

# **Medical Monitoring Project 2008 Protocol**

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## Abbreviations, Acronyms, and Definitions

|                                   |   |
|-----------------------------------|---|
| <b>2008 data collection cycle</b> | The period of time during which MMP interview and medical record abstraction data will be collected for the 2008 patient sample. This period of time is from May 1, 2008 through May 31, 2009.  |
| <b>Abstraction application</b>    | Software program for collecting MMP medical record data on laptop computers developed by CDC utilizing Visual Basic.net and a Microsoft database engine.  |
| <b>ASD</b>                        | Adult/Adolescent Spectrum of HIV Disease  |
| <b>CAPI</b>                       | Computer Assisted Personal Interview – A method of administering interviews in person using a personal computer, typically either a laptop or tablet personal computer.   |
| <b>Computed variables</b>         | Computed variables have values that are the result of arithmetical or logical manipulations performed using values from other, pre-existing variables.  |
| <b>Design effect</b>              | 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.   |
| <b>EPL</b>                        | 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), laboratory reports of HIV-related tests, and facility contacts, and are used to select eligible facilities for MMP participation.   |
| <b>Facility</b>                   | 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.

|                         |  |
|-------------------------|--|
| <b>HAPI</b>             | Handheld Assisted Personal Interview – A method of administering interviews in person using a hand-held personal computer.   |
| <b>HARS</b>             | HIV/AIDS Reporting System  |
| <b>HIV medical care</b> | 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 2008 data collection cycle. |
| <b>IRB</b>              | Institutional Review Board   |
| <b>MHF</b>              | Medical History Form   |
| <b>MMP</b>              | Medical Monitoring Project   |
| <b>MRA</b>              | Medical Record Abstraction   |
| <b>Minimum data set</b> | Basic core surveillance information obtained for all sampled patients. This information will be obtained from HARS (or from the facility through which the patient was selected under very limited circumstances). These data are referred to as minimal data.   |
| <b>PDP</b>              | 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 2008 data collection cycle is the 4 month period from January 1 – April 30, 2008.   |
| <b>PDP PL</b>           | 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.  |
| <b>PPS</b>              | 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 2008 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 personal laptop and hand-held 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 transfer of all MMP data (such as sampling frames, workbooks, interview data, etc.) between project areas and CDC.



|                                 |   |
|---------------------------------|---|
| <b>SHAS</b>                     | Supplement to HIV/AIDS Surveillance   |
| <b>SHDC</b>                     | Survey of HIV Disease and Care  |
| <b>SHDC-Plus</b>                | Survey of HIV Disease and Care Plus   |
| <b>Short-form questionnaire</b> | 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.   |
| <b>SPIF</b>                     | Surveillance Period Inpatient Form  |
| <b>SPSF</b>                     | Surveillance Period Summary Form  |
| <b>SPVF</b>                     | Surveillance Period Visit Form  |
| <b>Standard questionnaire</b>   | Unabridged form of the questionnaire  |
| <b>Surveillance Period</b>      | 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.<sup>1</sup> 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.<sup>2-6</sup>

The need for data on HIV-infected persons' risk behaviors and their 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.<sup>7</sup> 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.<sup>7-15</sup>

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 United States.<sup>16</sup> 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  
Maryland Department of Health and Mental Hygiene  
Massachusetts Department of Public 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  
South Carolina Department of Health & Environmental Control  
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)
- 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 1 community representative and 1 provider representative from each of the 26 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 the RAND Corporation to provide methodological, statistical, and operational advice. RAND conducted the HIV Cost and Service Utilization Survey (HCSUS), the only other nationally representative survey of HIV-infected persons in care conducted in the United States.<sup>17, 18</sup>

#### **D. Initiation, Duration, and Project Period**

This project was initially funded for 4 years (mid-2004 through mid-2008). A cost extension was approved to extend funding through mid-2009. 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. All 26 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 will take place in year 5 (patients in care in 2008); data collection for this 2008 cycle will terminate on May 31, 2009. The project will be extended for an additional 5 years (2009-2014).

## **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 2008 data collection cycle, the PDP is uniform across all project areas and extends from January 1 through April 30, 2008.

### **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. The decision was made to include the six areas separately funded for other surveillance activities (Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco) 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 2008 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 also should be excluded from the FSF. Veterans Administration (VA) facilities in every project area are eligible for participation and must be included on the 2008 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 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 old at the beginning of the PDP; and (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 United States. 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 for the 2008 data collection cycle, a sample of eligible outpatient facilities providing HIV care in each of the project areas will be selected during early to mid-2008. The measure of size for PPS sampling of 2008 facilities will be the number of eligible HIV-infected patients who received care at the facility during either the most recent 4 month reporting period for which measure of size data are complete, or the 4 month period from January 1 to April 30, 2007 with appropriate adjustment for anticipated deviations in staffing or other facility-specific factors projected to occur between that time and the 2008 PDP. 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 United States 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 in which subsequent stages of sampling are conducted annually. See Appendix A for more information regarding first stage selection.

## **2. Second-Stage Sampling**

During the second stage of sampling for the 2008 data collection cycle, outpatient facilities known to provide HIV medical care to adults will be sampled separately within each funded project area. A facility is defined as any clinic, health care facility, group or private physician practice, or grouping of these entities in which medical records or a medical records system is shared.

### **a. Constructing the sampling frame of facilities**

In each funded project area, the FSF previously constructed for each project area, which was used to select the 2005 (for project areas that collected data during the 2005 cycle) and 2007 facility sample, will be updated 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. Because facilities will be sampled PPS, a timely estimate of the number of HIV-infected adult patients in care at each facility during the PDP (i.e., the estimated patient load [EPL]) must be included on the frame for each facility.

All project areas are funded to collect data during the 2008 project period. The January 1 through April 30, 2008 PDP will be the same across all project areas. The following information briefly describes how to update the previously constructed FSF for 2008 facility selection. For more detailed information, please refer to Appendices B.1 through B.5.

### **i. Developing a list of eligible facilities**

To update the FSF, project areas start by reviewing the most recent version of the FSF which was used to select the 2005 (for project areas that collected data during the 2005 cycle) and 2007 facility sample. This frame was developed using an initial list of facilities that reported patients with HIV or AIDS to HARS. However, because the goal for this stage of sampling is to have a complete list of facilities known to provide HIV medical care in each project area, during previous development of the FSF this facility list from HARS was supplemented with lists of HIV care facilities from other data sources. These supplemental sources may have included state or local laboratory reporting databases (which give information on providers who order laboratory tests), and state or local databases for particular programs such as the AIDS Drug Assistance Program (ADAP) (which includes information on providers prescribing antiretroviral drugs), Medicaid (which includes information on providers from claims for payment for HIV care), or prescription drug lists (which include information on prescribers of antiretroviral drugs). HIV medical association membership lists also may have been

used. Note that some of these sources listed individual providers, rather than facility names, and associating individual providers with facilities may have required additional effort.

Once the lists of facilities from HARS and each of the supplemental sources were obtained, cleaned, and standardized, they were combined into a single FSF for each project area, on which each facility only appeared once. Any outpatient facility that met the MMP facility definition and was a known provider of HIV medical care during the recent time periods used for each data source was eligible to be included on the FSF. This may have included facilities that had not seen an HIV patient during the EPL time frame (i.e., they had an EPL of 0).

For the purposes of FSF construction and updates, HIV medical care is defined as requesting CD4 and/or HIV viral load testing, and/or providing prescriptions for antiretroviral medications. Thus, facilities providing HIV care could include outpatient facilities such as hospital-affiliated clinics, free-standing clinics or private physician offices. VA facilities also are considered eligible for the 2008 data collection cycle, although in 2005 and 2007 their inclusion was optional and varied by project area.

Facilities that are known not to provide HIV-related medical care, such as counseling and testing sites, should have been excluded from the FSF. Other facilities that should have been excluded from the FSF are emergency departments, inpatient facilities (including inpatient psychiatric and drug treatment facilities), facilities located outside the funded project area, facilities that have closed, federal penitentiaries, and health facilities located on military installations. Facilities that provided HIV care only to patients under the age of 18 also should have been excluded from the FSF. A separate list of excluded inpatient and other ineligible facilities should have been kept by each project area.

## **ii. Updating the list of eligible facilities for the 2008 data collection cycle**

For 2008 facility sampling, the list of eligible facilities must be updated to include all eligible facilities within a project area's jurisdiction that will potentially provide HIV care to HIV-infected patients during the 2008 PDP. In order to update the previous FSF, project areas first should review all records entered into HARS 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 HARS, used to identify facilities for the first FSF (i.e., the data sources that provided the most facilities not also found in HARS), 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 for the 2005 and 2007 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 2008 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 2008 cycle. Although correctional facilities such as prisons and jails are not eligible for selection in 2008, 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.

### **iii. Creating a matrix of EPLs from each data source**

The EPL is an estimate of the actual number of eligible patients which will be seen at a facility during the PDP for a given data collection cycle. For each data source used during previous FSF development 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 2005 and/or 2007 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 2008 data collection cycle, a new matrix of 4 month EPLs should be created using the more recent data from each data source as well as from facility contacts. Four month, rather than 1 year, EPLs should be used to more accurately reflect the patient load for the January 1 through April 30, 2008 PDP. A 4 month EPL from the most recent reporting period, or from January 1 through April 30, 2007 if more recent information is not available, should be obtained from all facilities that have been determined to be eligible for MMP. Because the EPL is an estimate of the 2008 PDP patient load, which is later in time, if January – April 2007 is used to derive facility contact EPLs, the project area also should ascertain whether it is likely the facility's patient load during the 2008 PDP may be higher or lower than the patient load for the same 4 month period during 2007. If so, the facility staff should provide an estimate of the extent of the anticipated deviation, and the EPL included on the updated matrix should be adjusted by this inflation/deflation factor if necessary.

### **iv. Selecting the best EPL for each facility**

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 for 2008, 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 updating the 2008 FSF.

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

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 person's selection probability across all three sampling stages. Small facilities will be identified prior to 2008 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 2008 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.

**c. Selecting the sample of facilities**

Each project area will send its final, updated matrix of 2008 EPLs (including the designated best EPL for each facility) to CDC through the Secure Data Network (SDN). 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, with input from RAND consultants, will select the PPS sample of facilities. In most project areas, 25 to 50 facilities will be sampled for the 2008 MMP data collection cycle. 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.

#### **d. 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. 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 2008 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.

The goal of MMP is to obtain participation from all sampled facilities. The generalizability of a probability sample depends on an acceptable response rate. The validity of population estimates from MMP will be questionable if the overall response rate is less than 80%. Therefore, overall response rates of at least 80% 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 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.

### **3. Third-Stage Sampling**

At each participating facility, eligible patients will be sampled for inclusion in MMP. Patients will be sampled from lists of patients seen at each facility during the PDP, i.e., January 1 through April 30, 2008. 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.

#### **a. Constructing the patient sampling frame**

A list of HIV-infected adults who received medical care during the 2008 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 (e.g., patients seen for care early 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, 2008). 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.

#### **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 CDC. 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 2008 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 2008 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, a copy of this file should be made in preparation for transmitting the patient lists to CDC. The copied file next should be stripped of the 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 CDC via the SDN.

For each project area, patient sampling will be conducted in a single phase shortly after the end of the PDP (April 30, 2008), as soon as the patient lists have been received from all participating facilities. 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 2008 patient sample for the project area. See Appendix E for more information regarding third stage patient selection.

### **c. Patient recruitment for participation in MMP**

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 who are being recruited. The MMP staff, after obtaining the patient contact information, 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.

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. The validity of population estimates derived from MMP interview data will be questionable if the overall response rate is less than 80%. Therefore, overall response rates of at least 80% should be obtained at both the project area and the national level. The MMP overall national response rate is the product of project area, facility, and patient response rates. If 100% of project areas, 80% of facilities, and 80% of patients from each participating facility are enrolled in MMP, the overall response rate is  $1.00 \times 0.80 \times 0.80 = 0.64$ , or 64%, which is very low. All 26 funded project areas selected in the first stage of sampling have agreed to participate, so an overall 80% response rate at the local and national levels can be achieved through a number of facility and patient response combinations, such as:

| Facility response rate | Patient response rate | National response rate |
|------------------------|-----------------------|------------------------|
| 80%                    | 100%                  | 80%                    |
| 85%                    | 94%                   | 80%                    |
| 90%                    | 89%                   | 80%                    |
| 95%                    | 84%                   | 80%                    |

### **d. Project area patient sample sizes**

MMP staff in all 26 project areas will interview patients and abstract medical records during the 2008 data collection cycle. MMP patient sample sizes in the project areas range from 100 to 800 during 2008 (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**

| <b>N</b> | <b>CI half-width<br/>design effect = 1</b> | <b>CI half-width<br/>Design effect = 2</b> | <b>CI half-width<br/>design effect = 3</b> | <b>CI half-width<br/>design effect = 4</b> | <b>CI half-width<br/>design effect = 5</b> |
|----------|--|--|--|--|--|
| 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 prevalences. Sample sizes for states with moderate to high AIDS prevalences 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 2008 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 on each sampled patient.

**1. Personal Interview**

The MMP interview is an in person, face-to-face interview administered to sampled patients.

## **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 a Spanish translation (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 in a Spanish translation (Appendix G.4).

The 2008 Standard Questionnaire consists of 7 modules to be administered in all project areas: demographics; access to health care; unmet needs; sexual behavior; drug and alcohol use history; assessment of prevention activities; and health and well-being.

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 using either a handheld-assisted personal interview (HAPI) device, such as a personal digital assistant (PDA) or computer-assisted personal interview (CAPI) device such as 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 of HAPI/CAPI malfunction. A complete checklist of all interview-related materials and equipment is provided in Appendix G.5.

## **b. Interviewees**

### **i. Sampled patients**

The sampled patient should be the respondent participating in the MMP interview in all but a few specific situations. Unless circumstances preclude it, sampled patients should be administered the Standard Questionnaire. 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 2008 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 on the following page 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. Incarcerated populations are not eligible to participate in MMP.

## **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 2008 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/lep/>.

Project areas should anticipate ahead of time 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 to consider 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, and 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 always will be administered in a setting in which respondent 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 also will 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 \$25 (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 2008 interviews. CDC will also conduct training to provide instruction and technical assistance on use of HAPI and CAPI devices, using the QDS interview application software, conducting the interviews, archiving the collected data, and secure transfer of data to CDC. 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 2008 interviews in order to assure high quality data are collected. For additional quality assurance purposes, approximately 10% 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 2008 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 CDC 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). 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. Medical records will be abstracted by project area staff trained to abstract clinical variables from medical charts. Paper abstraction forms will be provided by CDC to project areas.

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, provision of preventive therapies, prescription of antiretroviral medications, laboratory results, assessment of adverse events due to medications, and review of health services utilization. If a patient can not be located for recruitment, the patient's medical record will be abstracted without interview, if allowed under local surveillance authority.

MMP will capture clinical data from facilities providing primary HIV medical care and HIV-related care during a twelve month period (the surveillance period or 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 will only occur in project areas where abstraction can be performed without consent from the patient.

To collect information on the entire SP, project staff will need to abstract medical record information from multiple sources. The facility from which the patient was sampled will be the initial source of medical record information for abstraction. If other eligible facilities are reported during the interview or documented in the medical record, local MMP staff will travel to the additional facilities to abstract clinical data.

Whenever possible, medical record information should be obtained from **all**

facilities where a participant has received medical care for HIV infection during the surveillance period. These facilities, in addition to the facility where the participant was sampled, may be identified from the following:

- 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, high priority should be placed on completing abstraction at the following places:

- the facility where the participant was sampled
- the facility reported by 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 visits to the facility during the surveillance period, will be abstracted using the following forms:

- A single Medical History Form (MHF), covering the period from the date of first HIV-related care to the date prior to the surveillance period start date, will be completed for all facilities at which medical record abstraction is performed (see Appendix K.1).
- A Surveillance Period Visit Form (SPVF) will be completed for each visit the patient made to a given facility during the surveillance period (see Appendix K.2).
- A Surveillance Period Summary Form (SPSF) will be completed once for each facility at which abstraction was performed. Information collected in the SPSF mainly focuses on events that are not likely to recur in the surveillance period (eg., PAP smear, pneumovax, pregnancy) and thus are not appropriate for inclusion on the SPVF (see Appendix K.3).
- If a discharge summary from an inpatient facility is found in the medical record of the facility at which the abstraction is performed, or if the abstraction is conducted in an inpatient facility, a fourth form the Surveillance Period Inpatient Form (SPIF), will be completed; only one of these forms is completed per inpatient visit (see Appendix K.4).

The personal identifying information used in recruiting and contacting patients will not be recorded; medical record abstraction form data 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.

CDC will conduct abstractor training and will also provide project areas with a manual containing detailed abstraction instructions. Project areas will track abstractions of each patient's records using an abstraction assignment workbook provided by CDC. This workbook 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 participating state and local health departments with a manual containing detailed instructions on conducting MMP 2008 medical record abstractions. CDC will also conduct training to provide instruction and technical assistance on use of the medical record abstraction forms, and shipping the forms to CDC. 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 forms must be checked for completeness by project area supervisory staff prior to shipment to CDC. For additional quality assurance purposes, approximately 10% 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 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.

CDC will provide project areas with a SAS program that should be used to extract MDS data from HARS/eHARS and an Excel workbook with all Participant IDs for all sampled patients. All project areas will need to identify and add the statenos for each sampled patient. Since there are different versions of HARS, all project areas will be required to use the HARS Prodas engine to extract the minimum data elements to assure uniformity of the data source. 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: one copy will include the patient's HARS/eHARS ID number (statenos) and should remain at the project area only; it should not be sent to CDC. The other copy of the SAS and Excel minimum data set files will exclude the statenos and should be transmitted to CDC over the SDN.

### **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 tracking data 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 and abstraction data consist of the information obtained 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. If possible, these minimal data will be extracted from a single source (e.g., HARS, or from the facility). The tracking, interview, abstraction, and minimum data set data will be used to create analytic data files, which will be used at the project area and national levels to describe the populations of HIV-infected patients receiving medical care and address project-related questions.

#### **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 will be accessed only by a limited number of users at each project area and at CDC, using a secure digital identification system. Information that identifies facilities and patients, such as facility name or patient medical record number, will not be sent to CDC.

Tracking data will be collected and stored by each project area using Excel workbooks developed by CDC. The following is a brief description of these workbooks; for more detailed information, please refer to the Medical Monitoring Project Project Area Data Management Manual.

| <b>Workbook</b>                 | <b>Description</b>   | <b>Naming Convention</b>                            |
|---------------------------------|--|---|
| Facility Sampling Frame         | Contains a comprehensive, unduplicated list of all known HIV-care providers in a given project area, with their associated estimated patient loads (EPLs)  | <i>AreaAbbreviation_CycleYear_FacFrame_mmddyyy</i>  |
| Facility Tracking Workbook      | Contains information for all sampled facilities that were selected for MMP recruitment and is used to record facility information, contact assignments, and recruitment status   | <i>AreaAbbreviation_CycleYear_FacTrack_mmddyyy</i>  |
| Patient List Workbook           | Contains MMP Participant IDs corresponding to each patient eligible to participate in MMP and is used by CDC to create the Patient Sampling Frame.   | <i>AreaAbbreviation_CycleYear_PatList_mmddyyy</i>   |
| Patient Tracking Workbook       | Contains information for all sampled patients selected for recruitment and is used by project areas to record patient contact information, contact assignments, and recruitment status   | <i>AreaAbbreviation_CycleYear_PatTrack_mmddyyy</i>  |
| Abstraction Assignment Workbook | Contains information for all medical record abstractions identified for sampled patients and is used by project areas to record facility contact information pertaining to medical record access, medical record abstraction assignments, and abstraction status | <i>AreaAbbreviation_CycleYear_AbsAssign_mmddyyy</i> |

## **2. Personal interview data**

Interview data will be collected with either HAPI or CAPI devices, 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 three QDS data files with the extension .QAD (the standard questionnaire, local questions (if applicable) and the completion module for the standard questionnaire). 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 three types of information which are collected and stored during the interview: core data (all questionnaire modules except the local questions and interview completion modules), local question data, and interview completion data. The local question .QAD files will be kept only at the project area for local use – this local question data file will not be sent to CDC.

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 (core or completion), 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 frequent 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 which 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 on an interview data change list, using a template provided by CDC for this purpose.

Copies of recently uploaded interview .QAD files will be sent to CDC on a periodic basis via the SDN using encryption software which 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, and no data from local questions will be sent to CDC.

Once the data files are received at CDC, additional quality assessment programs will be implemented which 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 sent to CDC, documented, and the updates will be made to the data stored at CDC. The change lists also may 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 Project Area Data Management Manual.

### **3. Medical record abstraction data**

Abstraction data will be collected using paper forms provided by CDC. These forms will be shipped to CDC for data entry and abstraction datasets will be returned to the project areas.

### **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, many project areas will be able to conduct medical record abstractions in one or more facilities. In the event the medical records are missing or the MMP staff are unable to locate them, the minimal data specified on the minimum data set (MDS) form will be obtained (see Appendix L). This minimal data will be obtained for **all** sampled patients.

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 be extracted from the project area HARS/eHARS using the Prodas engine and SAS programs provided by CDC. 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\_mmddyyyy.xls* (Excel workbook)

*AreaAbbreviation\_cycle year\_MDS\_CDC\_mmddyyyy.sas7bdat* (SAS data file)

## **5. Analytic data**

The interview, medical record abstraction and minimal data will be linked at CDC using the MMP participant ID. A SAS analytic file containing each project area's data also will be created at CDC. The appropriate SAS analytic file will be sent to each project area via the SDN after the 2008 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 collection, management, and 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. MMP-Related Projects**

### **A. MMP Provider Survey**

Supplemental surveillance projects, such as MMP, collect information on the provision of HIV care and treatment from interviews with and medical record reviews of persons living with HIV/AIDS in care. However, ascertaining information about the clinicians providing HIV care to MMP patients and the factors that influence the type of care they provide is also important for HIV prevention and care planning.

The MMP Provider Survey will collect data from a nationally representative sample of HIV care providers selected to participate in MMP. These providers will be asked to complete a brief survey about their education, training, characteristics of their practice, and the care they provide to their HIV-infected patients.

The MMP Provider Survey has its own protocol, implementation procedures and questionnaire (See Appendix M). The MMP Provider Survey will not link responses from providers to the participating patients in MMP.

The MMP Provider Survey will use the first two stages of MMP's three stage approach to identify providers of HIV care. Providers whose facilities were sampled to participate in MMP, but who declined participation in MMP, will still be given the opportunity to participate in the MMP Provider Survey. This survey will be a confidential, self-administered, standardized instrument. Depending on the provider's preference, the survey can either be completed using a web-based or paper-format version. Follow-up to non-responders will use the Dillman method.<sup>19</sup>

The main evaluation points of the MMP Provider Survey will include health care provider's professional training history, ongoing sources of training and continuing education about HIV care and treatment, perceptions of patients' barriers to care and reasons for declining HIV care, awareness of HIV-related resources, and approach to antiretroviral therapy management and HIV risk reduction counseling. Results from this survey will be used to assess who is providing HIV care, to examine the impact of provider characteristics on the standard of care being provided to patients with HIV, and to identify opportunities to improve resources available to HIV care providers.

## **B. Facility Attributes**

In order to provide the most comprehensive description of factors affecting the health outcomes of HIV patients, facility attributes information will be collected from all sampled eligible facilities chosen for participation in MMP. In this way, facility-level data will complement the information collected from the patient (interview and medical record abstraction) and provider (Provider Survey). The facility attributes data collected will answer the following questions:

- Where are patients accessing care for HIV infection?
- What types of facilities are providing care?
- What types of services are available?

The Facility Attributes Worksheet (Appendix N) contains 14 questions related to facility characteristics such as: type of facility, ownership and financial support, inpatient and outpatient care, and services provided. Project areas will obtain this information through various means, including published facility documents, resource inventories and direct facility contact.

Information on the level of urbanization of each facility location will be entered into the Urbanization Level Worksheet. These data will be collected for both main facility as well as satellite locations. The worksheet will contain two measures of urbanization: the Urban Influence Code (UIC) and the Rural-Urban Commuting Area (RUCA). Both measures were developed by the United States Department of Agriculture (USDA) and more information can be found on their website at <http://www.ers.usda.gov/Briefing/Rurality/>.

## **V. 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 area, 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.

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 2008 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 HARS office of the project area, under the same security procedures as those for HARS 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. All data records contained in the warehouse will be encrypted and transmitted to CDC on a periodic basis via the SDN, using standardized transmission and receipt verification procedures across all project areas.

## **VI. 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 O). 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, non-English, non-Spanish speaking 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.

## **VII. 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 conduits, such as local publications, epidemiologic profiles, and presentations to local AIDS service organizations and community planning groups and at conferences and workshops.

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