Medical Monitoring Project

0920-0740

Supporting Statement
Part B

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Project Officer:
Dr. Jacek Skarbinski
Medical Epidemiologist, 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) 639-8235
Fax: (404) 639-8640
E-mail: dvo5@cdc.gov

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1. Respondent Universe and Sampling Methods

The respondent universe is HIV-infected adults receiving medical care during the population definition period (January 1 – April 30) from sampled HIV care facilities in the 23 participating project areas in 16 sampled states and Puerto Rico. The Medical Monitoring Project (MMP) uses a three-stage sampling approach designed in collaboration with statisticians from the RAND Corporation. The first stage of sampling conducted in 2005 resulted in the selection of 20 of 52 eligible geographic primary sampling units (PSUs, defined as 50 states; Washington, DC; and Puerto Rico) using probability proportional to size sampling methods. The six cities separately funded for HIV/AIDS surveillance were included in the 20 selected PSUs and were thus also funded as project areas, resulting in a total of 26 project areas. In preparation for the 2009 data collection cycle, three states were 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.

In the second stage, HIV care facilities (i.e., facilities that prescribe antiretroviral therapy [ART] or order CD4+ lymphocyte or HIV viral load tests) are sampled. The sampling frame of facilities is developed every other year in each participating state using data from local HIV/AIDS case surveillance, laboratory reporting, AIDS Drug Assistance Programs and other available data sources. Facilities are sampled with probability proportional to their patient caseloads. For the third sampling stage, local HIV/AIDS surveillance staff will work with each selected facility to develop a list of HIV-infected patients who received care from the facility at least once during the population definition period of the relevant calendar year. From this list, a sample of patients will be chosen by systematic random sampling.

Sampled states will have a minimum sample size of 400 patients. Some states will enroll more patients, because the sample size in each state or city is proportional to the size of its epidemic. This sample size will allow the description of outcomes of interest – for example, the proportion of eligible patients prescribed prophylaxis for *Pneumocystis jiroveci* pneumonia.

These methods will result in a representative sample of patients receiving HIV care in the nation and in each project area. More detail about each of these 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 with probabilities proportional to a measure of size. Because the goal of MMP is 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 probability proportional to size sampling 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]) (collected under OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) at the end of 2002. Based on available funding, it was decided to select 20 PSUs 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, PR, and 6 separately funded cities within sampled state) have been funded to conduct MMP since 2009.

Facility Sample Selection Methods

At the second stage of sampling (conducted every other year), HIV medical care facilities serving HIV-infected adults will be sampled separately within each project area. A facility is defined as any hospital, clinic, health care facility, group or private physician practice or network of the above that share common medical records or a medical records system.

In each funded area, an updated sampling frame of unique (i.e., unduplicated) facilities currently caring for HIV-infected patients during the project period will be constructed every other year. In addition, because facilities are sampled with probability proportional to size methods, an estimate of the number of patients currently receiving HIV medical care at each facility, or estimated patient load, is also needed. Detailed procedures for facility sampling frame development and updates are provided to project areas and are documented in the MMP Protocol (see Attachment 14).

Facility inclusion criteria

Any facility delivering outpatient HIV care during the population definition period is eligible to be included in the facility sampling frame. “Delivering outpatient HIV care” is defined as

conducting CD4+ lymphocyte or HIV viral load testing or providing prescriptions for antiretroviral medications. Thus, facilities providing HIV medical care might include outpatient facilities such as hospital-affiliated clinics, free-standing clinics, health maintenance organizations (HMOs), or private physician offices.

Facility exclusion criteria
Facilities providing HIV-related services, but not HIV medical care (as defined), such as HIV counseling and testing sites, are excluded from the facility sampling frame. Other facilities that are excluded from the facility sampling frame are: emergency rooms, inpatient facilities, facilities located outside of the funded area, facilities that have closed or at which access to medical records is known to be impossible, prisons and jails, and health facilities located on military installations. Facilities that have provided HIV care only to patients less than 18 years of age are also be excluded from the facility sampling frame.

Each project area will send its facility sampling frame, which must include an estimated patient load for each facility, to CDC so that sampling may be conducted. Project areas are instructed to send the facility sampling frames to CDC without identifying information; facilities are identified only by a unique numeric identification (ID) number that will be assigned at the project area. Facility ID numbers will be made unique across all project areas by the addition of a 4 digit numeric project area code in front of the initial 4-digit facility ID number.

Facilities will be stratified before sampling, based on size (i.e., the estimated patient load during the four-month population definition period, or PDP) into either the large, medium, or small stratum. Assignment of facilities to these three size strata will be made according to each facility’s proportion of total patients in the project area. Between 40 and 60 facilities will be sampled in each project area.

The goal is to obtain participation in MMP from all sampled facilities. The generalizability of a probability sample depends on an adequate overall coverage or response rate. The higher the overall response rate, the more precise the population estimates obtained will be. Because the project area response rate was 100%, the overall response rate is the product of the facility and patient response rates. Project areas have been marketing the project to facilities and patients in their jurisdictions and support for the project is strong, which should contribute to

higher response rates.

Even if a facility is not willing to participate, the facility will remain in the sample. No substitutions will be made for facilities that cannot be persuaded to participate. Substitution of sampled facilities or patients would invalidate the sampling design of the project. If substitutions were allowed, inference to the population of HIV-infected patients receiving HIV medical care in the US could not be made. Patients from facilities that were not selected may not have the same attributes as patients of sampled facilities. Substitutions would potentially bias the sample in a manner that cannot be predicted nor adjusted for.

Respondent Sampling Methods

Patients of each participating facility will be sampled for inclusion in MMP with equal probability of selection. Patients will be sampled from lists of patients who had a care visit during the PDP, which corresponds to January 1-April 30 of the data collection year.

Participant inclusion criteria
All patients of each selected facility who meet the following conditions are eligible for inclusion: (1) the patient has a diagnosis of HIV infection, with or without AIDS-defining conditions; (2) the patient is at least 18 years old at the beginning of the PDP; and (3) the patient received medical care (defined as any visit to the facility or prescription of medications, including refill authorizations) at a sampled facility during the PDP.

Participant exclusion criteria
All patients of each selected facility who meet the following conditions are ineligible for inclusion: (1) the patient does not have a diagnosis of HIV infection; (2) the patient is not at least 18 years old at the beginning of the PDP; and (3) the patient did not receive medical care (defined as described in the paragraph above) at a sampled facility during the PDP.

Other subsets of patients in care, such as those who received all their HIV-related care from emergency rooms or medical facilities on military bases, or in prisons or jails, are excluded based on facility ineligibility for selection. Note that these exclusions are aimed at eliminating certain types of facilities from the facility sampling frame, *not at eliminating all patients who receive any care at such facilities.* Information on patient visits to Emergency Departments and inpatient facilities will be

obtained during interviews and may be abstracted from medical records.

When a project area has obtained patient lists from each participating facility, the lists are stripped of identifying information and sent to the CDC using the Secure Data Network. Individual patients will be identified only by a 12-digit numeric participant ID number that will be assigned at the project area. The allocation of the patient sample among the facility size strata will be done such that it results in equal probability of selection at the patient level. In general, this means that an equal number of patients will be sampled from each facility within a facility size stratum. Sampling of patients will be done using SAS Proc Survey Select to draw a simple random sample of each participating facility's patients. Lists of selected patients' ID numbers will be returned to the project area after patient sampling is completed.

All patients selected for the sample will be recruited for enrollment in MMP. Patients are considered eligible if they received HIV medical care in a project area jurisdiction, even if they are a resident of another jurisdiction. The total number of sampled patients will be the denominator for calculating patient response rates.

Sample sizes

Because MMP is mainly descriptive, power calculations – which are used in sample size determinations for testing specific hypotheses – were not performed. Instead, the level of precision – i.e., the estimated 95% confidence interval half-width – was the criterion used to determine individual project area sample sizes. Ninety-five percent (95%) confidence interval half-widths were calculated for a variety of sample sizes and design effects. It was decided that the minimum sample size that would be necessary for a state to obtain total population estimates with an acceptable level of precision (assuming a moderate design effect) was 400. This sample size was assigned to the states with the lowest AIDS prevalence. Sample sizes for states with higher AIDS prevalence were determined by considering the distribution of cases among the 17 sampled states and jurisdictions, and 6 separately funded cities contained within them and a target national sample size of approximately 9,300. This sample size will allow national estimates to be obtained with an acceptable level of precision (assuming a moderate design effect) for subpopulations that comprise as little as 5% of the total

population of interest. Attachment 15 outlines the target patient sample size for each project area.

The required precision of estimates from the patient sample will depend on the purpose for which an analysis is done. CDC, in consultation with the states, has determined that the expected precision will result in estimates and confidence intervals that are useful for local planning and policy purposes. For some comparisons, data will need to be combined at the national level to have acceptable precision. In addition, the design effect will be different for different outcomes, and also depends on the within-facility correlation.

Based on previously reported prevalence, estimates that will likely have acceptable level of precision at both the national and local level will include the following:

- The distribution of patients receiving HIV care by demographic characteristics (sex, race/ethnicity, age group, education).
- The proportion of eligible persons prescribed highly active antiretroviral therapy.
- The proportion of persons reporting sex without a condom in the past 12 months.

When estimates are stratified by patient characteristics or for rare events, we may not have adequate precision for estimates using data from a single year at the local level. Instead, national or multi-year analyses may have to be performed to provide adequate precision.

Expected response rates

Because MMP has a multistage design, the overall response rate is the product of site, facility, and patient response rates. If 100% of project areas, 75% of facilities, and 75% of patients from each participating facility are enrolled, the overall response rate is 1.0*.75*.75=.56 or 56%. The formulas used in the calculation of response rates are included in Attachment 16.

All 23 project areas selected in the first stage of sampling have agreed to participate. In the 2009 cycle, the facility response rate was 76% and the patient interview response rate was 56%, resulting in a crude overall response rate of 42%. Final 2010 response rates are in the process of being calculated, but examination of unadjusted response rates indicates improvement in both facility and patient interview response.

Response rates for all epidemiologic studies have declined in recent decades (Morton 2006). Although MMP's response rates are lower than desired, the project's use of probability sampling strengthens the quality of estimates obtained because it utilizes unbiased sampling methods from well-defined sampling frames (Groves 2006). Through applying rigorous standards and repetition, the high quality of MMP facility and patient sampling frames is maintained. MMP has better information about nonrespondents than most household and phone surveys, which allows the data to be adjusted for nonresponse bias. Nevertheless, CDC's goal for future cycles is to interview 80% of 9400 sampled patients.

2 Procedures for the Collection of Information

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 approved Project Determination Form (Attachment 11) indicates that because CDC considers MMP a surveillance activity, the protocol will not be reviewed by CDC's IRB. Participating health departments may obtain IRB approval prior to data collection according to local needs and regulations.

The MMP design is a three-stage sampling approach. The first stage of sampling resulted in the selection of eligible geographic primary sampling units (PSUs, defined as 50 states, Washington, DC, and Puerto Rico) using probability proportional to size sampling methods based on AIDS prevalence. In the second stage, HIV care facility (i.e., facilities that prescribe antiretroviral therapy [ART] or order CD4 or HIV viral load tests) are sampled biannually using probability proportional to size methods based on their patient caseload. In the third stage, an annual sample of patients will be chosen from selected facilities with equal probability of selection.

The MMP patient level weights consist of a base weight, three non-response adjustments (at facility, minimum dataset, and patient levels), and one multiplicity adjustment (to correct for patients whose probability of selection was higher due to visits to multiple care facilities during the population definition period). The most significant predictors of patient response were facility size, race/ethnicity, years since HIV diagnosis and age group. This information was used, along with selection

probabilities, to refine the weight adjustment procedures developed for the 2009 MMP data for calculating weighted estimates. In particular, those predictors with statistically significant effects were used in the development of weight adjustment classes. MMP weights are calculated based on the final patient project area weight multiplied by the inverse of the state probability of selection with a trimming adjustment (to correct for extreme weights).

Persons selected during third stage sampling may be offered enrollment through two recruitment scenarios; staff-contact enrollment, or provider-referred enrollment. The recruitment strategy utilized by facilities will vary based on clinic needs and patient load. Instead of giving the health department the names of the sampled patients, some providers prefer to contact the patient first and let them know they have been selected to participate. It is anticipated that each project area may utilize a variety of recruitment scenarios.

During staff-contact enrollment, facilities will provide local MMP staff with contact details for patients being sought for recruitment. Local MMP staff will use patient contact lists 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 next scheduled health care visit and the interview conducted at that time or scheduled for a later date. Standardized contact scripts developed by the project areas with CDC input will be used by sites to ensure a standardized approach is used for recruitment. Model patient recruitment scripts are included as Attachments 13a and 13b. 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 MMP 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. Interviews of patients who engage in few risk behaviors or have no risk behaviors (sexual behavior, drug and alcohol use) or who take few HIV-related medications or no medications will take slightly less time. Interviews of patients who engage in

many risk behaviors or are taking many HIV-related medications may take slightly longer. The interview will collect behavioral information relevant to medical care and clinical outcomes.

The standardized interview instrument (Attachments 2a and 2b) will be provided by CDC in a Handheld or 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 MMP 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: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) will be extracted using a computer program run by MMP staff in each project area (Attachment 4). 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. This request proposes to augment the linkage of MMP data with the National HIV/AIDS Surveillance System by adding an additional 56 data elements to be extracted from HARS. The purpose of this change

is to allow prospective monitoring of MMP respondents' HIV disease progression and receipt of medical care. This change, if approved, will add a prospective element to MMP's cross-sectional design. HIV-related laboratory test data will be used to monitor HIV disease progression and receipt of medical care.

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 handheld 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.

MMP data collection activities occur annually during each data collection cycle, for 3 years from the approval date. Every other year a sample of facilities will be drawn. Sampled facilities will participate for two data collection cycles. From each selected facility, patients will be sampled for participation in the MMP. It is possible that a patient receiving HIV care will be selected for participation in MMP in more than one year, as patients in care will have some probability of being selected each project year. Patients selected during a data collection cycle are only eligible to participate once during that cycle. There are no legal obstacles to reduce the burden.

Data for prevention and resource planning must be collected on an annual basis to meet reporting requirements of CDC and HRSA. Collecting data less than annually would not be advantageous, nor would it meet the needs of the grantees collecting the data and planning groups that rely on the data for resource allocation.

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 MMP 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 MMP protocols, observe interviews and medical record abstractions, and obtain feedback on study procedures.

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

Because the MMP interview 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 (Yancy 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 MMP 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.

A national provider advisory board, made up of providers of HIV care, provides input on the project to CDC regarding how data are collected and how to increase facility participation. 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. 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.

MMP uses telephone interviewing as an optional mode for questionnaire administration in order to increase response rates. 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 are held on a monthly basis to review response rates and provide technical assistance to improve patient and facility response.

Assessing Non-Response Bias

Minimal data on all sampled patients from the HIV/AIDS Reporting System [HARS] (OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) will be extracted using a computer program run by MMP staff in each project area (Attachment 4). In rare cases where 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. Assessment of non-response bias has been completed for the 2009 MMP data collection cycle, and project statisticians used these findings to calculate non-response adjustment weights. The most significant predictors of patient response were facility size, race/ethnicity, years since diagnosis and age group. This information was used, along with selection probabilities, to refine the weight adjustment procedures developed for the 2009 MMP data for calculating weighted estimates. In particular, those predictors with statistically significant effects were used in the development of weight adjustment classes. These adjustments were made to increase the generalizability of the information obtained to the universe of HIV-infected adults in care. 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 for all data collection cycles 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.

4. Tests of Procedures or Methods to be Undertaken

The MMP data collection instruments were developed using questions from previous CDC surveillance projects.

Since these questions comprising the data collection instruments have been previously tested and used, only internal testing by CDC staff was needed. CDC staff tested the skip patterns and responses both electronically and using paper versions of the data collection instruments. CDC staff also conducted mock

interviews of CDC staff members using the handheld computers to interview other CDC staff. Mock medical records were developed to serve as training aides to the data abstractors. CDC staff also used the mock medical records to test the data abstraction instrument. 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 only. They are not involved in collecting or analyzing the data.

RAND Corporation:

Ms. Sandra Berry, MA
Senior Behavioral Scientist
RAND Corporation
1700 Main Street
Santa Monica, CA 90407-2138
berry@rand.org
(310) 393-0411 X7051

Dr. Sam Bozzette, MD, PhD
Senior Natural Scientist
1776 Main St., m5s
Santa Monica, CA 90407
(310) 393-0411
bozzette@smmail1.rand.org

Dr. Marty Frankel, PhD
Statistician
14 Patricia Lane
Cos Cob, CT 06807
(203) 869-1324
Martin_Frankel@abtassoc.com

Dr. Martin Shapiro, MD, PhD
Researcher
911 Broxton Ave
LA, CA 90024
(310) 393-0411
mfshapiro@mednet.ucla.edu

ICF Macro:
Tonja M. Kyle, M.A.
Senior Manager
ICF Macro
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
301.572.0820
301.572.0986 (f)
tkyle@icfi.com

Ronaldo Iachan, Ph.D.
Senior Statistician
ICF Macro
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
301.572.0820
301.572.0986 (f)
rIachan@icfi.com

Pennington Biomedical Research Center:

Stephanie Broyles, Ph.D.
Assistant Professor
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808-4124
P: (225) 763-2500
stephanie.broyles@pbrc.edu

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:

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) 639-2090

Jacek Skarbinski, MD
Team Leader
Clinical Outcomes Team
Dvo5@cdc.gov

Christine Mattson, PhD
Epidemiologist
Email: ggi8@cdc.gov

Linda Beer, PhD
Epidemiologist
Email: lbeer@cdc.gov

Sandra Stockwell, RN
Nurse Consultant
Email: sstockwell@cdc.gov

Janet Blair, PhD MPH
Epidemiologist
Email: jblair@cdc.gov

Stanley Wei, MD
Medical Epidemiologist
Email: bge3@cdc.gov

Catherine Sanders, MA
Public Health Advisor
Email: hge3@cdc.gov

John Weiser, MD
Medical Epidemiologist
Email: eqn9@cdc.gov

Ann Do, MD, MPH
Medical Epidemiologist
Email: ado@cdc.gov

Lydia Poromon, MPH
Public Health Advisor
Email: fks9@cdc.gov

Jennifer Fagan, MA
Behavioral Scientist
Email: jafagan@cdc.gov

Jeanne Bertolli, PhD, MPH
Associate Director for Science,
Behavioral and Clinical
Surveillance Branch
Email: JBertolli@cdc.gov

Emma Frazier, PhD

James Heffelfinger, MD, MPH

Epidemiologist
Email: elf3@cdc.gov

Chief, Behavioral and Clinical Surveillance Branch
Email: JHeffelfinger@cdc.gov

Christopher Johnson, MS
Statistician
Email: cjohnson@cdc.gov

The following contracted staff will analyze MMP data.

ICF International CDC CIMS Contract Project Staff

All CDC CIMS contracted 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) 639-2090

Stella Chuke
Data Manager
Slc7@cdc.gov

Shetul Shah
Data Manager
Gwq5@cdc.gov

Ping Huang
Data Manager
Hyv0@cdc.gov

Bertram Thomas
Data Manager
Bct7@cdc.gov

Glenn Nakamura
Data Manager
Gcn5@cdc.gov

Yan Zhang
Data Manager
Vtt3@cdc.gov

Roshni Patel
Data Manager
Jqe6@cdc.gov

CDC personnel responsible for receiving and approving CIMS contract deliverables:
Roseanne English
Associate Director for Data Management
Division of HIV/AIDS Prevention
REnglish-Bullard@cdc.gov

ICF International Data Coordinating Center Contract Project Staff

All Data Coordinating Center contracted staff can be reached at the following address and phone number:
ICF International
11785 Beltsville Drive, Suite 300
Calverton, MD 20705
Phone: (800) 393-5936

Gia Badolato
SAS Programmer
gbadolato@icfi.com

Baibai Chen, MA
Senior Lead SAS Programmer
bchen@icfi.com

Christian Evans, MA, M Div
Deputy Project Director
cevans2@icfi.com

Deirdre Farrell, MPH
Analytical Epidemiologist
dfarraell@icfi.com

Lee Harding, MS
Statistician
lharding@icfi.com

Ronaldo Iachan, PhD
Senior Statistical Team Lead
riachan@icfi.com

Kamya Khanna
Jr. SAS Programmer
kkhanna@icfi.com

Tonja Kyle, MS
Project Director
tkyle@icfi.com

Mirna Moloney, MS
Statistician
mmoloney@icfi.com

Stephanie Richelsen, MA
Technical Assistance Coordinator
srichelsen@icfi.com

Walter Rives, MA
Technical Assistance Coordinator
wrives@icfi.com

Luz Rodriguez
Technical Assistance Coordinator
lrodriguez@icfi.com

Pedro Saavedra, PhD
Senior Statistical Advisor
psaavedra@icfi.com

Joe Singh
SAS Programmer
dsingh@icfi.com

Wen Song, MS
SAS Programmer
wsong@icfi.com

CDC personnel responsible for receiving and approving Data Coordinating Center contract deliverables:
Alicia Edwards
Health Scientist
Division of HIV/AIDS Prevention
Aje0@cdc.gov