

**Formative Research and Tool Development for the Medical
Monitoring Project: Testing Solutions for Challenges of Sampling**

Generic Information Collection request under 0920-0840

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**Supporting Statement
Part B**

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B. Collection of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Method

The respondent universe is persons ≥ 18 years old, currently residing in one of five field test sites who meet the HIV case definition and have been reported to the National HIV Surveillance System (NHSS; OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS] formally known as: Adult and Pediatric Confidential HIV/AIDS Case Report) and who have been diagnosed with HIV as of a reference date, hereafter referred to as the sampling date. Five field test sites have been selected by an open, competitive process from among the 23 current MMP project areas: Los Angeles, CA; Mississippi; New York City, NY; San Francisco, CA; and Washington State. Persons whose death is documented in NHSS records will be excluded from the sampling frame.

The proposed formative research project will test solutions to implementation challenges associated with a new sampling method for MMP, to assess the new method's feasibility as a replacement for current MMP sampling methods. The new method, stratified sampling directly from NHSS, allows for selection of HIV-diagnosed persons both receiving and not receiving care. When MMP was designed, no sampling frame existed from which to select a probability sample representing HIV-diagnosed persons in the United States. Therefore, a facility-based multi-stage cluster sampling approach was employed. The current MMP sampling method excludes an important group—HIV-diagnosed persons who are not receiving care. Because NHSS includes all HIV-diagnosed persons, both receiving and not receiving HIV care, it could potentially serve in place of the facility-based sampling frame MMP currently employs.

If successful, stratified sampling using NHSS as a sampling frame could significantly reduce costs associated with the current complex sampling design, and increase the scope and usefulness of MMP by including HIV-diagnosed people who are not receiving care. By design, the new method, unlike MMP's current sampling method, oversamples recently diagnosed patients in order to allow collection of information critical for improving HIV testing and linkage to care services and enhancing HIV prevention interventions among those not receiving care. CDC HIV case surveillance staff will draw a sample of eligible persons from national surveillance data whose case records indicate they are residing in the jurisdictions of the five participating health departments. Health department staff in these jurisdictions will

find and recruit sampled persons (i.e., screen them for eligibility and offer enrollment in the proposed formative research), and conduct interviews with and abstract the medical records of those who consent. The use of NHSS as a sampling frame in the proposed formative research eliminates the need for sampling of facilities, as patients will be sampled directly from NHSS. The data from this field test of solutions to CSBS implementation challenges will guide the future design of MMP.

Sampling Frame

The estimated number of persons available for selection is 52,870 in Los Angeles, 10,039 in Mississippi, 112,605 in New York City, 22,430 in San Francisco, and 14,751 in Washington State, for a total of 212,695 persons. Sampling frames for the five participating areas will be constructed from the aggregated NHSS dataset, which combines data from 56 states and dependent areas. Using national rather than local HIV surveillance datasets takes advantage of reported residential location information from all 56 NHSS jurisdictions. Using an algorithm to identify the most recently recorded address for each person ≥ 18 years old and diagnosed as of the reference date in one of the participating project areas, we will exclude from each project area sampling frame persons whose most recently recorded address is not in one of the five participating project areas. A sample will be selected independently from each project area sampling frame.

Drawing the sample

Three-hundred participants per year will be sampled from each project area frame by stratified random sample. The HIV/AIDS epidemic was first described in 1981 and life expectancies for HIV patients on anti-retroviral therapy are approaching those in the general population. In the five project areas, 3% were diagnosed < 1 year ago, 16% were diagnosed between 1 and 5 years ago, and 81% were diagnosed ≥ 5 years ago. In a simple random sample, only 19% would be expected to have been diagnosed < 5 years ago. However, some of the most critical public health questions concern the younger and more recently diagnosed HIV-infected population.

Therefore, recently diagnosed persons will be oversampled according to the following stratification scheme:

- 10% diagnosed ≤ 1 year from the sampling date
- 40% diagnosed 1-4 years from the sampling date

- 50% diagnosed \geq 5 years from the sampling date or among whom date of diagnosis is unknown

In order to determine a minimum sample size, the expected precision of estimates derived from the entire sample and from subpopulations were considered for different sample size options. It was determined that a sample size of 300 persons per project area or 1500 persons overall would have both acceptable precision and feasibility based on estimates of precision.

In calculating these estimates, the impact of weighted data analysis on precision was taken into account. Weighted analysis is necessary because the use of stratified random sampling within project areas and adjustment for non-response bias cause unequal selection probabilities. Both unequal selection probabilities and correlation of observations within project areas mean that variance estimates will be larger than they would be for a simple random sample of the same size. This variance inflation is called design effect (df). A design effect of 2 is used in the calculations because that level of design effect is commonly encountered in national surveys.

The following table shows the expected precision of an estimate from these data, such as an estimate of the proportion of persons who identified finances as a barrier to receiving care. The confidence interval (CI) half-widths in the table are the maximum that would be expected for estimates based on sample sizes of 300 and 1500 for project area and aggregated estimates, respectively.

The table shows the level of precision to be expected not only for estimates for the entire population (column 2), but also for subpopulations that comprise 50%, 33%, and 10% of the total population (column 3, 4, and 5 respectively).

	CI half-width	CI half-width	CI half-width	CI half-width
N	total population	subpopn = 50%	subpopn = 33%	subpopn = 10%
300	8.00%	11.24%	13.86%	24.50%
1500	3.58%	5.05%	6.20%	11.24%

As stated above, the sampling frame will be defined based on current residence in the project area as best determined from NHSS records. However, address information may be inaccurate or outdated, and those found to have moved away from the project area will be classified as ineligible. If a high proportion of the original sample is ineligible, then the original sample of

300 persons per project area may be supplemented by no more than an additional 300 persons. This supplementary sample will be prepared in advance by drawing the additional 300 persons without replacement at the same time as the original sample using the same stratification scheme. The original sample will be supplemented by no more than the number of persons who are deemed ineligible, and the public burden will not exceed the figures presented in Exhibit A.12.A. Specifically, within the 5 project areas, no more than 1200 total persons will be interviewed, and facility office staff will be asked to look up contact information for, pull medical records for, and approach no more than 300, 1200, and 150 persons, respectively.

Expected Response Rate

The proposed formative research is designed to field test solutions to implementation challenges for a new sampling method as a potential replacement for the current MMP sampling methodology. Current facility-based MMP methods require facility participation as a pre-requisite for patient participation. Facilities can sometimes be barriers to patient recruitment and thus affect overall response rates. The facility response rate for MMP was 76% in 2009 and 80% and 83% in 2010 and 2011, respectively. The use of the NHSS as a sampling frame would remove facilities as a potential barrier to patient recruitment. The response rate is expected to be the same as or better than the MMP response rate for diagnosed persons receiving HIV care. In 2010, 55% of eligible persons sampled for MMP were successfully interviewed.

B.2. Procedures for the Collection of Information

The proposed project will field test solutions to implementation challenges of a new sampling methodology for the OMB-approved data collection—MMP (0920-0740, expires 5/31/2015). Patients will not be sampled from facilities, and therefore, recruitment will be unlike MMP in that it will not occur exclusively through providers. In most cases, recruitment will be through direct contact with participants or with contact through providers employed as a back-up if direct contact fails for participants with a known provider. Otherwise, data collection procedures, described below, will be exactly the same as for MMP.

All eligibility screening and interviews will be conducted by trained project staff. 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.

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, has determined that MMP is not research and that it is a routine disease surveillance activity, with data being used for disease control program or policy purposes. Because NCHHSTP has determined that MMP is not research, it is not subject to human subjects regulations, including federal institutional review board (IRB) review and approval. All federal, state, and local MMP staff must adhere to the ethical principles and standards by respecting and protecting the privacy, confidentiality, and autonomy of participants to the maximum extent possible.

The CDC Clinical Outcomes Team, which manages MMP, has requested a non-research determination for the proposed data collection. This application is currently under review.

Project areas should follow state and/or local procedures to determine whether the proposed data collection is subject to state and/or local human subject regulations. The need for state/local IRB review, and the IRB approval and renewal dates, if applicable, must be kept on file in every project area. Copies of this documentation should be provided to CDC on an annual basis.

Sampled persons will be offered enrollment primarily through staff-contact enrollment. However, some providers may prefer to contact the patient first and let them know they have been selected to participate. For direct contact by project staff, potential participants will be initially contacted using letters or personal- and telephone-contact scripts developed using CDC templates.

Contact information for sampled persons being sought for recruitment will be obtained from project area NHSS records. Prior to making phone contact, project areas may send information about the project by mail, although such mailings will refer in general to conduct of a health survey rather than specifically mention HIV. Local project staff will use patient contact information to initiate phone contact with eligible persons to describe the project and offer enrollment. Difficult to locate or contact patients may be approached at their home or via the sampled person's current care facility. Model patient recruitment scripts are included as Attachments 7. Project areas can modify these scripts to meet their specific needs. Unless the CDC model

scripts are modified, additional OMB approval will not be sought for modifications made by individual project areas. The individual project area modifications will likely be minor.

All patient interviews (**Attachments 2a and 2b**) will be conducted by trained project staff in a private location either as part of a routine visit to a medical facility, or by an interview at home, in a hospital or clinic, or other mutually agreed upon location. Interviews may also be conducted over the telephone. The entire interview is expected to last for approximately 45 minutes.

The interview instrument (**Attachments 2a and 2b**) will be provided by CDC in a Computer Assisted Personal Interview format so that data will be collected electronically. The interview will be administered face-to-face or through the telephone using electronic handheld devices or computers. The interview instrument was developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland).

Participants will receive prevention materials at the end of the interview, referrals to local prevention and care services, and also prevention information from the project staff, as requested.

In order to avoid data loss, and to ensure data security, at the end of each field visit the interviewers will be responsible for downloading and saving all data records into the local database. Once the downloading has occurred, all patient records should be deleted from the data collection computer's hard drive before leaving for the next interview.

Medical record abstraction (**Attachments 3a, 3b, 3c, and 3d**) will be conducted by local project staff trained in the abstraction of clinical variables from medical charts. Standardized software on a laptop computer will be used for medical record abstraction. The information to be collected will be primarily related to diagnosis of opportunistic illnesses, provision of preventive therapies, prescription of antiretroviral medications, adverse events due to medications, and health services utilization.

Minimal data on all sampled patients from the HIV/AIDS Reporting System [HARS] (OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS]) will be extracted using a computer program run by project staff in each project area (data to be extracted are listed in **Attachments 4a, b, c**). In rare cases in which a sampled patient cannot be located in HARS, information on patient demographics may be obtained from HIV care

facility records. Minimal data on respondents and non-respondents will be compared to assess non-response bias. In addition, demographic data collected will be used for quality control purposes to ensure that patients are not sampled more than once.

The personally identifying information used to select patients will not be collected on the completed data collection forms; instead, each person will be assigned a unique ID.

The tablet and laptop computers used for data collection will be password protected and the data on them will be encrypted using standard, 128-bit encryption software. No personal identifiers will be collected or included. All data will be downloaded onto a secure computer at the health department and deleted from the field computers upon return to the office from the field.

Quality Control

For quality assurance purposes, a 5% subset of interviews will be observed by the project coordinator to determine accuracy and completeness. Additionally, interviewers will have periodic peer review of interviews to ensure the consistency in administration techniques across interviewers.

CDC will regularly train the interviewers and convene lessons learned meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Training topics will include how to use the CDC-provided software and hardware, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide a manual with detailed instructions on interview conduct to participating state and local health departments. Automated edit checks will be built into the computer software programs as a further quality control measure.

CDC is responsible for overseeing the development and distribution of the medical record abstraction software program to the participating state and local health departments. CDC will conduct abstractor training, and also provide a manual with detailed instructions for data abstraction to participating state and local health departments.

CDC will ensure regular training of abstractors and convene lessons learned meetings to understand the problems that can occur with the software and hardware that are used for conducting the abstraction. Automated edit checks will be built into the

computer software programs as a further quality control measure.

Completed electronic abstraction records (**Attachments 3a, 3b, 3c, and 3d**) will be visually scanned to check for completeness. A 5% subset of medical records will be re-abstracted by a second, independent reviewer and compared to the original abstraction forms to determine completeness and discrepancies. The medical records selected for re-abstraction should be from a variety of facilities, abstractors, and time periods.

CDC conducts at least one site visit to each grantee per cycle. The purpose of the site visit is to monitor adherence to the project protocol, observe interviews and medical record abstractions, and obtain feedback on study procedures. Additional site visits specific to the proposed data collection will be conducted as needed.

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

The proposed project will use the same methods for maximization of response rates and for dealing with nonresponse as the OMB-approved data collection—MMP (0920-0740, expires 5/31/2015). Because the interview for the proposed data collection takes approximately 45 minutes to administer, contains sensitive questions, and a significant portion of the population of HIV-infected adults in care are members of racial and ethnic minorities, patients will be offered remuneration for their participation to increase response rates. Participants will receive approximately \$25 in cash for participation in the interview. If local regulations prohibit cash reimbursement, equivalent reimbursement may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

Research indicates that providing remuneration to respondents helps raise response rates for long, sensitive, in-person surveys (Kulka 1995). In addition, persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (Thiede 2009; MacKellar 2005). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes (Whiteman 2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancey 2006). Data from MMP's 2007 cycle indicate that 65% of respondents reported a race or ethnicity other than non-Hispanic white. Providing remuneration to respondents is critical to

achieve acceptable response rates.

Reimbursement is also provided to persons who participate in CDC's HIV-related data collections among other populations, such as the National HIV Behavioral Surveillance System (NHBS) (OMB 0920-0770, exp. 3/31/2014) and the Transgender HIV Behavioral Survey (OMB No. 0920-0794, exp. 12/31/2010). Reimbursement was also used in the Supplement to HIV/AIDS Surveillance (SHAS) project (OMB 0920-0262, exp. 06/30/2004) (described in A.1.), for persons who agreed to participate in the interview. Participants were offered \$25 as reimbursement for their time.

The same advisory boards that provide input into MMP will provide input on the proposed formative research. A national provider advisory board, made up of providers of HIV care, provides input on MMP (and will provide input on the proposed project) to CDC. A national community advisory board (CAB), made up of community members from each project area, serves as a link between MMP staff and patients who participate, and will also serve as a link between project staff and participants. The national CAB shares information about the project and provides feedback to CDC about patient recruitment, data collection, and how the project is perceived by the community. Input from these two groups help to maximize facility and patient response and minimize patient non-response.

Like MMP, the proposed project will attempt to maximize participant convenience as a means of increasing response rate. In MMP, telephone interviewing is offered in some project areas as an optional mode for questionnaire administration in order to increase response rates. Participating project areas will be required to develop and implement procedures for telephone interviews as an option for respondents who prefer it. Use of mixed mode for survey administration has been found to result in improved response rates (de Leeuw 2005). In addition, conference calls between CDC and the project areas will be held on a monthly basis to review response rates and provide technical assistance to improve patient and facility response. Project staff will also be encouraged to offer evening and weekend interview hours in order to maximize convenience.

Assessing Non-Response Bias

The same procedures for assessing non-response bias that are currently used for MMP will be used for the proposed project. Minimal data (Attachments 4a-4c) on all sampled patients from NHSS will be extracted using a computer program run by project staff

in each project area. Minimal data on respondents and non-respondents will be compared to identify predictors of non-response. Those predictors with statistically significant effects will be used in the development of weight adjustment classes. Along with selection probabilities based on the sampling design, non-response data will factor into calculation of analytic weights so as to increase the generalizability of the information obtained to the universe of HIV-diagnosed adults.

These methods will be based on the assessment of non-response bias that has been completed for the 2009 MMP data collection cycle. In those analyses, the most significant predictors of patient response were facility size, race/ethnicity, years since diagnosis and age group. The ability to assess and adjust for nonresponse is a strength of probability surveys that may compensate for lower than desired response rates (Groves 2006).

Recruitment will be monitored through on-going data reports generated weekly and monthly from the data submitted to CDC. The field staff and CDC will use the data in these reports to identify problems with recruitment. When a problem with response or recruitment arises during data collection, field staff will be instructed to consult with local stakeholders and facility staff to identify solutions to the problem.

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

The purpose of the proposed formative data collection is to field test solutions to implementation challenges for a new sampling methodology for MMP that will expand the MMP target population beyond HIV-diagnosed persons receiving care to HIV-diagnosed persons not receiving care. MMP provides high-priority national indicators that must be monitored continuously to measure progress toward National HIV/AIDS Strategy objectives. Changing to a new sampling methodology before exploring how identified challenges might be addressed could potentially interrupt monitoring of national indicators. The investigators will evaluate the effectiveness of proposed solutions to implementation challenges as described below, to determine whether CSBS methods should replace current MMP sampling methods in all MMP data collection sites.

Persons ≥ 18 years old who were diagnosed in a participating project area as of the sampling date and reported to NHSS are eligible for selection if they currently reside in one of the five participating project areas. Sampling persons who move from a participating jurisdiction to a non-participating jurisdiction results in wasted effort spent locating ineligibles. Identifying

current location of residence so that ineligibles may be excluded from the sampling frame is expected to be a significant challenge for project areas. NHSS is designed to monitor diagnoses of HIV, HIV disease and mortality in funded jurisdictions. However, information about a person's migration away from the jurisdiction where he/she was diagnosed with HIV is often missing or incomplete in the jurisdiction's HIV surveillance data.

For the proposed formative research project, the investigators will explore two solutions to this problem. First, we will develop an algorithm to identify persons diagnosed in the five participating jurisdictions whose most recently recorded residential location indicates that they live in one of the five participating jurisdictions. Second, we will apply this algorithm to aggregated data from all 56 NHSS jurisdictions across the United States. Preliminary analyses suggest that constructing project area sampling frames with use of data aggregated from all NHSS jurisdictions, rather than using the individual project areas' surveillance data, would identify 10% of persons in project area datasets as ineligible because they had moved, reducing wasted effort. We will evaluate these methods for sampling frame construction based on the proportion of sampled persons who are contacted and classified as ineligible due to residence outside of a funded jurisdiction on the sampling date. The proportion ineligible because they moved outside the jurisdiction after diagnosis will be compared to other published estimates from projects that sampled from project area surveillance data. For example, in the NOTICE project in King County, WA, 36% of the initial sample was excluded due to relocation out of King County (Buskin 2011).

To assess the effectiveness of this solution, we will also estimate the proportion of persons included on sampling frames drawn from project area surveillance databases who would have been excluded as ineligible (because of residence outside the jurisdiction) if the sampling frames had been drawn for the project areas from aggregated NHSS data. This evaluation will involve constructing sampling frames from individual project area surveillance databases for comparison with frames constructed for those areas from aggregated NHSS data.

Another anticipated challenge for CSBS implementation is the difficulty of making contact with HIV-diagnosed persons not receiving HIV medical care to recruit them. Making contact with individuals sampled from NHSS is problematic in that contact information in NHSS may be out-of-date. For the proposed project, we will develop search algorithms to query other databases to

obtain contact information for persons sampled by CSBS methods. Such databases include health department surveillance and intervention databases for other communicable diseases such as tuberculosis or sexually-transmitted diseases, electronic medical record systems to which health departments have access, as well as the Social Security Death Index. We will collect process data on the proportion of the time project areas looked for contact information in supplementary data sources, and the proportion of these efforts that were successful. In this manner, we will define best practices for identifying contact information for sampled persons.

A third challenge expected for CSBS implementation will be difficulty recruiting HIV-diagnosed persons not receiving HIV medical care. Poor retention in HIV medical care has been shown to be associated with many factors that may also lead to lower participation rates such as younger age, history of injection drug use, unstable housing, psychiatric disorders, and incarceration (Rebeiro 2013; Pecoraro 2013). In the proposed project, we will strive to keep response rates high by using recruitment scripts developed in collaboration with our community advisory board. We will also explore measures that maximize participant convenience such as evening and weekend availability as well as telephone interviews in addition to in-person interviews. Refusal rates in this formative research project will be compared to the refusal rate in MMP (approximately 12%). We will also evaluate whether refusal rates varied when people were contacted during evening or weekend hours rather than during work hours.

A central objective of the proposed formative research is to explore the feasibility of expanding the MMP target population to persons diagnosed with HIV who are not receiving care. In addition to maximizing the proportion of persons in this group who agree to participate, we will explore increasing the effective sample size for this group by oversampling persons diagnosed within 12 months of the sampling date. Oversampling the recently diagnosed has the potential to enrich the sample with persons not receiving medical care as the proportion of persons not receiving HIV care is higher among those recently diagnosed. We will evaluate whether oversampling had an effect on the overall proportion of participants not receiving medical care by comparing the distribution of persons not receiving care among those diagnosed within 12 months of the sample date and more than 12 months from the sample date.

These efforts to field test potential solutions to implementation

challenges and thereby establish standards for CSBS sampling and recruitment methodology are expected to improve data collection and inform the future direction of MMP.

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

Consultants on Statistical Aspects

The following individuals consulted on statistical aspects only. They are not involved in collecting or analyzing the data.

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Individuals Collecting and/or Analyzing Data

CDC is not directly engaged with human subjects during data collection. However, CDC Project Staff below will train health department staff in data collection methods, monitor the progress of recruitment by health department staff, and analyze the data.

CDC Project Staff

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

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