Medical Monitoring Project

0920-0740

Supporting Statement
Part B

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1. Respondent Universe and Sampling Methods

The respondent universe for prospective data collection remains the same as in the previously approved project: adults (>18 years old) who meet the HIV case definition, have been reported to the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 11/30/2022) and reside in one of the 23 participating project areas, including Puerto Rico, 19 sampled states, and 6 separately funded cities within the sampled states). The proposed respondent universe is estimated to number approximately 754,070 persons. Eligible adults are those who, on the date of sampling, were: alive, diagnosed with HIV, and a resident of the project area according to the most recent address documented in NHSS records.

MMP has a two-stage sampling design. The first stage of sampling, conducted at the project's inception using probability proportional to size sampling methods, resulted in the selection of 20 of 52 eligible geographic primary sampling units (PSUs, defined as 50 states; Washington, DC; and Puerto Rico). The six cities separately funded for HIV/AIDS surveillance were included in the 20 selected PSUs and were, for administrative reasons, also funded separately to conduct MMP, resulting in a total of 26 project areas. Budget restrictions applied to the 2009 data collection cycle necessitated dropping 3 project areas. In preparation for the 2009 data collection cycle, three states were randomly selected to be removed from the PSU sampling frame in coordination with statisticians from the RAND Corporation, leaving 23 participating project areas (16 states, Puerto Rico, and six separately funded cities). This modification was approved by OMB. Sampling methods ensured representation of all regions of the US.

The 23 MMP project area sample is retained to preserve operational efficiencies and because MMP is an important source of population-based estimates at the state and city level for guiding allocation of prevention and care resources. Resampling the primary sampling units was considered and rejected because the epidemiology of HIV infection had not changed sufficiently from the time of the original sample to outweigh operational considerations and the need to preserve the continuity of data in participating areas. It would be operationally inefficient and resource-intensive to sample persons directly from NHSS because this would require the establishment and maintenance of the infrastructure to collect MMP data in every state and territory, the majority of which would have very few cases sampled. Further, clustering the sample in geographic areas allows for a sample size sufficient to produce local estimates of HIV care and treatment that are needed for planning purposes.

The second stage of sampling remains the same as in the previously approved data collection, and involves random sampling of eligible persons directly from NHSS. CDC HIV case surveillance staff will draw a sample from NHSS of eligible persons whose case records indicate they are residing in the 23 participating project areas. Health department staff in these jurisdictions will find and recruit sampled persons (i.e., screen them for eligibility and offer enrollment in the project), conduct interviews with consenting individuals, and abstract their medical records.

Sampled states will have a minimum sample size of 400 persons after combination with separately funded cities, if applicable (**Attachment 17**). Some states will enroll more than 400, because the sample size in the project area is roughly proportional to the number of persons living with HIV in each state. A minimum sample size of 400 will allow the description of outcomes of interest, e.g., the proportion of participants with an undetectable viral load, with sufficient statistical precision.

These methods are expected to yield a probability sample of persons diagnosed with HIV in the nation and in each project area. More detail about each of the stages of sampling is provided below.

Primary Sampling Unit Selection Methods

The first stage of sampling, conducted in 2005 (and not to be repeated in the next three years) employed a random, stratified sample. Because the goal of MMP was to obtain a national

probability sample of adults receiving HIV medical care in the US, all 50 states plus the District of Columbia (DC) and Puerto Rico (PR) were considered eligible to participate. Systematic sampling with probability proportional to size was used, with the measure of size being the total number of persons living with AIDS reported to the national HIV/AIDS Reporting System [HARS]), (OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) at the end of 2002. Given available funding, 20 PSUs were selected at the first stage of sampling. In 2009, in coordination with statisticians from the RAND Corporation, the first stage of sampling was revised and three states were removed from the PSU sampling frame. This modification was approved by OMB. Twenty-three project areas (16 states, Puerto Rico, and 6 separately funded cities within sampled states) have been funded to conduct MMP since 2009. We estimate that the current 23 project areas contain 72% of all persons with an HIV diagnosis in the United States.

As mentioned above, resampling the primary sampling units was considered and rejected. At the inception of MMP, AIDS prevalence in 2002 was the most comprehensive proportional measure of size of the population of interest available in all 52 jurisdictions. A comparison of AIDS prevalence in 2002 and HIV prevalence in 2015 showed the two distributions to be highly similar, although Maryland constituted a larger proportion of cases. The value of preserving the existing project area infrastructure and of maintaining the capacity to track trends in locally representative estimates were judged to outweigh the potential benefits to be gained, i.e., with regard to optimizing the sampling design, from resampling primary sampling units.

Respondent Sampling Methods

For the currently approved project, sampling involves the construction, by CDC staff, of respondent sampling frames for each of the 23 participating areas from the aggregated National HIV Surveillance System dataset, which combines data from 56 states and dependent areas. Each project area’s sampling frame will include adults diagnosed with HIV and reported to the project area and CDC NHSS as of the sampling date. Persons whose death preceded the sampling date and persons not residing in the jurisdiction, according to the most recently recorded address in NHSS, will be excluded from each project area sampling frame. Random samples will be selected independently from each project area sampling frame.

Sample size

A combined total of 9,700 participants per year will be sampled from the project area sampling frames (**Attachment 17**). 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. A sample size of 400 persons per state or 9,700 persons overall would have both acceptable precision and feasibility.

In calculating the precision of estimates from project area samples of 400 persons and a total combined sample of 9,700, the impact of weighted data analysis on precision was taken into account. Weighted analysis is necessary because the use of systematic random sampling within project areas and adjustment for non-response bias cause unequal selection probabilities. Both unequal selection probabilities across project areas and correlation of observations within project areas produce variance estimates that are larger than they would be for a simple random sample of the same size. This variance inflation is called design effect. A design effect of 2 is used in the calculations because this level of design effect is commonly encountered in national surveys.

The following table shows the expected precision of an estimate from these data, e.g., the proportion of persons who identified insufficient financial resources 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 400 and 9,700 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).

N	CI half-width total	CI half-width subpopn = 50%	CI half-width subpopn = 33%	CI half-width subpopn = 10%
400	6.93%	9.81%	12.09%	22.06%
9,700	1.41%	2.00%	2.45%	4.45%

Expected Response Rate

The response rate for the first cycle of MMP that sampled directly from NHSS, the 2015 data collection cycle, was 40%. Because MMP response rates have improved over time as the project has become more routinized, response rates for the proposed project are also expected to improve over time. Response rates for all epidemiologic studies and many federal surveys have declined in recent decades (**Attachment 7 references 15 and 16**). Although MMP's response rate is lower than desired, the quality of estimates obtained from MMP is strengthened by unbiased sampling methods from well-defined sampling frames (**Attachment 7 reference 17**). Because MMP annual samples are drawn from the NHSS database maintained by CDC (NHSS, OMB Control No. 0920-0573, exp. 11/30/2022), this ensures that MMP has better information about nonrespondents than most household and phone surveys, allowing adjustment of the data for nonresponse bias.

The following table presents our national and project area response rates for the 2015-2018 cycles.

Table 1a. MMP response rates: 2015 – 2018

Area	2015	2016	2017	2018
California	40	47	48	41
Delaware	44	47	51	53
Florida	39	44	38	43
Georgia	33	43	45	37
Illinois	40	43	45	36
Indiana	35	42	48	48
Michigan	46	45	47	46
Mississippi	43	44	39	48
New Jersey	34	42	49	50
New York	40	43	45	47
North Carolina	41	42	48	44
Oregon	49	53	57	50
Pennsylvania	39	43	46	42
Texas	39	44	46	43
Virginia	31	44	47	47
Washington	45	42	47	48
Puerto Rico	43	43	47	48
Total	40	44	46	45

2. Procedures for the Collection of Information

The proposed project will employ the same data collection procedures as those currently approved for MMP. Participants will be sampled from NHSS and recruited primarily by project area MMP staff. However, if direct contact cannot be made, and a sampled person has a known health care provider, contact through the provider may be employed as a back-up mechanism.

All interviews will be conducted by trained project area staff. Participation in the project is voluntary. Respondents may refuse to participate at all or in part. Respondents may refuse to answer questions or discontinue 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 monitoring or policy purposes (**Attachment 14**). Because NCHHSTP has determined that MMP is not research, federal institutional review board

(IRB) review and approval is not required. All applicable Federal and state privacy laws must be followed.

Project areas 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.

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.

Sampled persons will be offered enrollment primarily through contact with MMP project area staff. However, some providers may prefer to notify the patient before MMP staff initiate contact. Otherwise, potential participants will be initially contacted using letters or telephone, text, and E-mail-contact scripts developed using CDC templates (**Attachments 8a, 8b, 8c, and 8d**).

Contact information for sampled persons being sought for recruitment will be obtained from project area NHSS records. Before making phone contact, project areas may send information about the project by mail. To protect the confidentiality of persons recruited, such mailings will refer in general to a health survey rather than specifically mentioning HIV. The nature of the survey will be revealed through the informed consent process (**Attachment 3a**) when contact is established with the sampled person. Non-substantive modifications were made to the model consent form to improve readability and decrease the reading comprehension level. The previously approved consent form is provided in Attachment 3b.

All patient interviews (**Attachments 5a and 5b**) will be conducted by trained project staff over the telephone, videoconference, or in a private location, either as part of a routine visit to a medical facility, in a hospital or clinic or at the respondent’s home, or in another mutually agreed-upon location. The expected duration of the interview is approximately 40 minutes.

The interview instrument (**Attachments 5a and 5b**) will be provided by CDC in a Computer Assisted Personal Interview format to allow data to be collected electronically. The interview will be administered through the telephone, by videoconference, or face-

to-face using electronic tablet devices or computers. The interview instrument was developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland).

At the end of the interview, participants will receive HIV prevention materials, referrals to local prevention and care services, and prevention information from the project staff, as requested.

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 health department secure MMP database. Interviewers will be instructed to delete all patient records from the data collection computer's hard drive after downloading the records and before conducting the next interview.

Local project staff trained in the abstraction of clinical variables from medical charts will abstract the medical records of persons who have received HIV medical care (**Attachment 6** for abstraction data elements) Staff will use standardized web-based software accessed from a secure laptop computer for medical record abstraction. The information to be collected is primarily related to the diagnosis of opportunistic infections, provision of preventive therapies, prescription of antiretroviral medications, adverse events due to medications, and health services utilization.

Minimal data on all sampled persons from the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 11/30/2022) will be extracted using a computer program run by project staff in each project area or at CDC (data to be extracted are listed in **Attachment 4**). These data on respondents and non-respondents will be compared to assess non-response bias. Additionally, because CD4 t-lymphocyte counts and viral load test results used to stage HIV disease and as proxies for receipt of care are reported to states through NHSS prospectively, the link to case surveillance data through the minimum dataset can also be used to monitor MMP respondents' receipt of care services, progression of HIV disease, and potential for ongoing transmission of HIV over time.

The personally identifying information used to select participants (i.e., date of birth) will not be collected on the interview and medical record abstraction forms; instead, each person will be assigned a unique coded identifier.

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 health department.

Quality Control

For quality assurance purposes, a 10% subset of interviews will be observed by the project coordinator to determine accuracy and completeness. Additionally, interviewers will discuss each other's interviews to facilitate 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 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 written, detailed instructions on conducting interviews to participating health departments. Computer applications will have automated edit checks built in for quality control.

CDC is responsible for overseeing a contract with the Cerner Corporation for the development and distribution of the medical record abstraction software to the participating health departments. CDC provides the medical record abstraction data elements and rules for entry, and Cerner develops the software. CDC will conduct abstractor training, and also provide a manual with detailed instructions for data abstraction to participating 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. The software application for medical record abstraction will have built in edit checks for quality control.

Electronic abstraction records (**Attachment 6**) 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 data to determine completeness and discrepancies. The medical records selected for re-abstraction should be from a variety of facilities,

abstractors, and time periods.

CDC regularly conducts site visits to each project area. 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.

Because MMP is primarily a descriptive project, power calculations, which are used in sample size determinations for studies that test specific hypotheses, were not performed. Instead, the level of precision (i.e., the estimated 95% confidence interval half-width) was the criterion for determining sample sizes in individual project areas. Ninety-five percent (95%) confidence interval half-widths were calculated for a variety of sample sizes and design effects.

Table. 95% Confidence Interval half-widths for total population estimates for various sample sizes and design effects

N	CI half-width design effect = 1	CI half-width Design effect = 2	CI half-width design effect = 3	CI half-width design effect = 4	CI half-width design effect = 5
100	9.80%	13.86%	16.97%	19.60%	21.91%
200	6.93%	9.80%	12.00%	13.86%	15.50%
300	5.66%	8.00%	9.80%	11.32%	12.65%
400	4.90%	6.93%	8.49%	9.80%	10.96%
500	4.38%	6.20%	7.59%	8.77%	9.80%
600	4.00%	5.66%	6.93%	8.00%	8.95%
700	3.70%	5.24%	6.42%	7.41%	8.28%
800	3.46%	4.90%	6.00%	6.93%	7.75%
900	3.27%	4.62%	5.66%	6.53%	7.30%
1000	3.10%	4.38%	5.37%	6.20%	6.93%
1200	2.83%	4.00%	4.90%	5.66%	6.33%

Four hundred was determined to be the minimum sample size for a state to obtain total population estimates with an acceptable level of precision (assuming a design effect, or increase in variance of estimates due to using a multistage sampling design, of 2). This sample size was assigned to most of the states with the lowest AIDS prevalence. Sample sizes for states with moderate to high AIDS prevalence were determined based on the distribution of cases among the 17 sampled states/territory and the 6 separately funded cities in those states, to achieve a national sample size of approximately 10,000. These project area sample

sizes will allow national estimates at an acceptable level of precision for subpopulations as small as 10% of the total population of interest (as shown in the table in the section "Sample size" above).

3. Methods to Maximize Response Rates and Deal with Non-response

Please see Supporting Statement A, Section 9 for information on methods to maximize response rates.

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 (**Attachment 4**) on all sampled persons from NHSS will be extracted using a computer program run by project staff in each project area or at CDC. Minimal data on respondents and non-respondents will be compared to identify predictors of non-response. 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 results to the universe of HIV-diagnosed adults.

Weights will be developed based on the assessment of non-response bias for each cycle. In the analysis of non-response that was completed for the 2018 MMP data collection cycle, significant predictors of patient response were sex, receipt of HIV care, and age of latest contact information. The ability to assess and adjust for nonresponse is a strength of probability surveys that may compensate for lower than desired response rates (**Attachment 7 reference 17**).

Recruitment will be monitored through on-going data reports generated weekly and monthly from the data submitted to CDC. The project area 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.

4. Tests of Procedures or Methods to be Undertaken

The data collection methods and instruments to be used in this project were previously pilot tested (Formative Research and Tool Development for the Medical Monitoring Project: Testing Solutions for Challenges of Sampling, OMB Control No. 0920-0840, expiration

1/31/2019) and are the same as in the currently approved project

OMB will be informed of any changes to data collection procedures or instruments as quickly as possible.

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

Consultants on Statistical Aspects

The following individuals consulted on statistical aspects:

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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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