Improving Surveillance Data Collection among Persons Not Receiving HIV Care: A Qualitative Project to Enhance the MMP

GenIC Information Collection Request under OMB #0920-0840

April 18, 2018

Supporting Statement B

CONTACT:

Jennifer Fagan, MA
Clinical Outcomes Team
National Center for HIV, Hepatitis, STD and TB Prevention
Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS E-46
Atlanta, Georgia 30333
Phone: (404) 639-8396
E-mail: chx5@CDC.GOV

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B.1. Respondent Universe and Sampling Methods

The collection of information for this project does not involve statistical methods.

This project is intended to improve the Medical Monitoring Project (MMP) (OMB No. 0920-0740 exp. 06/30/2018). The respondent universe will be derived from respondents who participate in the MMP structured interview during the 2018 data collection cycle. Respondents will be recruited from the 23 project areas that participate in MMP.

Staff in health departments participating in MMP will recruit until 40 respondents who are eligible have been interviewed. Through an informed consent process, eligible persons will be asked to participate in a semi-structured in-depth telephone interview.

Participant inclusion criteria

Some of the eligibility criteria for this project mirror that of MMP, as respondents should have met MMP eligibility criteria to be considered for participation. To be eligible for MMP a person has to be diagnosed with HIV, aged ≥ 18 years and living in one of the 23 MMP project areas on the sampling date. Additionally, eligibility for this project will be determined based on responses to certain questions in the MMP questionnaire [23]. Specifically, respondents must have:

- Been out of care for 12 months or more based on self-report to MMP question:
  - What month and year was your most recent visit to a doctor, nurse, or other healthcare worker for HIV care?

Or

- Never received care based on self-report to MMP question
  - Since testing positive for HIV in __ __/__ __ __ __ [INSERT date first tested positive for HIV], have you ever seen a doctor, nurse, or other healthcare worker for HIV care?

Interviews will be conducted in English only. Persons who speak do not speak English will not be eligible for participation.

Persons incarcerated at the time of the MMP interview who otherwise meet eligibility will be excluded from participation because access to HIV care and care-related issues for persons who are incarcerated are different from those who are not incarcerated. Additionally, due to an anticipated low number of eligible incarcerated persons, sufficient data would not be available to compare adequately the care of incarcerated persons to those who are not incarcerated.

Selection of respondents

Quota sampling will be used to identify and recruit MMP project respondents for participation in this project. Quota sampling is a tailored approach that accounts for potentially relevant variations in responses. The quota sampling strategy ensures inclusion from people who may have otherwise been underrepresented by convenience or purposive sampling.

The quota sampling strategy will consider three characteristics as important for sampling strategy: race/ethnicity, length of time since last receipt of HIV care, and the region of residence (at the time of the MMP interview). The combinations of these characteristics represent the profiles of people to be sampled for this project. These characteristics were chosen because these factors have been related to HIV disparities [24, 25] and we expect there to be some relevant variations in the experiences of people not in care who differ on these characteristics.

We aim to collect data from at least five MMP respondents for each profile described in the quota sampling strategy. Therefore, we expect that 40 interviews will be required. Persons who are eligible for this project will be identified to health department staff through a pop-up message display after the completion of a MMP structured interview.

Expected response rates

Since 2015, MMP has recruited people living with HIV who are out of care. Based on the number of people who self-reported during the MMP structured interview that they never received care or were out of care for 12 months or more (n=105 in 2016; n=99 in 2015), we expect at least 100 people to be eligible for this project in 2018. We intend to recruit 40 of those eligible people to participate in semi-structured in-depth telephone interviews.

A sample size of 40 assumes a 40% participation rate among people who are eligible for this project. Qualitative studies typically have a smaller number of respondents compared to survey research. Previous research has indicated that it is possible to reach data saturation after 7-12 interviews and meaning saturation after 13-24 interviews for more difficult concepts [26]. With our intended sample of 40 people, we expect to reach data and meaning saturation while accounting for possible non-participation from people who are eligible for this project.

Table B1: Expected Response Rates and Sample Size

Length of time	12 ≥ months ≤ 23	≥24 months or never in care

without care									
Race/Ethnicity	Black, non-Hispanic		Non-black		Black, non-Hispanic		Non-black		
Region	South[a]	Other[b]	South[a]	Other[b]	South[a]	Other[b]	South[a]	Other[b]	
Expected Participants	5	5	5	5	5	5	5	5	40
Expected Eligible[c]	15	20	15	30	10	20	5	15	130

Note. [a] South: Delaware; Florida; Georgia; Houston, Texas; Mississippi; North Carolina; Texas; and Virginia

[b] Other: California; Chicago, Illinois; Indiana; Los Angeles, California; Michigan; New Jersey; New York City, New York; New York, Oregon; Pennsylvania; Philadelphia, Pennsylvania; Puerto Rico; San Francisco, CA; and Washington

[c] This is first time this specific data collection will happen. However, based on data from the 2015 and 2016 MMP cycles, we estimated an approximate number of people who will meet the eligibility criteria based on our quota sampling strategy.

B.2. Procedures for the Collection of Information

The approved Project Determination Form (**Attachment 5**) indicates that because this project is a formative data collection, the protocol will not be reviewed by CDC's IRB. Each participating project area will be required to obtain approval for this project from their IRB as required by their local review and approval processes and federal regulations before data collection.

Eligibility screening will be done automatically through computer software. Persons eligible to participate in this project will be identified to health department staff through a pop-up message display that will appear on the computer screen after a structured interview is completed for MMP. For this pop-up message to be displayed, the participants must have been out of HIV care for 12 months or more, or never received HIV care.

Project area staff will conduct all recruitment procedures for this project. Project area staff will explain to eligible persons that they are eligible to participate in this project. Participation in the project is voluntary. Respondents may refuse to participate at all or in part. Respondents may refuse to answer questions or stop participation at any time without penalty.

If the MMP respondent chooses to participate, the MMP data collector will schedule an appointment for the respondent to complete the semi-structured in-depth interview with CDC staff via phone. The MMP data collector will not schedule appointments with people who cannot speak

English well or participate in a 60-minute long interview in English only. The appointment will be reserved for informed consent procedures and a 60-minute semi-structured interview.

Each project area will be responsible for providing reminders and rescheduling appointments as needed for people who are eligible for this project. Project areas may use all methods acceptable to the respondent to contact respondents for appointment reminders or rescheduling (e.g., phone, text). The CDC will not call or initiate contact with MMP respondents for any reason; the interview call will always be initiated by the respondent.

During the recruitment process, project area staff will give eligible MMP respondents a unique code created by the project area. The unique code will be shared with the CDC interviewer by telephone. This code will be used for identification of persons who are eligible for the qualitative interview and, if those persons consent to, and participate in the qualitative interview, linkage of the data from the semi-structured interview the MMP interview and medical record abstraction.

Prior to beginning the interview, CDC staff will read the informed consent document (**Attachment 3**). This consent will address potential benefits and risks of participation. As part of the oral consent process, the interviewer will ask each respondent if they have a clear understanding of the project, its purpose, risks, benefits, and right to withdraw from the project without consequence. Respondents will provide oral consent twice: before the interview to obtain permission for audio recording and after permission is obtained to document the consent on the audio recording.

The qualitative interview will take approximately 60 minutes. The interview will be administered via phone in English by a trained interviewer (**Attachment 1**). Qualitative interviews will be audio-recorded. No personally identifying information will be collected. The interviewer will take detailed notes during the interview (notes will not contain personal identifiers). Approximately ten percent of interview audio-recordings will be reviewed by a CDC supervisor for quality assurance.

Interview audio-recordings will be fully transcribed verbatim together with the interviewer’s verbal cues. Transcripts will be stored electronically on a secure network at the CDC. Anyone who accesses the audio-recording for transcription purposes will have completed security and confidentiality training. Project areas will have access to the transcripts for the respondents who participated in their project area. Audio-recordings and transcripts will be stored electronically and backed-up on a secure network at the CDC. Everyone

who accesses the data will complete security and confidentiality training. Data will only be accessed on password-protected computers on a secure network at the CDC.

B.3. Methods to Maximize Response Rates and Deal with Non Response

The collection of information for this project does not involve statistical methods.

Response rate calculations

Since 2015, MMP has recruited people living with HIV who are out of care. Based on the number of people who self-reported during structured interview that they never received care or were out of care for 12 months or more (n=105 in 2016; n=99 in 2015), we expect at least 100 people to be eligible for this project in 2018. We intend to recruit 40 people to participate in semi-structured in-depth interviews—an anticipated 40% response rate.

We are using quota sampling to ensure variation in the type of respondents. Our sampling strategy is based on three characteristics: race/ethnicity, length of time since last receipt of HIV care, and the region of residence at the time of the MMP interview. These characteristics were chosen because these factors have been related to HIV disparities [24, 25] and we expect there to be some relevant variations in the experiences of people not in care who differ on these characteristics.

We reviewed data collected from the 2015 and 2016 MMP cycles to determine whether we could recruit at least 5 people for each category who meet the criteria outlined in the quota sampling. We determined that 5 people for each category would represent on average between 16-50% of people in each category who are eligible for this project. Additionally, our sample size of 40 respondents assumes a 40% participation rate among people who are eligible for this project. We also believe that a sample size of 40 respondents is sufficient to achieve the goal of the sampling strategy.

Methods to maximize response rates

Our sample size of 40 respondents assumes a 40% participation rate among people who are eligible for this project based on their responses to the MMP structured interview questionnaire in 2018. Qualitative studies typically have a smaller number of respondents compared to survey research. Previous research has indicated that it is possible to reach data saturation after 7-12 interviews, and meaning saturation after 13-24 interviews for more difficult concepts [26]. With our intended sample of 40 people, we expect to reach data

and meaning saturation while accounting for possible non-participation from people who are eligible for this project.

To ensure that we meet our sample size of 40, project areas will be responsible for reminding eligible persons who were scheduled for an in-depth interview about their appointment and contacting persons who missed their interview. Project areas will try to reschedule missed interviews until the data collection for this project ends one year after OMB approval.

In his memorandum for the President's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are also often used in studies used to develop surveys. For example, research subjects who participate in cognitive research protocols and focus groups are typically paid an incentive for their participation." This statement implies that tokens of appreciation are appropriate for studies using qualitative methods with the intention to improve survey research. Tokens of appreciation have been found to increase willingness to participate in qualitative research [22]. A token of appreciation is also useful for groups that are hard to reach, including those for whom conventional means of motivation may not work, such as disenfranchised populations like those recruited for this project [27, 28]. Providing a token of appreciation to respondents is critical to achieve acceptable response rates.

Assessing non-response bias

The use of an eligibility screener embedded within the MMP structured interview questionnaire will allow for comparison of the demographic and eligibility-related behavioral data among those who are eligible and participated and those who are eligible but did not choose to participate in this project.

Generalizability

Data collected for this project will be used to improve MMP and is not intended to be generalizable to any broader population. Given the qualitative nature of this project, it is not expected that any generalizable data will be produced.

B.4. Tests of Procedures or Methods to be Undertaken

The collection of information for this project does not involve statistical methods.

CDC staff conducted mock interviews with their CDC colleagues using the interview guide. The MMP Community Advisory Board also provided

consultation on the interview guide. OMB will be informed of any changes to data collection procedures or instruments as quickly as possible.

B.5. Individuals Consulted on Statistical Aspects

Consultants on statistical aspects

The collection of information for this project does not involve statistical methods.

Individuals collecting and/or analyzing data

CDC project staff
All CDC project staff can be reached at the following address and phone number:

Behavioral and Clinical Surveillance Branch
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd, NE MS E-46
Atlanta, GA 30333
Phone: (404) 639-6438

Jennifer Fagan, MA
Health Scientist, Clinical Outcomes Team
Email: chx5@cdc.gov

Linda Beer, PhD
Epidemiologist, Clinical Outcomes Team
Email: gur0@cdc.gov

Shana Green, PhD, MPH
ORISE Fellow, Clinical Outcomes Team
Email: odj2@cdc.gov

Ansley Lemons, MPH
Health Scientist, Clinical Outcomes Team
Email: imk2@cdc.gov

Amy Baugher, MPH
Health Scientist, Clinical Outcomes Team
Email: yda1@cdc.gov

Mabel Padilla, MPH
Public Health Analyst, Clinical Outcomes Team
Email: ymj0@cdc.gov

Kathleen Wu, MPH
Public Health Analyst, Clinical Outcomes Team
Email: ncq3@cdc.gov

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