Local Effectiveness Assessment Project (LEAP), Part II

Generic Information Collection Request under OMB #0920-1091
(Expires 12/31/2018)

Section B: Supporting Statement

June 1, 2016

CONTACT
James W. Carey, PhD, MPH
Project Officer
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop E-37
Atlanta, GA 30333
Phone: 404-639-1903
Fax: 404-639-1950
E-mail: jfc9@cdc.gov

TABLE OF CONTENTS

EXHIBITS

1. Respondent Universe and Sampling Methods

City Selection

This study will be carried out in four metropolitan statistical areas in the United States: Houston, TX, Miami, FL, New Orleans, LA and Washington, DC. These locations were selected because of the high concentrations of men who have sex with men (MSM) residing within each district and also because of the high number of newly diagnosed HIV infections reported among MSM in these jurisdictions over the past decade.[1]

In 2014, Houston ranked 11th among metropolitan regions in estimated HIV infection diagnosis rate (24.1 per 100,000); there were an estimated 1,567 new diagnoses in Houston that year.[2] At the end of 2014, just over 23,000 people were living with HIV in Houston and Harris Counties.[3] Approximately 60% of newly diagnosed cases in Houston were transmitted through male-to-male sexual activity, and the majority of new cases were among Black or African-Americans (52.1%), at a rate approximately six times that among Whites and four times that of Hispanic/Latinos.[4]

Miami ranked 2nd highest in estimated HIV infection diagnosis rate (42.8 cases per 100,000) compared to other MSAs in the US in 2014.[2] There were an estimated 2,535 new HIV diagnoses in Miami in 2014, resulting in more than 26,000 individuals are living with HIV in the Miami metro.[5] Among those living with HIV in Miami-Dade, 44% were non-Hispanic black or African American and 43% were Hispanic/Latino; male-to-male sexual contact accounted for 51% of HIV and AIDS cases in the County.[5]

In 2014, New Orleans ranked 3rd highest in estimated HIV infection diagnosis rate (36.9 cases per 100,000), with an estimated 462 new diagnoses.[2] According to the Louisiana Department of Health, of the new HIV cases in Louisiana in 2013, 69.6% were among blacks or African Americans, and 61.2% were among MSM.[6] The racial disparity in HIV infection was even greater among youth, where 83% of new cases among youth 13-24 years old were among black or African Americans.[6] At the end of 2013, an estimated 18,895 Louisianans were living with HIV infection.

The Washington, DC metro area ranked 16th highest in estimated HIV infection diagnosis rate (21.6 per 100,000) in 2014, and there were an estimated 1,304 new diagnoses in DC that year.[2] More than 16,000 individuals are thought be living with HIV in the Washington, DC area, 40% of whom are MSM, and nearly 75% of whom are black or African American.[7]

Target population:

This study plans to select 30 individuals to participate in key participants interviews (KPIs) in each of the four study sites: Houston, TX, Miami, FL, New Orleans, LA and Washington, DC (Total n=120). As shown in Exhibit 1.1 below, the study population will be drawn from 3 distinct groups of individuals within each jurisdiction: 1) Local health department staff involved in MSM HIV prevention, care, or treatment programs, 2) Representatives of community-based organizations (CBOs), other local HIV care providers, and 3) Activists, advocates, or other local stakeholders who interact with or provide services to MSM in the community.

Inclusion criteria:

- At least 18 years old

- Able to speak English
- Positional or reputational leaders in HIV prevention, care or treatment in the jurisdiction (i.e. named as knowledgeable about HIV prevention and care for MSM in the jurisdiction by at least two other HIV care and treatment site leaders, advocates, or health providers serving MSM in the jurisdiction)
- Have at least 1 year of most recent continuous work experience in HIV-related service, treatment, or care delivery, and/or HIV-related legislative, policymaking, volunteer, education, or advocacy work during the past year within the jurisdiction.

Exclusion criteria:

- Inability to provide consent for any reason
- Inability to comprehend and converse in English
- Failure to meet other inclusion criteria

We will use a two-phased, purposive, snowball sampling approach to recruit participants to this study. This method has proven effective for identifying special populations including key informants with unique knowledge to a specific situation. The phased sampling approach will allow us the flexibility to adapt the case study to the specific situation in each city. It also allows us to include the community experts in the identification of the voices that need to be included in the study to form a full picture of challenges and successes in the jurisdiction.

In Phase 1, we will compile a list of potential KPI respondents in each city based on Health Department recommendations and referrals from pre-existing contacts in the jurisdiction. Based on length of service, number of recommendations from the contacted organizations, and professional position, we will select 5 jurisdictional leaders in each location for Phase 1 interviews (n=20 total in Phase 1). Phase 2 will consist of 25 key participant interviews in each jurisdiction (n=100 total in Phase 2). We will review the phase 1 interview data to help us determine any new areas of interest to pursue for each specific jurisdiction prior to selecting participants for Phase 2. We will supplement our initial sampling frame with additional key participants identified during Phase 1 interviews. We will interview a total of 120 participants across the two phases. Exhibit 1.1 below outlines sample size requirements for each of the phases in further detail.

Exhibit 1.1: Summary of Recruitment Targets

Phase		Houston	Miami	New Orleans	Washington DC	Total
1	Health Department Leaders	1-3	1-3	1-3	1-3	4-12
	CBOs/HIV Providers	1-3	1-3	1-3	1-3	4-12
	Community Members	1-3	1-3	1-3	1-3	4-12
	Subtotal	5	5	5	5	20
2	Health Department Leaders	4-12	4-12	4-12	4-12	16-48
	CBOs/HIV Providers	4-12	4-12	4-12	4-12	16-48
	Community Members	4-12	4-12	4-12	4-12	16-48
	Subtotal	25	25	25	25	100
Total		**30**	**30**	**30**	**30**	**120**

The distribution of KPI respondents will vary somewhat from place to place based on local particularities, but we will strive for a reasonable balance of different types of respondents in each of the relevant categories. This is a qualitative research study and is not designed to make comparisons

between groups or to make generalizations. We intend to use a standard qualitative sampling methodology that ensures a wide range of experiences are captured. Rather than using probabilistic methods (i.e., random selection with known, non-zero chances of selection for each unit in the population) to generate a sample, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest.

2. Procedures for the Collection of Information

We will work with local health department staff to identify initial key participants and finalize plans for contacting potential respondents (**Attachment 1**). For all potential KPI respondents, if a telephone number is available, recruiters will first attempt to contact them by telephone to determine if they are eligible and to invite them to participate in the study. If we are unable to reach the potential respondent or we do not have a telephone contact number, we will contact the respondent by email or regular mail, stating that they have been identified as a potential participant.

We will send interested participants a follow-up email that includes information about the study. Participants who choose to enroll in the study will be scheduled for an in-depth interview at a time and location that is convenient to them. We will confirm that participants are at least 18 years old during recruitment, but because participants will be selected from a pre-determined list, no additional screening will be required. At the time of the interview, staff will review the study procedures, after which participants will complete the informed consent and will receive a copy of the consent for their records (**Attachment 2**).

We will use qualitative, in-depth interviews lasting one hour, on average, to collect information for this study (**Attachments 3a-b**). Interviews will be conducted in a private setting (e.g., participant's office) by trained interviewers. With the respondent's permission, interviewers will digitally audio record each KPI interview and will remind participants not to use their full names or other identifying information. Interviews will include a short, structured response section to collect participants' demographic information and to assess their experience in HIV prevention or MSM outreach within the community. The key-participant interviews will primarily include open-ended questions designed to elicit information on HIV prevention, care and treatment among MSM in the jurisdiction and to address special topics relevant to the local context of each jurisdiction. Because all KPI respondents will be selected based on their prominent roles in HIV prevention, care, and treatment with MSM in each city or in MSM community advocacy roles, the open-ended format of all these questions will allow the respondents to explain their views and describe their knowledge of the current situation in the city.

Contact information collected for the study will be stored on paper form only, only for the purpose of scheduling interviews, will be stored in locked cabinets, and will be destroyed after the recruitment period. All audio files will be stored on the recorders; transcription will be done in house by listening to the recording device and transcribing to stand-alone computers that are not networked, taking care to remove any accidental personal identifying information (PII) happening during the transcription process. Each KPI will be transcribed into an encrypted MS Word document. Transcripts will be coded and analyzed used the NVivo qualitative data analysis software program. Information from the structured response questions will be analyzed using the Microsoft Excel and SPSS software programs. Individual transcripts, NVivo files, and other structured response data files will be stored on and edited from a

CDC-approved encrypted USB drive plugged into a standalone, non-networked computer without Internet access. Only project staff will have access to the records, study documents, and data.

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Key participants will be identified through past and existing partnerships with health departments in each of the jurisdictions.
- A token of appreciation of $40, in the form of cash, will be provided to key participants upon completion of the interview.
- All recruitment materials indicate the voluntary nature of the study and high participation is due in part to interest in the study and participation from key participants.

4. Tests of Procedures or Methods to be Undertaken

Our research team includes experts with experience conducting HIV research with health departments, CBOs, MSM populations and qualitative research, including screening and interview development and testing. The contracting team will conduct pretesting of the screening tool and interviews on three to five mock respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and to estimate response burden for each respondent. Non-CDC members of the research team will be responsible for recruiting respondents and collecting the KPI data in the four cities, as well as for generating transcripts that contain no PII.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff will neither collect data from nor interact with research participants. Data will be collected by members of contractor project staff listed. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

Exhibit 5.2: Statistical Consultants

Team Member	Organization	Phone	Email
James Carey	CDC	404-639-1903	Jfc9@cdc.gov
Brittney Baack	CDC	404-639-6297	jcx3@cdc.gov
Aisha Wilkes	CDC	404-639-6473	bki6@cdc.gov
Patricia Bessler	CDC	404-639-8239	vey4@cdc.gov

Alisu Schoua-Glusberg	Research Support Services	847-864-5677	alisu@researchsupportservices.com
Katherine Kenward	Research Support Services	847-864-5677	katherine@researchsupportservices.com
Paula Frew	Emory University	404-712-8546	pfrew@emory.edu
Laura Randall	Emory University		laura.randall@emory.edu
Susan Berkowitz	IMPAQ International	202-774-1943	sberkowitz@impawint.com
Valerie Betley	IMPAQ International		vbetley@impaqint.com

References

1. Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas, 2014. HIV Surveillance Reports 2015;26. http://www.cdc.gov/hiv/library/reports/surveillance/.
2. Centers for Disease Control and Prevention. Diagnosis of HIV infection in the United States and its dependent areas, 2014; 2015.
3. Texas Department of State Health Services. Texas HIV Surveillance Report: Texas Department of State Health Services, TB/HIV/STD Epidemilogy and Surveillance Branch; 2015 July 22.
4. Ryan White Planning Council, HIV Prevention Community Planning Group. The 2013 Houston Area Integrated Epidemiologic Profile for HIV/AIDS Prevention and Care Services Planning. Reporting period: January 1 to December 31, 2011; 2013.
5. Health FDo. Monthly HIV/AIDS Surveillance Report October 2015. HIV/AIDS Surveillance 2015; Available from: http://miamidade.floridahealth.gov/programs-and-services/infectious-disease-services/hiv-aids-services/_documents/hiv-surveillance-monthly-report-2015-10.pdf
6. Department of Health and Hospitals. 2013 STD/HIV Surveillance Report: State of Louisiana, Department of Health and Hospitals, Office of Public Health; 2014.
7. HIV/AIDS H, STD and TB Administration,. Annual Epidemiology & Surveillance Report: District of Columbia, Department of Health, HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA); 2015.