# Medical Monitoring Project
# 2007 Protocol

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**National Center for HIV, STD and TB Prevention**
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## Abbreviations, Acronyms, and Definitions

**2007 data collection cycle** The period of time during which MMP interview and medical record abstraction data will be collected for the 2007 patient sample. This period of time will range from May 1, 2007 through spring of 2008.

**Abstraction application** Software program for collecting MMP medical record data on laptop computers developed by CDC utilizing Visual Basic.net and a Microsoft database engine.

**ASD** Adult/Adolescent Spectrum of HIV Disease

**CAPI** Computer Assisted Personal Interview – A method of administering interviews in person using a personal computer, typically either a laptop or tablet personal computer.

**Computed variables** Computed variables have values that are the result of arithmetical or logical manipulations performed using values from other, pre-existing variables.

**Design effect** Design effect is the increase in statistical variance that is introduced by using a multi-stage complex sampling design to obtain patient or other samples. Mathematically, design effect is the variance obtained using a complex sampling design divided by the variance that would have been obtained from a simple random sample of the same size. A design effect of 2 means that the variance obtained using a complex sampling design was twice as large as the variance that would have been obtained from a simple random sample of the same size.

**EPL** Estimated Patient Load - The estimated number of patients in care for HIV at a facility during the period of time specified for facility sampling frame construction. This time period may differ across various data sources used to obtain the EPLs.

**Facility** For MMP, a facility is defined as any clinic, health care institution, private or group physician practice that shares common medical records or a medical records 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 records 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 records system from those of the other 4 physicians, then each physician would be defined as a unique MMP facility.

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| **HAPI** | Hand-held Assisted Personal Interview – A method of administering interviews in person using a hand-held personal computer. |
| **HARS** | HIV/AIDS Reporting System |
| **HIV medical care** | For identifying facilities that are eligible for MMP, HIV medical care is defined as conducting CD4 or HIV viral load testing and/or providing prescriptions for antiretroviral medications. Thus, facilities providing HIV care could include outpatient facilities such as hospital-affiliated clinics, free-standing clinics or private physician offices; prisons; jails; and Veterans Health Administration facilities. Although inpatient facilities, federal military and penitentiary facilities, and emergency departments may provide HIV care, these types of facilities are not considered eligible for the 2007 data collection cycle. |
| **IRB** | Institutional Review Board |
| **List-based sampling** | List-based sampling uses a list of population elements to select a sample of these elements. For example, list-based sampling is used in MMP when patients are sampled from lists of patients seen at each facility during the PDP, i.e., January 1 – April 30, 2007. |
| **List pick up** | Obtaining either a list or an accurate count of all eligible patients at each sampled, participating facility during a specified time period. |
| **1-list pick up** | Obtaining a single list of eligible patients for the 4 month PDP from each sampled, participating facility for which 1-list pick up is used. These lists will be collected shortly after the end of the PDP (April 30, 2007). |
| **2-list pick up** | Obtaining two lists of eligible patients for the 4 month PDP from each sampled, participating facility for which 2-list pick up is used. The first set of lists will be collected shortly after the middle of the PDP (February 28, 2007). The second set of lists will be collected shortly after the end of the PDP (April 30, 2007). |
| **MMP** | Medical Monitoring Project |
| **Minimum data set** | Basic core surveillance information obtained for all selected patients for whom neither interview nor medical record abstraction data are collected. This information will be obtained from HARS or from the facility through which the patient was selected. These data are referred to as minimal data. |
| **PDP** | Population Definition Period – For a given year of data collection, persons who are eligible to be included on patient sampling frames are HIV- |

infected patients who receive care at a sampled facility during a specified period of time which is called the population definition period (PDP). For the 2007 data collection cycle the PDP is the 4 month period from January 1 – April 30, 2007.

**PDP PL** Population Definition Period Patient Load - The actual count of HIV-infected patients seen at a selected facility during the entire 2007 PDP (i.e., the total PDP patient load derived from a facility's patient list or lists). These counts will differ from the selected best EPL used to construct the facility sampling frame.

**PPS** Probability Proportional to Size – A method of sampling in which the probability of selection for each unit on the sampling frame is proportional to some measure of size. For MMP, the measure of size for first stage sampling is the number of reported living AIDS cases as of December 2002 and for second stage sampling of HIV care facilities it is the estimated number of patients currently in care for HIV or EPL. Thus, in the second stage of sampling, facilities with more 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).

**Proxy interview** Abbreviated form of the patient interview using the proxy questionnaire in which responses are obtained from a proxy (i.e., stand-in or substitute) respondent for a patient who is either too incapacitated to provide responses or who has died after being sampled.

**Proxy PDP** A proxy (substitute) time period and other information are used to develop an accurate estimate of the January through April 2007 PDP PL for each sampled facility when 2-list pick up will be used at any facility in a project area. The best proxy time period to use for the proxy PDP will be based on input from each facility regarding previous time periods that are most likely to accurately represent patient presentations for HIV medical care during January 1 – April 30, 2007. Additional information from the facility, such as projected increase in patient volume for the actual PDP relative to the proxy PDP, should be used to obtain the most accurate estimate possible for the PDP PL. The proxy PDP used may differ across participating facilities within a project area.

**PSU** Primary Sampling Unit – The element, or entity, that is sampled in the first stage of sampling. For MMP the 50 states plus the District of Columbia and Puerto Rico, are 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 should be 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 some 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 these sampling frames does not list all elements in the entire population, however, after the first stage of selection each subsequent frame must list 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 HIV infected persons in care in the project area but only those in care at the sampled 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 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.

**SHAS** Supplement to HIV/AIDS Surveillance

**SHDC** Survey of HIV Disease and Care

**SHDC-Plus** Survey of HIV Disease and Care Plus

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| **Short-form interview** | Abbreviated form of the patient interview obtained using the short-form questionnaire when a patient is to ill or otherwise unable to complete the longer standard interview, or when translation to a language other than Spanish is required. |
| **Standard interview** | Unabridged form of the patient interview obtained using the standard questionnaire which contains all core and optional modules. |
| **Surveillance period** | The 12-month period prior to patient interview. Thus, in MMP, the surveillance period for each patient will be determined based the date the individual is interviewed, rather than using a pre-specified uniform time period for all interviewed patients. |

# I. Introduction

## A. Background

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

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

The need for data on HIV-infected persons' risk behaviors and 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.[7] Analyses examining reasons for late HIV testing, quality of life, drug use, and sexual behaviors have contributed to local planning and the tracking of behavioral trends among persons with HIV infection in care.[7-15]

During the past decade, ASD and SHAS have provided much-needed information that has been used to understand the HIV epidemic. However, in recent years, several factors have progressively limited the usefulness of these surveillance projects. First, early in the epidemic, HIV/AIDS cases were concentrated in large urban areas, primarily on the East and West coasts. Currently, a much larger number of cities and states are heavily affected by the HIV/AIDS epidemic, limiting the usefulness of data collected from the geographic areas in the ASD and SHAS projects. Second, the lack of linked medical record and interview data in these projects limited the ability to estimate key indicators, such as the quality of HIV-related ambulatory care and the severity of need for HIV-related care and services. Third, the generalizability of results from ASD and SHAS to the rest of the adult HIV-infected community was limited because these projects used non-probability samples.

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.[16] In SHDC-Plus, a modification of SHDC conducted in 3 areas during 2003–

2004, a subset of persons whose medical records had been abstracted were interviewed. Both projects were conducted in limited geographic areas. The Medical Monitoring Project (MMP) grew out of experience with ASD, SHAS, SHDC and SHDC-Plus and incorporates some of their features, but unlike these earlier projects, it is designed to provide nationally representative, population-based surveillance data. Furthermore, MMP's design addresses the limitations described above.

### B. Purpose and Scope

The primary objectives of MMP are to obtain data from a national probability sample of HIV-infected persons receiving 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 state and local health departments to use in collecting data on behaviors and clinical outcomes from a probability sample of adults receiving care for HIV infection or AIDS in their jurisdictions. The method involves the selection of patients currently receiving care by means of a 3-stage sampling design, in-person interview 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 levels of 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 participation and enrollment 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

The 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, 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, which will 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, and American Academy of HIV Medicine). 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.[17, 18]

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

This project has been funded for 4 years (2005–2008). 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 will be funded for data collection in years 2 to 4. Year 2 project activities including preparations for data collection began in all project areas in January 2006. 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 2006 data collection (data collected on patients in care in 2006) and begin the first full year of

data collection in year 3 (2007). Sampling and data collection will also take place in year 4 (2008). The project period may be extended if funding permits.

## II. Methods

### A. Population of Inference

The national population of inference for MMP is HIV-infected adults (18 years of age or older) who received care from known providers of 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 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 2007 data collection cycle, the PDP is uniform across all project areas and extends from January 1 through April 30, 2007.

### 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 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) in 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 (i.e., during the time period examined for each data source, generally the most recent calendar year for which complete data are available) is eligible for MMP participation. For the purposes of MMP facility sampling frame construction, providing HIV care is operationally defined as conducting CD4 or HIV viral load testing 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, prisons, and jails. 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 the facility sampling frame. Other facilities that should be excluded from each project area's 2007 facility sampling frame are facilities that provide exclusively inpatient care, including hospices; psychiatric and drug treatment facilities; emergency departments; facilities located outside the funded project area; facilities that have closed; federal prisons; 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 facility sampling frame. Facility sampling frames developed and facility samples drawn for 2006 data collection will be used for 2007.

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. Similarly, while a hospice may in some instances provide some short-term HIV medical care, these facilities also are not considered to be know providers of regular HIV medical care. Prior to and during the 2007 data collection cycle, the potential bias resulting from the exclusion of inpatient facilities from MMP will be evaluated (see section IID3e. Inpatient Evaluations for more information on this activity). A separate list of excluded inpatient facilities should be kept by each project area.

Emergency departments are excluded from MMP for reasons similar to those for inpatient facilities. Outpatient psychiatric facilities may also be excluded as these facilities primarily treat HIV-infected patients for conditions not associated with HIV, and as such may not be considered known providers of HIV medical care.

### 3. Patients

At each eligible facility, all patients who meet the following conditions during the PDP 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 the facility 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 facility sampling frame. Note that exclusion of these patients is based on eliminating certain types of facilities from the facility sampling frame; 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. Three-Stage Sampling

MMP will use a 3-stage sampling design which will result in annual cross-sectional probability samples of adults in care for HIV infection in the United States. During the first stage of sampling, 20 geographic primary sampling units (PSUs) were selected using probability proportional to size (PPS) sampling based on AIDS prevalence at the end of 2002. During the second stage, a sample of facilities providing HIV care in each of the project areas will be selected. The measure of size for PPS sampling of facilities will be the number of HIV-infected patients who received care at the facility during the most recent reporting year for which measure of size data are complete. During the third stage of sampling, participants will be randomly selected from all eligible patients seen during the PDP at selected 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 there was no data system that collects 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 will be conducted annually. See Appendix A for more information regarding first stage project area selection.

### 2. Second-Stage Sampling

During the second stage of sampling, 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, a sampling frame will be constructed of unique facilities known to provide HIV medical care during a recent time period. Because facilities will be sampled PPS, an estimate of the number of HIV-infected patients currently in care at each facility, i.e., the estimated patient load (EPL), must be included on the frame.

All project areas are funded to collect data during the 2007 project period. The majority of project areas had completed their facility sampling frame construction in 2006. Project areas that were funded to collect data during 2005 either will use the same facilities selected for their 2005 facility sample, or will have a separate facility sample selected for 2007 data collection. Project areas that had a facility sample drawn for 2006 will use this sample of facilities for 2007 data collection. The start date for 2007 data collection will vary across project areas, depending on the type(s) of patient sampling (1-list or 2-list pick up) conducted in the area, however, the PDP will be the same across all project areas.

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

To construct the facility sampling frame, project areas start by developing an initial list of facilities that have 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, this facility list from HARS must be supplemented with lists of HIV care facilities from other data sources. These supplemental sources may include 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 AIDS Drug Assistance (which gives information on providers prescribing antiretroviral drugs), Medicaid, (which gives information on providers from claims for payment for HIV care), or prescription drug lists (which give information on prescribers of antiretroviral drugs). HIV medical association membership lists also may be used. Note that some of these sources list individual providers, rather than facility names, and associating individual providers with facilities may require additional effort. Once the lists of facilities from HARS and each of the supplemental sources have been obtained, cleaned and standardized, they will be combined into a single facility sampling frame for each project area, on which each facility only appears once. Any outpatient facility that meets the MMP definition and is known to provide HIV medical care during the recent time periods used for each data source is eligible to be included on the facility sampling frame.

For the purposes of facility sampling frame construction, 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. State prisons, local jails, and Veterans Administration facilities also are eligible for inclusion in MMP.

Facilities that are known not to provide HIV-related medical care, such as counseling and testing sites, should be excluded from the facility sampling frame. Other facilities that should be excluded from the facility sampling frame 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 have provided HIV care only to patients under the age of 18 also should be excluded from the facility sampling frame. A separate list of excluded inpatient facilities should be kept by each project area.

#### ii. Creating a matrix of EPLs from each data source

For each data source used, an EPL for each facility should be determined and documented using templates provided by CDC. A matrix, or table, of EPLs from each data source should be constructed for all facilities. This matrix will be used to derive the facility sampling frame. During this step, the quality of the different EPLs for each facility should be evaluated in order to determine, for each facility, which EPL will be the most accurate to use for facility sampling.

#### iii. Selecting the best EPL for each facility

A high quality EPL is one which accurately represents the true count of HIV-infected individuals who received care at a given facility within the recent complete one year period of reporting. The process of determining, from among the various data sources available for a given facility, which EPL to use in the final facility sampling frame 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 which 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 eligible facilities and construct the matrix of EPLs, and the information used to determine the quality of the EPLs from each of those sources. See Appendix B for more information regarding constructing the facility sampling frame.

### 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 are identified prior to facility sampling in order to adjust the second stage selection probability for these facilities, either by increasing the EPL for each small facility to a minimum value, or by performing facility linkage prior to facility sampling to achieve combined EPLs for the linked facilities that meet or exceed a minimum value.

For three MMP project areas (Houston, Los Angeles, and Washington), the approach of increasing the EPLs of small facilities prior to facility sampling activities in 2006 was employed using a minimum value of 10. For all other project areas, 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 depends in part on the distribution of EPLs across the entire facility sampling frame 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 is performed by CDC staff, in conjunction with project area MMP staff, prior to selecting the facility sample.

### c. Selecting the sample of facilities

Each site will send its final, complete matrix of EPLs, which also must include a 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. The file that is sent to CDC, which includes the matrix of EPLs, 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.

RAND consultants, in conjunction with CDC staff and MMP staff in each project area, will select the PPS sample of facilities. In most project areas, 25 to 50 facilities will be sampled for each annual 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 persons who receive care at the facility during the 2007 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 75%. Therefore, overall response rates of at least 75% 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 on 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 randomly sampled for inclusion in MMP. Patients will be sampled from lists of patients seen at each facility during the PDP, i.e., January 1 to April 30, 2007.

When conducting list-based sampling, a project area may elect to use either 1-list or 2-list pick up at the participating facilities. For 1-list pick up, a single list of patients seen during the PDP is obtained from the facility. One-list pick up is conducted after the

conclusion of the PDP. As each facility is recruited for MMP participation, the facility contacts should be informed that a list of every HIV-infected patient seen at the facility during the PDP will be requested shortly after April 30, 2007. Two-list pick up is similar to 1-list pick up, but lists of HIV-infected patients who received care at each facility are obtained at two points in time, once shortly after the midpoint of the PDP (February 28, 2007) and a second time after the end of the PDP.

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

One (1-list pick up) or two (2-list pick up) lists of HIV-infected patients who received care during the PDP should be requested from all sampled facilities. In addition, accurate and reliable estimates of patient counts, or patient loads, for the entire PDP (PDP PLs) should be obtained from facilities if necessary, as described in the sections below. Templates for collecting and recording this information will be provided to project areas by CDC.

The patient lists should include each patient only once; 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 patients presenting for any type of care at that facility are eligible for inclusion**.**

#### i. Obtaining lists and/or estimates of PDP PLs from each participating facility

Regardless of the types of patient sampling methods used, 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).

If 1-list pick up is the only patient sampling method used in all sampled facilities in a given project area, a list of eligible patients will be collected from every participating facility after the end of the PDP (April 30, 2007). If 2-list pick up, or a combination of 1- and 2-list pick up will be used in a project area, accurate estimates of the PDP PL are needed from **all** participating facilities immediately after the mid-point of the PDP (February 28, 2007). For facilities in which 2-list pick up will be used, two patient lists,

corresponding to the first and second halves of the PDP, must be obtained and the patients included on the first list should not be included on the second. The first set of patient lists will be collected shortly after the mid-point of the PDP, while the second set of lists will be collected at the end of the PDP. For any remaining facilities in which 1-list pick up will be used patients only will be sampled at the end of the PDP, therefore, only a single patient list corresponding to the entire PDP should be obtained.

To obtain accurate and reliable projections of facility-specific PDP PLs when 2-list pick up will be used at any sampled facility, a proxy PDP may be selected to represent the appropriate time period for each sampled facility. The use of a proxy PDP may be the best method for obtaining accurate PDP PL estimates (i.e., proxy PDP PLs). The best prior time period to use for this proxy PDP will be based on input from each facility regarding previous time periods that are most likely to accurately represent HIV-infected patient presentations for care during January 1 – April 30, 2007.

#### ii. Creating a file of PDP patient lists and/or estimated PDP PLs

As patient lists and/or estimates of PDP PLs 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 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 PLs or estimated PDP PLs

For each facility, the actual count of unique patients seen during the entire 2007 PDP (the PDP PL, which is derived from a facility's patient list or lists, and the estimated PDP PL) will differ from the selected best EPL used to construct the facility sampling frame. The extent to which this EPL for each selected facility differs from the PDP PL or from the estimated PDP PL should be determined 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 or estimated PDP PLs 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 patient 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. Patient 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 patient 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.

### i. List-based sampling

One-list pick up only: If 1-list pick up is employed for patient sampling across all facilities in a project area, patient sampling is conducted in a single phase shortly after the end of the PDP (April 30, 2007). 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 patients' ID numbers will be returned to the project area via the SDN after patient sampling has been completed; this set of patient IDs will comprise the entire 2007 patient sample for the project area.

Two-list pick up: If 2-list pick up will be used in a project area, patient sampling will be conducted in 2 phases. The first phase of patient sampling will occur shortly after the middle of the PDP (February 28, 2007) for all facilities in which 2-list pick up will be used. A list of patients seen from January 1 through February 28, 2007 should be obtained from all 2-list pick up facilities. In addition, accurate estimates of the PDP PLs for **all** participating facilities must be obtained at this time. These estimated PDP PLs are needed from both 1- and 2-list pick up facilities in order to determine how many patients to select for the first half of the PDP from the facilities for which 2-list pick up will be used. The first phase patient sample which will be returned to the project area via the SDN will contain selected patient IDs only for those facilities at which 2-list pick up will be used.

The second phase patient sample will be selected after the end of the PDP (April 30, 2007). Shortly after the end of the PDP, a list of all HIV-infected patients seen from March 1 through April 30, 2007 should be obtained from every participating 2-list pick up facility, while a list from January 1 – April 30, 2007 will be obtained from the 1-list pick up facilities that provided estimated PDP PLs during the first phase. For the 2-list pick up facilities, the March 1 – April 30 patient lists should not include patients seen at those facilities during the first half of the PDP (January 1 – February 28), since these patients were on the first set of lists obtained and thus were available for sampling in the first phase. The second phase patient sample returned to the project area via the SDN will contain all remaining selected patients for 2007 in the project area. This sample will include patients sampled from the entire PDP for facilities using 1-list pickup and patients sampled from the second half of the PDP for facilities using 2-list pick up. See Appendix E for more information regarding third stage patient selection using list-based sampling.

### 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.

For MMP staff-contact enrollment, facilities at which list-based sampling is conducted 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. 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. 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.

**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 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 × 0.80 × 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 | Overall 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 2007. MMP patient sample sizes in the project areas range from 100 to 1000 during 2007 (Appendix F).

Because MMP is primarily a descriptive project, power calculations, which are used in sample size determinations for studies that test specific hypotheses, were not

performed. Instead, the level of precision (i.e., the estimated 95% confidence interval half-width) was the criterion for determining sample sizes in individual project areas. Ninety-five percent (95%) confidence interval half-widths were calculated for a variety of sample sizes and design effects.

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

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

It was determined that 400 is the minimum sample size for a state to obtain total population estimates with an acceptable level of precision (assuming a moderate design effect, or increase in variance of estimates due to using a multistage sampling design). This sample size was assigned to most of the states with the lowest AIDS 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. Inpatient evaluations

Evaluations will be conducted during the 2007 data collection cycle to determine the number and proportion of HIV-infected patients receiving care only at inpatient facilities, and the proportion of HIV-infected patients with an inpatient visit during the PDP that also had an outpatient visit during the PDP. This information will be used to inform facility and patient eligibility decisions for the 2008 data collection cycle.

#### i. All project areas

As part of the MMP interview and medical record abstraction, data will be collected regarding inpatient facilities where the patient was seen for care during the past 12 months. These data can be used to assess the proportion and characteristics of respondents who received care at inpatient facilities.

In addition, interview and medical record abstraction data collected will include information about inpatient facilities where the patient received care during the PDP. These data can be used to assess the number and proportion of patients that would have had a chance of being selected from an inpatient facility if inpatient facilities were included on the facility sampling frame.

### ii. Project areas that included inpatient facilities on the facility sampling frame

Patients should not be sampled from inpatient facilities for inclusion in the 2007 state/local and national sample. If the project area's 2007 facility sample has been drawn (or they are using their 2005 facility sample for the 2007 data collection cycle) and the sample contains inpatient facilities, these inpatient facilities will not be asked to provide PDP patient lists.

In areas that have the capacity and are willing to assist in the evaluation, a limited number of HIV-infected inpatients should be sampled (in addition to those included in the project area's patient sample) and interview and medical record data collected. This limited number of patients should be sampled from several selected inpatient facilities, or if no inpatient facilities were sampled these patients can be selected from several inpatient facilities that were on the facility frame. CDC project officers will work with their project areas to accomplish this.
Data should be examined for all respondents selected from inpatient facilities to determine the number, proportion and characteristics of patients who only received care from inpatient facilities and compare these characteristics to patients who did not receive HIV care exclusively at inpatient facilities.

For inpatient facilities with associated outpatient clinics, separate lists of HIV-infected patients who received care from the inpatient and outpatient facilities during the PDP can be obtained and compared. These comparisons will provide an estimate of the number of HIV-infected inpatients who did not receive care from the associated outpatient facility during the PDP.

### iii. Project areas that did not include inpatient facilities on the facility sampling frame

For several inpatient facilities with associated outpatient clinics that were excluded from the facility sampling frame, separate lists of HIV-infected patients who received care from the inpatient and outpatient facilities during the PDP can be obtained and compared. Project areas should work with their CDC project officer to determine which facilities would be appropriate to participate in this activity. These comparisons will provide an estimate of the number of HIV-infected inpatients who did not receive care from the associated outpatient facility during the PDP.

## E. Data Collection

For the 2007 data collection cycle, all project areas will conduct interviews for all participating sampled patients, and also will perform medical record abstractions.

Patients will be interviewed first, and then their medical records will be abstracted from all facilities from which they received HIV care during the 12 months prior to interview.

### 1. Personal Interview

Trained MMP staff may conduct patient interviews in a variety of settings, including: as part of a routine visit to a medical facility; in the patient's home; in a hospital or clinic; or at another, mutually agreed-upon location. Interviewers will administer the *standard questionnaire (English)* (Appendix G.1) or the *standard questionnaire (Spanish).* The core interview is expected to take approximately 45 minutes to complete, however, the duration will vary somewhat depending on respondent characteristics. For example, a respondent with a history of substance use during the surveillance period will be asked more questions than a respondent with no history of substance use.

In addition to the two standard versions of the questionnaire, there are two condensed versions designed for unique situations when it is impossible to administer a standard version. Completion of a condensed version of the questionnaire is expected to take 5 to 15 minutes. These condensed versions are the *short questionnaire* and *proxy questionnaire*. The *short questionnaire* is intended for persons who participate in the interview but are too ill to complete the longer standard version or require a translator present during the interview to answer the questions (Appendix G.2). The *proxy questionnaire* is intended for persons who complete the interview as a stand-in for selected patients who are either too ill to be interviewed or have died after sampling (Appendix G.3).

The standard questionnaire consists of 5 core modules to be administered in all project areas: demographics, access to health care, unmet needs, sexual behavior, and drug and alcohol use history. It is always preferable to complete the interview during a single encounter. However, follow-up interviews may be done if the interview cannot be completed during a single encounter. In the latter instance, the interviewer should attempt to complete the interview as soon as possible.

All versions of the questionnaires will be provided by CDC to be implemented using either a handheld-assisted personal interview (HAPI) or computer-assisted personal interview (CAPI) (i.e., data will be collected electronically). The interview instruments were developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland).

CDC will conduct training and site visits to provide instruction and technical assistance on use of HAPI and CAPI, using the QDS software, conducting the interviews, archiving the collected data, and on data transfer. CDC will also provide participating state and local health departments with a manual containing detailed instructions on conducting interviews.

At the end of the interview, participants will receive prevention materials and referrals to local prevention and care services; they also may ask the MMP staff

questions about prevention methods. Participants who completed the survey will also receive a reimbursement for their time either in cash or a cash equivalent.

### a. Quality control and assurance

For quality assurance purposes, approximately 10% of interviews will be observed by the project coordinator to determine accuracy and completeness. Periodic peer review of interviews will ensure that interviewers use the same techniques in administering the questionnaire. Automated edit checks will be built into the computer software programs as an additional quality control measure.

CDC will regularly train the interviewers and convene meetings about lessons learned in order to understand the problems that can occur with the software and hardware used in conducting the interviews.

## 2. Medical Record Abstraction

Medical records will be abstracted by local project staff trained to abstract clinical variables from medical charts. Software applications implemented on laptop computers will be used for medical record abstraction. Information abstracted will reflect the patient's clinical condition and experience before and during the surveillance period. The information to be collected 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.

MMP will capture clinical data directly from the facilities providing primary HIV medical care and HIV-related care in the twelve months prior to the interview (the surveillance period) for each patient. To accomplish this, 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 (see below) are documented in the medical record, local MMP staff will travel to the additional facilities to abstract clinical data. Likewise, if during the interview the participant identifies facilities where he/she went for HIV medical care (in addition to the facility from which the patient was sampled) local MMP staff will travel to these additional facilities to abstract the medical record information as well. The interview information obtained about the additional facilities will be recorded in the facility visit log that is completed throughout the interview. The additional facilities that are eligible for medical record abstraction include:

- infectious disease specialists or other providers of primary HIV care
- sexually transmitted disease clinics
- tuberculosis clinics
- obstetrics and gynecology practices or clinics
- inpatient facilities

Information about all visits during the surveillance period to the facility from which the patient was sampled, and all other eligible facilities identified, will be abstracted. A single Medical History record covering the period from the first HIV-related visit to the

visit prior to the surveillance period will be completed for each facility at which the patient was seen for HIV medical care during the surveillance period (Appendix H.1). A Surveillance Period (Visit) record will be completed for each visit the patient made to a given facility during the surveillance period (Appendix H.2). The personal identifying information used in recruiting and contacting patients will not be recorded; however, each person will be assigned a unique ID number as defined in the protocol section on third stage sampling.

CDC is responsible for developing, reproducing, and distributing the medical record abstraction software to the project areas. CDC will conduct abstractor training and will also provide project areas with a manual containing detailed instructions. Project areas will track abstractions of each patients' records using the abstraction assignment workbook to make sure all identified 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 contacted and abstractions have been completed at all facilities.

### a. Quality control and assurance

MMP abstraction records must be checked for completeness. 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. Automated edit checks will be built into the software programs as a further quality control measure. In addition, to enhance the quality of the collected data, standardized definitions, codes, abstraction instructions, and training for data abstractors will be provided to all project areas. Periodic site visits by CDC will be made to all project areas, and technical assistance will be available through CDC Project Officers.

CDC will regularly train the abstractors and convene meetings to discuss the lessons learned about the software and hardware.

## 3. Minimum Data Set

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-response 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, the chart 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 can be collected. 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.

A form displaying the data fields in the minimum data set is shown in Appendix I. Because this information will be available electronically in many instances, project areas are not required to complete this form but instead may simply convert electronic data to the formats and value codes indicated on the minimum form, if needed. If the data are obtained from HARS, this conversion will not be necessary.

In summary, for MMP the following data will be collected and contribute to the state/local area and national data sets:

- Interview/abstraction
- Abstraction only (for those who refuse to be interviewed or cannot be located)
- Minimum data set (for those who refuse to be interviewed and project areas cannot get access to or locate their medical records)

### F. Reimbursement

Participants will be reimbursed approximately $25 (this amount may differ by project area) in cash for participation in the interview. If local regulations prohibit cash reimbursement, equivalent reimbursement may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

## 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.

The tracking data will be collected and stored by each project area using an integrated internet-based system maintained by CDC. 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.

**2. Personal interview data**

Interview data will be collected with either HAPI or CAPI methodology, 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 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 <u>not</u> 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 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 the 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. No facility or patient identifiers, other than MMP-specific IDs, will be transmitted to CDC, and no local data 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.

### 3. Medical record abstraction data

Abstraction data will be collected with laptop computers, using an MMP abstraction application which has been developed by CDC using Visual Basic.net and a Microsoft database engine. In rare instances, abstraction data may be collected using paper forms, such as in the event of device failure. In these cases, the data will be entered using a laptop computer as soon as is feasible.

The medical record abstraction data will be exported into encrypted flat comma separated values (CSV) format using a feature included as part of the application. Each Medical History record and Surveillance Period record is exported as a separate record in a single .CSV file; multiple records may be contained in each .CSV file.

The filenames of the abstraction .CSV files will be automatically generated by the abstraction application, and will include the project area abbreviation, the data collection cycle, and the date and time the .CSV file was created. In order to uniquely identify each file, each file name also will include the identification number of the laptop computer 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 .CSV abstraction data files will be uploaded from the laptop computers using procedures described in written documentation provided to each project area by CDC. The uploaded .CSV data files will be saved onto a secure network computer drive, which will serve as the physical storage location of all abstraction data files for the project area. The file folder structure used on this drive will be based on guidelines provided by CDC. Abstraction data will be uploaded on a daily basis, or as soon as is feasible for staff who must travel long distances to collect the data.

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

Copies of recently uploaded abstraction .QAD files will be sent to CDC on a periodic basis via the SDN using encryption software which has been provided to project areas. No facility or patient identifiers, other than MMP-specific IDs, will be transmitted to CDC, and no local data 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 abstraction information and produce reports specifying any discrepancies found. These reports will be provided to

the project area, and after project area review any corrections to be made to the data will be entered on the abstraction data change list. The updated cumulative change lists will be sent to CDC, 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 abstraction data files maintained locally.

### 4. Minimal data

Minimal data will be obtained for all sampled patients for whom neither interview nor medical record abstraction data were collected. The goal of MMP is to collect interview and medical record abstraction data on all selected 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 form will be obtained. 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). These minimal data will be extracted from the project area HARS when feasible; otherwise these data will be obtained from the facility.

As the minimum data set information is collected, copies of the data files 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:
*project area_cycle year*_MDS_*mmddyyyy*.*ext* (*ext* denotes any filename extension).

In the event that more than one MDS file is created in a single day, sequential numeric suffixes (i.e., 1, 2, 3, etc.) should be used to distinguish the different files. For example, the third Excel file created June 8, 2006 containing 2006 minimal data sent to CDC by the Los Angeles project area would be named as follows:
LAC_2006_MDS_06082006_3.xls.

### 5. Analytic data

The tracking, interview, medical record abstraction and minimal data will be linked using the MMP patient IDs and merged into combined relational databases at CDC. 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 2007 data collection cycle has ended across all project areas. 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. 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 2007 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.

Both the QDS software that will be used to collect the interview data and the Visual Basic.net software that will be used for medical record abstraction support 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 and abstraction database 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.

## V. Human Subjects Considerations

### A. Non-research Determination

The National Center for HIV, STD, and TB Prevention (NCHSTP), CDC, has determined that MMP is a surveillance project, and as such is a non-research activity used for disease control program or policy purposes (Appendix J). Because NCHSTP 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. Prisoners and 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.

### 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.

All project areas must maintain a secure file of informed consent forms to document that informed consent was obtained for each participant. These secure files should be available upon request. See Appendix K for a model informed consent form.

## VI. Data Dissemination

### A. Notifying Providers, Patients and the Community of Findings

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

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

Patients and community members will be informed of MMP findings through multiple conduits. National data results will be released on the CDC's MMP Web site and through national publications and presentations at conferences. Similarly, local data results will be reported to the community through multiple 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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