transmitted to CDC or any other agency. CDC staff will not have access to any identifying information. De-identified data (including the baseline, follow-up questionnaires, success case study data, arm assignment (i.e., assignment to the experimental or control arm), client satisfaction surveys, and session attendance (i.e., number of intervention sessions attended) will be transmitted to CDC via a secure data network. The linking file and the locating information will be destroyed once follow-up is complete. Deidentified study data will be maintained at the site and CDC indefinitely.

Items of Information to be Collected

Participant Screening Data

Screening data to be collected include items related to study eligibility criteria, which are: 1) male, 2) 18 to 29 years of age, 3) reside within Los Angeles County, 4) African-American, 5) no previous participation in ITMT closed-group session, 6) report anal sex with a male partner in the past 12 months, 7) no participation in an HIV prevention intervention in the past 3 months, 8) identify as male, 9) not planning on moving out of Los Angeles County in the next 8 months. Screening data will not involve the collection of information in identifiable form.

Outreach staff will ask 8 items to determine eligibility (in italics below) and 2 "red herring" items (not in italics). The red herring items are included to minimize the potential that the screening criteria become known in the community. The questions are: *What is your age? In what county do you currently live? What is your race or ethnicity? Have you ever attended a small, closed-group session at In the Meantime Men's Group? In the past year, have you been either a bottom or a top with another man? Have you participated in an HIV prevention intervention, either as an individual or in a group, in the past 3 months? Do you identify as Male or Transgender?* Do you currently smoke? Have you seen a medical doctor in the past 12 months? *Do you plan to move out of LAC in the next 8 months?* The screening questions can be found in **Attachment 3b**.

Screening Procedures

MLMS recruiters will approach potential participants during street and venue-based outreach (active recruitment). Each person approached will be given a MLMS project information handcard or flyer that provides a telephone number and basic information about the general nature of the study. Interested men will be screened in-person for eligibility using a brief eligibility screener—Outreach Recruitment Assessment (**Attachment 3b**). The Limited Locator information form (**Attachment 3c**) will be completed by individuals who are screened and eligible in order to schedule their baseline interview appointment. The Limited Locator form will also be completed by interested individuals unable to complete screening during outreach in

order to contact and screen potential participants on the phone at a more convenient time. If contact information is not collected from a potential participant at the recruitment venue, the MLMS recruiter will encourage the individual to use the MLMS handcard or flyer to contact the ITMT office at a later time for screening by study staff.

Men recruited using passive techniques (e.g. referrals/word-of-mouth, placement of handcards or flyers, posting via Facebook or other on-line announcements) will be instructed to contact ITMT if interested in participating and will be screened over the phone. Responses to the brief eligibility screener, for both men screened either in-person or over the phone, will be entered onto the Outreach Recruitment Assessment (**Attachment 3b**) and study staff will determine eligibility based on responses. All eligible men will be scheduled to complete the informed consent process and up to a 1-hour baseline interview via ACASI.

Participant Limited Locating Information

A Limited Locator information form (**Attachment 3c**) will be completed by individuals who are eligible in order to schedule their baseline interview appointment. The Limited Locator form will also be completed by interested individuals unable to complete screening during outreach in order to contact and screen potential participants on the phone at a more convenient time. The form will contain the following categories of information in identifiable form (IIF): name, availability information for groups, email address, phone number and indication whether the appointment if for screening or baseline assessment. To improve retention for MLMS sessions as well as the three- and six-month follow-up assessments, enrolled participants will provide more extensive locator information using the Participant Contact Information Form (**Attachment 3e**). This information will be used to contact participants to remind them of intervention sessions and follow-up visits. The form will contain the following categories of information in identifiable form (IIF): name, address, phone numbers, email address, Facebook name, MySpace name, relative, friend, or partner name, phone numbers, and email address. The locator information will be kept as a hard copy separately from other study materials in a secured location.

Baseline, Immediate Follow-up and Three Month Follow-up Data

The data elements collected in the baseline questionnaire (**Attachment 3d**) include the following:
Socio-demographics: age, income, sexual identity, education level, marital status, insurance status, employment status, number of children, housing status, incarceration history
Behavioral and other characteristics: integrated race and sexuality; sexual risk behaviors (condom use, number of partners, sex partner characteristics, exchange sex, sex while on drugs/alcohol); sexual abuse history; internalized homophobia; gender role conflict, social support for safer sex/risk reduction; experiences with homophobia and sexual identity/sexual relationships; knowledge of HIV risk for self and community; HIV knowledge and risk reduction; self-efficacy for condoms and partner communication; anal and penile health knowledge, pre-exposure prophylaxis use, alcohol/drug use; internet and cell phone use for meeting sexual partners; psychological distress; and participation in previous HIV interventions

Clinical variables: date of last HIV test, HIV status, STD history, HIV care and treatment history (for HIV-positive patients)

The data elements collected in the three- and six-month (**Attachment 3g**) follow-up questionnaires include the following:
Socio-demographics: income, sexual identity, insurance status, employment status, housing status, incarceration history
Behavioral and other characteristics: integrated race and sexuality; sexual risk behaviors (condom use, number of partners, sex partner characteristics, exchange sex, sex while on drugs/alcohol); gender role conflict, social support for safer sex/risk reduction; experiences with homophobia and sexual identity/sexual relationships; knowledge of HIV risk for self and community; HIV knowledge and risk reduction; self-efficacy for condoms and partner communication; anal and penile health knowledge, alcohol/drug use; internet and cell phone use; psychological distress; and participation in previous HIV interventions
Clinical variables: date of last HIV test, HIV status, STD history, HIV care and treatment history (for HIV-positive patients)

Client Satisfaction Survey

Participants will be asked to complete brief, pen-and-paper client satisfaction surveys immediately following each group session (**Attachment 3f**). These data will assess participant satisfaction with specific content areas within the 3 modules and other aspects of the groups. These surveys will be anonymous.

Success Case Study Interviews

Qualitative in-depth discussions with a subset of 36 randomly selected intervention group participants will be conducted to develop an understanding of successful and less successful participants' experiences with the intervention and to determine the exact nature and extent of their success. To identify potential participants for our success case study, we will analyze the baseline and six-month follow-up data on intervention participants and sort participants into one group who did and one group who did not reduce HIV risk behaviors during the short-term post-intervention period. Thus, "success" will be operationalized as the self-reported presence of UAS at baseline and subsequent report of no UAS behaviors with male partners at six months post-intervention. Conversely, "less success" will be defined as a) any UAS at six months post-intervention or b) attendance at only one of the three scheduled MLMS sessions. Men who qualify for the individual interviews will be contacted by the project's Evaluation Assistant by phone or another preferred method specified during the six-month follow-up data collection session.

Questions will be asked, using a qualitative interview guide (**Attachment 3h**), to help us understand: 1) what strategies were used to recruit the participant, how many sessions did the participant attend, what are his perceptions of the efficacy of the sessions, and what other elements (i.e., facilitator or module characteristics, attendance at other ITMT programs or events) may have contributed to his sexual risk at six months post-intervention. To address these questions, the project's Evaluation Assistant will conduct a 60- to 90-minute, semi-structured

interview with 16 successful program participants. Qualitative data to be collected from participants will cover: a) opinions/experiences regarding the MLMS intervention; b) impact of homophobia on sexual identity and sexual relationships c) beliefs about being black and gay/bisexual d) knowledge of HIV risk for AAMSM community; e) knowledge of sexual health risk. The Evaluation Assistant will conduct a similar set of interviews with 20 of the less successful program participants to develop an understanding of the less successful participants' experiences and impressions of the program. The same interview guide will be used for both successful and less successful participants.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

ITMT has established an Internet presence to appeal to its younger clientele (men aged 18-24) via Facebook and MySpace accounts (e.g., http://www.facebook.com/pages/In-The-Meantime-Mens-Group-Inc/57067853938, http://www.myspace.com/inthemeantimemen). ITMT generally uses a more passive recruitment approach to gain new participants with these social networking sites. For example, on a weekly or more frequent basis, ITMT staff post brief announcements to ITMT's Facebook homepage to alert Facebook "friends" about any number of upcoming social events or HIV prevention groups sponsored by ITMT. Men recruited using posting via Facebook or MySpace will be instructed to contact ITMT if interested in participating and will be screened over the phone. Children under the age of 13 are not eligible to participate and all content on these social networking websites are directed at persons 18 years or older. .

2. Purpose and Use of Information Collection

The data to be collected for this study will be used to establish the preliminary efficacy of a homegrown intervention for young African American MSM and will provide important information about sexual risk behaviors and the context in which they occur. The study will use a randomized controlled trial designed to determine if men who are assigned to the experimental condition report less frequent HIV risk behavior three-months and six-months following the intervention compared to men in the control condition. The intermediate outcomes to be measured are unprotected anal sex with all partners regardless of status; increase frequency of communication with partner(s) about safer sex, HIV status, STD status; decrease frequency of unprotected sex because condom was not available; decrease number of sexual partners, increase help-seeking behaviors for sexual health, e.g., STI testing, HIV testing, health screenings. The secondary objective of this study is to conduct a comprehensive program evaluation to identify intervention elements associated with program success, such as: a) intervention components, processes, and characteristics; b) recruitment and retention strategies; and c) requirements of the organization's infrastructure necessary to deliver the intervention.

While a number of individual- and group-level HIV interventions have been created by and for a variety of AAMSM organizations across the U.S., evaluation data to document the efficacy of these programs are practically non-existent. Without the proposed data collection, we will continue to lack effective and appropriate interventions for this at risk population and current HIV incidence trends will continue. Additionally, published findings from the study can be reviewed by the DHAP Prevention Research Synthesis Project as an intervention to be featured

in future Compendium of Evidence Based Prevention Interventions, which community-based HIV prevention programs can use to select appropriate evidence-based interventions to implement in the field. If effective, the intervention could also be replicated via a Replicating Effective Programs project or disseminated through a Diffusion of Effective Behavioral Interventions project (both DHAP activities that aim to translate scientific evidence into program practice). A secondary use of the information collected in this study will be to improve our current understanding of HIV risk behavior and its correlates among young African-American MSM. Understanding the correlates of sexual risk behavior is important as it informs the appropriate development of risk reduction interventions.

Privacy Impact Assessment Information

These data are being collected to establish the preliminary efficacy of the MLMS intervention, which has been developed specifically for young African-American MSM. Specifically, the screening instrument will allow the determination of eligibility to participate in the study. The participant limited locator form will be used for the recruitment and enrollment of young men and the more extensive participant contact information form will facilitate participant retention by allowing study staff to follow-up with participants on a regular basis and to remind them of upcoming sessions and assessments. **The baseline questionnaire will collect information on**:
Socio-demographics: age, income, sexual identity, education level, marital status, insurance status, employment status, number of children, housing status, incarceration history
Behavioral and other characteristics: integrated race and sexuality; sexual risk behaviors (condom use, number of partners, sex partner characteristics, exchange sex, sex while on drugs/alcohol); sexual abuse history; internalized homophobia; gender role conflict, social support for safer sex/risk reduction; experiences with homophobia and sexual identity/sexual relationships; knowledge of HIV risk for self and community; HIV knowledge and risk reduction; self-efficacy for condoms and partner communication; anal and penile health knowledge, pre-exposure prophylaxis use, alcohol/drug use; internet and cell phone use; psychological distress; and participation in previous HIV interventions
Clinical variables: date of last HIV test, HIV status, STD history, HIV care and treatment history (for HIV-positive patients)
Three-month and six-month follow-up questionnaires will gather similar variables to the baseline measurement with the exception of immutable demographic characteristics:
Socio-demographics: income, sexual identity, insurance status, employment status, housing status, incarceration history
Behavioral and other characteristics: integrated race and sexuality; sexual risk behaviors (condom use, number of partners, sex partner characteristics, exchange sex, sex while on drugs/alcohol); gender role conflict, social support for safer sex/risk reduction; experiences with homophobia and sexual identity/sexual relationships; knowledge of HIV risk for self and community; HIV knowledge and risk reduction; self-efficacy for condoms and partner communication; anal and penile health knowledge, alcohol/drug use; internet and cell phone use; psychological distress; and participation in previous HIV interventions
Clinical variables: date of last HIV test, HIV status, STD history, HIV care and treatment history (for HIV-positive patients)
As a whole, the questionnaire data will allow us to establish the efficacy of the intervention in reducing HIV risk behavior. The client satisfaction survey will capture participant satisfaction and comfort with the intervention. This information will allow intervention developers to refine

and enhance the curriculum. The success case study interviews will help determine how the intervention is working. From the individual success case study interviews, we are seeking to understand: 1) what strategies were used to recruit the participant, how many sessions did the participant attend, what are his perceptions of the effectiveness of the sessions, and what other elements (i.e., facilitator or module characteristics, attendance at other ITMT programs or events) may have contributed to his sexual risk at six months post-intervention.

All data will be collected by the Grantees and will be maintained at the local site. Following data processing and cleaning procedures, de-identified data (quantitative baseline, follow-up questionnaire, and success case study data) will be transmitted to CDC via a secure data network (SDN) for analyses. Study data files will never include any personally identifying data and data observations will be indexed using only the unique Study ID numbers. The project officers will establish a Memorandum of Understanding between CDC and the study site which prohibits them, under any circumstances, from providing the CDC team the linkage between study ID numbers and participants' names. Results from the study will be shared with the research community via peer-reviewed journals and presentations at national conferences. In order to reach the maximum benefit to existing HIV prevention, CDC will share the study results with the scientific community in the form of publications and presentations.

This study involves the collection of sensitive information. There would likely be an effect on the respondent's privacy if there were a breach of privacy. Therefore, stringent safeguards will be implemented to protect against a breach of security and illegal access to individually identifiable information. Project staff are trained and sensitized to never discuss an individual's behaviors in a public setting in a manner or volume that would compromise client privacy. Paper copies of consent forms or other forms will be stored in locked filing cabinets that are maintained in secure office environments with limited and controlled access. Equipment used to administer the ACASI data entry programs will be password protected. Computers, flash drives, and networks where data will be transferred and stored will also be password protected. Only authorized study staff will have access to completed interview data and study files. Study staff will be trained to conduct research activities in ways that adhere to the ethical principles and standards by respecting and protecting to the maximum extent possible the privacy of participants. In addition, CDC collaborators will not obtain individually identifiable private information. Study data files will never include any personally identifying data and data observations will be indexed using only the unique Study ID numbers.

3. Use of Improved Technology and Burden Reduction

The screening instrument will be conducted face-to-face or over the phone by a study recruiter and will be limited to items that directly assess study eligibility, plus two additional questions to prevent eligibility criteria from becoming known in the community. Three study questionnaires will be administered (baseline, 3-month follow-up, and 6-month follow-up) using ACASI. The use of ACASI has been found to reduce respondent burden and enhance respondent privacy during data collection. ACASI has also been found to reduce interviewer bias in the collection of sensitive sexual behavior data [5]. In addition to enhancing the validity of self-report data, computerized assessments can be programmed to customize question wording for individual

respondent and prevent respondents from having to answer questions that are not applicable to them. All data collection instruments were designed to be as brief as possible. We will only collect the information necessary to evaluate the effect of the intervention, assess potential interactions, and identify specific predictors of sexual risk and protective behavior.

4. Efforts to Identify Duplication and Use of Similar Information

CDC staff conducted several activities to identify duplication and use of similar information. We reviewed currently-funded programs and did not identify potential areas of duplication. No known department or agency develops and evaluates new behavioral HIV risk reduction interventions for young African American MSM that are developed and implemented by a local CBO. There are no known sources for data on the MLMS behavioral intervention for young African American MSM in Los Angeles (with adequate sample sizes to support analysis) available within the department or agency. Hence, this is a unique study.

One significant effort has been a review of the literature. In a 2002 review of 137 HIV-prevention interventions that included ethnic minorities in the United States in 1985-2000 [6], the authors found only one rigorous, randomized controlled trial (RCT) with the specific objective of reducing HIV infections in African American men who have sex with men (MSM) [7]. In a more recent review of HIV interventions published between 2000 and 2004, there were no interventions identified that showed efficacy in reducing HIV infection among African American MSM [4, 8]. Currently, CDC endorses "Many Men, Many Voices" as the only group-level intervention for MSM of color. A recent efficacy trial [3] showed that "Many Men, Many Voices" reduced HIV risk behaviors among its AAMSM intervention subjects—specifically, a 66% greater reduction in any unprotected anal intercourse (UAI) and a 51% greater reduction in UAI with casual male partners at 6 months post-intervention. Given significant and continuing disparities in HIV infection among African Americans in the United States, and specifically among AAMSM, more intervention programs must be planned, implemented, and tested in order to reduce the heavy toll of HIV/AIDS in this population. Components of these intervention programs must be culturally competent and should include promotion of HIV counseling and testing to reduce the high prevalence of unrecognized HIV infection in AAMSM. Interventions should also take into consideration the many co-factors that may hinder AAMSM from addressing their HIV risk such as racism, poverty, stigma, and homophobia.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The data collection activities will occur from May 2012 through January 2014. The study involves multiple, but discrete, data collection points, all of which are needed to conduct the study and evaluate the effect of the intervention. Participants are allowed to participate in the study only once.

If data were not collected, we would not be able to test preliminary efficacy of a homegrown intervention and provide important information about sexual risk behaviors and the context in which they occur. It would therefore be impossible to develop, test, and distribute a needed intervention for at-risk young African-American MSM, a population for whom there are currently few effective risk-reduction interventions.

There are no legal obstacles to reduce the burden for Respondents.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day notice to solicit public comments was published on 8/3/11, page numbers 46813-46814. A copy of this publication is attached (**Attachment 2**). One non-substantive comment was received.

Several consultations were conducted with various scientists and public health practitioners outside the agency.

In July 2010, CDC held a principal investigator meeting with external researchers, who were funded under the Cooperative Agreement and have experience conducting behavioral surveys among African-American and MSM populations. The purpose of this meeting was to discuss the study design, eligibility criteria, and behavioral outcomes.

From May 2010 through March 2011, the external Principal Investigator and Sub-Investigators and CDC Project Officers worked as a team to develop the data collection instruments. All team members are experienced in conducting behavioral surveys among AAMSM. During this time, the team met either weekly or bi-weekly to develop the IRB protocol which includes the procedures for sampling, recruitment and retention, screening and randomization, and data collection. External investigators developed the power calculations and analysis plan. The team finalized the IRB protocol and refined the domains to be included in the data collection in March 2011.

In addition to collaboration with external scientists, the study site collaborated with their local Community Advisory Board (CAB). These are composed of representatives from the target population, staff from partner agencies, and members of AIDS service organizations. The CAB was convened in November 2010 to assist with refining the intervention logic model's behavioral determinants, intervention activities, and behavioral outcomes by ensuring that intervention content is relevant and appropriate for the target population.

In accordance with congressional mandate Content of AIDS-Related Written Materials, Pictorial, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992), all

intervention materials and research instruments will be reviewed by a local program review panel to ensure that these materials are in accordance with community standards.

9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for participation are an important tool used in research and are particularly important for the population in this study. This study seeks to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV status, and substance use. To enhance our ability to recruit 528 young AAMSM and retain at least 75% of those randomized to each study arm, we will provide participants with tokens of appreciation for their time spent attending group sessions and for completing the three- and six-month follow-up interviews.

Previous research experience by members of the CDC study team indicates that tokens of appreciation, either in the form of money or other material goods (e.g., bus passes) encourage participation. Furthermore, ITMT's long history of providing HIV prevention programs to members of the target population indicate that modest tokens of appreciation for participation in group discussions are critical to involve a broad range of AAMSM ages 18 to 29 years. Likewise, local research projects (e.g., MAALES Project, Brothers Project, LA Men's Survey) involving AAMSM cite numerous examples of improved recruitment and retention of study participants with modest tokens of appreciation ranging from $20 to $50. Discussions regarding the appropriate amount and form of the tokens of appreciations took place during the development of this study.

Investigators at the site drew upon their experience working with this population and community norms to come up with the following participant token of appreciation plan:

Participants will be given a token of appreciation of $20 for completing the baseline ACASI questionnaire. Intervention participants will be given a token of appreciation of $25 for each of three MLMS sessions they complete over a three-week period. Wait-list control participants will also be given a token of appreciation of $25 for each of these same three sessions but the sessions will occur seven or more months later. All RCT participants will be given a token of appreciation of $30 for completing the three- month follow-up ACASI sessions and $30 for completing the six-month follow-up ACASI sessions. Finally, a subset of 36 intervention participants will be given a token of appreciation of $50 for the time and effort associated with completing a 90-minute qualitative Success Case Study interview.

The token of appreciation amounts proposed for the study are based on the Co-PIs experience engaging young MSM in similar research projects. The token of appreciation amounts proposed for the baseline, follow-up, and Success Case Study data collection sessions address the project team's concern about data quality and burden on the respondent for completion of lengthy computerized questionnaires and in-depth personal interviews. These amounts also address the project team's concerns about making participation equitable for AAMSM from a range of socio-economic backgrounds. For example, members of the target population reside throughout LA County, a metropolitan region covering more than 400 square miles. Depending on participants' economic and transportation resources, it is not unusual for round-trip travel to the

ITMT office to require multiple bus lines and up to two hours. Tokens of appreciation for participation in MLMS sessions is based on standards used in Los Angeles County for HIV programs that seek to engage members of hard-to-reach/vulnerable populations such as young AAMSM. In addition, all RCT participants will be offered referrals to and materials with appropriate prevention information, medical services, and other support services.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by ICRO, who determined that the Privacy Act does apply. The applicable System of Records Notice is "09-20-0160, Records of Subjects in Health Promotion and Education Studies."

The screening instrument will allow determination of eligibility to participate in the study. The participant limited locator form will be used for the recruitment and enrollment of young men and the participant contact information form will facilitate participant retention by allowing study staff to follow-up with participants on a regular basis and to remind them of upcoming sessions and assessments. The baseline and follow-up questionnaire data will allow us to establish the efficacy of the intervention in reducing HIV risk behavior. The client satisfaction survey will capture participant satisfaction and comfort with the intervention. The success case study interviews will help determine how well the intervention is working.

All data will be treated in a secure manner. Participant names or other personal identifiers will not be stored with any electronic questionnaire files (e.g., baseline, follow-up questionnaires) that are associated with the project. In order to prevent inadvertent linkage of research-related data with participant names, signed consent forms will be labeled with a Study ID number that will be the only hard-copy connection between study-related process or outcome data and a participant's identity. Study staff will assign Study ID numbers as participants are enrolled. Signed consent forms affixed with the Study ID will be stored in locked filing cabinets initially at ITMT and ultimately at HEP. An additional password-protected Excel spreadsheet located on a double password-protected data network will be maintained by HEP's Project Epidemiologist to provide an electronic linkage between participants' identities and their unique Study ID.

ITMT study staff will use participant names or nicknames to contact and communicate with research participants over the 8-month follow-up period. Use of participant names and contact information by ITMT staff is standard practice and enables appropriate follow-up and communication with program participants. ITMT study staff will protect participants' privacy on contact logs by limiting personal identifiers to a first name and initial of the last name. All contact logs containing contact information will be kept in locked files in the ITMT project offices when not in use. Once the contact logs have been completed and the relevant data on attendance and follow-up have been entered into a database, the hard copy of the form will be shredded by the Project Assistant. No personal identifiers will be transmitted to CDC. Exceptions to the participants' privacy will be made in the event that a participant discloses information to study staff that indicates he poses a risk of harm to himself or others. Participants will be informed of this exception to privacy in the written informed consent document and the informed consent process (see **Attachments 4a and 4b**).

Local IRB approval granted for this study.

Privacy Impact Assessment Information

A.
This request is in compliance with the Privacy Act.

B.
All potential participants will be asked to provide Limited Locator information. Only first names and the initial of the last name will be recorded on these forms of potential participants to provide increased privacy. Limited locator information will be kept in a secure location (locked in filing cabinet in locked office when not in use) at ITMT. Once potential participants have enrolled in the project, their limited locator information will be destroyed by project staff and the participant will be asked to provide follow-up locator information. Participant contact information will be kept separately from other study materials in a secured location (locked in filing cabinet in locked office when not in use) at ITMT offices and will be destroyed once participants have completed their six-month follow-up questionnaires. All participant contact information, such as name, phone number, email addresses, will be kept in locked files in the project offices when not in use.

A password-protected Excel spreadsheet located on a double password-protected data network will be maintained by HEP's Project Epidemiologist and will provide the only electronic linkage between participants' identities and their unique Study ID until the completion of all follow-up data collection. In order to prevent inadvertent linkage of research-related data with participant names, two additional hard copies (non-electronic files) will provide only temporary linkage between participant names and Study IDs (e.g., the Follow-up Interview Log--**Attachment 3j** and completed signed consent forms labeled with the unique Study ID--**Attachment 4a and 4b**). The Follow-up Interview Logs will be shredded as soon as follow-up assessments are completed for each Intervention group. This action will occur approximately 8 months following the initiation of the MyLife sessions for each Intervention group. The originals of the signed consent forms (**Attachment 4a and 4b**) will be initially stored in locked filing cabinets at ITMT and ultimately transferred to HEP for secure storage in locked file cabinets within a locked private office. The Study ID numbers that label the informed consent forms will be marked out or removed by the HEP Project Epidemiologist so that there is no detectable linkage between a participant's consent form signature and his unique Study ID. The HEP Project Epidemiologist will eliminate the linkage between the consent form and the Study ID at the same time the Follow-up Interview Logs are shredded. Thus, data collected via baseline and follow-up assessments as well as the Success Case Study interviews will not include identifiable information. Only Study ID numbers will be recorded as part of these data collection items.

The Project Assistant will telephone, email, or text each participant on a monthly basis to check in with the men and to confirm that their contact information is current. ITMT study staff will use participant names or nicknames to contact and communicate with research participants over the 8-month follow-up period. Use of participant names and contact information by ITMT staff is standard practice and enables appropriate follow-up and communication with program

participants. Logs of these contacts will provide details of the interaction (e.g., participant responded to phone call/email/text message, provided new contact information, etc.). To protect participants' privacy, all contact logs containing participant information will be limited to a first name and initial of the last name. All contact logs will be kept in locked files in the project offices when not in use. Contact logs will be entered into an Excel spreadsheet. Once the contact logs have been completed and entered into a database, the hard copy of the form will be shredded by the Project Assistant.

Hard copies of enrollment logs and other process data instruments (i.e., Recruitment logs, enrollment logs, attendance logs, satisfaction surveys) will be entered by ITMT project staff into Excel files and other computerized data entry systems. Hard copies of process data will be stored at ITMT's offices in locked cabinets in locked offices when not in use. Once all data contained in hard copy files are successfully entered electronically, they will be transferred to HEP. Computers, flash drives, and networks where process data will be transferred and stored will be password protected.

HEP will develop data entry screens for the baseline and follow-up ACASI instruments using Questionnaire Development System (QDS) software. These QDS data entry systems will be loaded on laptop computers for the baseline and follow-up data collection sessions. Equipment used to administer the ACASI data entry programs will be password protected. The Project Assistant will be responsible for moving password-protected and encrypted QDS interview files to a flash drive in preparation for transfer to HEP's main data warehouse. ITMT's Project Coordinator will work with HEP's Project Epidemiologist to establish a regular schedule for transferring the encrypted electronic files of the completed QDS interview data.

Once the baseline and follow-up questionnaires are complete on all enrolled RCT participants, the password-protected Excel spreadsheet that provides the link between the participant names and Study ID numbers will be destroyed by the HEP Project Epidemiologist. The destruction of this electronic file will eliminate any linkage between participant identifiers and questionnaire data that may contain information on illegal drug use or other illegal activities. Thus, the quantitative assessment files used for analysis will be anonymized files that do not include any direct or indirect subject identifiers.

All case study interviews will be digitally recorded with the consent of the participants and we will produce transcripts of each 90-minute session. Digital interview files and transcripts will be stored on password-protected computers within a password-protected project network file at the HEP project office. The digital recording will be deleted once the transcript is accurate and complete.

All electronic and hardcopy data will be destroyed once data analysis is complete.

Only authorized ITMT and HEP study staff will have access to completed interview data and study files. Following data processing and cleaning procedures, client satisfaction surveys, quantitative baseline and follow-up data and success case study transcripts will be encrypted and transferred to CDC Project Officers using CDC's secure data network (SDN). CDC collaborators will not obtain individually identifiable private information. Study data files will never include

any personally identifying data and data observations will be indexed using only the unique Study ID numbers. Contact log data will not be sent to the CDC. The project officers will establish a Memorandum of Understanding between CDC and the study site which prohibits them, under any circumstances, from providing the CDC team with the linkage between study ID numbers and participants' names.

CDC staff will not have access to any identifying information. De-identified data (including the baseline, follow-up questionnaires, arm assignment (i.e., assignment to the experimental or control arm), client satisfaction surveys, success case study transcripts, and session attendance (i.e., number of intervention sessions attended) will be transmitted to CDC via a secure data network. De-identified study data will be maintained at the site and CDC indefinitely.

C.

All eligible participants interested in participating in the study will be asked to provide written consent before enrolling in the study. Participants will take part in an informed consent process either with ITMT's Project Coordinator or the Data Collection Assistant in a private location. These study staff will be trained to introduce the RCT and to discuss informed consent with the young AAMSM. Study staff will read the consent information to potential participants prior to beginning the baseline ACASI session and thus prior to randomizing participants into the intervention or wait-list control condition. Participants will be offered a copy of the consent form to read along with the study staff member; they may have a copy of the consent form to keep if they wish. A separate informed consent procedure will be conducted for the Success Case Study. Consenting participants will be asked to sign the informed consent document. The originals of the signed consent forms will be transferred to the HEP for secure storage in locked file cabinets within a locked private office.

The informed consent document is provided in **Attachment 4b** for the Success Case Study Interviews. Consent forms provide details of the study procedures, risks, benefits, site contact information, and the nature of privacy and voluntary participation. The consent process also provides information about the trial and that the participant will receive a token of appreciation. Participants will be informed that their data will be kept in a secure manner, the data will be reported in aggregate format, and names will not be in any report about this study. Participants will also be informed that no identifying information will be attached to the assessments, just an ID number. Participants will be told that personal information will not be disclosed, unless otherwise compelled by law. This project was approved by the local IRB on March 25, 2011 (**Attachment 5a**) and NCHHSTP project determination (**Attachment 5b**).

D.

All participants will be informed that participation in this RCT is completely voluntary. Potentially eligible young men may refuse to participate in the project without penalty. Once consenting participants have begun the baseline questionnaire or even if they have completed the baseline questionnaire, they can refuse to answer any question or end their participation without any penalty. Men who consent to the research study and who are randomly assigned to the intervention arm will be informed of the start date of the MLMS sessions. All subjects may

decline to be contacted by study staff for MLMS sessions and/or for the three- and six-month follow-up interviews at anytime. ITMT study staff will have available alternative resource-referral information for participants who decide to withdraw from the study. Participants whom ITMT study staff deem mentally unable to give informed consent will not be consented for the research but will be eligible for other locally available resources.

11. Justification for Sensitive Questions

Baseline and follow-up assessments used to evaluate the MLMS group-level HIV prevention intervention will include questionnaire items commonly considered of a sensitive nature. These questionnaire items will assess RCT participants' oral and anal sexual behaviors with partners who are male, female and transgender. Although these questions are considered private, and while some participants may feel uncomfortable answering such questions, the goal of most HIV prevention research is to evaluate hypothesized reductions in potentially "risky" sexual behaviors, including specific sexual practices where condoms are not used. The only currently available method for assessing the efficacy of HIV prevention interventions among study participants is to pose such questions in a private data collection session. To increase our participants' comfort and honesty in answering potentially sensitive questions, we are implementing two specific procedures: 1) we will conduct an informed consent process that indicates the nature of questions to be assessed during the data collection session and the option to refuse to answer any question at any time for any reason; and 2) we are using ACASI data collection methods for sensitive questions to reduce the embarrassment of participants in answering these types of questions. Additional questions that may be considered sensitive by our study population are related to attitudes and beliefs about homosexuality, substance use, incarceration, sexual abuse, experiences with racism, and sexually transmitted infections. To reduce any anxiety about participants' responses to these potentially sensitive items, the informed consent process will assure participants that their responses will not be linked to their names and that their responses are grouped with the responses of other study participants so that there is no possible way to identify a person with their answers.

This study includes the following sensitive questions in the baseline and follow-up assessments:

Section Name	**Questionnaire**	
	Baseline	**Follow-up**
Demographics	X	X
Integrated Race and Sexuality	X	X
Sexual Behaviors	X	X
Sexual Abuse History	X	
Internalized Homophobia	X	X
Gender Role Conflict	X	X
Social Support for Safer Sex/Risk Reduction	X	
Homophobia and Sexual Identity/Sexual Relationships	X	X
HIV and STD Testing	X	X

Self-efficacy for Condoms and Partner Communication	X	X
HIV Care and Treatment	X	X
Alcohol and Drug Use	X	X
Internet and Cell Phone Use	X	X
Psychological Distress	X	X

Without this information the study would not be able to answer the primary research question of whether the proposed risk reduction intervention is effective. These data will increase our understanding of the HIV prevention needs among AAMSM. During the consent process, participants will be informed that this study involves collecting sensitive information. Participants will also be informed at the beginning of each assessment of their right to skip questions that they do not wish to answer. The screening instrument involves several sensitive questions; however, this information is critical to determine eligibility for the study. Participants will be consented before answering the screening questions.

12. Estimates of Annualized Burden Hours and Costs

12A.
Based on our time tests of the study instruments, the estimated time needed to complete Outreach Recruitment Assessment on 700 potential participants for eligibility is 5 minutes per participant. It is expected that we will enroll 75% (n=528) of all men screened for eligibility. The limited locator form will take 5 minutes, the contact information form 10 minutes, the baseline assessment 60 minutes, the 3 client satisfaction surveys that will be completed at the end of each session will take 10 minutes each, the 3-month follow-up assessment 60 minutes, the 6-month follow-up assessment 60 minutes and the Success Case Study interview 90 minutes.

Table 12.A presents participant burden hours for completion of the study. The total participant burden for this data collection is estimated at 1662 hours.

Exhibit A12.A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses Per Respondent	Average Burden Per Respondent (in hours)	Total Annual Burden in Hours
Prospective Participant	Outreach Recruitment Assessment (screener)	700	1	5/60	58
Prospective Participant	Limited Locator Information	700	1	5/60	58
Enrolled Participant	Participant Contact Information Form	528	1	10/60	88
Enrolled Participant	Baseline Questionnaire	528	1	1	528
Enrolled Participant	Client Satisfaction Survey	224	3	5/60	56
Enrolled Participant	3 month follow up Questionnaire	420	1	1	420
Enrolled Participant	6 month follow up Questionnaire	400	1	1	400
Enrolled Participant	Success Case Study Interview	36	1	1.5	54
Total					1662

Table A12.B displays the annualized cost to Respondents for burden hours shown in Table 12.A. In order to estimate the cost to the Respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private nonfarm payrolls proposed for January 2010 by the US Department of Labor.

Exhibit A12.B. Estimated Annualized Burden Costs

Type of Respondent	Total Annual Burden in Hours	Average Hourly Wage Rate	Total Annual Respondent Cost
Prospective Participant- Outreach Recruitment Assessment	58	$19.30	$1,119.40
Prospective Participant-Limited Locator Form	58	$19.30	$1,119.40
Enrolled Participant-Participant Contact Information Form	88	$19.30	$1,698.40
Enrolled Participant - Baseline Questionnaire	528	$19.30	$10,190.40
Enrolled Participant - Client Satisfaction Survey	56	$19.30	$1,080.80
Enrolled Participant - 3 month Follow up Questionnaire	420	$19.30	$8,106.00
Enrolled Participant - 6 month Follow up Questionnaire	400	$19.30	$7,720.00
Enrolled Participant - Success Case Study Interview	54	$19.30	$1,042.20
Total			$32,076.60

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to Respondents or record keepers associated with this study.

14. Annualized Cost to the Government

The cost of the study for the five years is estimated to be $2,000,000. The annual cost to the government for the data collection is $663,908 (Exhibit A.14).

Exhibit A14. Annualized Cost to Government

Expense Type	Government Related Expenses	Annual Costs (dollars)
Direct cost to the Federal Government		
	CDC Project Officer (GS-13, .35 FTE)	$29,925
	CDC Co-Project Officer (USPHS O-3, .35 FTE)	$18,940
	CDC Project Coordinator (GS-11, .12)	$7,198
	CDC Statistician (GS-13 .05 FTE)	$4,845
	Travel	$3000
	Subtotal, direct costs to the government	$63,908
Contractor and other expenses		
	Cooperative Agreement: Los Angeles Department of Public Health, HIV Epidemiology Program	$600,000*
	TOTAL COST TO THE GOVERNMENT	**$ 663,908**

*Average cost for data collection period (years 3 and 4of Cooperative Agreement)

Salary estimates were obtained from OPM salary scale at the following web address: http://www.opm.gov/oca/10tables/html/atl.asp

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Analysis Plan

Our analyses will focus on questions related to the study objectives. Our analysis plans for assessing the efficacy of the intervention include a tabular analysis to examine baseline variables across the RCT arms to assess characteristics that were not evenly distributed via random assignment. Specifically, we will examine differences in various demographic and behavioral variables (e.g., age, income, education level, drug use) across the intervention and control groups with logistic regression. Distribution of continuous variables will be analyzed by t-tests. Observed differences across experimental groups will be statistically controlled in the final outcome analysis.

Logistic regression analysis will be used to examine the effect of the MLMS to reduce UAS with male partners among intervention participants compared with the wait-listed controls at three and six months post-intervention. We will use an intent-to-treat approach to examine the hypothesized reductions. We will also examine the hypothesized effect of the intervention on

additional intermediate outcomes such as increased communication with partners, reduced number of sex partners, and decreased UAS because of unavailability of a condom.

Our analysis plans for Success Case Study involve a qualitative comparison of case study data collected on successful and less successful participants of the MLMS intervention. The Evaluation Assistant will be responsible for conducting a qualitative analysis of the 36 interviews with the assistance of the Evaluation Consultants. Results of the success case study will be communicated in a narrative form that differs from more typical quantitative methods. Our "success stories" will not be a testimonial or a critical review; they will be a factual and verifiable account citing evidence that demonstrates how a person achieved success as a result of participation in MLMS. The contrasting "less successful" participants' stories will offer us information about what program components and strategies are not effective and what may detract from program success.

Timeline

Exhibit A16. Project Time Schedule

Activities	**Time Schedule**
Begin recruitment	1 month post OMB approval
Complete recruitment, intervention implementation, and data collection	33 months post OMB approval
Data management and validation	34 months post OMB approval
Analysis of key outcomes	35 months post OMB approval
Dissemination of results	36 months post OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

CDC is not seeking approval to not display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.

References

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3. Wilton, L., 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.* AIDS Behav, 2009. 13(3): p. 532-44.
4. Bing, E.G., T. Bingham, and G.A. Millett, *Research needed to more effectively combat HIV among African-American men who have sex with men.* J Natl Med Assoc, 2008. 100(1): p. 52-6.
5. Ghanem, K.G., et al., *Audio computer assisted self interview and face to face interview modes in assessing response bias among STD clinic patients.* Sex Transm Infect, 2005. 81(5): p. 421-5.
6. Darbes, L., et al. *Systematic review of HIV behavioral prevention research in African Americans*. 2002; Available from: http://hivinsite.ucsf.edu/InSite?page=kb-07-04-09.
7. Peterson, J.L., et al., *Evaluation of an HIV risk reduction intervention among African-American homosexual and bisexual men.* AIDS, 1996. 10(3): p. 319-25.
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