Local Effectiveness Assessment Project (LEAP): A Case Study of a Local Jurisdiction Providing HIV Services to MSM

Sub-Collection request under Generic 0920-0840

Section A: Supporting Statement

January 30, 2021

CONTACT
James Carey, PhD, MPH
Contracting Officer's Representative
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention, PRB
1600 Clifton Road, NE, Mailstop E-37
Atlanta, GA 30329-4027
Phone: 404-639-1903
Fax: 404-639-1950
E-mail: jcarey@cdc.gov

TABLE OF CONTENTS

EXHIBITS

LIST OF ATTACHMENTS

- **Goal of the study:** The goal of the Local Effectiveness Assessment Project (LEAP) data collection is to increase understanding of a local jurisdictional (Philadelphia, PA) trends and needs for HIV prevention among men who have sex with men (MSM).
- **Intended use of the resulting data**: Inform ongoing DHAP and Philadelphia Health Department recommendations, and approaches to more effectively address HIV prevention activities among men who have sex with men (MSM).
- **Methods to be used to collect**: Qualitative case study method, utilizing thirty (30) in depth interviews with key participants.
- **The subpopulation to be studied:** Thirty (30) key participants at the public policy (n=9), community (n=15), and individual/network (n=6) level.
- **How data will be analyzed:** Conduct qualitative coding of 30 interview transcripts using NVivo 10.0

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)/Division of HIV/AIDS Prevention (DHAP) is requesting approval of a sub-collection under a generic approval (Formative Research and Tool Development, OMB #0920-0840, expiration 2/29/2016), for a data collection entitled, "Local Effectiveness Assessment Project (LEAP): A Case Study of a Local Jurisdiction Providing HIV Services to MSM". The purpose of the Local Effectiveness Assessment Project (LEAP) project is to increase understanding of local jurisdictional trends and needs for HIV prevention among men who have sex with men (MSM). To understand strategies and improve the burden of the HIV epidemic among MSM, CDC will conduct a case study in Philadelphia, PA. The LEAP case study will ultimately inform ongoing recommendations and approaches to more effectively address the HIV epidemic.

The burden of HIV among MSM is both alarming and undeniable. In 2011, MSM accounted for nearly two-thirds of new HIV infections, while only comprising 2% of the United States population.[1] This disproportionate burden is experienced across age and racial categories.
To address the burden of HIV among MSM, CDC recognizes that as the HIV epidemic changes and new strategies and approaches are implemented, it is essential to provide context to the behaviors, barriers, and facilitators experienced by those at increased risk of infection. To understand strategies and improve the burden of the HIV epidemic among MSM, CDC will conduct a case study in Philadelphia, PA.

Philadelphia's HIV incidence rate is approximately five times the national average and the sixth highest of any metropolitan region nationwide.[3] Of these newly-diagnosed HIV cases, 42% are MSM.[4] Factors such as jurisdictional HIV testing; provision of healthcare; and fiscal, social, and environmental climate are critical to understanding the context within Philadelphia and across

other local jurisdictions. This project allows an opportunity to conduct a detailed, specific, and real-time assessment to understand these factors.

Data collection instruments have been approved by the contracting team's (Atlas and Abt Associates) IRB (**Attachment 4**) and are included with this submission as attachments. Thirty (30) key participants from three different categories a) public policy stakeholders, b) community leaders, and 3) individual community members will be purposively sampled and selected from a pre-determined list. Recruiters will schedule in-depth interviews at time and place convenient to the key participants. Interviewers will review study information and consent form (**Attachment 3**), and administer in-depth interviews (**Attachments 2a-2c**). The contracting team (Atlas and Abt Associates) will recruit key participants using a recruitment flyer script (**Attachment 5a)** and study overview **(Attachment 5b**). Key variables to be explored are described in Exhibit A1.1.

Exhibit A1.1 Items of Information to be Ccollected

Variables to be explored	Data collection tool and citation	Study Related Procedures	Target Population
• Benefits/Services offered by government agencies (eligibility and process) • Barriers to and facilitators of: (1) HIV prevention services and activities, and (2) HIV care and treatment • Collaborations across local government agencies • Innovative aspects of service model	2a. Interview guide Public Policy Stakeholders	In-Depth Interviews	Public Policy Key Participants
• Benefits/Services offered by local NGOs and other service providers • Outreach activities • Barriers to and facilitators of: (1) HIV prevention services and activities; and (2) HIV care and treatment • Collaborations among service providers and between service providers and government agencies • MSM advocacy activities	2b. Interview guide Community Leaders	In-Depth Interviews	Community Leader Key participants
• HIV risk perception • HIV prevention strategies (e.g., negotiated safety) • Perceptions of PrEP and nPEP	2c. Interview guide Individual/ Networks	In-Depth Interviews	Individual/Social and Sexual Networks

2. Purpose and Use of Information Collection

The purpose of the Local Effectiveness Assessment Project (LEAP) project is to increase understanding of local jurisdictional trends and needs for HIV prevention among men who have sex with men (MSM). Utilizing a case study method, LEAP will ultimately inform ongoing recommendations, and approaches to more effectively address the HIV epidemic.

3. Use of Improved Information Technology and Burden Reduction

The contracting team will conduct individual interviews with selected key participants at the Philadelphia Department of Public Health. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing the necessary rapport between interviewer and respondent for a successful qualitative interview on a sensitive topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer's ability to read both. Thus, the contracting team will conduct the individual, in-depth interviews (IDIs) in person. After asking for and receiving permission from the respondent, the contracting team will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

4. Efforts to Identify Duplication and Use of Similar Information

The interviews will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other survey 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 contract, and determined that this study is collecting unique information from the populations. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

5. Impact on Small Businesses or Other Small Entities

This collection request does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative data needed for federal policy makers to assess barriers and facilitators, and to increase their understanding of local jurisdictional trends and needs for HIV prevention among men who have sex with men (MSM). If this case study were not conducted, it would not be possible to have an in-depth contextual understanding of local jurisdictional trends and needs for HIV prevention among men who have sex with men (MSM). The length of data collection is 2-3 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

A 60 day federal register notice to solicit public comments was published in the Federal Register on August 2, 2012, Vol. 77, No. 149, Pages 46094-46095. No public comments were received.

9. Explanation of any Payment or Gift to Respondents

The contracting team will conduct individual interviews with selected key participants at the Philadelphia Department of Public Health. The team will provide key participants who participate with a token of appreciation totaling $40 in cash to encourage their participation, and convey appreciation for contributing to this important study. 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.[1,2] Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research. Barriers cited related to recruitment of minorities included (1) lack of trust among minority communities towards the medical research process and research[3,4,5] (2) a lack of competence among researchers to use culturally competent approaches for recruitment and[6] (3) reluctance to participate due to inconvenience and a lack of time[1,5,6]. In a recent study of recruitment and retention of Black men who sleep with men (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[7]. Concern with potential social labeling and HIV-related stigma also may have contributed to their hesitation[7]. Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later[7]. In this study, some agreed to participate in the evaluation because of the tokens of appreciation that was offered[7]. Respondents will receive the token of appreciation regardless of whether they complete the interview or skip any questions.

---

[1] Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association.*

[2] Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15,* 231–250.

[3] Quinn S. C *(1997). Belief in AIDS as a form of genocide: Implications for HIV prevention programs for African Americans. Journal of Health Education, 28,(Suppl. 6)S6–S11*

[4] Wrobel AJ, Shapiro NEK. Conducting research with urban elders: Issues of recruitment, data collection, and home visits. Alzheimer Dis Assoc Disord. 1999;13(suppl 1):S34–S38

[5] Gauthier, M. A., & Clarke, W. P. (1999). Gaining and sustaining minority participation in longitudinal research projects. *Alzheimer Disease and Associated Disorders,* 13(Suppl. 1), S29-S33

[6] Goodwin, P. Y., Williams, S. W., & Dilworth-Anderson, P. (2006). The role of resources in the emotional health of African American women: Rural and urban comparisons. In R. T. Coward, L.A. Davis, C.H. Gold, H. Smiciklas-Wright, L.E. Thorndyke, & F.W. Vondracek, (Eds.). Rural women's health: Mental, behavioral, and physical issues (pp. 179 — 196). New York: Springer

[7] Painter, T. M., Ngalame, P. M., Lucas, B., Lauby, J. L., & Herbst, J. H. (2010). Strategies used by community-based organizations to evaluate their locally developed HIV prevention interventions: Lessons learned from the CDC's innovative interventions project. *AIDS Education and Prevention*, *22*(5), 387-401.

10. Assurance of Confidentiality Provided to Respondents

We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the evaluation 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.

10.1 Privacy Impact Assessment Information

As the nature of this study is to better local jurisdictional trends and needs for HIV prevention among men who have sex with men (MSM), we are sensitive to the need to protect personal health information (PHI). To ensure that respondents' PHI is protected, we take several measures to separate personally identifiable information (PII) from study-related data. All respondents will receive unique identification codes which will be stored separately from PII. Contact information collected for the purposes of recruiting (i.e., name and telephone number) will be collected and stored securely and separately from responses to screening or interview questions. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. We will be prepared to describe these procedures in full detail and to answer any related questions raised by interviewees.

Access to all data that identify respondents (or such keys that link de-identified codes to personal information) will be limited to research staff that has a data collection or analysis role in the project. Such data will be needed only for scheduling interviews with respondents, and will not be used in the analyses. Transcripts will be completed on password protected standalone (non-networked) computers without internet access. Access to the transcript files on these computers will require password, and will only be allowed for staff working on this project and with a need to access. No PII will be included in the transcription. If the respondent divulges PII during the interview, the transcriber will convert the PII to bracketed non-PII descriptor information (i.e., [Daughter's Name]). Although transcripts will *not* contain PII, all transcripts will also be encrypted. No names or identifiers will be used when transcribing the data. Any data sent to CDC will not contain personal identifiers or any other identifier that would allow individual identification of study respondents.

In conjunction with the data policy, members of contractor project staff are required to:

- Comply with a Privacy Pledge and Security Manual procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.

- Notify their supervisor, the Project Director, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the Project Directors and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by the project staff cover all aspects of data handling for hard copy and electronic data. Transcriptions (stripped of PII) will be stored on encrypted flash drives. Additional information about the security protocols for all materials and transcripts can be found in the Information Security Plan (**Attachment 6**) submitted with this document. We will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. Unless otherwise required by CDC, these documents will be destroyed when no longer needed for the project.

11. Justification for Sensitive Questions

This study is an initiative aimed to learn local jurisdictional trends and needs for HIV prevention among MSM. As such, our study entails measurement of sensitive HIV-related information. All contracting staff will be trained to provide respondents with city-specific hotlines for HIV and mental health care organizations as needed. No sensitive information will be collected during the semi-structured interviews with key participants about the people they work with. We will inform all key participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimated Annualized Burden Hours

Exhibits A12.1 and A12.2 provide details about how the estimates of burden hours and costs were calculated. We anticipate that consent forms will take 5 minutes to complete (**Attachment 3**). Potential respondents will be selected from a pre-determined eligible list and will not incur additional screening time. We anticipate individual interviews are expected to take a total of 60 minutes (1 hour) total (**Attachments** 2a-**c**). The total number of burden hours is 33.

Exhibit A12.1: 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	2a. Interview Guide - Public Policy	9	1	1	9
General Public-Adults	2b. Interview Guide - Community Leader	15	1	1	15

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	2c. Interview Guide - Individual/Network	6	1	1	6
General Public-Adults	3a. Key participant Information Sheet and Consent Form	30	1	5/60	3
				Total	**33**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A12.B. The United States Department of Labor Statistics May, 2014 http://www.bls.gov/oes/current/oes_nat.htm was 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 $749.43 per year. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate ($22.71).

Exhibit A12.B. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	2a. Interview Guide Public Policy	9	$22.71	$204.39
General Public-Adults	2b. Interview Guide Community Leader	15	$22.71	$340.65
General Public-Adults	2c. Interview Guide Individual/Network	6	$22.71	$136.26
General Public-Adults	3a. Key participant Information Sheet and Consent Form	3	$22.71	$68.13
				Total $749.43

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

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

14. Annualized Cost to the Government

The estimated annualized cost to carry out the data collection activities is **$238,112**. 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 ($40 per completed interview, for a total of $1,200).

Exhibit A14.1: Annualized Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC, COR (GS-14 0.20 FTE)	$23,362
	CDC, Contracting Officer (GS-14, 0.20 FTE)	$23,362
	CDC, Contracting Officer (GS-13, 0.10 FTE)	$9,885
	CDC, Contracting Officer (GS-12, 0.30 FTE)	$23,471
	Subtotal, Direct Costs	**$80,080**
Cooperative Agreement or Contract Costs	Annual Contract Cost (ATLAS)	$158,032
	Subtotal, Cooperative Agreement or Contract Costs	**$ 158,032**
	TOTAL COST TO THE GOVERNMENT	**$ 238,112**

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

A final meeting to present the findings from the findings will be held in person at CDC in Atlanta at least two weeks before the end of the contract. Tabulation will include descriptive characteristics of study respondents collected in the first part of the interview (e.g., demographics, city, place in the treatment cascade, type of treatment center). The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	**Time Schedule**
Data collection tools, sampling and data pans, study protocol development	2-3 months before OMB approval
Recruitment	1 month after OMB approval
Data Collection	2-3 months after OMB approval
Data analysis finalized and report	4 months after OMB approval

drafted	
Final data set and final report submitted to CDC	5 months after OMB approval

Publication

Rather than providing a traditional final report, CDC has requested that the final report consists of multiple manuscript documents that will be ready or near-ready for submission for publication. The final manuscripts will be submitted March 2, 2016. In addition, a PowerPoint presentation describing results and manuscript production would be produced to describe the findings. A final data set will also be provided. At the same time, in addressing a new and untested method of presenting findings it is expected that members of the contractor project staff will need to work closely together to develop expectations for the number and draft-to-final quality each manuscript and presentation material achieves by the end of the contract period.

We anticipate that multiple manuscripts will be published in peer reviewed journals, presented at national conferences, and provided on conference websites. Links to these publications will be available through the CDC website.

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

We do not seek approval to eliminate the expiration date.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.