

Project Engage 2.0: Engaging Gay “Community” Activism for Syphilis Prevention

Generic Information Collection Request under OMB #0920-0840

Section A: Supporting Statement

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CONTACT

Monique Carry, PhD, MA
Behavioral Scientist
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop E-44
Atlanta, GA 30329
Phone: 404-639-2275
Fax: 404-639-8622
E-mail: mcarry@cdc.gov

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- **Goals of the study:** In this study, we intend to explore findings from the **first iteration** of Project Engage (which took place from September 2016 to December 2017) and their implications for sexual health community engagement and mobilization efforts. Specifically, we will explore the concept of community belongingness, syphilis and PrEP knowledge, awareness, and opportunities, and differences between the black/African gay community and the larger gay community.
- **Intended use:** Findings from this qualitative assessment will be used to inform the development of strategies to prevent and reduce syphilis transmission and promote sexual health among Black/African-American men who have sex with men (BMSM).
- **Methods to be used to collect data:** We plan to conduct eight (n=8), 90-minute in-person qualitative focus groups with BMSM age 18+ in New Orleans, LA and Washington, DC (four focus groups per city). The participant pool will be stratified by age, falling into one of two groups: 18-34 (n=2 per city), and 35 and older (n=2 per city). Each focus group will have a max of eight (n=8) participants, for a maximum total of n=64 participants across both cities.
- **The subpopulation to be studied:** BMSM, 18+, recruited from New Orleans, LA and Washington, DC.
- **How data will be analyzed:** Qualitative coding and thematic analysis of eight focus group transcripts using computer-assisted qualitative data analysis software.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of STD Prevention, (DSTDP) requests OMB approval for a qualitative extramural research study entitled, "Project Engage 2.0: Engaging Gay "Community" Activism for Syphilis Prevention" in New Orleans, LA and Washington, DC under "Formative Research and Tool Development" Generic Clearance OMB #0920-0840 (expires 1/31/2019). CDC will sponsor this data collection activity. Data collection will be carried out by CDC's cooperative agreement partner, National Network of Public Health Institutes (NNPHI), in conjunction with its subcontracting local partners, the Louisiana Public Health Institute (LPHI), in New Orleans and the Institute for Public Health Innovation (IPHI), in Washington, DC.

The notion of "community," whether conceived of as "place" or "network," is important to understand because it relates to constructs such as social identity and social cohesion that have implications for social norm diffusion and change. Understanding individuals' perceptions of community can inform STD prevention efforts and intervention development. Findings from interviews with MSM in Australia (Holt 2011), Europe (Ross 2013), and the US (Goltz 2014; Rowe 2008) suggest that although the term "community" has always evoked ambivalence among MSM, in the pre-antiretroviral (ART) era, AIDS activism was viewed to a large degree as a unifying aspect and collective purpose, and that developments such as widespread availability of ART, the decline of funding for AIDS service organizations, and other recent social changes have eroded this value. In more recent years, generational shifts and changes in the way MSM meet and socialize, due to the proliferation of social media sites and mobile apps, and broader sociocultural changes, including social assimilation and "mainstreaming" of gay culture, make it necessary for STD programs to re-evaluate the salience of this concept for current STD prevention efforts.

Syphilis rates have increased dramatically in the United States since 2000, with most of the increases among MSM. In 2015, over 90% of primary and secondary syphilis cases occurred among men, with 81.7% of cases among males reporting a male sex partner (CDC 2015). Syphilis increases the risk of HIV transmission and acquisition; in 2015, nearly half of MSM with syphilis were HIV-positive. According to sentinel surveillance data, 33% of MSM syphilis cases were among Black/African-American men who have sex with men (BMSM), a disproportionate burden of disease (CDC 2015). Untreated syphilis can lead to serious sequelae, including neurosyphilis, which has increased in recent years. Cases of ocular syphilis, which can lead to permanent blindness, have been reported among MSM

in recent months (CDC 2016). The reasons for syphilis increases among MSM are not entirely clear; however, sex without condoms, sero-sorting among HIV positive men, and the perception among some men that syphilis is relatively benign and easily cured, are factors. The increased availability and use of PrEP (pre-exposure prophylaxis), which protects against HIV transmission but not STDs, further increases the need for STD programs to devise new and effective strategies for engaging MSM in STD prevention efforts.

Among BMSM, social isolation compounded by racism, homophobia, high prevalence of HIV and STD in sexual networks, and lack of access to health care also increases vulnerability to syphilis and other STDs (Maulsby 2014). The findings from this project will help ensure the relevance of prevention efforts, including but not limited to influencing dissemination strategies and identifying appropriate content.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to conduct a series of focus groups among BMSM. This collection will provide the primary qualitative data needed to understand barriers and facilitators to HIV/STI prevention, care and treatment among BMSM at the greatest risk for HIV/STI infection and transmission in the U.S. This work is a follow-up to the **first iteration** of Project Engage which took place from September 2016 to December 2017 under the CDC Generic Formative Research and Tool Development (0920-0840(17YJ) . Project Engage explored the meaning of and relevance of “community” through qualitative interviews among Black/African-American MSM in two cities with high rates of HIV and syphilis, New Orleans, Louisiana and Washington D.C. Major themes from the first iteration of Project Engage were:

1. Similar ideologies, overcoming adversity, creating “safe spaces” and emotional support are key factors in forming a community/developing a sense of belongingness in a community.
2. The gay community is not talking about syphilis.
3. The larger gay community has more representation and access to resources than the black gay community.
4. There are still knowledge gaps among the gay community when it comes to sexual health, especially as it relates to Pre-exposure prophylaxis (PrEP).

The second iteration of Project Engage intends to explore these findings and their implications for sexual health community engagement and mobilization efforts, and will be used to refine and tailor current outreach and communication strategies for reaching Black/African-American MSM.

The planned study design includes eight (8), ninety (90)-minute focus groups conducted among BMSM to discuss the notion of community and its relevance to sexual health activism. Focus group participants will be selected from two Metropolitan Statistical Areas (MSAs) with high HIV and syphilis prevalence: New Orleans, LA and Washington, DC.

The sample will be stratified by city (New Orleans and Washington, DC) and age (18-34, 35+). In each city, we will target recruiting approximately sixteen black/African American MSM age 18-34 and sixteen age 35+. The following table shows the participant pool (N=64) stratification:

Age	New Orleans	Washington DC
18-34	16	16
35+	16	16
Total Desired Number of Participants		64

We will use qualitative, focus groups to collect data for this study (**Attachment 5b**). The focus group guide will primarily include open-ended questions designed to elicit information on importance of community belonging, importance of topics like syphilis and PREP, and STD relevant care among BMSM (**Attachment 5b**). Key variables to be explored through the focus groups are described in Exhibit 2.1 below. All data collection instruments have been approved by the MPHI Institutional Review Board (**Attachment 6**).

CDC, in partnership with partner staff, will identify and develop appropriate dissemination opportunities for these findings. The results of this study are not to produce statistical results that may be generalizable to the larger population, but the lessons and findings may indeed be generalizable. Information collected will be used to revise, augment or finalize communication campaign platforms and systems.

Exhibit 2.1: Overview of Key Variables

BMSM and Key Informants (Attachment 5b)
<ul style="list-style-type: none"> • Community • Access to Sexual Health /STD Prevention Resources • PrEP • Syphilis • Health Activism /Engagement

3. Use of Improved Information Technology and Burden Reduction

National Network of Public Health Institutes (NNPHI) will conduct focus groups at a time and location that is convenient, accessible, and centrally located to the selected respondents to reduce burden on respondents' time and resources. After asking for and receiving permission from the respondent, NNPHI will audio-record the interviews and transcribe recordings after the completion of focus groups. This also limits the burden on the respondent (no additional burden after completing the focus groups) and allows the interviewer to focus on building and maintaining rapport with focus group participants.

4. Efforts to Identify Duplication and Use of Similar Information

The focus groups will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the cooperative agreement, and determined that this study is collecting unique information from the populations. Therefore, our study requires the collection of this new primary data. There would be no reason for another Federal Agency to conduct a similar study this.

5. Impact on Small Businesses or Other Small Entities

This study will partner with local partners (the Louisiana Public Health Institute, LPHI, in New Orleans and the Institute for Public Health Innovation, IPHI, in Washington, DC) to facilitate recruitment to aid in recruiting potential respondents by identifying eligible potential respondents through their routine and regularly occurring activities and referring them to the study. We do not anticipate substantial burden.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative data needed to understand barriers and facilitators to HIV/STI prevention, care and treatment among BMSM at the greatest risk for HIV/STI infection and transmission in the U.S. If this evaluation were not conducted, it would not be possible to identify barriers and facilitators and to use this information to strengthen HIV/STI prevention, care, and treatment with these vulnerable populations. The length of data collection is 2-4 months and data will only be collected once.

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

This data collection effort does not involve any special circumstances.

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

8a. For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. A 60-Day Federal Register Notice for the generic clearance 0920-0840 was published on 06/25/2015, Vol. 80 No. 122, pages 36540-36542, exp. 01/31/2019.

In addition, the following partnering staffs at NNPHI were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60-day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

8b. NNPHI consultants on this project include:

<p>Brittany Bickford, MPH Project Manager National Network of Public Health Institutes 1100 Poydras St., Suite 950 New Orleans, LA 70163 504.872.0755 bbickford@nnphi.org</p>	<p>Aaron Alford, Ph.D., MPH Principal Investigator National Network of Public Health Institute 1300 Connecticut Ave., NW, Suite 510 Washington, DC 20036 202.830.0771 aalford@nnphi.org</p>
<p>Jennifer Edwards, PhD Project Assistant National Network of Public Health Institutes 1100 Poydras St., Suite 950 New Orleans, LA 70163 703.776.9022 jedwards@nnphi.org</p>	

9. Explanation of Any Payment or Gift to Respondents

Interview respondents will each receive a \$50 token of appreciation in the form of a Visa gift card. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses (Abreu & Winters 1999; Shettle 1999). Additionally, offering tokens of appreciation is cost-efficient, decreasing cost to government by reducing the number of contact attempts necessary to gain participation when no token of appreciation is offered (Bricker 2014).

Participating in a 90-minute focus group requires a considerable investment of personal time on the part of the respondent, with the potential for inconvenience to the respondent. Data quality depends on being

able to recruit engaged respondents who are willing to spend time and share their perspectives with the interviewer. The study team feels that anything less than \$50 is likely to hamper recruitment and would not be reflective of the level of appreciation warranted by the respondent's contribution to the study aims.

Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups into research. In a recent study of recruitment and retention of BMSM by a Community Based Organization (CBO), recruiters found it difficult to obtain information from the BMSM because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program (Painter et al 2010). Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later. In this study, offering a token of appreciation improved participation among BMSM (Painter et al 2010). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among this group (Yancey, Ortega, & Kumoniyka 2006).

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), which included similar populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection activity. Personally identifiable information (PII) will not be transmitted to the CDC and records are not retrievable by any PII.

We will inform respondents that their responses will be kept private to the extent permitted by the law. All focus group participants will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the research team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval:

This study has been reviewed and approved by the MPHI Institutional Review Board IRB (**Attachment 6**).

Sensitive Questions:

This study is an initiative aimed to inform the development of strategies to prevent and reduce syphilis transmission and promote sexual health among BSM. We do not plan to collect any sensitive information from respondents. However, all cooperative agreement partner staff will be trained to provide respondents with city-specific hotlines for HIV/STI and mental health care organizations as needed. We will inform all focus group participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

Exhibits 12.1 and **12.2** provide details about how the estimates of burden hours and costs were calculated. We calculated the overall burden per respondent by multiplying the frequency of response by the time to complete each data collection item. We anticipate that screener forms will take 5 minutes to complete. We anticipate 50 percent of BSM screened will be eligible for the study. Focus groups are not expected to exceed 90 minutes. We will complete eight (8) focus groups for a maximum total of 64 BSM in New Orleans, LA, and Washington, DC. We anticipate screening 128 potential respondents. The total number of burden hours is 107.

12A. Estimated Annualized Burden Hours

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Eligibility Screener (Att. 5a)	128	1	5/60	11
General Public-Adults	Focus Group Guide (Att. 5b)	64	1	1.5	96
Total					107

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in **Exhibit 12.3**. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2016

(http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to respondents is approximately \$2,553.02. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate (\$23.86).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Eligibility Screener (Att. 5a)	11	\$23.86	\$262.46
General Public-Adults	Focus Group Guide (Att. 5b)	96	\$23.86	\$2,290.56
Total				\$2,553.02

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

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The estimated annualized cost to carry out the data collection activities is \$203,017. This estimate includes the cost of recruitment, screening, conducting the interviews, analysis and reporting, as well as the total cost of the tokens of appreciation (\$50 per completed interview, for a total of \$3,200).

Exhibit 14.4: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Project Lead (GS-13, 0.20 FTE)	\$20,158.80
	Subtotal, Direct Costs	\$20,158.80
CoAg Costs	Annual Cooperative Agreement (NNPHI # CDC-RFA-OT13-1302)	\$150,000
	TOTAL COST TO THE GOVERNMENT	\$170,158.80

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of respondents collected during screening (e.g., city, and age). Data collection will occur between June to July 2018, analyses will be carried out in September – November 2018, and the final data set and report will be submitted in September 2018. The project timeline is detailed in **Exhibit 16.1**.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol, IRB and PD approvals	Oct 2017- Apr 2018
OMB Submission	May 2018
Recruitment	After OMB Approval
Data Collection	1-3 months after OMB Approval
Data analysis finalized and report drafted	4-6 months after OMB Approval
Final data set and final report submitted to CDC	7 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation. This database will be made publicly available within 30 months of the end of data collection, if the final de-identified data are of sufficient quality and usefulness, and can be shown to result in generalizable value to science.

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

References:

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