Medical Monitoring Project
2011 Protocol

Clinical Outcomes Team
Behavioral and Clinical Surveillance Branch
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
September 2010

Table of Contents

List of Appendices

Abbreviations, Acronyms, and Definitions

2011 data collection cycle	The period of time during which MMP interview and medical record abstraction data will be collected for the 2011 patient sample. This period of time is from May 1, 2011 through April 30, 2012.
Abstraction application	Software program for collecting MMP medical record data on laptop computers developed by CDC utilizing Visual Basic.net and a Microsoft database engine.
ASD	Adult/Adolescent Spectrum of HIV Disease
CAPI	Computer Assisted Personal Interview – A method of administering interviews in person using a personal computer, typically either a laptop or tablet personal computer.
Computed variables	Computed variables have values that are the result of arithmetical or logical manipulations performed using values from other, pre-existing variables.
DCC Portal	The Data Coordinating Center portal allows field staff to securely exchange data with CDC that are considered sensitive or critical in nature.
Design effect	Design effect is the increase in statistical variance that is introduced by using a multi-stage complex sampling design to obtain patient or other samples. Mathematically, design effect is the variance obtained using a complex sampling design divided by the variance that would have been obtained from a simple random sample of the same size. A design effect of 2 means that the variance obtained using a complex sampling design was twice as large as the variance that would have been obtained from a simple random sample of the same size.
EPL	Estimated Patient Load - The estimated number of eligible patients in care for HIV at a facility during the population definition period (PDP). These estimates are obtained prior to the end of the PDP from various data sources, including the HIV/AIDS Reporting System (HARS) or the electronic HIV/AIDS Reporting System (eHARS), laboratory reports of HIV-related tests, and facility contacts, and are used to select eligible facilities for MMP participation.
Facility	For MMP, a facility is defined as any clinic, health care institution, private or group physician practice that shares common medical records or a medical record system. Thus, a facility is defined in terms of medical record storage, not in terms of a physical location (address) or the names of individual practitioners. For example, if the 5 physicians who comprise a group practice keep their patients' charts in a single medical record system, that group practice would be considered a single facility for MMP.

If, however, each of those 5 physicians stored his/her patients' charts in a different medical record system from those of the other 4 physicians, then each physician would be defined as a unique MMP facility. Note that facilities must meet additional eligibility requirements for participation in MMP.

HAPI Handheld Assisted Personal Interview – A method of administering interviews in person using a hand-held personal computer.

HARS HIV/AIDS Reporting System

eHARS Electronic HIV/AIDS Reporting System

HIV medical care For identifying facilities that are eligible for MMP, HIV medical care is defined as conducting CD4 or HIV viral load testing and/or providing prescriptions for antiretroviral medications in the context of treating and managing a patient's HIV disease on an outpatient basis. Thus, facilities providing HIV care could include outpatient facilities such as hospital-affiliated clinics, free-standing clinics or private physician offices; and Veterans Administration facilities. Note that although inpatient facilities, prisons and jails, federal military and penitentiary facilities, and emergency departments may provide HIV care, these types of facilities are not considered eligible for the 2011 data collection cycle.

IRB Institutional Review Board

MHF Medical History Form

MMP Medical Monitoring Project

MRA Medical Record Abstraction

MDS Minimum Data Set – Basic core surveillance information obtained for all sampled patients. This information will be obtained from HARS. These data are referred to as minimal data.

PDP Population Definition Period – For a given year or cycle of data collection, a predetermined period of time which defines the population of inference. The PDP for the 2011 data collection cycle is the 4 month period from January 1 – April 30, 2011.

PDP PL Population Definition Period Patient Load - The actual count of individual HIV-infected patients seen at a facility during the PDP (i.e., the total PDP patient load derived from a facility's patient list or lists). These counts will differ from the EPLs used to construct the facility sampling frame, because the latter only estimate the PDP PL.

PPS Probability Proportional to Size – A method of sampling in which the probability of selection for each unit on the sampling frame is proportional to some measure of size. For the 2011 MMP data collection cycle, the measure of size for first stage sampling of project areas was the number of reported living AIDS cases as of December 2002. For second stage sampling of HIV care facilities, it is the best estimate of the number of eligible HIV-infected patients who received care at each facility during the PDP (i.e., the best EPL obtainable). Thus, in the second stage of sampling, facilities with more eligible HIV patients have higher selection probabilities than facilities with fewer patients.

Provider A provider is an individual health practitioner (physician, nurse, etc.) within a facility (see Facility definition).

PSU Primary Sampling Unit – The element, or entity, that is sampled in the first stage of sampling. For MMP the 50 U.S. states, plus the District of Columbia and Puerto Rico, were the 52 primary sampling units.

QDS Questionnaire Development System - Software (NOVA Research Company, Bethesda, Maryland) used to develop the MMP interview questionnaire applications deployed on laptop and hand-held personal computers (see CAPI and HAPI definitions).

Sampling frame In probability sampling, the probability of selection of any element or unit, such as a patient, in the population must be known. In order for selection probabilities to be known, a list of population elements is developed from which the sample can be selected. Such a list is called a sampling frame and has the property that every element in the population has a known chance of being selected for the sample. For multistage sampling, a separate sampling frame is developed for each stage of sample selection. Each of the sampling frames after the first selection stage does not list all elements in the entire population, however; each subsequent frame only includes the population of elements within a sampled unit from the prior stage of selection. In MMP, patient sampling frames within a project area will not list all eligible HIV infected persons in care in the project area but only those in care at the sampled participating facilities. Because the probability of selection for each facility from which patient lists are obtained is known, the overall probability of selection for each patient selected during the final patient sampling stage can be determined.

SDN Secure Data Network – The SDN allows field staff and public health partners to securely exchange data with CDC that are considered sensitive or critical in nature. The SDN will be used for any confidential communication directly from the project areas to CDC.

SHAS Supplement to HIV/AIDS Surveillance

SHDC Survey of HIV Disease and Care

SHDC-Plus Survey of HIV Disease and Care Plus

Short Questionnaire Abbreviated form of the questionnaire conducted only under limited circumstances, such as when a patient is too ill or otherwise unable to complete the longer standard interview, or when translation is required.

SPIF Surveillance Period Inpatient Form

SPSF Surveillance Period Summary Form

SPVF Surveillance Period Visit Form

Standard Questionnaire Unabridged form of the questionnaire

Surveillance Period The 12 months prior to patient interview, if the sampled patient was interviewed, or the 12 month period prior to the date of first attempt to contact the sampled patient, if an interview is not obtained (e.g., the participant refused to participate, is known to have died, or is lost to follow-up).

I. Introduction

A. Background

HIV/AIDS surveillance programs in all U.S. states collect a core set of information on persons with a diagnosis of HIV infection or AIDS, persons who are living with HIV infection or AIDS, and persons who have died from HIV infection or AIDS. Historically, supplemental surveillance projects have provided complementary information about the clinical outcomes of HIV infection and the behaviors of HIV-infected persons with respect to seeking medical care, access to and utilization of health care services, and ongoing risk behaviors.

The Adult/Adolescent Spectrum of HIV Disease (ASD) project was implemented in 1990 as a supplemental surveillance system to collect information on the treatment and clinical outcomes of HIV-infected persons who were in care.[1] ASD, a facility-based, observational medical record abstraction project, involved the abstraction of medical records of more than 60,000 people receiving HIV care in 11 U.S. cities. ASD data have been used to examine trends in the incidence of AIDS-defining opportunistic illnesses, to determine whether eligible patients were receiving prophylactic and antiretroviral medications, and to provide information for treatment and prevention guidelines.[2-6]

The need for data on HIV-infected persons' risk behaviors and health care seeking behaviors led to the implementation of the Supplement to HIV/AIDS Surveillance (SHAS) project in 1990. SHAS surveyed persons in 19 areas who were newly reported as having HIV infection or AIDS; these persons were asked about HIV testing, care seeking, access to health care and related services, and ongoing risk behaviors.[7] Analyses examining reasons for late HIV testing, quality of life, drug use, and sexual behaviors have contributed to local planning and the tracking of behavioral trends among persons with HIV infection in care.[7-15]

During the past decade, ASD and SHAS have provided much-needed information that has been used to understand the HIV epidemic. However, in recent years, several factors have progressively limited the usefulness of these surveillance projects. First, early in the epidemic, HIV/AIDS cases were concentrated in large urban areas, primarily on the East and West coasts. Currently, a much larger number of cities and states are heavily affected by the HIV/AIDS epidemic, limiting the usefulness of data collected from the geographic areas in the ASD and SHAS projects. Second, the lack of linked medical record and interview data in these projects limited the ability to estimate key indicators, such as the quality of HIV-related ambulatory care and the severity of need for HIV-related care and services. Third, the generalizability of results from ASD and SHAS to the rest of the adult HIV-infected community was limited because these projects did not use probability sampling methods.

To address some of these concerns, the Survey of HIV Disease and Care (SHDC) was piloted in several areas during 1999. SHDC was a cross-sectional, population-based medical-record abstraction project in which 2-stage sampling was used to obtain probability samples of HIV-infected patients in care in the U.S.[16] In SHDC-Plus, a modification of SHDC conducted in 3 areas during 2003–2004, a subset

of persons whose medical records had been abstracted were interviewed. Both projects were conducted in limited geographic areas. The Medical Monitoring Project (MMP) grew out of experience with ASD, SHAS, SHDC and SHDC-Plus and incorporates some of their features, but unlike these earlier projects it is designed to provide nationally representative, population-based surveillance data. Furthermore, MMP's design addresses the limitations described above.

B. Purpose and Scope

The primary objectives of MMP are to obtain data from a national probability sample of HIV-infected persons who received care in the United States to:

- describe the clinical and virologic status of these persons
- describe the prevalence of co-morbidities related to HIV disease
- describe HIV care and support services received and the quality of such services determine prevalence of ongoing risk behaviors and access to, and use of, prevention services among persons living with HIV
- identify met and unmet needs for HIV care and prevention services to inform prevention and care planning groups, health care providers, and other stakeholders

The primary purpose of this protocol is to provide a consistent method for U.S. state and local health departments to use in collecting data on behaviors and clinical outcomes from a probability sample of adults who received care for HIV infection or AIDS in their jurisdictions. The method involves the selection of patients who received care during a predefined time period by means of a 3-stage sampling design, in-person interviews of eligible patients, and abstraction of their HIV-related medical records.

Collection of data from interviews with HIV-infected patients will provide information on the current behaviors that may facilitate HIV transmission; patients' seeking of, access to, and use of HIV-related prevention services; utilization of HIV-related medical services; and adherence to medication regimens. Through abstraction of medical records and interviews with eligible persons, MMP will provide information on clinical conditions that result from HIV-infected persons' disease or the medications they take, as well as the HIV care and support services they receive and the quality of these services. Ultimately, this surveillance project will describe met and unmet needs for HIV care and prevention services, information that can be used to evaluate these services and to direct future resources for HIV-infected persons.

The design will allow for national and state or local estimates of certain characteristics and behaviors that will be generalizable to adults in care for HIV infection in the United States. In order to make estimates that are truly representative, it will be necessary to obtain very high enrollment and participation rates of sampled facilities and patients. State and local HIV/AIDS surveillance programs, which have been operating for more than 20 years, have a history of collaboration with the medical providers and patients in their jurisdictions on projects involving both interview and medical record abstraction. Surveillance programs will need to build on these collaborations to ensure the high participation rates required for this project.

C. Collaborating Agencies and Stakeholders

MMP is conducted through cooperative agreements between CDC's Division of HIV/AIDS Prevention–Surveillance and Epidemiology and the following state and local health departments:

California Department of Health Services
Chicago Department of Public Health
County of Los Angeles Department of Health Services
Delaware Division of Public Health
Florida Department of Health
Georgia Department of Human Resources
Houston Department of Health and Human Services
Illinois Department of Public Health
Indiana State Department of Health
Michigan Department of Community Health
Mississippi State Department of Health
New Jersey Department of Health and Senior Services
New York State Department of Health
New York City Department of Health & Mental Hygiene
North Carolina Department of Health and Human Services
Oregon Department of Human Services
Philadelphia Department of Public Health
Pennsylvania Department of Health
Puerto Rico Department of Health
San Francisco Department of Public Health
Texas Department of Health
Virginia Department of Health
Washington State Department of Health

In addition to CDC, stakeholders for this project include other agencies and groups such as:

- State and local health departments
- National Institutes of Health (NIH)
- Health Resources and Services Administration (HRSA)
- National Association of AIDS Education and Training Centers (AETCs)
- National Alliance of State and Territorial AIDS Directors (NASTAD)
- American Academy of HIV Medicine (AAHIVM)
- Communities Advocating Emergency AIDS Relief (CAEAR)
- Association of Nurses in AIDS Care (ANAC)
- Council of State and Territorial Epidemiologists (CSTE)
- HIV Medicine Association (HIVMA)
- National Association of People with AIDS (NAPWA)
- National Alliance of State and Territorial AIDS Directors (NASTAD)
- National Minority AIDS Council (NMAC)
- HIV prevention planning groups
- Ryan White planning councils and consortia

- Providers of HIV medical care and prevention services
- HIV-infected persons

CDC established relationships with other federal stakeholders during the conception and development of MMP. Communications with these federal partners will continue for the duration of this project. CDC will maintain communication with state and local health departments through e-mails, conference calls, site visits, and meetings with Principal Investigators, Project Coordinators and other project staff.

Participating health departments should ensure the involvement of local stakeholders in MMP, including affected communities and providers of HIV care. Community input may be sought from established groups that represent HIV-affected communities (such as community planning groups and other potential consumers of the surveillance data) or if already established groups cannot provide appropriate input, from a group of community representatives convened to consult with the health department about this project. Provider input may be obtained by presenting – at local medical society meetings or through newsletters for local providers or other networks – the project, its aims, and its effect on the providers selected to participate.

Many state and local health departments have established relationships with local community planning groups and Ryan White planning groups. These groups should be made aware of the purpose and status of MMP, and the data it may provide to support local HIV planning activities.

At the national level, CDC has convened community and provider advisory boards for MMP, which include one community representative and one provider representative from each of the 23 project areas. These boards also include members of national organizations (e.g., National Association of People With AIDS, National Minority AIDS Council, HIV Medical Association, American Academy of HIV Medicine, and others). These boards provide input on the data collection instruments, operational considerations, barriers to participation, the usefulness of collected data, and optimal methods for data dissemination. The community members and providers who serve on the national boards are the designated contact persons at the local level and serve as a resource to patients or providers who are approached about participating but who wish input from a peer before deciding whether to do so.

CDC has contracted with ICF Macro to provide data management support. The scope of the work for the contract as it pertains to MMP consists of Macro independently, and not as an agent of the Government, furnishing all necessary personnel, facilities, supplies, and equipment to establish and implement a Data Coordinating Center as an integral part of MMP to achieve each of the following objectives:

1. Receiving data from the 23 MMP project areas (CDC designated project areas)
2. Processing data for quality assurance
3. Creating and transferring cumulative and final data sets to CDC and to project areas

4. Providing ad-hoc technical assistance to MMP project areas
5. Providing formal training sessions for MMP project areas
6. Communication and reporting to CDC

D. Initiation, Duration, and Project Period

MMP was initially funded for 4 years (mid-2004 through mid-2008). A cost extension was approved to extend funding through mid-2009 and the project was funded for an additional 5 years (mid-2009 through mid-2013). Thirteen project areas were funded to pilot data collection during year 1: Delaware, Florida, Houston (Texas), Illinois, Los Angeles (California), Maryland, Michigan, New Jersey, New York City (New York), Philadelphia (Pennsylvania), South Carolina, Texas, and Washington. Twenty-six project areas were funded for data collection in years 2 through 5. Year 2 project activities, including preparation for data collection, began in all project areas in June 2005. Because of delays in the Office of Management and Budget Office clearance process and the time needed to complete project activities, the decision was made to skip data collection for the 2006 cycle (data collected on patients in care in 2006) and begin the first full year of data collection in year 4 (patients in care in 2007). Sampling and data collection also took place in year 5 (patients in care in 2008) and will take place in years 6 through 10. Data collection for the 2011 cycle will begin January 1, 2011 and will terminate April 30, 2012. Twenty-three project areas are funded for the 2011 cycle.

II. Methods

A. Population of Inference

For each MMP data collection cycle, the national population of inference is HIV-infected adults (18 years of age or older) who received care from known providers of outpatient HIV medical care in the United States during the population definition period (PDP). For each project area, the population of inference is HIV-infected adults who received care from known providers of outpatient HIV medical care operating within the project area during the PDP.

B. Population Definition Period (PDP)

The PDP is a predefined time period during which HIV-infected patients must have received care at sampled facilities to be eligible to be selected to participate in MMP. For the MMP 2011 data collection cycle, the PDP is uniform across all project areas and extends from January 1 through April 30, 2011.

C. Eligibility Criteria

1. State and Local Health Departments

The goal of MMP is to obtain a national probability sample of HIV-infected adults receiving care from known providers of outpatient HIV medical care in the United States; therefore, all 50 states plus the District of Columbia and Puerto Rico were eligible to participate. Six areas separately funded for other surveillance activities (Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco) were included as part of their respective states for first-stage sampling. Therefore, the entities eligible for first-stage sampling were the 50 states plus the District of Columbia and Puerto Rico. Fifty states, the District of Columbia, Puerto Rico, and the 6 cities above were eligible to receive MMP funding.

2. Facilities

In each selected project area, any outpatient facility that provided HIV medical care during the time period(s) used to construct the facility sampling frame (FSF) (i.e., during the time periods for which records were available from each data source) is considered eligible for MMP. For the purposes of MMP FSF construction, providing HIV care is operationally defined as conducting CD4 or HIV viral load testing or providing prescriptions for antiretroviral medications in the context of treating and managing a patient's HIV disease. Thus, facilities providing HIV care could include outpatient facilities such as hospital-affiliated clinics, free-standing clinics or private physician offices. In addition, for MMP a facility is defined as any clinic, health care facility, group or private physician practice, or grouping of such entities that share medical records or a medical records system (in this protocol, this will be referred to as the "MMP facility definition").

Facilities that are known not to provide medical care, such as HIV counseling and testing sites, should be excluded from selection for MMP (i.e., excluded from the FSF). In addition, if all medical providers at a facility obtain CD4 T-lymphocyte counts and HIV viral loads only for referral purposes or if they only provide antiretroviral refill prescriptions – but do not play a more active role in managing their patients' HIV infection – then that facility should also be excluded from MMP selection. Other facilities that should be excluded from each project area's FSF are facilities that provide exclusively inpatient care, including hospices; emergency departments; facilities located outside the funded project area; facilities that have closed; federal, state and local correctional and work-release facilities; tribal facilities; and health facilities located on military installations. Facilities that have provided HIV care only to patients under the age of 18 should also be excluded from the FSF. Some facilities providing HIV care for patients under the age of 18 also do so for those 18 years and older; these facilities are eligible to be included on the FSF as well. Veterans Administration (VA) facilities in every project area are eligible for participation and must be included on the FSF.

Inpatient facilities are excluded from MMP eligibility because in these facilities the medical care provided to HIV-infected patients often may not be HIV-related. In addition, acute care providers in inpatient hospital facilities, such as medical residents, are not known providers of regular HIV medical care and as such may not be able to

participate in patient contact and recruitment if required by a project area or selected facility. Emergency departments are excluded from MMP for similar reasons. Although a hospice may in some instances provide some short-term HIV medical care, these facilities also are not considered to be known providers of regular HIV medical care. A separate list of excluded inpatient and other ineligible facilities should be kept by each project area.

3. Patients

At each eligible facility, all patients who meet the following conditions are eligible for inclusion:

1. Diagnosed with HIV, with or without AIDS at any time prior to the end of the PDP
2. At least 18 years of age at the beginning of the PDP
3. Received medical care (defined as any visit to a known provider of HIV medical care for medical care or prescription of medications, including refill authorizations) during the PDP

HIV-infected patients who received all of their care solely from emergency departments or inpatient facilities will be excluded from MMP, given that these facilities are excluded from the FSF. Note that exclusion of these patients is based on eliminating certain types of facilities from the FSF; HIV-infected patients who received care at an eligible facility but who also have visited an emergency department or inpatient facility will be eligible for selection to participate in MMP. Information on patient visits to emergency departments or inpatient facilities will be obtained during interviews, or may be documented in medical records.

D. Sampling Methods

MMP uses a 3-stage sampling design resulting in annual cross-sectional probability samples of adults receiving outpatient care for HIV infection in the U.S. During the first stage of sampling, which was conducted during early 2004, 20 geographic primary sampling units (PSUs) were selected using probability proportional to size (PPS) sampling based on AIDS prevalence at the end of 2002. **For the second stage of sampling, the areas will use their 2011 facility sampling frame for the 2011 cycle**. During the third stage of sampling, patients will be selected with equal probability sampling methods from all eligible patients seen during the PDP at selected participating facilities. More detail about each of these stages of sampling is provided in the following sections.

1. First-Stage Sampling

For the first stage of sampling, geographically stratified random sampling was used in which selection probabilities were proportional to a known measure of size. Because the goal of MMP is to obtain a series of national probability samples of adults

in care for HIV infection in the United States, all 50 states plus the District of Columbia and Puerto Rico were eligible for selection. Although 6 cities (Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco) were qualified to receive separate funding for MMP, these separately funded cities were included with their respective states for the purposes of first stage sampling. Therefore, the first-stage sampling frame consisted of 52 PSUs: the 50 states plus the District of Columbia and Puerto Rico.

First stage sampling for MMP was conducted in early 2004. During this stage of selection, systematic PPS sampling was used in which the measure of size for each PSU was the estimated total number of persons living with AIDS, as reported to the national HIV/AIDS Reporting System (HARS) at the end of 2002. Note that although the target population for MMP is all persons diagnosed with HIV in care in the US, since at the time there was no data system that collected information on HIV infected persons in care, the best available proxy (indirect) measure of PSU size, i.e., the estimated number of persons living with AIDS, was used during this stage of sampling. Using an indirect measure of size at any given sampling stage does not affect the validity of the statistical estimates derived from the overall sample. Because the first stage of MMP sampling was conducted using probabilities proportional to the measure of the number of persons living with AIDS associated with each PSU, it is estimated that this first-stage sample included more than 80% of the persons living with AIDS in the U.S. during 2002.

On the basis of available funding, 20 PSUs were selected during the first stage of sampling. All 20 state and 6 local (for the separately funded cities within the states) health departments in areas selected for the first stage sample agreed to participate in MMP, resulting in 26 project areas. For the current data collection cycle, 23 project areas were funded. See Appendix A for more information regarding first stage selection.

2. Second-Stage Sampling

a. Constructing the sampling frame of facilities

The Facility Sampling Frame (FSF) is a comprehensive list of all facilities providing HIV medical care within the local project area's jurisdiction. HIV medical care is defined as the treatment and management of HIV disease, and includes monitoring CD4 and HIV viral load tests and/or the prescription of antiretroviral medications. To be eligible for MMP the facility must be a provider of HIV medical care and share a common medical record system. Project areas must also obtain from each eligible MMP facility an Estimated Patient Load (EPL) – an estimate of the number of HIV-infected adult patients served for a pre-determined 4 month time period. The EPL is integral to the facility sample selection process. A high-quality EPL is one based on a data run or other objective information source. The FSF serves as the frame from which the MMP facility sample is selected. Because facilities are sampled PPS, an accurate estimate of the number of HIV-infected adult patients in care at each facility during the PDP (i.e., the EPL) must be included on the frame for each facility. The initial FSF was developed by all project areas prior to the first cycle of MMP data collection.

For the purposes of FSF construction and updates, HIV medical care is operationally defined as conducting CD4 or HIV viral load testing and/or providing prescriptions for antiretroviral medications in the context of treating and managing a patient's HIV disease. Thus, facilities providing HIV care could include outpatient facilities such as hospital-affiliated clinics, free-standing clinics or private physician offices.

Facilities that are known not to provide HIV-related medical care, such as counseling and testing sites, should be excluded from the FSF. Other facilities that should be excluded from each project area's FSF are facilities that provide exclusively inpatient care, including hospices; emergency departments; facilities located outside the funded project area; facilities that have closed; federal, state and local correctional and work-release facilities; tribal facilities; and health facilities located on military installations. Facilities that provided HIV care only to patients under the age of 18 also should be excluded from the FSF. A separate list of excluded inpatient and other ineligible facilities should be kept by each project area.

b. Facility Sampling Frame Activities for the 2009-2013 Cycle

All MMP project areas started the 2009-2013 funding period with an updated FSF that was reconstructed from the original FSF used in the previous 5-year cycle. The reconstructed FSF will be used through the entire 5-year funding period, with an updating every two years in which project area staff note which facilities opened, closed, merged, or experienced changes in the EPLs. For detailed information on activities that are used to reconstruct or update the FSF, please see below and Appendices B.1 through B.5.

i. Updating the Facility Sampling Frame

In each funded project area, the previously constructed FSF for that project area will be updated every two years to reflect the most recent information available regarding all eligible outpatient facilities known to provide HIV care to adults within the project area's jurisdiction. The objectives of an FSF update are to prepare an accurate, complete, and up-to-date list of facilities eligible for MMP from which a representative sample of facilities can be drawn. As a starting point in conducting an update of the FSF, project area staff should review their existing FSF. These facilities, having previously met the criteria for MMP eligibility, are likely to remain eligible for the upcoming MMP cycle.

For the 2011 and 2013 MMP data collection cycles, the period of time since the FSF was updated will be greater than one year. During this period of time, new HIV care-providing facilities may have begun operations within the jurisdiction of the project areas. CDC recommends that the MMP project area staff meet with HIV core surveillance staff by June 30 of the year before the data collection cycle begins to identify new facilities that are providing HIV care, as well as obtain information about previously eligible facilities whose status has changed (e.g., closed, HIV provider left,

etc). MMP staff should take advantage of this meeting with HIV core surveillance staff to obtain contact information for these new facilities and any other information that might be useful to obtain an EPL. To ensure the completeness of the updated FSF, project areas should use two other sources of information (facility visits log and medical record abstractions) to identify potentially eligible facilities.

A new sample of facilities will be drawn from the updated FSF for the 2011 and 2013 data collection cycles. In order to prepare for the 2011 FSF, project areas should update and correct their FSF throughout the 2010 cycle.

ii. Reconstructing the Facility Sampling Frame

In each funded project area, the previously constructed FSF for that project area will be reconstructed every five years. For the 2011 data collection cycle, the 2011 updated FSF will be used. As such, the following information is presented for reference only. The list of eligible facilities included all eligible facilities within a project area's jurisdiction that would potentially provide HIV care to HIV-infected patients during the 2009 PDP. In order to reconstruct the FSF, project areas first should review all records entered into eHARS since the first HARS extract was performed to develop the previous FSF. Project areas should also choose the two to three most useful data sources, aside from eHARS, used to identify facilities for the first FSF (i.e., the data sources that provided the most facilities not also found in eHARS), and obtain records that were entered for each source subsequent to the previous data extract. Information obtained from MMP interview or medical record abstraction data from previous cycles also should be used to identify facilities not on the previous FSF.

Once the records from each of these data sources have been obtained, they should be cleaned and standardized using methods developed for the initial FSF. These facilities then should be combined into one list, and this list compared to those that were considered eligible for the previous FSF and those that were considered ineligible. Any facilities not on either list are considered newly identified for the data collection cycle. These newly identified facilities should be contacted to determine whether they are eligible for MMP participation; in addition, previously identified eligible and ineligible facilities also should be contacted to confirm their eligibility status for the data collection cycle. Although correctional facilities such as prisons and jails are not eligible for selection, they should be included on the list of facilities sent to CDC with an indication in the comments field that they are correctional facilities. See Appendices B.1 through B.3 for additional information.

The FSF will be reconstructed again for the 2014-2018 funding period during the 2013 cycle.

iii. Creating a matrix of EPLs from each data source

For the 2011 data collection cycle, the 2011facility sampling frame will be used. The EPL is an estimate of the actual number of eligible patients that will be seen at a facility during the PDP for a given data collection cycle. In the original construction of the FSF, for each data source from which EPLs could be derived, a 1 year EPL for each facility was determined. Project areas also obtained 1 year EPLs directly from the facilities, either from a data run or other record-based source or as a less precise estimate, at the time facilities first were contacted to determine MMP eligibility. One year EPLs were obtained because it was thought this might be the most feasible time period for EPL determinations by facilities. A matrix, or table, of EPLs from each data source was constructed for all eligible facilities using templates provided by CDC, and this matrix was used to create the FSF used to select facilities for the previous data collection cycles. During this step, the quality of the different EPLs obtained across the various data sources should have been evaluated in order to determine, for each facility, which EPL was the most accurate to use for facility sampling.

For the 2011 FSF, the matrix of 4 month EPLs for all large facilities and a sample of medium sized facilities was created from facility contacts where facility staff provided information either from a data run or other record-based source.. For all other facilities, project areas will use the most recent data available from existing data sources to accurately reflect the patient load for the January 1 through April 30, 2011 PDP.

iv. Selecting the best EPL for each facility

For the 2011 data collection cycle, the 2011 facility sampling frame will be used. A high quality EPL is one that accurately represents the true count of HIV-infected individuals who receive care at a given facility within the PDP for a given data collection cycle. The process of determining, from among the various data sources available for a given facility, which EPL to use in the final FSF is somewhat subjective. This determination is made based on the purpose of the data source, as well as the completeness and comprehensiveness of the data source with regard to the HIV care variable collected in the data base. For example, a complete source of laboratory reports is one which includes all CD4 and HIV viral load values; a comprehensive source of laboratory reports is one that includes all reportable CD4 and HIV viral load tests ordered by all eligible facilities in the project area.

MMP staff members in each project area should have periodic discussions with their CDC Project Officer regarding the data sources used to identify newly eligible facilities and update the matrix of EPLs, and the information used to determine the quality of the EPLs from each of those sources. See Appendices B.1 through B.5 for more information regarding reconstructing and updating the FSF.

The complete FSF were due to CDC by November 30, 2010 so that facility samples could be drawn by December 31, 2010.

c. Small facilities: adjusting EPLs to a minimum value or linking to other facilities for sampling purposes

Please note, for the 2011 data collection cycle, the 2011 facility sampling frame will be used. For MMP, it is desirable that the overall probability of selection for each sampled patient be uniform, because this uniformity will result in greater statistical efficiency (i.e., confidence limits for estimates derived from MMP data will be minimized). Small facilities (i.e., facilities with very low EPLs) are technically problematic when multistage probability sampling is conducted and uniformity of the overall patient selection probabilities is desired, because the overall selection probability for a given participant is the product of that patient's selection probability across all three sampling stages. Small facilities will be identified prior to facility sampling in order to adjust the second stage selection probability for these facilities by performing facility linkage prior to facility sampling to achieve combined EPLs for the linked facilities that meet or exceed a minimum value.

Facilities designated as small are linked to one or more other facilities so that the small facility is selected for the sample only if the facilities to which it is linked also are selected. The desired minimum EPL across each project area ranges between 40 and 80, and will depend in part on the distribution of EPLs across the entire FSF for that project area. Minimum values of 40 to 80 have been determined to be optimal for selecting the facility sample across project areas.

In project areas of large geographic size, or with variations in facility attributes by region, this linkage can be performed within pre-specified regions to facilitate efficient use of project area resources during data collection, as well as to ensure facilities from every region are selected. Facility linkage will be performed by CDC staff, in conjunction with project area MMP staff, prior to selecting the facility sample.

d. Selecting the sample of facilities

For the 2011 data collection cycle, the 2011facility sample will be used. Each project area will send its final, updated matrix of EPLs (including the designated best EPL for each facility) to CDC through the DCC. Any small facility linkage will be performed by CDC staff in conjunction with project area staff, and included as a separate sheet in the workbook containing the matrix of EPLs. All files sent to CDC should be stripped of identifying information for each facility; facilities will be identified only by unique numeric facility identification (ID) number, which will be assigned by the project area. Facility ID numbers for all project areas will be made unique by adding a 4-digit project area code (see Appendix C) in front of the assigned 4-digit facility ID number.

CDC staff will select the PPS sample of facilities. In most project areas, 25 to 50 facilities will be sampled for the 2011 and 2012 MMP data collection cycles. However, the overall requirements of the sampling design, as well as the number and size distribution of facilities within a given project area, will determine the number of facilities that will be selected from each stratum. See Appendix D for more information regarding second stage facility selection.

e. Facility recruitment for participation in MMP

Once the sample of facilities has been selected, project area staff will contact each sampled facility to inform the appropriate contact person(s) that the facility has been selected to participate in MMP. Facilities that are selected in 2011 will be recruited for participation in the 2011 and 2012 data collection cycles. At this time, issues related to how the facility can develop a list or obtain an accurate and reliable count of HIV-infected adults who receive care at the facility during the 2011 PDP, and when this list can be provided to project area staff, should be discussed. Discussions regarding data collection activities for patients selected from the facility should also be initiated at the time the facility is contacted.

Facility recruitment should occur prior to the PDP (January 1 – April 30, 2011) so that patient lists can be obtained as soon as possible following the PDP end date.

The goal of MMP is to obtain participation from all sampled facilities. The generalizability of a probability sample depends on an acceptable overall response rate. Therefore, high overall response rates should be obtained at both the project area and the national level. The overall response rate is dependent on the facility response rate; therefore, facility response rates should be as high as possible. See the sections on third stage sampling for more information regarding the overall response rate.

It is expected that sustained effort will be necessary from project area staff in order to successfully recruit each sampled facility to participate in MMP. Every funded project area should have a strategy, based on their experience conducting MMP and similar projects and discussions among all funded project areas, for contacting and recruiting sampled facilities. Experience from previous surveillance projects suggests that reluctant or otherwise difficult-to-enroll facilities are most likely to respond favorably if contacted by the medical director of the health department or HIV program. Alternatively, the local MMP Provider Advisory Board (PAB) member might be helpful for recruiting facilities that are initially reluctant to participate. Because a high facility response rate is critical to the success of MMP, each project area should develop a strategy for facility recruitment that will maximize facility participation.

Even if a facility is not willing to participate, the facility is retained as part of the facility sample for a given project area. No substitutions will be made for facilities that refuse to participate in MMP. **A facility that refuses to participate is refusing participation for all of its patients**; these patients, and similar patients, will have a lesser opportunity or no opportunity at all, to be represented by MMP. If a facility refuses to participate in 2011, they will still be eligible for participation in the 2012 data collection cycle, since the same facility sample will be used for 2011 and 2012.

3. Third-Stage Sampling

At each participating facility, eligible patients will be sampled for inclusion in MMP. Patients will be sampled either using List Based Sampling (i.e. from lists of patients seen at each facility during the 2011 PDP) or through Real Time Sampling (RTS). The selection of the patient sample will be done in a manner that will result in an equal probability of selection method sample at the patient level. This means that

patients will be sampled from each facility with a third-stage sampling probability which, when multiplied by the second-stage selection probability, results in the same overall selection probability for every patient selected in the project area.

I. List Based Sampling

a. Constructing the patient sampling frame

A list of HIV-infected adults who received medical care during the 2011 PDP should be requested from all sampled facilities. Templates for collecting and recording this information will be provided to project areas by CDC. The patient lists should include each patient only once (i.e., patients seen for care in the PDP should not be included an additional time if they had another visit to the facility later in the PDP). Methods for constructing patient lists may vary by facility. Strategies could include using lists of patients whose classifications according to the International Classification of Diseases (ICD-9 or ICD-10) for procedures, tests or prescriptions during the PDP are related to HIV. This should not be the only method used by a facility to identify eligible patients, however, because for third stage sampling all HIV-infected adult patients presenting for any type of care at that facility are eligible for inclusion**.**

i. Obtaining lists of PDP patients from each participating facility

Patients will be eligible for selection only at their first reported visit to the facility during the PDP in order to ensure that multiple visits to the same facility do not lead to multiple opportunities for selection. Note that the operational definition for this component of patient eligibility (receipt of any care at the facility during the PDP) is different from that which is used to operationalize facility eligibility (CD4 or HIV viral load testing or prescription of antiretroviral therapy). Care is defined as any visit to the facility for medical care or prescription of medications, including refill authorizations and vaccinations. It is important that the list contain only patients who received care at the facility; facilities should exclude patients who made appointments but did not keep them.

The list of eligible patients will be collected from every participating facility after the end of the PDP (April 30, 2011). Lists should be obtained from each facility as soon as they are available; patient sampling cannot be conducted until patient lists are received from **every** participating facility within a project area. Patient lists are due to CDC by June 30, 2011, and patient samples should be drawn by July 31, 2011.

ii. Creating a file of PDP patient lists

As patient lists are received from participating facilities, each project area will create a file containing these lists or estimates. A template for this purpose will be provided by the DCC. Project areas should request patient lists that contain unique identification information or, at minimum, codes for individual patients within each participating facility. The patient information provided by each facility should include

unique identifying information which will enable the facility to fully identify each patient that is selected for MMP participation.

If feasible, the project area should review the information received from each facility to ensure no patient appears on a given facility's list more than once. Since information used to identify patients will differ across facilities, the lists should not be unduplicated across any of the facilities; instead, adjustments will be made to the statistical weights used in data analysis to account for multiple patient visits to different facilities during the PDP.

iii. Comparing the selected best EPLs with PDP patient loads

For each facility, the actual count of unique patients seen during the entire PDP (the PDP patient load, which is derived from a facility's patient list or lists) will differ from the selected best EPL used to construct the FSF. The extent to which this EPL for each selected facility differs from the PDP patient load should be reviewed by the project areas, in conjunction with the CDC Project Officer, as patient lists and estimated PDP PLs are received during facility recruitment.

b. Selecting the patient sample

Once a project area has obtained PDP patient lists from all participating facilities where list based sampling will be used, a copy of this file should be made in preparation for transmitting the patient lists to the DCC. The copied file should then be stripped of patient identifiers used by the facilities. If estimated PDP PLs have been obtained, lists of individual patients should be generated from these estimates. Patients on every patient list will be identified only by a 12-digit participant ID number that will be assigned by the project area. This unique identifier will be associated with each patient throughout a data collection cycle in MMP and should appear on all data collection forms and in all databases. Participant ID numbers will be formed using 4-digit numbers that are assigned consecutively to patients on each facility's patient list. The first 8 digits of the participant ID will be the full ID of the state/city and facility from which the patient was sampled. The edited, copied file should be encrypted and sent to the DCC via the data portal.

For each project area using list based sampling, patient sampling will be conducted shortly after the end of the PDP (April 30, 2011), as soon as the patient lists have been received from all participating facilities (all patient lists should be sent to CDC by June 30, 2011). The file containing lists of HIV-infected patients seen during the PDP at all participating facilities will be used to select the patient sample. The selected participant ID numbers will be returned to the project area via the SDN after patient sampling has been completed; this set of participant IDs will comprise the entire patient sample for the project area. See Appendix E for more information regarding third stage patient selection using list based sampling.

c. Patient recruitment for participation in MMP using List Based Sampling

Persons selected during third-stage patient sampling may be offered enrollment through two general recruitment processes: MMP project area staff-contact enrollment or facility-referred enrollment. The recruitment strategy will vary according to facility preference, and state or local project area Institutional Review Board (IRB) requirements.

For MMP staff-contact enrollment, facilities will provide project area MMP staff with contact information for patients selected for recruitment. After obtaining patient contact information, the MMP staff will contact selected patients to describe the project and offer enrollment. Telephone scripts will be used by all project areas to ensure a standardized recruitment approach within project areas. Patients who are eligible for enrollment and agree to participate will be scheduled for an interview at a location that is convenient for the patient and meets the need for patient privacy or will be interviewed over the phone.

Patients recruited through facility-referred enrollment initially will be contacted by staff of the facility from which they were sampled. This may be done by telephone, in person, through chart insert and/or letter mailed from the facility. If by telephone or in person, the facility staff will describe the project briefly and ask permission to provide contact information to MMP staff so that enrollment can be completed, or the facility staff will ask the patient to contact the MMP staff. If recruitment takes place via chart insert or letter, the documents will describe the project briefly and will provide contact information to enable the participant to reach MMP staff.

All patients selected for the sample should be recruited for enrollment in MMP. Patients are considered eligible if they receive care in a project area jurisdiction even if they are a resident of another jurisdiction.

II. Real Time Sampling

a. Constructing the patient sampling frame

HIV infected persons receiving care at certain care facilities selected for participation in MMP may be recruited for participation in MMP using RTS methods. RTS is a variation of time-space sampling in which persons are recruited for participation at pre-specifed intervals during pre-selected time blocks at pre-selected locations. For MMP, RTS activities will take place during the PDP of any given cycle (i.e. January 1st to April 30th). The project area and CDC will determine the most appropriate facilities in which to conduct RTS. Factors considered include: size of patient population, number of patients sampled for MMP, clinic patient flow, entry point(s) for patient check in, prior MMP patient contact and participation rates, and cooperation of facility staff. The project area will collect detailed information from facilities chosen so that a patient selection algorithm can be developed. This information will be determined by CDC and will include information such as: schedule of facility operations during the RTS period, number and description of patient check in entry point(s), predicted clinic patient volume by day and time, and facility contact persons for RTS implementation. This information will be used to develop a sample of

office-period units where offices are nested within facilities and periods are nested within days. CDC will then develop a patient sampling algorithm that will be used by MMP staff at the facility to produce a sample of patients selected from the first-stage sampling units (office-period units).

b. Selecting the patient sample

MMP staff, in consultation with CDC,will work with facility staff to identify eligible patients, and will use existing protocols used for on-site recruiting in list-based samplingto ensure that patient confidentiality will be maintained during the selection process. Recruitment and data collection after RTS patient selection will follow established MMP protocols. See Appendix E for more information regarding third stage patient selection using real time sampling.

c. Patient recruitment for participation in MMP using Real TimeSampling

Persons selected during third-stage patient sampling using RTS will be enrolled by MMP project area staff-contact.

For MMP staff-contact enrollment, the MMP staff will contact selected patients to describe the project and offer enrollment. Patients who are eligible for enrollment and agree to participate will be scheduled for an interview after their medical appointment or at a later date at a location that is convenient for the patient and meets the need for patient privacy. Telephone interviews will also be an option for interviews scheduled at a later date.

All recruitment and data collection after RTS patient selection will follow established MMP protocols.

All patients selected for the sample should be recruited for enrollment in MMP. Patients are considered eligible if they receive care in a project area jurisdiction even if they are a resident of another jurisdiction.

III. Project area patient sample sizes

MMP staff in all project areas will interview patients and abstract medical records during the 2011 data collection cycle. MMP patient sample sizes in the project areas range from 100 to 800 during 2011 (Appendix F).

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.

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%

It was determined that 400 is the minimum sample size for a state to obtain total population estimates with an acceptable level of precision (assuming a moderate design effect, or increase in variance of estimates due to using a multistage sampling design). 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 20 sampled states and the 6 separately funded cities in those states, in order 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 (assuming a moderate design effect) for subpopulations as small as 5% of the total population of interest.

E. Data Collection

For the 2011 data collection cycle, all project areas will conduct interviews for all participating sampled patients. Each project area also will perform medical record abstractions, and will collect minimal data elements on each sampled patient.

1. Personal Interview

The MMP interview is a face-to-face or telephone structured interview administered to sampled patients who consent. Interviews for the 2011 data collection cycle should begin as soon as the project area receives their patient sample or no later than July 1, 2011, and should be completed by April 30, 2011. All interview data should be sent to the DCC according to DCC submission schedules.

a. Interview instruments/applications

There are two instruments used to collect interview data for MMP: the Standard Questionnaire and Short Questionnaire. The Standard Interview takes approximately 45 minutes to complete and is available in English (Appendix G.1) and in Spanish (Appendix G.2). The Short Questionnaire is an abridged version of the Standard

Questionnaire and takes approximately 20 minutes to complete. The Short Questionnaire is available in English (Appendix G.3) and Spanish (Appendix G.4).

The 2011 Standard Questionnaire consists of 10 modules to be administered in all project areas: Preliminary Information; Demographics; Access to Health Care; HIV Treatment and Adherence; Sexual Behavior; Drug and Alcohol Use; Prevention Activities; Anxiety and Depression; Health Conditions and Preventive Therapy; and Gynecological and Reproductive History. An optional module, Acculturation Scale, is also available.

It is always preferable that the interview be completed during a single encounter. However, follow-up time may be scheduled to complete an interview if it cannot be completed during a single encounter. In the latter instance, the interviewer should attempt to complete the interview as soon as possible after the encounter in which the interview is initiated.

Electronic versions of all questionnaires will be provided by CDC for administration by means of a handheld-assisted personal interview (HAPI) , utilizing a device such as a personal digital assistant (PDA), or computer-assisted personal interview (CAPI) via a laptop computer. HAPI and CAPI interview applications were developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). Paper versions of the questionnaires will also be provided for administration of the interview in the event that a devices malfunction and HAPI or CAPI cannot be conducted. A complete checklist of all interview-related materials and equipment is provided in Appendix G.5.

i. Local questions

Project areas may choose to develop questions for local use. These questions are not part of the CDC MMP. However, because the addition of local questions can have an impact on MMP, CDC strongly recommends the following guidelines:

- The administration time for local questions should not exceed 10 minutes.
- If local questions pertain to subject matters that are sensitive or have potential legal implications (e.g. childhood or sexual abuse, suicide), the project area must ensure that interviewers are properly trained to deal with adverse events and are knowledgeable about and able to offer appropriate referrals.
- Local questions must be administered after all other interview questions are completed, at the conclusion of the MMP interview.
- A courtesy copy of all local questions in use by a project area should be provided to the CDC Project Officer.
- Local questions and data from local questions that are presented at scientific meetings, shared with colleagues for scientific input, used for publication in abstracts or journals, or disseminated in any other format should include a disclaimer indicating that such questions were developed by the respective state/local health department and are not part of the CDC MMP.

- Obtaining approval for the use of local questions (e.g. IRB approval or any other type of required approval, as applicable) is the sole responsibility of the project area.

b. Interviewees

i. Short Questionnaire

Unless circumstances preclude it, the Standard Questionnaire should be administered. Patients who are too ill to complete the Standard Questionnaire, but are able to complete an abridged version, may be administered the Short Questionnaire. All respondents administered the Standard or Short Questionnaire must provide appropriate consent prior to interview participation, in compliance with all state and local, and when necessary, facility-specific IRB guidance. See Appendices H.1 and H.2 for English and a Spanish translation of the "MMP Statement of Informed Consent" as example informed consent forms that could be used for this purpose.

Non-English, non-Spanish speaking patients requiring a translator should be administered the Short Questionnaire through the translator or interpreter (see section ii, subheading c entitled "**Interviews using an interpreter**". Project areas should follow their state or local IRB guidance regarding any consent forms or confidentiality agreements necessary for circumstances in which a translator or interpreter is required.

ii. Special populations

When interviewing a patient with hearing impairment, a sign language interpreter may be required. These instances should be treated as all other interpreted interviews (see below). Administration of the MMP interview questionnaire does not pose any special risk to pregnant women. While prisons are no longer included in the sample frame, the eligibility of incarcerated persons recruited at an eligible facility, yet residing in jail or prison, will be determined by the project areas according to local regulations and requirements.

c. Interviews using an interpreter

Persons considered to be acceptable interpreters for the MMP interview will vary by project area. Health departments may already have standards in place and some state or local IRBs may have specific requirements for interpreters. At a minimum, the interpreter must sign a confidentiality agreement in accordance with project area requirements.

All project areas should create standards for translated interviews and adhere to them throughout the data collection cycle. Reference material may be found at the Office of Civil Rights, Title VI. Additional information about Title VI and Limited English Proficiency or LEP guidance may be found on the Department of Health and Human Services website at http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/ .

Project areas should anticipate what non-English, non-Spanish languages they are likely to encounter, and what resources and arrangements they may need to make to secure an effective interpreter.
Below are some general guidelines for identifying appropriate translators/interpreters:

- The interpreter needs to be proficient in both English and the other language.
- The interpreter should be culturally competent and demonstrate that he or she is capable of accurately conveying information in both languages.
- The interpreter should be provided orientation and training that includes interpretation/interviewing skills, ethical considerations, and confidentiality considerations.
- Family members or friends of the patient must not be used as interpreters for MMP.

d. Interview locations

Interviews may be conducted in a variety of settings, including medical facilities; in the patient's home; in a hospital; at another, mutually agreed-upon location where security and confidentiality can be guaranteed.

e. Concluding the interview

Interviews will always be administered in a setting where the respondent's privacy and confidentiality is assured. At the end of the interview, participants will receive prevention materials and referrals to local prevention and care services; they will also be given the opportunity to ask the MMP staff questions about prevention methods. At the conclusion of the interview, participants will be reimbursed for their time.

f. Reimbursement

Participants will be reimbursed approximately $40 (this amount may differ by project area) either in cash or a cash equivalent, for their 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.

g. Interviewer training

CDC will provide participating state and local health departments with a manual containing detailed instructions on conducting MMP interviews. CDC will convene meetings in which lessons learned throughout the interview process are discussed by staff from all project areas.

h. Interview quality control and assurance

Automated edit checks will be built into the QDS software applications used to conduct MMP interviews in order to assure high quality data are collected. For additional quality assurance purposes, a minimum of 5% of interviews will be observed

by the project coordinator or other supervisory staff to ensure data quality and completeness. Periodic review of interviews also will ensure that interviewers use the same techniques in administering the questionnaire. Appendix I contains the MMP Interviewer Evaluation Form that may be used by project areas for this purpose.

i. Interviews conducted in other MMP project area jurisdictions

Sampled patients that have moved out of the jurisdiction of the project area from which they were sampled may be interviewed if circumstances allow. If the patient is still receiving care in the original project area's jurisdiction, it may be possible to interview the patient at their next appointment. If the patient has moved and is no longer receiving care in the original jurisdiction, then the following guidelines apply:

- If the patient has moved to an area that is not conducting MMP, the patient will not be interviewed, but the patient's medical records may be abstracted if the project area's surveillance authority allows them to do so.
- If the patient has moved to an area that is conducting MMP, the original project area may contact the new project area to determine whether an interview can be conducted by the new project area's MMP staff. It is up to the Principal Investigators of both areas to agree upon a protocol for recruiting the patient and obtaining informed consent. Procedures for patient contact, recruitment and interview must meet the IRB requirements of the new jurisdiction (to which the patient has moved and where the patient will be interviewed). For certain project areas, IRB restrictions from the original jurisdiction also may apply.

If the second condition is met, staff from the new project area should interview the patient and should submit the patient's data to ICF Macro through the DCC portal using the original project area's MMP Participant ID. CDC will store the data record for this participant in the appropriate data set (that of the original project area). Information in the DCC portal must be updated to reflect that that patient has been interviewed. An email should be sent to the DCC notifying them that there is an interview that belongs to another project area that has been submitted with your data. A descriptive flow chart for this process is in Appendix J. Regardless of whether an interview is administered, the original project area should collect minimal data and medical record abstraction data for this patient to the extent allowed by their surveillance authority.

2. Medical Record Abstraction

Patients who consent to participate in MMP will be interviewed first, and then their medical records will be abstracted after the interview is completed. Trained staff will abstract clinical data from medical charts using an electronic medical record abstraction application provided by CDC. Medical record abstractions for the 2011 data collection cycle should begin as soon as the project area receives the patient sample and conducts the first interview, or no later than July 1, 2011, and should be completed by April 30, 2011. All medical record abstraction data should be sent to ICF Macro.

The electronic medical record abstraction application consists of 4 modules, representing 4 data collection forms: Medical History Form; Surveillance Period Visit Form; Surveillance Period Summary Form; and Surveillance Period Inpatient Form. Information abstracted will reflect the patient's clinical condition and experience before and during the surveillance period. The information will be primarily related to the diagnosis of opportunistic illnesses and other HIV-related conditions, provision of preventive care, prescription of antiretroviral medications, laboratory results, and health services utilization. If a patient cannot be located for recruitment, the patient's medical record will be abstracted without interview, if allowed under local surveillance authority. In addition, if MMP is considered to be research by the local IRB in the project areaand a patient is known to have died before recruitment, a waiver of consent can be obtained for medical record abstraction *[HIPAA Privacy Rule 45 CFR 164.512(i)(1)(iii), which can be found at www.dhhstgov/ocr/privacy/hipaa/understanding/special/research/research.pdf]*,according to the project areas' discretion (i.e., local IRB requirements)

MMP will capture clinical data from facilities providing primary HIV care during the surveillance period (SP). For patients participating in the interview, the SP is the twelve months prior to the interview date. For sampled non-participants, the SP is the twelve months prior to the first attempt to recruit the patient for interview. Medical record abstraction for non-participants who are not known to be deceased will only occur in project areas where abstraction can be performed without consent from the patient. However, as previously mentioned, the medical records of deceased patients may be abstracted after obtaining a waiver of consent in those project areas where MMP is considered research by the local IRB. The SP for deceased patients is the twelve months prior to the date of death.

Whenever possible, medical record information should be obtained from **all** facilities where a participant has received medical care for HIV infection during the SP. Sources of information about where patients received care during the SP are as follows:

- Interviews – facilities at which the participant reported receiving care during the MMP interview are recorded on the interview facility visits log
- Medical records – during abstraction, references to medical care received at other facilities (e.g., hospital admissions, medical referrals, transfers) found in the medical record are recorded on the Surveillance Period Summary Form.

When it is not possible to conduct abstraction at all facilities that provided HIV care to a participant during the surveillance period, the following priority (in decreasing order) should be followed for abstractions:

- the facility where the participant was sampled
- the facility reported by the participant as being the primary provider of his/her medical care for HIV
- facilities where the participant received inpatient care during the surveillance period.

Information about the patient's medical history, and all information on care provided during the SP will be abstracted using the following modules in the electronic medical record abstraction application:

- A single Medical History Form (MHF), covering the period from the date of first medical care after HIV diagnosis to the date prior to the surveillance period start date, will be completed for every facility at which medical record abstraction is performed (see Appendix K.1).
- A Surveillance Period Summary Form (SPSF) will be completed once for each facility at which abstraction was performed. Information collected in the SPSF captures selected events, including those that are not likely to recur in the SP (e.g., Pap smear, pneumovax, pregnancy) and thus are not appropriate for inclusion on the SPVF (see Appendix K.2).

- A Surveillance Period Visit Form (SPVF) will be completed on each eligible outpatient visit the patient made to a given facility during the SP (see Appendix K.3).

- A Surveillance Period Inpatient Form (SPIF), will be completed for each inpatient stay during the SP (see Appendix K.4).

The personal identifying information used in recruiting and contacting patients will not be transmitted outside the project area; medical record abstraction form data received by the CDC will be identified only through the use of the Participant ID, the Facility ID, the form type, and (for Surveillance Period Visit Forms) the visit date.

Project areas will track abstractions of each patient's records using the DCC tracking system, which will be used to make sure all identified eligible facilities at which the patient had at least one health care visit (which was HIV-related or at one of the eligible facilities listed above) during the surveillance period have been recorded and abstractions have been completed at all assigned facilities.

a. Medical record abstraction training

CDC will provide training on conducting MMP medical record abstractions and on use of the medical record abstraction application and ICF Macro will provide training on data transfer. Detailed written instructions and guidance will be provided in an abstraction manual given to abstractors, as well as through the Call Center – a mechanism for abstractors to request help with specific abstraction or data management issues and receive technical assistance through the DCC. CDC will convene meetings in which lessons learned throughout the abstraction process are discussed by staff from all project areas.

b. Medical record abstraction quality control and assurance

MMP abstraction modules must be checked for completeness by project area supervisory staff prior to transfer to ICF Macro. For additional quality assurance purposes, a minimum of 5% of medical records will be re-abstracted by a second,

independent reviewer. The two abstractions will then be examined for discrepancies and compared for completeness. The medical records selected for re-abstraction will be from multiple facilities, representing the work of all abstractors, over varying periods of time.

3. Minimal Data

It is important to obtain information on every patient who was selected to participate in MMP in order to provide basic descriptive information regarding the population of inference. In addition, this information can be used to assess potential non-participation bias for the data collected through interview and medical record abstraction.

Ideally, interview and medical record abstraction data will be collected on each patient. If the patient refuses to participate in the interview, in project areas that have the surveillance authority to abstract the medical records of selected patients without their consent, medical record abstraction should be completed for these patients, in addition to those who are not interviewed because they cannot be located. In project areas where there is a more narrow definition of surveillance and medical record abstraction cannot be completed without patient consent (or the provider denies MMP staff access to the medical records), minimal data will be collected. Regardless of level of participation, minimum data should be collected on **all** sampled patients, including those persons for whom interview and medical record abstraction data is obtained. The minimum data set will contain the same fields as the HARS case report form, and therefore these data can be collected in all project areas under their HIV/AIDS surveillance authority. In order to appropriately assess non-participation bias, these data should ideally be collected from a single source within each project area; this source should be HARS/eHARS. A form displaying the data fields in the minimum data set is provided in Appendix L. If the data cannot be collected via HARS/eHARS, MMP project area staff will ask the facility to complete the MDS form (Appendix L). .

CDC will provide project areas with a SAS program that should be used to extract MDS data from eHARS and an Excel workbook with all Participant IDs for all sampled patients. All project areas will need to identify and add the HARS/eHARS ID number (stateno) for each sampled patient. The SAS program will read the CDC supplied Excel workbook which includes the statenos and will generate the minimum data set in two formats - an Excel workbook and a SAS file. Two copies of each of these files are generated by the SAS program: one copy will include the patient's stateno and should remain at the project area only; it should <u>not</u> be sent to ICF Macro. The other copy of the SAS and Excel minimum data set files will exclude the statenos and should be transmitted to ICF Macro using a secure data network.

III. Data Management and Analysis

Four types of data will be collected for MMP: tracking data, interview and abstraction data, and minimal data for the minimum data set. The <u>tracking data</u> consist of information collected in order to select and recruit facilities and patients for

participation in MMP, and will be used to inform project staff regarding progress and to create statistical weights for data analysis. The interview data and abstraction data consist of the information about selected patients obtained through conducting interviews and abstracting medical records. The minimum data set consists of very basic demographic and clinical data, and will be collected for all selected patients in order to obtain data on everyone sampled. These minimal data will be extracted from a single source (eHARS). The tracking, interview, abstraction, and minimum data set data will be used by ICF Macro to create analytic data files, which will be used by the CDC and the project areas to describe the populations of HIV-infected patients receiving medical care and address project-related questions. All data management and transfer for the 2011 cycle are within the scope of the Data Coordinating Center contract with ICF Macro. All data analysis for MMP will be conducted by CDC and/or project areas.

The purpose of the Data Coordinating Center (DCC), managed by ICF Macro, is to implement a data management system (DMS) to provide MMP project areas with a secure web based data portal system through which project areas can submit data to CDC, revise submitted data sets, and receive final data from CDC. The system also allows the project areas and CDC staff to track critical respondent and medical record abstraction (MRA) activities. The DCC data portal is equipped with an access control system that supports different levels of access so that the project areas can see only their own data, and unauthorized use can be prevented. The three main features of the DMS are the data portal, which enables data to be uploaded and downloaded, the tracking component, and the reporting component. Each of these features has a specific function:

- The data portal provides project areas with a secure web-based mechanism by which they can submit interview data, data changes, and MRA data. The data portal also allows project areas and CDC to track the status of data submissions, provide transfer of data error reports between the DCC and project areas, and enable project areas and CDC to download the most recent data sets. In addition, the data portal provides access to the respondent tracking component. The respondent tracking component of the data management system assists project areas in managing contacts with sampled facilities, interview assignments, respondent dispositions, and MRA assignments.
- Finally, the DCC data portal provides the project areas and CDC with management-level reports that include information on data collection status at each project area such as number of completes, number of refusals, number lost to follow-up, number ineligible for participation. Reports will be available by project area and in aggregate.

Data management procedures performed by the DCC have been implemented using standard data processing and analysis tools such as SQL and SAS that will process all incoming data, generate error reports, incorporate data changes, and produce the necessary management reports required by CDC. The system also incorporates a secure web-based interface that allows CDC and project area staff to easily submit data, track project area activities, retrieve data sets and reports.

A. Data Management

1. Tracking data

Various elements of tracking information will be collected during the following phases of MMP conduct: project area sampling, facility sampling, facility recruitment, patient sampling, patient recruitment, interview, medical record abstraction, and acquiring minimal data. Examples of tracking data include EPLs for all facilities determined to provide HIV care in the project area, facilities selected to participate in MMP, PDP PLs at participating facilities, and interview status for sampled patients who agree to participate.

This data tracking system, which is part of the DCC data portal, is accessed only by a limited number of users at each project area and at CDC, using a secure digital identification system. Information that identifies patients, such as name or patient medical record number, is not sent to CDC or to ICF International.

Tracking data is collected and stored by each project area using a system developed by ICF Macro via the DCC data portal. In addition to delivering the tracking system, Macro is also responsible for providing any technical assistance to project areas on how to use the tracking system.

2. Personal interview data

Interview data will be collected with either HAPI or CAPI, using an MMP interview application which has been developed by CDC using the QDS software. In rare instances, interview data may be collected using paper forms, such as in the event of device failure. In these cases, the data will be entered using a hand-held or laptop computer as soon as is feasible.

Interview data will be stored in, and uploaded from, the electronic devices as two QDS data files with the extension .QAD [the standard questionnaire (including completion module) and local questions (if applicable). Upload procedures have been demonstrated via CD and described in written documentation, which have been provided to each project area. Multiple interview records may be contained in each .QAD file. The .QAD files will correspond to two types of information which are collected and stored during the interview: core data, (all questionnaire modules except the local questions) and the local question data. The local question .QAD files will be kept only at the project area for local use – this local question data file will <u>not</u> be sent to CDC or ICF Macro.

The filenames of the interview .QAD files will be automatically generated by the QDS software, and will include the project area abbreviation, whether the data were collected via HAPI or CAPI, the data collection cycle, type of data, and the date and time the .QAD file was created. In order to uniquely identify each file, each file name

also will include the identification number of the electronic device with which the data were collected as specified below.

The project area abbreviations for state and local project areas are provided in Appendix C. The device code is a three digit code unique to the device (such as 073) used to collect the data. The date part of the file name will be the eight digit date when the file was created (e.g., 02152006 for February 15, 2006), and the time part will be the hour, minute and second the file was created (e.g., 172347 for 5:23:47 pm).

The uploaded .QAD data files will be saved onto a secure network computer drive, which will serve as the physical storage location of all interview and abstraction data files for the project area. The file folder structure used on this drive will be based on guidelines provided by CDC. Interview data will be uploaded from the electronic devices on a daily basis, or as soon as is feasible for staff who must travel long distances to collect the data.

In instances where the project area is using contract or regional surveillance staff to collect MMP data in certain locations, the project area will ensure that a secure data system with data encryption software is available at the contract or regional site. Interview data collected by contract or regional staff will be encrypted and transmitted to the central project area location on a periodic basis, using protocols to verify record-specific transmission and receipt. These data then will be stored on a secure drive as described above. Project area staff must back up and store the .QAD files on a periodic basis.

Once the data are transferred to the secure drive, project area staff will perform quality assessment reviews of each data record, including checks for duplicate records, incomplete records, and inappropriate data values, using software applications and/or programs supplied by CDC. The applications will allow staff to review each record visually and export the data to an external file that can be accessed using standard data management and analysis software such as MS Access and SAS. Any data revisions identified will be documented and transmitted to ICF Macro via the DCC data portal.

Copies of recently uploaded interview .QAD files will be sent to the DCC data portal on a periodic basis via a secure network using encryption software that has been provided to project areas (or using other approved encryption software). No facility or patient identifiers, other than MMP-specific IDs, will be transmitted to CDC or ICF Macro, and no data from local questions will be sent to CDC or ICF Macro.

Once the data files are received by the DCC, additional quality assessment programs will be implemented that will compare tracking and interview information and produce reports specifying any discrepancies found. These reports will be provided to the project area, and after project area review any corrections to be made to the data will be entered on the interview data change list. The updated cumulative change lists will be entered in the DCC data portal, documented, and the updates will be made to the data. The change lists may also be used by the project area to update the interim interview data files maintained locally. For information on the standard naming

conventions for interview data, please refer to the Medical Monitoring Project Data Management Manual.

3. Medical record abstraction data

Medical record abstraction data will be collected with using laptop computers, using an application which has been developed by CDC using the Net software. In rare instances, abstraction data may be collected using paper forms, such as in the event of device failure. In these cases, the data will be entered using a laptop computer as soon as is feasible.

Data from the electronic medical record abstraction tool will be exported in a standardized format and structure, encrypted, and then uploaded to the DCC portal. Once at the DCC portal, the data will be decrypted, cleaned, and processed according to CDC guidelines. As part of this processing, the medical record abstraction data will be linked to patient interview data. The processed data will be provided to CDC and to the project areas in a timely manner following the close of data collection.

The uploaded data files will be saved onto a secure network computer drive, which will serve as the physical storage location of all interview and abstraction data files for the project area. The file folder structure used on this drive will be based on guidelines provided by CDC. Abstraction data will be uploaded from the electronic devices on a daily basis, or as soon as is feasible for staff who must travel long distances to collect the data.

In instances where the project area is using contract or regional surveillance staff to collect MMP data in certain locations, the project area will ensure that a secure data system with data encryption software is available at the contract or regional site. Abstraction data collected by contract or regional staff will be encrypted and transmitted to the central project area location on a periodic basis, using protocols to verify record-specific transmission and receipt. These data then will be stored on a secure drive as described above. Project area staff must back up and store the files on a periodic basis.

Once the data are transferred to the secure drive, project area staff will perform quality assessment reviews of each data record, including checks for duplicate records, incomplete records, and inappropriate data values, using software applications and/or programs supplied by CDC. The applications will allow staff to review each record visually and export the data to an external file that can be accessed using standard data management and analysis software such as MS Access and SAS. Any data revisions identified during this initial project area review will be documented and transmitted to CDC or ICF Macro on an abstraction data change list, using a template provided by CDC for this purpose.

Copies of recently uploaded abstraction files will be uploaded to the DCC data portal on a periodic basis via the secure network using encryption software that has been provided to project areas (or using other approved encryption software). No

facility or patient identifiers, other than MMP-specific IDs, will be transmitted to CDC or ICF Macro, and no data from local questions will be sent to CDC or ICF Macro.

Once the data files are received, additional quality assessment programs will be implemented that will compare tracking and abstraction information and produce reports specifying any discrepancies found. These reports will be provided to the project area, and after project area review any corrections to be made to the data will be entered on the abstraction data change list. The updated cumulative change lists will be sent to CDC or ICF Macro, documented, and the updates will be made to the data stored at CDC. The change lists may also be used by the project area to update the interim abstraction data files maintained locally. For information on the standard naming conventions for interview data, please refer to the Medical Monitoring Project Data Management Manual.

4. Minimal data

The goal of MMP is to collect interview and medical record abstraction data on all sampled patients. For sampled patients who refuse to be interviewed or whom project staff are not able to locate, project areas should collect minimal data. This minimal data will be obtained for **all** sampled patients (see Appendix L).

Minimal data include basic demographic information, such as sex and age, and a very limited number of clinical fields (first CD4 count and viral load). Minimal data will preferably be extracted from the project area HARS/eHARS using SAS programs provided by CDC. In situations where the Minimal data cannot be extracted from HARS/eHARS, the data may also be collected directly from the facilities. As the minimum data set information is collected, copies of the data files without statenos and with the _CDC_ included in the file names will be sent to CDC via the SDN. The file names for these data will use naming conventions similar to those for the interview data:

AreaAbbreviation_*cycle year*_MDS_CDC_mmdd*yyyy*.xls (Excel workbook)

*AreaAbbreviation_cycle year*_MDS_CDC_mmdd*yyyy*.sas7bdat (SAS data file)

Minimal Data for the 2011 data collection cycle should be completed and sent to ICF Macro by the end of the data collection period.

5. Analytic data

The interview, medical record abstraction, and minimal data will be linked by ICF Macro using the MMP Participant ID. A SAS analytic file containing each project area's data also will be created by the DCC. The appropriate SAS analytic file will be sent to each project area via the DCC data portal after the data collection cycle has ended. The SAS analytic data files for all MMP project areas will be used to create MMP national analytic files. The project area files as well as the national files will contain both 'raw' and computed variables. 'Raw' variables values represent the direct untransformed responses to items on the interview questionnaire and abstraction forms. Computed

variables values are the result of calculations performed on ‘raw’ and/or other computed variables.

B. Data Analysis

Project areas will have the primary responsibility for analysis and use of data at the state and local levels, and for developing reports based on individual and/or combined project area data. CDC will be responsible for analysis of these data at the national level, as well as for developing annual reports based on data collected across all project areas.

The MMP project area and national data will be analyzed using the sample survey procedures contained in the SAS version 9.1.3 (or higher) software package (SAS Institute, Inc., Cary, NC) and using SUDAAN software (Research Triangle Institute, Research Triangle Park, NC). These or similar software packages must be used for MMP data analysis in order to produce valid population estimates from the MMP data.

IV. Security and Confidentiality of MMP Data

MMP data will be subject to the same security and confidentiality requirements as those implemented for HIV/AIDS surveillance data at state and local project areas, as well as at CDC. These requirements include adherence to CDC guidelines for the security and confidentiality of HARS data. Specifically, MMP interviewers, abstractors, and data managers will undergo the same security and confidentiality training as that required for health department staff who conduct HIV/AIDS surveillance. While conducting MMP, protocols will be strictly followed at the project area and national level to ensure the integrity, confidentiality, and security of all MMP data.

Security and confidentiality of 2011 cycle data is within the scope of the ICF Macro Data Coordinating Center Contract. Macro will adhere to the Guidelines for HIV/AIDS Surveillance – Security and Confidentiality. In addition, all software developed by Macro for MMP (Phase III) will adhere to CDC Confidentiality and Security Guidelines.

HIV and AIDS case surveillance data are currently collected according to the Assurance of Confidentiality under Sections 306 and 308(d) of the Public Health Service Act (42 U.S.C. Sections 242k and 242m(d)). Information collected in the surveillance system that would permit identification of any individual or establishment is collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual or the establishment in accordance with Section 306 and 308(d) of the Public Health Service Act. Because data collected for the MMP constitutes

enhanced surveillance activity, these data will be reported to and maintained by CDC in the same manner as are current HIV and AIDS surveillance data, and accordingly are covered by the existing Assurance of Confidentiality.

MMP interview and abstraction data records will not contain specific participant identifiers (e.g., name, address, social security number) and are linkable to HARS only through the HARS surveillance numbers. No specific identifiers will be included on the data collection instruments. Paper forms, when used, will be filed by the unique ID and date of interview and stored under lock and key; information collected on paper will be entered into the appropriate data system at the project area and the paper forms will be destroyed 6-12 months after the data collection cycle has ended. Lists of HARS numbers linking MMP data to specific identifiers (e.g., the facility or patient name) will be kept under lock and key, and destroyed once they are no longer needed; access to them will be strictly limited. If signed informed consent forms for MMP are required, these will be securely stored separately from the data collection instruments, preferably at the central eHARS office of the project area, under the same security procedures as those for eHARS surveillance forms.

The QDS software that will be used to collect the interview data supports the ability to encrypt response data and password-protect interviews and abstractions so that unauthorized users are unable to view, export, or modify collected data.

Security of the data files while on the electronic data collection devices is enhanced by the use of individual passwords, which are known only to the user and to data managers at the project area and CDC.

The interview data warehouse for each project area will be stored on the area's HIV/AIDS surveillance data drive, which is located on a secure server with limited access. Frequent backup of the interview and abstraction records will be performed by the project area using protocols developed by CDC. Project areas upload data on a monthly basis to the DCC data portal. The DCC has 1 month from receipt of project area data to upload a cumulative project area specific data set to the data portal. Project areas will be able to download data from the data portal on a monthly basis. The DCC will also post project area specific reports on the data portal which can only be accessed by the CDC and the project area.

V. Human Subjects Considerations

A. Non-research Determination

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 (Appendix M). 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.

MMP project areas should follow state and/or local procedures to determine whether the MMP protocol 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.

IRB approval of MMP also may need to be obtained at the facility level. In these instances, the project area's Principal Investigator should identify an appropriate provider to present the protocol to the facility IRB, if necessary, and assist the provider by preparing required documentation and attend the IRB presentation to address any concerns that may arise. The IRB approval and renewal dates for each facility must be kept on file in every project area. A template for this purpose will be provided by CDC.

B. Anticipated Risks and Benefits

Participation in MMP presents no more risks to patients than those that might occur outside the context of surveillance. Non-surveillance contexts include participation in individual or group HIV prevention activities and interactions with HIV prevention and health care providers in public or clinical settings.

Participating patients may benefit from participating in MMP by better recognizing their own risks for transmitting HIV or other sexually transmitted infections, talking with trained staff about how to reduce those risks, learning more about local HIV prevention efforts, and obtaining prevention materials and referrals for health care, social, and prevention services. MMP participation will benefit communities by helping HIV prevention and care planners more appropriately allocate state and local HIV prevention resources and federal, state, and local HIV care services.

C. Vulnerable Populations

Persons under the age of 18 will not be included in MMP. Pregnant women may be included in MMP if they are sampled from a participating facility. Persons with mental disabilities may be included in the patient sample; however, any person alive at the time of interview who cannot provide informed consent will be excluded from participation in the project. All participants will be afforded the same human rights protections.

D. Adverse Events

No serious adverse events are anticipated as a result of this project. Potential adverse experiences are expected to be rare and limited to emotional distress resulting from concerns about patient confidentiality. Although unlikely, it also is possible that participants may experience anxiety or emotional distress when responding to interview questions on sensitive topics such as health status or sexuality.

Potential adverse experiences are most likely to be identified during initial contact with potential participants or during the consent and interview process. Patients will first be contacted in person or by telephone; the wording of the contact scripts will be

developed by MMP staff in local project areas and will use language that includes assurance of confidentiality. Local informed consent forms will incorporate the language used in the standard informed consent form approved by CDC and, as appropriate, the local IRB, which also includes assurance of confidentiality and the person to contact if an adverse event occurs.

Interviews will be conducted by local public health personnel trained to respond appropriately to concerns about the security and confidentiality of the information collected. Project interviewers also will be trained in interview techniques for sensitive topics. Project interviewers or the adverse-event contact (depending on the interviewer's training and expertise) will be able to refer patients to psychiatric care or a social service agency if necessary. The local MMP Principal Investigator and the patient's health care provider will supervise all referral activities performed by project staff.

Project areas should develop procedures for dealing with adverse events that meet the requirements of their governing institutions and/or IRBs, which should include procedures for reporting adverse events. Project areas should report all serious adverse events to CDC within 24 hours of occurrence. All adverse events, regardless of severity, should be reported to CDC within two weeks.

E. Informed Consent

Informed consent for the interview must be obtained according to the federal Assurance of Confidentiality requirements and as required by state and local IRBs for participating project areas. Informed consent may be obtained by any of the following methods:

- The participant reads and signs the informed consent form.
- The interviewer reads the form to the participant and asks the participant to sign the form.
- The interviewer reads the form to the participant or the participant reads the form and the interviewer indicates on the form that the participant provided oral consent.

Participants should be advised, when consent is obtained for interview, that information from their medical records also will be collected and analyzed along with their answers to the interview questions. In many project areas, state legal surveillance authority will allow surveillance staff to collect medical record information even if the patient declines to participate in the MMP interview, and in those instances medical records should be abstracted. In project areas where this is not possible, only minimal data will be obtained for those patients for whom neither interview nor medical record abstraction data were collected.

Patients who are too ill to complete the Standard Questionnaire, but are able and willing to complete an abridged version, may be administered the Short Questionnaire. Likewise, patients requiring a translator should complete the Short Questionnaire through the translator. Informed consent should be obtained from the participant in both cases. The Statement of Informed Consent (Model Consent Form) are two examples of

consent forms, one in English and one in Spanish that can be modified for local area use (Appendices H.1 and H.2, respectively). Project areas should follow their own regulations regarding any consent forms or confidentiality agreements necessary for a translator.

Project areas should modify the templates of the consent forms to fulfill the requirements of their IRB. These consent forms should also be modified to be used by hearing and visually impaired participants.

All project areas must maintain a secure file of informed consent forms to document that informed consent was obtained for each participant.

VI. Data Dissemination

A. Notifying Providers, Patients and the Community of Findings

Data from MMP are expected to improve surveillance activities, contribute to prevention programs and treatment services, provide information about unmet needs in HIV care, and increase knowledge about medical care for persons with HIV. Results are also expected to guide national surveillance efforts, particularly in the use of both self-report and medical abstraction information by increasing our understanding of conditions that were difficult to assess by using only interview data or only medical record abstraction. Because MMP is a surveillance system that represents HIV-infected persons in the United States, it will be imperative to notify the project areas and stakeholders of the findings of this project as soon as they are available.

Most of the results are expected to be useful at the local level; other results will be more meaningful after the data from all project areas have been aggregated. Each project area will have responsibility for the release of local data. CDC will have primary responsibility for the release of data aggregated from the project areas and will provide this information. These data will be distributed to the providers, researchers, policymakers, and other interested persons through presentations at local, national, and international conferences, publications in peer-reviewed journals, and presentations at forums such as continuing medical education courses and seminars. Furthermore, CDC will regularly publish surveillance reports based on the data collected annually.

Patients and community members will be informed of MMP findings through multiple conduits. National data results will be released on the CDC's MMP Web site and through national publications and presentations at conferences. Similarly, local data results will be reported to the community through multiple channels, such as local publications, epidemiologic profiles, and presentations to local AIDS service organizations and community planning groups and at conferences and workshops.

All project areas are encouraged to provide a copy of all MMP data releases (abstracts, publications, fact sheets, etc.) prior to the date of data release.

VII. References

1. Farizo K, Buehler J, Chamberland M, et al. Spectrum of disease in persons with human immunodeficiency virus in the United States. *JAMA* 1992; 267:1798–1805.

2. Chu S, Hanson D, Ciesielski C, Ward J. Prophylaxis against *Pneumocystis carinii* pneumonia at higher CD4+ T cell counts. *JAMA* 1995; 155:1537–1542.
3. Centers for Disease Control and Prevention. Guidelines for preventing opportunistic infections among HIV-infected persons—2002: recommendations of the U.S. Public Health Service and the Infectious Diseases Society of America. *MMWR* 2002; 51(RR-8):1–46.

4. Jones J, Hanson D, Chu S, et al. Toxoplasmic encephalitis in HIV-infected persons: risk factors and trends. *AIDS* 1996; 10:1393–1399.

5. Jones J, Hanson D, Dworkin M, Kaplan J, Ward J, and the Adult/Adolescent Spectrum of Disease Group. Trends in AIDS-related opportunistic illnesses among men who have sex with men and among injecting drug users, 1991-1996. *J Infect Dis*. 1998; 178:114-120.

6. Kaplan J, Hanson D, Navin T, Jones J. Risk factors for primary *Pneumocystis carinii* pneumonia in human immunodeficiency virus–infected adolescents and adults in the United States: reassessment of indications for chemoprophylaxis. *J Infect Dis* 1998; 178:1126–1132.

7. Buehler JW, Diaz T, Hersh BS, Chu SY. The supplement to HIV-AIDS surveillance project: an approach for monitoring HIV risk behaviors. *Public Health Rep* 1996; 111(suppl 1):134–137.

8. Diaz T, Chu SY, Byers RH, et al. The types of drugs used by HIV-infected injection drug users in a multistate surveillance project: implications for intervention. *Am J Public Health* 1994;84:1971–1975

9. Wortley PM, Chu SY, Diaz T. HIV testing patterns: where, why, and when were persons with AIDS tested for HIV? *AIDS* 1995; 9:487–492.

10. Greene VA, Chu SY, Diaz T, Schable B, and the Supplement to HIV/AIDS Surveillance Project Group. Oral health problems and use of dental services among HIV-infected adults. *J Am Dent Assoc* 1997;128:1417–1422.

11. Diaz T, Chu SY, Weinstein B, Mokotoff E, Jones TS, and the Supplement to HIV/AIDS Surveillance Project Group. Injection and syringe sharing among HIV-infected injection drug users: implications for prevention of HIV transmission. *J Acquir Immune*

Defic Syndr Hum Retrovirol 1998;18(suppl 1):S76–S81

12. Sorvillo F, Kerndt P, Odem S, Castillon M, Carruth A, Contreras R. Use of protease inhibitors among persons with AIDS in Los Angeles County. *AIDS Care* 1999;11:147–155.

13. Lansky A, Nakashima AK, Jones J, and the Supplement to HIV/AIDS Surveillance Study Group. Risk behaviors related to heterosexual transmission from HIV-infected persons. *Sex Transm Dis* 2000;27:483–489.
14. Johnson DF, Sorvillo FJ, Wohl AR, et al. Frequent failed early HIV detection in a high prevalence area: implications for prevention. *AIDS Patient Care and STDs* 2003;17:277–282.

15. Campsmith ML, Nakashima AK, Davidson AJ. Self-reported health-related quality of life in persons with HIV infection: results from a multi-site interview project. *Health and Quality of Life Outcomes,* 2003;1:12.

16. Sullivan PS, Karon JM, Malitz FE, et al. A two-stage sampling method for clinical surveillance of persons in care for HIV infection in the United States. *Public Health Rep*. 2005 May-Jun; 120(3):230-9.

17. Shapiro MF. National probability samples in studies of low prevalence diseases, I: perspectives and lessons from the HIV cost and services utilization study*. Health Serv Res* 1999; 34:951–968.

18. Frankel M. National probability samples in studies of low prevalence diseases, II: designing and implementing the HIV cost and services utilization study. *Health Serv Res* 1999; 34:969–92.