Medical Monitoring Project

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A. Justification

1. Circumstances Making the Collection of Information Necessary

Human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) case reporting has been the underpinning of HIV/AIDS surveillance activities since the mid-1980s. All US states have reported AIDS cases using a standard case definition since 1985, and as of 2005, all states conduct surveillance for HIV infection without AIDS. Reported HIV and AIDS cases are entered into the HIV/AIDS Reporting System (HARS) database at the state and local level and data are shared with CDC, where the national HARS database is maintained. Early in the epidemic, case surveillance data were interpreted in the context of the natural history of HIV infection: clinical disease or severe immunosuppression was predictably (if distantly) related to the time of HIV infection, and AIDS trends accurately reflected past trends in HIV infections. However, as availability and prescription of highly active antiretroviral therapy (HAART) increased the interval between HIV infection and opportunistic infection (OI) diagnosis or development of severe immunosuppression became highly variable. Thus, case surveillance data on severe immunosuppression and AIDS-defining OI (AIDS-OI) diagnoses were no longer sufficient for monitoring clinical outcomes of HIV infection.

In response to the limitations of HIV/AIDS surveillance to characterize the evolving epidemic, supplemental surveillance systems were developed by the Centers for Disease Control and Prevention (CDC) and state surveillance programs during the 1990s to address emerging data needs. The Adult/Adolescent Spectrum of HIV Disease (ASD) project (clinically exempt from OMB/PRA Act), was implemented as a supplemental surveillance system to collect information on the natural history of HIV/AIDS, and later evolved to include data on treatment and clinical outcomes (e.g., AIDS-OIs, other illnesses, the impact of treatment and prophylaxis) of people with HIV infection who were in care (i.e., receiving care). ASD data were collected from 1990 to 2004 in 11 major U.S. cities.

Similarly, the Supplement to HIV/AIDS Surveillance (SHAS) project (OMB 0920-0262, exp. 06/30/2004) was implemented to collect behavioral information by interview of people living with HIV infection. SHAS interviewed people living with HIV infection from 1990 to 2004 in 19 states and local areas, providing important information on HIV testing and care-seeking behaviors, access to health care and ongoing sex and drug use behaviors.

CDC has played a critical role in providing data from supplemental surveillance projects to monitor the HIV/AIDS epidemic and provide data for use by HIV prevention planning groups and Ryan White CARE Act councils and consortia for resource planning and allocation. However, while ASD and SHAS each provided information useful for understanding the epidemic in its various stages, limitations, such as the lack of linked medical record and interview data, limited number of areas participating, and lack of nationally representative estimates for HIV-infected patients in care, resulted in the need for a new approach to collecting data on behaviors and clinical outcomes.

In 2000, CDC identified emerging issues in HIV surveillance, and called for restructuring HIV/AIDS surveillance systems to meet future challenges and the evolving epidemic. A multi-tiered surveillance system was proposed, in which all states would conduct case surveillance activities as the basis for monitoring the epidemic. The plan also called for the expansion of supplemental surveillance activities to at least 25 states, to collect information on clinical care and behaviors from a representative sample of persons diagnosed with HIV or AIDS – both those in care, and those not in care. These data would be used at local, state and national levels to supplement HIV and AIDS case surveillance data, and provide a more in-depth understanding of care and prevention needs.

At the request of Congress, an Institute of Medicine (IOM) committee in 2003 reviewed the status of HIV/AIDS surveillance data and the extent to which data currently collected by the HIV/AIDS case surveillance and supplemental surveillance systems were adequate for determining allocation of resources for treatment and care of HIV infection. The IOM committee recommended that the Health Resources and Services Administration (HRSA) and the CDC evaluate the cost and utility of redesigning studies to assess the specific needs and circumstances of people living with HIV. One of the approaches proposed by the

IOM was to coordinate HRSA and CDC efforts to survey a random sample of HIV-infected persons to develop more accurate measures of need for prevention and care services. The IOM recommendations influenced the development of the Medical Monitoring Project (MMP). Surveillance programs such as the MMP will be able to provide population-based estimates of clinical outcomes of interest (including quality of care), access to and use of HIV care, treatment, and prevention services, and levels of ongoing risk behaviors among persons living with HIV infection.

Based on the IOM recommendations and the benefits of obtaining locally and nationally representative data on behaviors and clinical outcomes, CDC is working with state and local health departments to obtain a national probability sample of patients in care for HIV infection – the MMP. The methods were developed in light of recommendations from the IOM, an earlier population-based survey of persons in care for HIV infection, and earlier CDC pilots of population-based methods.

As part of the work preparing for a national probability sample of HIV-infected patients in care, 9 MMP project areas have been piloting the MMP methods. These project areas have identified providers of HIV care, obtained samples of providers and patients, recruited providers and patients for participation, and have interviewed patients using questions from the SHAS project and 4 project areas abstracted data from patients' medical records using an abstraction instrument developed from the ASD instrument (which had a clinical exemption from OMB review). The questions used for MMP data collection are from SHAS and ASD, but the methods have changed as we have transitioned from SHAS and ASD to the population based methods of MMP. For these reasons, the program did not submit a formal request for OMB approval. Following a discussion between the Behavioral and Clinical Surveillance Branch and the Office of the Chief Science Officer (OCSO) staff October 27, 2006, Dr. Karr sent an e-mail to HHS requesting that they add the Medical Monitoring Project pilot to their Information Collection Budget for FY 2007. Pilot activities will not result in representative data at the local or national level.

Collection of HIV and AIDS case surveillance data is regulated by Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1).

2. Purpose and Use of Information Collection

At the national level, MMP data will be useful for tracking national trends in morbidity, and service access and utilization for focusing and prioritizing national initiatives to improve the provision of treatment and prevention resources, and for benchmarking and evaluating progress towards national prevention and treatment initiatives. Annual or bi-annual national estimates of rates of OI diagnoses will likely be the gold standard for measuring the effectiveness of reducing the severity of HIV-related disease, and for describing the characteristics of persons who have progressive HIV disease and the reasons for progression. This information can be used to inform treatment and prevention guidelines for HIV care and guide prevention efforts. Similarly, a nationally representative sample provides the ideal data source for evaluating progress towards national public health goals, such as describing the proportion of persons receiving appropriate care for HIV infection as described by Healthy People 2010 targets. CDC, HRSA and other governmental agencies are also required to account for use of resources to Congressional funders; for example, reporting of data on prevention of OIs and provision of prevention services, and on the proportion of CARE Act clients receiving CD4 counts and viral loads are required by the Government Performance and Results Act (GPRA).

National data will also be useful for documenting the need for treatment resources and the impact of treatment resources on care and treatment for people with HIV infection. Data on changing patterns of utilization of care and treatment resources will be critical to determining resource requirements for future funding cycles. Further, HRSA is required to provide documentation that care provided using CARE Act funds is at least as good as care supported by private funders of medical care. Data from the MMP will be used to answer national questions about care needs and impact of allocated resources.

MMP will collect data through face-to-face interviews and medical record abstraction. The data collected from the interview will include self-reported demographics, access to health care, adherence to antiretroviral medications, unmet needs for care and services, and sex and drug use behaviors (Attachment

2a). A short form (Attachment 2b) will be used to interview patients who are too ill to complete the standard interview or when the interview must be translated, and a proxy form (Attachment 2c) will be available if the patient consents to having a family member or other person answer the questions in the case of severe illness or in the event the selected participant died prior to being interviewed. Health department staff will attempt to collect basic demographic data on patients who refuse to participate in the interview from the patient or provider, or from existing surveillance data using a non-response form (Attachment 2d). In the event that the short or proxy form is used, the amount of time to administer the interview will be substantially less (approximately 20 minutes for each) compared with the standard interview (45 minutes).

The medical record abstraction will collect data on demographics, history of opportunistic and other illnesses, laboratory results, prescription of antiretroviral and other medications, resistance testing, and referrals to other care and services. Data will be collected using an electronic application on a laptop computer. A paper copy of what the electronic application looks like was developed to provide information on the abstraction data collection instrument for the OMB clearance process and for the local IRB process, when applicable (Attachment 3). Staff from participating providers' offices will pull medical records for MMP staff, or the staff will pull the medical records themselves. Medical records are pulled by clinic or health department staff for routine HIV/AIDS surveillance purposes, therefore, this activity should place minimal burden on providers or their staff.

Data from the interview portion of the project will also be relevant to evaluation of prevention initiatives for persons living with HIV infection, as envisioned in CDC's HIV Prevention Strategic Plan goals for reducing the number of people at risk for transmitting HIV infection. Data on key indicators of behavioral risks for transmitting HIV will be available with national, population-based inference, and can be used to determine progress towards national goals for HIV prevention and identify populations in need of additional research, improved interventions, or additional funds to support prevention programs.

At the local level, the MMP data will be useful for local HIV prevention program planning purposes, including the development of local epidemiologic profiles and responding to data requests from HRSA and other agencies which provide resources for HIV care and treatment. The MMP will provide information on the characteristics of persons in care for HIV infection and the types of care they are accessing, and will identify needs for prevention and care services among a representative sample of persons in care. Information about access to and use of these services can be used in the evaluation of local care and prevention services for people living with HIV.

The estimates of unmet need for HIV care and services, and quality of HIV care provided that are collected and reported using the MMP will assist state and local health departments in meeting reporting requirements of HRSA and other funders of HIV treatment and care. In an effort to reduce the burden on local health jurisdictions and improve comparability of data across reporting areas, HRSA and CDC collaborated on the development of data elements for the MMP, and will work together to determine reporting plans that will improve standardization of data collection methods.

A strategy to provide state-level estimates of important behaviors and clinical outcomes using a probability sample will change the quality of information available at the local level in two ways. First, in almost all cases in the past, HIV prevention community planning groups, CARE Act planning consortia and councils have utilized data from projects which, because of recruitment methods, were not necessarily representative of populations living with HIV in the community. Data from a local probability sample would improve the representativeness of the data available to planning groups. Second, data available from past supplemental surveillance projects have not generally been locally interpreted with confidence intervals to reflect the uncertainty around point estimates.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected electronically to minimize burden to respondents and interviewers. The standardized interview instrument (Attachment 2a) will be provided by CDC in a Handheld-Assisted Personal Interview computer format, i.e., an electronic handheld device. The interview instrument was developed using Questionnaire Development System (QDS) software (NOVA Research Company,

Bethesda, Maryland). All patient interviews will be conducted by trained state/local MMP staff.

An evaluation of supplemental surveillance data using handheld interview devices such as the ones being used for MMP has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per interview to .3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month.

In order to avoid data loss, and to ensure data security, at the end of each field visit the interviewers will be responsible for downloading and saving all data records into the local database. Once the downloading has occurred, all patient records should be deleted from the handheld computer's hard drive before leaving for the next interview.

Additionally, the cost of data collection using handheld devices instead of paper data collection forms is also reduced despite the increased startup costs associated with purchasing the handheld devices and interview software. The incremental cost of each collected survey decreases with each subsequent interview conducted, so that when collecting more than 195 interviews, it is less expensive to use the handheld devices than paper.

Provision of electronic data collection hardware and software, training and technical assistance will help to reduce the burden on grantees conducting MMP. Transfer of data collected electronically will eliminate the need for data entry at the state/local sites.

CDC/DHAP has piloted and implemented the use of handheld devices for other national surveillance systems. Many of the state and local health departments are licensed to use the software and have extensive experience with implementing interview projects using electronic data collection in the field.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the CDC-provided software and hardware, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide a manual (Attachment 4) with detailed instructions on interview conduct to participating state and local health departments. CDC will regularly train the interviewers and convene lessons learned meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the computer software programs as a further quality control measure.

Medical record abstraction will be conducted by state and local project staff trained in the abstraction of clinical variables from medical charts for all providers of HIV care who participate. Standardized software on a laptop computer will be used for abstraction of medical record data.

CDC is responsible for developing, reproducing and distributing the electronic medical record abstraction application (Attachment 3) to the participating state and local health departments. CDC will conduct abstractor training, and also provide a manual (Attachment 5) with detailed instructions for data abstraction to participating state and local health departments.

CDC will regularly train the abstractors and convene lessons learned meetings to understand the problems that can occur with the software and hardware that are used for conducting the abstraction. Automated edit checks will be built into the computer software programs as a further quality control measure.

4. Efforts to Identify Duplication and Use of Similar Information

There are currently no locally and nationally representative data on behaviors and clinical outcomes of patients in care for HIV infection.

Within CDC, data elements from the following previously used HIV supplemental surveillance projects

were reviewed and incorporated into MMP.

- Adult/Adolescent Spectrum of HIV Disease Project (ASD) (clinically exempt from OMB review)
- Supplement to HIV/AIDS Surveillance Project (SHAS) (OMB 0920-0262) exp. 06/30/2004
- National HIV Behavioral Surveillance (NHBS)

CDC discontinued the ASD and SHAS projects in anticipation of MMP and to avoid duplication of data collection efforts. The MMP study was also formed based on information taken from the behavioral surveillance data collected by state/local health departments for CDC. NHBS is currently collecting data on specific populations at increased risk for HIV infection (men who have sex with men, drug users and high risk heterosexuals), not on a population-based sample of HIV-infected patients in care. These local NHBS data collections are being done to pilot methods and data collection instruments and the project. Dr. Ida Onorato, Division of HIV Prevention Associate Director for Science in NCHSTP determined that these were local data collections, and that OMB review was therefore not required.

CDC has already established relationships with other federal stakeholders and consultants during the conception and development of MMP. Beginning in September 2003, consultations have been held with state and local health departments, the RAND Corporation, National Institutes of Health (NIH), HRSA, and other agencies. To promote collection of data that can be used by multiple agencies, ongoing communications with these federal and non-governmental partners will continue for the duration of this project. Meetings with these federal stakeholders and consultants who are aware of data collection on HIV-infected persons in care ensured that duplicate or similar data collection efforts do not exist. A one-time nationally representative sample of patients in care was drawn for the HIV Cost and Services Utilization Survey conducted by the RAND Corporation; this was done in 1996-1997 and has not been repeated.

5. Impact on Small Businesses or Other Small Entities

Initially, state or local health departments may be contacting providers of HIV care, including providers that are small businesses, to get an estimate of the number of HIV-positive patients to whom they provided care during the project period. Data collection will be kept to a minimum to lessen the burden on small businesses. Because providers are sampled proportionate to size, providers that are small businesses and have small patient loads will be less likely to be included compared with hospitals, clinics and group practices with larger patient loads. State and local health department MMP staff will work with facility staff to obtain records, similar to record review and data collection activities for reporting cases to HARS.

Data collected will be the same for patients from small and large providers. It is estimated that it will take providers an average of 5 minutes to pull each medical record for data abstraction. Staff from participating providers' offices will pull medical records for MMP staff, or the MMP staff will pull the medical records themselves. Medical records are pulled by clinic or health department staff for routine HIV/AIDS surveillance purposes, therefore, this activity places no additional burden on providers or their staff.

6. Consequences of Collecting the Information Less Frequently

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

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

Data must be collected more often than quarterly because patients will be approached at their health care appointments and ideally interviewed at that time. Data collection from the patient's medical record can be

done the same day or later in the project year. Quarterly data collection would not be logistically possible with approximately 400 patients to be interviewed and their medical records abstracted, because these 400 patients may have been selected for participation from 25-50 different facilities. Although data collection will occur on a more frequent basis than quarterly, each patient will only be approached, interviewed and have their medical records reviewed once during the project year. Each patient approached will be asked if they have been interviewed for the project during the project year. Patients who indicate that they have been interviewed previously will not be interviewed again.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8A. A 60-day notice to solicit public comments was published in the *Federal Register*, October 27, 2006, Volume 71, Number 208, page 63016. See Attachment 6 for a copy of the *Federal Register* notice. There were no public comments received.

8B. Several consultations outside of the agency were conducted with the following people:

Ms. Sandra Berry, MA Senior Behavioral Scientist RAND Corporation 1700 Main Street Santa Monica, CA 90407-2138 (310) 393-0411 X7051 berry@rand.org
Dr. Sam Bozzette, MD, PhD Senior Natural Scientist RAND Corporation 1776 Main St., m5s Santa Monica, CA 90407 (310) 393-0411 bozzette@smmail1.rand.org
Dr. Marty Frankel, PhD Statistician RAND Corporation 14 Patricia Lane Cos Cob, CT 06807 (203) 869-1324 Martin_Frankel@abtassoc.com
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Dr. Alice Kroliczak, PhD

Supervisory Health Scientist Health Resources and Services Administration Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 (301) 443-3592 AKroliczak@hrsa.gov Ms. Faye Malitz, MS Chief, Epidemiology and Data Branch Health Resources and Services Administration Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 (301) 443-3259 FMalitz@hrsa.gov Dr. Richard Conviser, PhD Health Scientist Health Resources and Services Administration Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 301-443-3075 RConviser@hrsa.gov Dr. Laura Cheever, MD Deputy Associate Administrator Health Resources and Services Administration Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 301-443-3067 LCheever@hrsa.gov
Dr. Robert Mills, PhD Health Statistician Health Resources and Services Administration Division of Science and Policy, HAB 5600 Fishers Lane, #7-90 Rockville, MD 20857 301-443-3899 RMills@hrsa.gov
Dr. Victoria Cargill, MD Director, Minority Research National Institutes of Health Office of AIDS Research 5635 Fishers Lane 4th Floor

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Drs. Bozzette, Frankel, Shapiro and Ms. Berry participated in the following consultations: in September, 2003 to discuss sampling methods and lessons learned from previous projects; in November, 2003 to commence planning, identify sampling approaches and design for clinical outcomes surveillance; in March 2004 to discuss Medical Monitoring Project domains; in October 2004 to discuss second and third stage sampling, review project progress and discuss sampling issues, stratification parameters, and review scientific quality issues; and in September 2005 to discuss patient sampling methods and tasks. They have also participated in bi-weekly conference calls from 2004 to the present.

Drs. Kroliczak, Mills, Cheever, Conviser, Bozzette and Ms. Malitz participated in a consultation in November 2004 to discuss how to use MMP data to meet HRSA data needs, how to avoid redundancy in data collections by CDC and HRSA grantees, and discuss research questions of interest to HRSA. The consultation also included discussions about future collaborations between CDC and HRSA on the MMP. Dr. Cargill has been consulted as needed since 2004. No major problems arose that could not be resolved during these consultation.

9. Explanation of any Payment or Gift to Respondents

Because the interview will take approximately 45 minutes to complete, to increase response rates, patients will be offered an incentive to participate. Participants will be given approximately $25 in cash for participation in the interview. The majority of project areas give $25, however, a few project areas have supplemented this amount using health department funds and give participants $30. If local regulations prohibit cash incentives, equivalent incentives may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

Incentives were used in the SHAS project (OMB 0920-0262, exp. 06/30/2004, described in #1 above), for persons who agreed to participate in the interview to help achieve adequate response rates. Participants were offered approximately $25 as compensation for their time. The decision was made to provide $25 as leverage to ensure adequate response rates as were obtained in the SHAS project. The SHAS project collected similar data from a similar population.

10. Assurance of Confidentiality Provided to Respondents

The CDC/ATSDR Privacy Act Officer has reviewed the MMP request and has determined that the Privacy Act does not apply to this data collection. Although the identities of respondents are known to health care providers and to the MMP project personnel who conduct interviews and abstract the respondents' medical records, data are not stored or accessed in a Privacy Act system of records, and the respondents' identifying information will not be submitted to CDC for inclusion in the final MMP dataset.

The Health Insurance Portability and Accountability Act (HIPAA) regulates how covered entities (including most health care delivery organizations) use and disclose certain individually identifiable information called protected health information (PHI). Surveillance data are specifically exempted from HIPAA because these data are required to be reported to the health department by state and local laws, and HIPAA permits health care providers to disclose PHI to public health authorities for the purposes of preventing or controlling disease. As a result, health department personnel can work with health care providers to identify potential respondents for the MMP. The project areas have a letter to providers from CDC's Acting Privacy Rule Coordinator to give to providers who would like further guidance regarding their participation in MMP and the impact of HIPAA on the disclosure of personally identifiable health information to a public health authority.

However, because respondent identities are known to the state and local health departments and other MMP staff that will collaborate with CDC on this data collection, MMP data will be covered by the appropriate CDC Assurance of Confidentiality ("Surveillance of Acquired Immunodeficiency Syndrome

(AIDS) and Infection with Human Immunodeficiency virus (HIV) and Surveillance-Related Data," RK-2001-036). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

In order to conduct the proposed MMP surveillance activities, CDC's health department collaborators and other MMP staff must have access to respondent identifiers in order to contact potential respondents, obtained informed consent, conduct respondent interviews, and facilitate medical record review and abstraction. Paper records that support these functions will be filed by the unique respondent ID code and the date of visit (not the respondent's name), and stored under lock and key. Respondents will be informed that their data will be maintained in a strictly confidential manner, that the data will only be used for stated surveillance purposes, and that the data will not be disclosed or released without their consent.

After MMP data are collected, health department personnel and other MMP personnel are responsible for deleting patient and physician names and other identifiers from the records transmitted to CDC (see Attachments 2a-2d and Attachment 3 for paper copies of the electronic data collection forms, and note that they do not contain specific identifiers). The records maintained by CDC are identified only by a computer-generated code number, the respondent's date of birth, and a state/city assigned patient identification number. CDC does not have access to information that would allow CDC personnel to re-link the data to respondent identifiers.

There is no linkage of MMP and HARS at the national level. State/local health departments may link patients in MMP with those in the HARS database, but the data collection applications used for MMP will not collect the HARS number.

Encryption security for all MMP data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

CDC is investigating several software products which will enhance the security of data stored on electronic devices. It is anticipated that licenses for this software will be provided to project areas by CDC prior to the start of data collection for the 2007 MMP cycle. The MMP data files must be transferred, or uploaded, from the electronic devices to the project area's secure storage drive on a frequent basis. All MMP data files must be transmitted to CDC using the Secure Data Network (SDN).

Informed consent will be obtained from all respondents prior to the interview. The informed consent process for respondents may be fulfilled by obtaining a consent document signed by the respondent, or if the participant is unable or prefers not to sign, by having the interviewer sign a consent document attesting to the respondent's verbal consent. CDC does not require this surveillance project to be reviewed by the CDC IRB, however, local data collection sites may require review and approval by a local IRB. A model consent document is included as Attachment 7; local IRBs may require minor modifications. All project areas must obtain consent from respondents and store the forms in a secure location. Even project areas that do not require local IRB approval for this project have agreed to obtain consent to insure that participants understand the purpose and the content of the interview prior to participating.

The Assurance of Confidentiality (Attachment 8) is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the

confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (http://www.cdc.gov/hiv/topics/surveillance/index.htm) and are required to undergo security and confidentiality training. MMP interviewers, abstractors, and data managers will undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." CDC-funded cooperative agreements to state and local health departments reference that successful awardees must comply with the requirements of the Assurance of Confidentiality as a condition of award. The authority for this data collection is provided by Section 306 of the Public Health Service Act (Attachment 8).

11. Justification for Sensitive Questions

HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. These modes of transmission necessitate the collection of sensitive data regarding HIV/AIDS status and medical history, sexual orientation, and sexual practices as well as alcohol and drug use. The MMP data collection will also request sensitive information relating to race/ethnicity, alcohol and drug use, mental health conditions such as depression and psychosis, history of suicide attempt, and history of arrest. Although the information requested is highly sensitive, the purposes of the MMP cannot be accomplished without their collection. Collection of these data will be used to understand barriers to HIV care and treatment and the impact of behaviors on the clinical course of HIV disease. These data will also be used to enhance HIV prevention programs designed to reduce high risk behaviors in persons most likely to acquire or transmit HIV.

All patient interviews will be conducted by trained MMP staff in a private location either as part of a routine visit to a medical facility, or by an interview at home, in a hospital or clinic, or other mutually agreed upon location.

12. Estimates of Annualized Burden Hours and Costs

Health department staff in most project areas will recruit sampled patients to participate. The state and local health departments are funded to conduct the project activities in the 26 project areas through a cooperative agreement. The burden on the health department is accounted for by the funding for these activities. In some facilities, providers may inform the patient that they have been selected and refer them to the health department MMP staff. Model patient recruitment scripts for provider recruitment and health department staff recruitment are included in Attachment 9.

The goal is to interview 10,400 patients. If the response rate is 80%, 8,320 patients will complete the interview. Each interview will take approximately 45 minutes. Interviews of patients who engage in few risk behaviors or have no risk behaviors (sexual behavior, drug and alcohol use) or who take few HIV-related medications or no medications will take slightly less time. Interviews of patients who engage in many risk behaviors or are taking many HIV-related medications may take slightly longer. The proxy and the short interview, each which will be used on approximately 2% of patients, will take approximately 20 minutes. Burden time for consenting patients for participation in the project is included in the interview estimates.

The burden on facility staff includes providing estimated patient loads (EPLs), providing patient lists, pulling medical records, and provider-referral enrollment among those who choose to contact sampled patients. We estimate that 90% of facilities provide project areas with EPLs, taking an average of 120

minutes each. It is estimated that 90% (7488) of medical records at each project area will be pulled by the facility staff, each taking an average of 5 minutes to pull. In many facilities, health department staff will pull the medical records and there is no burden on the providers' staff. We estimate that 30% of facilities will utilize provider-referral enrollment, contacting an estimated 3120 respondents. Project areas will provide facility staff with all materials (project pamphlets, letters to patients describing the project), and each provider-referral enrollment is estimated to take an average of 5 minutes.

Table A-12-1: Estimate of Annualized Burden Hours

Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (In Hours)	Total Burden (Hours)
Persons interviewed with standard interview	7,988	1	45/60	5,991
Persons interviewed with short interview	166	1	20/60	55
Persons interviewed with proxy interview	166	1	20/60	55
Facility staff pulling medical records	7,488	1	5/60	621
Facility staff providing EPLs	936	1	120/60	1,872
Facility staff providing patient lists	1,030	1	30/60	515
Patients approached by facility staff for enrollment	3,120	1	5/60	259
Total	20,894			9,368

Table A-12-2: Annualized Cost to Respondents

Note: The hourly rate was determined by using information obtained from the US Department of

Labor, Bureau of Labor Statistics.

Respondent	Total Burden Hours	Hourly wage rate	Total Respondent Cost
Interviewed with standard form	5,991	$16.34	$97,893
Interviewed with short form	55	$16.34	$899
Interviewed with proxy form	55	$16.34	$899
Facility staff pulling medical records	621	$13.82	$8,582
Facility staff providing EPLs	1,872	$13.82	$25,871
Facility staff providing patient lists	515	$13.82	$7,117
Patients approached by facility staff for enrollment	259	$13.82	$3,579
Total	9,368		$144,840

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Government

Government Related Expenses	Total
Personnel	$147,823
Cooperative agreement funds to project areas	$11,642,400
Incentives to patients ($25 x 10,400)	$260,000
Travel	$30,000
Meetings	$67,500
Printing	$2,000

The personnel related to this data collection include project officers at the GS 14 and 13 levels, a GS 13 level public health analyst, a GS 14 level statistician, a project manager, a project coordinator, a data manager, and a programmer. Approximately fifteen percent of related personnel's time will be allocated to data collection. Incentives of $25 will be offered to each respondent. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that will be held include interviewer and abstractor training, the community and the provider advisory board, and the local principal investigators' meeting.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A projected timeline of the MMP activities including a detailed description of data collection and submission information was provided to the 26 grantees in December 2004 and November 2005. The following is a brief overview of the MMP Timeline.

Activities	**Time Schedule**
Facility recruitment	1 month after OMB approval
Patient lists obtained	2-3 months after OMB approval
Interview patients	3-6 months after OMB approval
Abstract medical records of interviewed patients	3-6 months after OMB approval
Evaluation	7-8 months after OMB approval
Analysis	9-12 months after OMB approval
Publication	12 months after OMB approval
Facility recruitment (year 2)	13 months after OMB approval
Patient lists obtained	14-15 months after OMB approval
Interview patients	15-18 months after OMB approval
Abstract medical records of interviewed patients	15-18 months after OMB approval
Evaluation	19-20 months after OMB approval
Analysis	21-24 months after OMB approval
Publication	24 months after OMB approval
Facility recruitment (year 3)	25 months after OMB approval
Patient lists obtained	26-27months after OMB approval
Interview patients	27-30 months after OMB approval
Abstract medical records of interviewed patients	27-30 months after OMB approval
Evaluation	31-32 months after OMB approval
Analysis	33-36 months after OMB approval
Publication	36 months after OMB approval

Data collection in years 2 and 3 will involve the same activities and follow the same time schedule listed in the timeline. Data from MMP are expected to improve surveillance activities, inform prevention programs and treatment services, inform about the unmet need in HIV care, and increase existing knowledge in the medical care of HIV disease. Results are also expected to guide national surveillance efforts particularly in the use of both medical abstraction information and self report from an interview by increasing our understanding of conditions that were difficult to asses using only interview or medical record abstraction. As MMP is a surveillance system that represents HIV infected persons in the US 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, while other results will be more meaningful once aggregated across sites. Each participating facility or practitioner will have authority over the release of their facility-specific data (i.e., they choose whether or not they will participate and if patients will be identified to the health department by name or coded identifier). Each participating health department will be responsible for the release of local data. CDC will have primary responsibility for the release of data aggregated from each geographic area and will provide this information to all collaborating health departments. These data will be distributed to the providers, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars. Furthermore, CDC will regularly publish surveillance reports using data collected annually.

Patients and community members will be able to be informed of MMP findings through multiple conduits of information. National data results will be released on the CDC, MMP website and through national

publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, presentations to local AIDS Service Organizations and community planning bodies and at conferences and workshops.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, Certification for Paperwork Reduction Act Submissions, of OMB Form 83-I.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Method

The MMP uses a three-stage sampling approach designed in collaboration with statisticians from the RAND Corporation. The first stage of sampling resulted in the selection of 20 of 52 eligible geographic primary sampling units (PSUs, defined as 50 states, Washington, DC, and Puerto Rico) using probability proportional to size (PPS) sampling methods. The six cities separately funded for HIV/AIDS surveillance were included in the 20 selected PSUs and were thus also funded as project sites, resulting in a total of 26 project areas. Sampling methods ensured representation of all regions of the US. In the second stage, providers of HIV care (i.e., providers that prescribe antiretroviral therapy [ART] or order CD4 or HIV viral load tests) are sampled. The sampling frame of providers is developed in each participating state using data from local HIV/AIDS case surveillance, laboratory reporting, AIDS Drug Assistance Programs and other available data sources. Providers will be sampled PPS based on their patient caseload. In the third stage, local HIV/AIDS surveillance staff will work with each selected provider to develop a list of HIV-infected patients who received care from the provider at least once during the previous calendar year. From this list, a sample of patients will be chosen by systematic random sampling.

Through an informed consent process, selected patients are offered participation in an interview with the understanding that their medical records will also be reviewed. Data collected from the interview and medical record abstraction include demographics, access to health care and quality of care received, prescription of ART and other medications, adherence to ART, met and unmet needs, high-risk sexual and drug use behaviors, laboratory indicators (e.g., CD4 counts, viral loads), AIDS-OIs, quality of life and access to prevention services. The questionnaires comply with OMB standards on race and ethnicity. Eligible patients will only be interviewed once during a project year. Health department staff will attempt to collect basic demographic data on patients who refuse to participate in the interview from the patient or provider, or from existing surveillance data using a non-response form (Attachment 2d).

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

These methods will result in a representative sample of patients receiving HIV care at the national and the project area level. More detail about each of these stages of sampling is provided below.

The first stage of sampling employed a random, stratified sample with probabilities proportional to a measure of size. Because our goal is to obtain a national probability sample of adults in care for HIV infection in the US, all 50 states plus the District of Columbia (DC) and Puerto Rico (PR) were considered eligible to participate. Fifty states, DC, PR, and six cities: Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco were eligible to receive funding. The decision was made to include these separately funded areas (cities) in their respective states for the purposes of sampling. Therefore the first stage sampling frame consisted of 52 PSUs: the 50 states plus DC and Puerto Rico.

Systematic PPS sampling was used with the measure of size being the total number of persons living with AIDS (reported to the national HIV/AIDS Reporting System [HARS]) (collected under OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Reports) at the end of 2002). Based on available funding it was decided to select 20 PSUs at the first stage of sampling. Since the first stage of sampling was carried out with probabilities proportional to a 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 prevalent AIDS cases in the United States.

At the second stage of sampling, facilities currently providing medical care for HIV-infected adults will be sampled separately within each project area. A facility is defined as any hospital, clinic, health care facility, group or private physician practice that share common medical records or a medical records system.

In each funded area a sampling frame of unique (i.e., unduplicated) facilities currently caring for HIV-infected patients during the project period will be constructed. In addition, because facilities will be sampled PPS, an estimate of the number of patients currently in care for HIV at each facility, or estimated patient load (EPL), is also needed.

A starting point for this sampling frame is facilities that have reported information on patients with HIV or AIDS to HARS. However, because the goal is to have a complete list of facilities ***currently*** caring for HIV-infected patients in each project area, the facility list from HARS will need to be supplemented with lists of facilities obtained from other data sources. These supplemental sources may include: state laboratory reporting databases, AIDS Drug Assistance Programs, Medicaid claims, and/or HIV medical association membership lists. For each data source used, an EPL for each unique facility should be determined.

Once the lists from HARS and each of the supplemental sources have been completed, they will be combined into a single facility sampling frame. The next step is to determine which EPL will be used for PPS sampling of the facilities. The determination of which of the EPLs from various sources should be used will be a subjective process. That is, health department staff, based on their knowledge of the facility and of the accuracy of the data sources will determine which data source produced the most accurate EPL, which will be the one they recommend will be used for sampling. Once the matrix of EPLs has been completed, each site should contact their CDC project officer to discuss the data sources used to construct the sampling frame and determine the reliability of the EPL from each of those sources.

Any facility which provided HIV care during the facility time period is eligible to be included in the facility sampling frame. For the purposes of MMP, HIV care is defined as conducting CD4 or HIV viral load testing or providing prescriptions for antiretroviral medications. Thus, facilities providing HIV care could include hospitals or other inpatient facilities (including psychiatric hospitals and drug treatment facilities), outpatient facilities such as hospital-affiliated clinics, free-standing clinics or private physician offices, prisons, jails, and Veterans Administration facilities.

Facilities known not to provide 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 rooms, facilities located outside of the funded area, facilities that have closed or at which access to medical records is known to be impossible, federal prisons and health facilities located on military installations. Facilities that have provided HIV care to only patients under the age of 18 should also be excluded from the facility sampling frame. We do not currently have an estimate of the proportion of state cases represented by these facilities where access is not possible, such as federal penitentiaries and military bases. This estimate would be difficult to determine without the direct cooperation from those facilities because the state the person was diagnosed and reported in may not be the state in which they are institutionalized or serving in.

Facilities will be stratified for sampling based on size (i.e., the EPL, during a one year time period) into either a large, medium, or small stratum. These three size strata will be formed based on the proportion of patients in each facility and the methodology of PPS sampling.

Before the stratification of facilities can occur, the number of facilities to be sampled within a project area (call this n_{fac_tot}) must be decided. Based on theoretical and practical consideration, between 40 and 60 facilities will be sampled in each project area. These considerations include having an adequate number of facilities included in the project area – not too few so the community and providers do not feel it could not be representative, and not too many so the amount of travel to reach all of them proves burdensome to health department staff conducting the project activities. The exact number is chosen by the RAND consultant sampling statistician, taking into account the number of large facilities, the total number of facilities, and the distribution of facilities within the different size strata. The facilities will be selected with probability proportional to size, and in most project areas, a total of 400 patients will be selected. Most states use 4 to 5 geographic strata to ensure face validity of the sample of facilities selected. We set a minimum number of 25 facilities sampled per project area, which is sufficient to select a representative sample of 400 patients from in areas with many large facilities (and therefore, large HIV patient loads). For example, Los Angeles and Houston will each have a sample of 400 patients drawn from 25 facilities. Areas with larger geographic areas and more medium and small facilities will need more facilities in their sample from which to draw patients. For example, California (excluding Los Angeles and San Francisco) has 68 facilities and Oregon has 60. These decisions are made on a project area-by-project area basis in consultation with the sampling statistician.

Several pieces of information are used to determine into which stratum (i.e., large, medium, or small) each facility is placed. These include:

- the number of facilities to be sampled (n_{fac_tot})
- the assigned patient sample size for each project area (call this n_{pat_tot})
- the total estimated patient load for all the facilities on the facility sampling frame (total EPL)
- the overall patient sampling rate (overall sampling rate = assigned patient sample size / total EPL)

We will make use of the following relationships:

- the number of facilities to be sampled in each stratum adds to the total number of facilities to be sampled ($n_{fac\_tot} = n_{fac\_large} + n_{fac\_medium} + n_{fac\_small}$)
- the number of patients to be sampled in each stratum adds to the total number of patients to be sampled ($n_{pat\_tot} = n_{pat\_large} + n_{pat\_medium} + n_{pat\_small}$)

Once these parameters are known they drive the definition of facility size strata and other aspects of the sampling.

We will use an example to describe the process of how facilities are placed into one of the three strata. In our example, we have the following values:

- the number of facilities to be sampled ($n_{fac\_tot} = 50$)
- the assigned patient sample size for the project area ($n_{pat\_tot} = 750$)
- the total estimated patient load for all the facilities on the facility sampling frame (total EPL = 7,500)
- the overall patient sampling rate (overall sampling rate = assigned patient sample size / total EPL = 750/7,500 = 1/10 = 0.10)

Under PPS sampling, any facility with at least ($100/ n_{fac\_tot}$)% of the total EPL is defined as a large facility and sampled with certainty. The number of patients to be sampled from large facilities is calculated as the total EPL for the large facilities times the overall patient sampling rate. The identification of facilities to be sampled with certainty is an iterative process.

In our example, any facility with at least 2% of the total EPL (i.e., (100/50)% = 2%) is defined as a large

facility and sampled with certainty. Another way of saying this for our example is that any facility with an EPL of 150 or larger is defined as large (i.e., 2% of 7,500 = 150) and sampled with certainty.

In this example, the overall patient sampling rate is 0.10; consequently, 10% of patients will be sampled overall. In addition, this is the rate at which patients will be sampled from facilities in the large facility stratum. Suppose in our example that there are only 3 large facilities (i.e., $n_{fac\_large} = 3$). Also suppose that the total EPL for the 3 large facilities is 1,500. Then 150 patients would be sampled from the large facilities (i.e., total EPL for the large facilities time the overall patient sampling rate = 1,500 x 0.10 = 150 patients).

The next step is to remove the large facilities from the sampling frame. The facilities remaining on the sampling frame will be partitioned into medium facilities and small facilities. The number of patients to be sampled from the medium and small facilities is the total patients to be sampled minus the number of patients to be sampled from the large facilities. The average cluster size for the remaining facilities is calculated as the total patients to be sampled from the medium and small facilities divided by the number of remaining facilities to be sampled. Those facilities with EPL smaller than the average cluster size are defined as small; all remaining facilities not previously identified as large are classified as medium.

In our example, there are 47 facilities remaining to be sampled (i.e., $n_{fac\_medium} + n_{fac\_small} = n_{fac\_tot} - n_{fac\_large} = 50 - 3 = 47$). The number of patients to be sampled from the small and medium facilities is 600 patients (i.e., $n_{pat\_medium} + n_{pat\_small} = n_{pat\_tot} - n_{pat\_large} = 750 - 150 = 600$). The average cluster size is 13 (i.e., $(n_{pat\_medium} + n_{pat\_small}) / (n_{fac\_medium} + n_{fac\_small}) = 600/47 = 12.8 \sim 13$). Any facility in our example that had an EPL less than 13 would be defined as a small facility and the remaining ones not previously identified as large would be defined as medium-size facilities.

Once completed, each site will send its facility sampling frame, which must include an EPL for each facility to CDC via the Secure Data Network for sampling. The sampling frame sent to CDC should be stripped of any identifying information; facilities will be identified only by a unique numeric facility ID number that will be assigned at the project area. Facility ID numbers will be made unique across all project areas by the addition of a 4 digit numeric site code in front of the initial 4 digit facility ID number.

For each site the RAND sampling statistician, in conjunction with the CDC project officer and the site, will select a PPS sample of facilities. Each project area will determine, in consultation with RAND and CDC, the number of facilities to be sampled; in most project areas, between 40 and 60 facilities will be sampled each year. While CDC, RAND and the state or local health department will jointly review the final stratified list of facilities, ultimately the demands of the sampling design will determine the number of facilities that will be selected from each stratum.

Once the sample of facilities is selected, the local area will contact each sampled facility to inform them that they have been selected to participate in the project, and to determine when and how a list of the HIV infected patients currently in their care will be obtained. Because the patient list is necessary for calculating sampling fractions, they must include all HIV-infected patients in care, whether or not they have been reported to HARS. Details of how medical record abstraction will be conducted and how patients will be recruited for interviews should also be discussed.

The goal is to obtain participation in MMP from all sampled facilities. The generalizability of a probability sample depends upon an adequate overall coverage or response rate. The validity of population estimates from MMP could be questioned if the overall response rate obtained is less than 75%. Therefore, an overall response rate of at least 75% should be obtained for MMP at both the local and the national level. The higher the overall response rate the more credible the population estimates obtained will be.

The overall response rate is the product of site, facility, and patient response rates. If 100% of project areas, 75% of facilities, and 75% of patients from each participating facility are enrolled, the overall response rate is 1.0*.75*.75=.56 or 56%. Since all 26 project areas selected in the first stage of sampling have agreed to participate, an overall 75% response rate at both the local and national level can be achieved through any of

the following scenarios:

Facility response rate = .80	Patient response rate = .94
Facility response rate = .85	Patient response rate = .88
Facility response rate = .90	Patient response rate = .83
Facility response rate = .95	Patient response rate = .79

The lower the facility response rate is the higher the patient response rate will need to be to achieve the same overall response rate.

It is expected that a high level of effort will be needed in order to get each sampled facility to participate in the project. Each site should have a strategy for contacting sampled providers based on their experience working with facilities on similar projects. Experience from previous surveillance projects suggests that difficult to enroll facilities might best be contacted by the medical director of the health department or HIV program. Alternatively, a local provider advisory board member might be used to recruit facilities that are reluctant to participate. Because a high facility response rate is critical to the success of MMP, each participating health department should develop a strategy for facility recruitment that will maximize this response rate. Project areas have been marketing the project to providers and patients in their jurisdictions and support for the project is strong, which should contribute to higher response rates.

Even if a facility is not willing to participate, the facility will remain in the sample. No substitutions will be made for facilities that cannot be persuaded to participate. A facility that refuses to participate has refused participation for all of its patients. This means that these patients and patients like them would have NO opportunity to be represented by this project. Substitution of sampled facilities or patients would invalidate the sampling design of the project. If substitutions are allowed, inference to the population of HIV infected patients in care in the US cannot be made. Facilities that were not selected and their patients may not have the same attributes as sampled facilities and their patients. Substitutions would bias the sample in a manner that cannot be predicted nor adjusted for.

Within each participating facility, patients will be randomly sampled for inclusion in MMP. Patients will be sampled from lists of patients seen during the PDP. The 2007 PDP is the 4 month period January 1-April 30, 2007

A list of patients who received HIV care during the PDP should be requested from all facilities selected into the sample during the second stage of sampling. The facility can give the health department a list of patient names without patient consent (facility and patient names are not sent to CDC). These patients should be in the HIV/AIDS reporting system; the health department in every area has explicit legal authority, conferred by state law, to collect information on patients with HIV within the state. In most cases, the health department will already have the names. Although this legal authority exists in every state, providers that do not want to provide a list of patient names can provide the health department with a list of coded identifiers. Methods for constructing patient lists may vary based on the type of facility. Most facilities have automated systems and can easily generate a list of patients. Providers without automated systems are generally those with small HIV caseloads. Starting at the beginning of the population definition period, these facilities can keep a log of all HIV-infected patients that receive care during the population definition period. Some suggested strategies for different types of facilities include using lists of patients seen in the specialty clinic or a list of patients with HIV-related ICD-9, ICD-10, procedures or tests (i.e., CPT), or prescription codes during the PDP**.** Health department staff can assist staff in providers' offices if needed. Note that HARS is only used as a way to identify facilities during the second stage of sampling. HARS is not used as a source for generating patient lists during this third stage of sampling.

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

Other subsets of patients in care, such as those who received all their HIV-related care from emergency rooms or medical facilities on military bases, may have been excluded in a project area when the facility sampling frame was constructed based on criteria set forth in the section on second stage sampling. Note that these exclusions are based on eliminating certain types of facilities from the facility sampling frame *not from excluding all patients who receive any care at such facilities.* Information on patient visits to ERs will be obtained during interviews and/or may be documented in medical records.

Note that these conditions are related neither to report to HARS as an HIV or AIDS case nor, if reported, to the current facility having reported data for this patient.

Once a project area has obtained patient lists, they should be stripped of identifying information and sent to the CDC using the Secure Data Network. It is not necessary to wait until all patient lists within a stratum are obtained before sending de-identified lists to CDC. Individual patients will be identified only by a 12 digit numeric patient ID number that will be assigned at the project area. This should be a unique identifier that will be associated with that patient throughout the project and which should appear on all data collection forms and in all data bases. Patient ID numbers will be formed starting as 4 digit numbers that are assigned consecutively to patients on each facility's edited patient list. The allocation of patient sample among the facility size strata will be done in a manner that will result in an equal probability of selection method (EPSM) sample at the patient level. In general this means that an equal number of patients will be sampled from each facility within a facility size stratum. Sampling of patients will be done using SAS Proc SurveySelect to draw a simple random sample of patients within each facility. Lists of selected patients' ID numbers will be returned to the site after sampling is completed for patients. All patients included in the sample should be pursued for enrollment in the study; the total number of sampled patients will be used in the denominator for calculating patient response rates.

Persons selected during third stage sampling may be offered enrollment through two recruitment scenarios; staff-contact enrollment, or provider-referred enrollment. The recruitment strategy utilized by facilities will vary based on clinic needs and patient load. It is anticipated that each project area may utilize a variety of recruitment scenarios.

During staff-contact enrollment, facilities will provide local MMP staff with contact details for patients being sought for recruitment. Local MMP staff will use patient contact lists to initiate phone contact with eligible persons to describe the project and offer enrollment. Standardized contact scripts developed by the project areas with CDC input will be used by sites to ensure a standardized approach is used for recruitment. Model patient recruitment scripts are included as Attachment 9. Project areas can modify these scripts to meet their specific needs. Unless the CDC model scripts are modified, additional OMB approval will not be sought for modifications made by individual project areas. The individual project area modifications will likely be minor. Patients who are eligible for enrollment and express interest in participating will be scheduled to have an interview done in a location meeting the needs for patient privacy.

Instead of giving the health department the names of the sampled patients, some providers prefer to contact the patient first and let them know they have been selected to participate. Patients recruited through this method - provider-referral enrollment - will have their initial contact with the project made by staff from the provider's office from which they were sampled. Staff from the clinic will provide patients with a brief verbal description of the project and ask permission to provide their contact information to MMP staff to complete enrollment or staff will provide the sampled patient with the MMP health department staff contact information. The same verbal description of the project used in the Model Patient Recruitment Script described above can be used on the phone or in the provider's office. Model scripts for facility use and health department staff use are included in Attachment 9. Consent for participation or providing information to the health department is not obtained at this time.

Based on experience from previous projects, the staff contact enrollment method appears to be able to achieve higher enrollment rates. In all cases, MMP staff will coordinate with the patient's provider in order to ensure that provider and patient privacy issues are addressed.

At high volume facilities using real-time sampling, MMP staff will approach eligible individuals attending the facility for enrollment into the project, describe the project and offer enrollment. Persons agreeing to participate then can either be administered the interview at that time or schedule an appointment for an interview in the future.

Nine MMP project areas conducted medical record abstraction and/or interview during 2005. The pilot testing of the project was determined not to require OMB approval. Sample sizes per site ranged from 100 to 500 during 2005. The remaining project areas were conducting start-up activities in 2005. Start-up activities included all project activities with the exception of participating in interviewer and abstractor trainings and data collection. In Years 3-4 (2007-2008) all areas will conduct both interview and medical record abstraction on sampled patients.

Because MMP is mainly descriptive, power calculations – which are used in sample size determinations for testing specific hypotheses – were not performed. Instead the level of precision – i.e., the estimated 95% confidence interval half-width – was the criteria used to determine individual project area sample sizes. Ninety-five percent (95%) confidence interval half-widths were calculated for a variety of sample sizes and design effects. It was decided that the minimum sample size that would be necessary for a state to obtain total population estimates with an acceptable level of precision (assuming a moderate design effect) was 400. This sample size was assigned to the states with the lowest AIDS prevalence. Sample sizes for states with higher AIDS prevalence were determined by considering the distribution of cases among the 20 sampled states and 6 separately funded cities contained within them and a target national sample size of approximately 10,000. This sample size will allow national estimates to be obtained with an acceptable level of precision (assuming a moderate design effect) for subpopulations that comprise as little as 5% of the total population of interest. Attachment 10 outlines the target sample size and associated activities for the project areas during 2007.

The required precision will depend on the purpose for which an analysis is done. CDC, in consultation with the states, have determined that the expected precision (which won't be known until after the data collection is complete) will result in estimates and confidence intervals (CIs) that are useful for local planning and policy purposes. For some comparisons, data will need to be combined at the national level to have acceptable precision. In addition, the design effect will be different for different outcomes, and also depends on the within-provider correlation. We will not know a priori what level of precision we will have until the first data are collected and analyzed.

The level of precision of these estimates will depend on the number of patients from whom data is obtained and also on the design effect. Design effect refers to the variance inflation that is introduced by using a multi-stage complex sampling design to obtain our patient samples.

Design effect is the variance obtained using the 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.

Because CIs are calculated using the standard error, which is the square-root of the variance, a design effect of 2 means that CIs are 1.41 times as wide as those that would have been obtained using a simple random sample of the same size. Similarly, 95% CI half-widths for a design effect of 4 will be 1.41 times as wide as those for a design effect of 2 given the same sample size and sampling design.

Less precision means that a wider 95% CI is obtained; more precision means that a narrower 95% CI is obtained. Please see the table and examples below.

95% Confidence Interval Half-widths
for various sample sizes and design effects*

Design effect = 2

	CI half-width	CI half-width	CI half-width	CI half-width	CI half-width
n	**total population**	**subpopn = 50%**	**subpopn = 25%**	**subpopn = 15%**	**subpopn = 10%**
100	13.86%	19.60%	27.72%	35.79%	43.83%
200	**9.80%**	13.86%	19.60%	25.31%	30.99%
400	6.93%	9.80%	13.86%	**17.90%**	21.91%
500	6.20%	8.77%	12.40%	16.01%	19.60%
800	4.90%	6.93%	9.80%	12.65%	15.50%
1000	4.38%	6.20%	8.77%	11.32%	13.86%
1200	4.00%	5.66%	8.00%	10.33%	12.65%
1300	3.84%	5.44%	7.69%	9.93%	12.16%
Design effect = 5					
	CI half-width	**CI half-width**	**CI half-width**	**CI half-width**	**CI half-width**
n	**total population**	**subpopn = 50%**	**subpopn = 25%**	**subpopn = 15%**	**subpopn = 10%**
100	21.91%	30.99%	43.83%	56.69%	69.30%
200	15.50%	21.91%	30.99%	40.02%	49.00%
400	10.96%	**15.50%**	21.91%	**28.30%**	34.65%
500	9.80%	13.86%	19.60%	25.31%	30.99%
800	7.75%	10.96%	15.50%	20.01%	24.50%
1000	6.93%	9.80%	13.86%	17.90%	21.91%
1200	6.33%	8.95%	12.65%	16.34%	20.00%
1300	6.08%	8.60%	12.16%	15.70%	19.22%

Consider Project Area A that obtains interview and medical record abstraction data on approximately 400 patients and where African-American patients comprise approximately 15% of the patients in their MMP data. For a design effect of 2 they could expect to obtain 95% CI half-widths of approximately $\pm$ 17.9% on an estimate for African-American patients. If a design effect of 5 is assumed the expected 95% CI half-width for the same subpopulation estimate would be approximately $\pm$ 28.3%.

By contrast, Project area B, where African-Americans comprise approximately 50% of the patients in a set of 400 observations, would expect a narrower 95% CI half-width of approximately $\pm$ 9.8% for the same subpopulation estimate for a design effect of 2. Assuming a design effect of 5 an estimate for African-American patients would have an expected 95% CI half-width of approximately $\pm$ 15.5%.

Estimates that will have acceptable level of precision at both the national and local level will include the following:

- The distribution of patients receiving HIV care by demographic characteristics (sex, race/ethnicity, age group, education).
- The proportion of eligible persons prescribed highly active antiretroviral therapy.
- The proportion of eligible persons prescribed prophylaxis for *Pneumocystis jiroveci* pneumonia.
- The proportion of persons reporting ever using injection drugs.
- The proportion of persons reporting sex without a condom in the past 12 months.

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

It is expected that this number of paired interviews/chart abstractions will be obtained while maintaining an interview response rate needed to achieve an overall response rate of at least 75%.

2. Procedures for the Collection of Information

The MMP design is a three-stage sampling approach. The first stage of sampling resulted in the selection of 20 of 52 eligible geographic primary sampling units (PSUs, defined as 50 states, Washington, DC, and

Puerto Rico) using probability proportional to size (PPS) sampling methods. The six cities separately funded for HIV/AIDS surveillance were included in the 20 selected PSUs and were thus also funded as project sites, resulting in a total of 26 project areas. In the second stage, providers of HIV care (i.e., providers that prescribe antiretroviral therapy [ART] or order CD4 or HIV viral load tests) are sampled PPS based on their patient caseload. In the third stage, a sample of patients will be chosen from selected providers by systematic random sampling.

Patients will be interviewed first and then their medical record will be abstracted. The time period of interest for the interview (i.e., the surveillance period) will be the 12-month period directly preceding the interview. Information from the patients' medical records will be abstracted for this same time period.

All patient interviews (Attachment 2) will be conducted by trained MMP staff in a private location either as part of a routine visit to a medical facility, or by an interview at home, in a hospital or clinic, or other mutually agreed upon location.

The entire interview is expected to last for approximately 45 minutes. Interviews of patients who engage in few risk behaviors or have no risk behaviors (sexual behavior, drug and alcohol use) or who take few HIV-related medications or no medications will take slightly less time. Interviews of patients who engage in many risk behaviors or are taking many HIV-related medications may take slightly longer. The interview will collect behavioral information relevant to medical care and clinical outcomes. The questionnaire (Attachment 2a) will consist of 5 required (core) modules that all sites will administer and an additional optional module which sites can opt to administer. Estimates of burden for the questionnaire were made including the optional module.

The standardized interview instrument (Attachment 2a) will be provided by CDC in a Handheld-Assisted Personal Interview format so that data will be collected electronically. The interview will be administered face-to-face using electronic handheld devices. The interview instrument was developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland).

Participants will receive prevention materials at the end of the interview, referrals to local prevention and care services, and also prevention information from the MMP staff, as requested.

For quality assurance purposes, a 10% subset of interviews will be observed by the project coordinator to determine accuracy and completeness. Additionally, interviewers will have periodic peer review of interviews to ensure the consistency in administration techniques across interviewers.

In order to avoid data loss, and to ensure data security, at the end of each field visit the interviewers will be responsible for downloading and saving all data records into the local database. Once the downloading has occurred, all patient records should be deleted from the handheld computer's hard drive before leaving for the next interview.

CDC will regularly train the interviewers and convene lessons learned meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the computer software programs as a further quality control measure.

Medical record abstraction (Attachment 3) will be conducted by local project staff trained in the abstraction of clinical variables from medical charts. Standardized software on a laptop computer will be used for medical record abstraction. The information to be collected will be primarily related to diagnosis of opportunistic illnesses, provision of preventive therapies, prescription of antiretroviral medications, adverse events due to medications, and health services utilization.

Similar information is being collected from both the interview and the medical record abstraction in this first full data collection year to evaluate which data elements are best collected by which data collection method. We will do analyses to test for concordance among information collected by self report and information documented in medical records for these variables. Once we have evidence that certain data elements are better collected using interview or abstraction, questions will be eliminated from the less

suitable instrument.

Inconsistencies will be examined to determine the reasons for discordant findings. We expect that patients will not know the answers to many of the clinical questions (e.g., highest ever HIV viral load), and that time since the event may decrease the patients' ability to recall (e.g., date and result of first CD4 test). We also expect that patient self report will result in better information on race/ethnicity since this information may be documented in the medical records without consulting the patient. Self-reported drug use, which may be fully disclosed to a provider in a clinical setting, may not be documented in detail in the medical record, and therefore, may be better ascertained through the interview process.

Information will also be used to help determine what data to collect in future data collection cycles. Some patients have been living with HIV for over 20 years and have seen multiple health care providers during that time. Historical data of important events (ever had an AIDS-defining opportunistic illness, ever been prescribed prophylaxis for *Pneumocystis jiroveci* pneumonia, types of antiretroviral medications prescribed) may not be available in patients' medical records if they have moved often or parts of their records have been archived. It is important to determine if this information can be obtained by patient self-report, or if efforts to collect such historical information are not worthwhile.

Information that will be collected in both the interview and medical record abstraction for evaluation include the following:

- Demographics (date of birth, sex, race/ethnicity, insurance status)
- CD4 count (value and date of first, lowest and most recent in past 12 months)
- HIV viral load (value and date of first, highest and most recent in past 12 months)
- Ever prescribed antiretroviral therapy and classes of drugs ever prescribed
- Ever prescribed prophylaxis for *Pneumocystis jiroveci* pneumonia or *Mycobacterium avium* complex
- Receipt of influenza and hepatitis vaccinations
- Diagnosis of sexually transmitted infection (syphilis, gonorrhea, herpes or human papillomavirus) in the past 12 months
- Drug use (injection and non-injection) in the past 12 months

Information collected using both instruments will not always be identical. For example, in the interview patients are asked about their drug use; in the medical record physical evidence of drug use or referral to drug treatment may be documented. This may indicate drug use among participants who denied drug use when interviewed. Another example is that respondents are asked during the interview if they had unprotected sex, and documentation of sexually transmitted infections is collected in the medical records.

The personally identifying information used to select patients will not be collected on the completed abstraction forms; however, each person will be assigned a unique ID as defined in the section Third Stage Sampling. If selected patients do not have medical records due to loss or misfiling, they will not be replaced by another patient. One record will be used for each patient visit; however, all visits that occur during the surveillance period to the selected facility need to be abstracted. A patient will have as many records as the number of visits he/she had during the surveillance period.

In addition to the facility from which the patient was sampled, data will also be abstracted from the medical records at other facilities from which the patient received care during the surveillance period. If records at the sampled facility document care received at another facility, or there is information captured by interview showing additional sources of care during the surveillance period, the project staff should abstract those records. Records are accessible from non-sampled facilities through the project areas' HIV/AIDS surveillance authority, but will be accessed with the facilities' permission. The additional facilities from which medical records will be abstracted will include:

Infectious disease specialists or other providers of primary HIV care
Sexually Transmitted Disease (STD) clinics
Tuberculosis (TB) clinics
OB/GYN practices or clinics (for women)

Acute care hospitals (for hospitalizations)

CDC is responsible for developing and distributing the medical record abstraction software program to the participating state and local health departments. CDC will conduct abstractor training, and also provide a manual with detailed instructions for data abstraction to participating state and local health departments.

CDC will regularly train the abstractors and convene lessons learned meetings to understand the problems that can occur with the forms, software and hardware that are used for conducting the abstraction. Automated edit checks will be built into the computer software programs as a further quality control measure.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the CDC-provided software and hardware, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide a manual with detailed instructions on interview conduct to participating state and local health departments.

Completed MMP electronic abstraction records (Attachment 3) should be visually scanned to check for completeness. A 10 % subset of medical records should be re-abstracted by a second, independent reviewer and compared to the original abstraction form to determine completeness and discrepancies. The medical records selected for re-abstraction should be from a variety of facilities, abstractors, and time periods.

In addition, to enhance the quality of the data collected, standardized definitions, codes, abstraction instructions and standard training procedures for data abstractors will be provided to all participating sites. Periodic site visits by CDC will be made to all project areas and technical assistance will be available through the CDC project officers.

3. Methods to Maximize Response Rates and Patient Non response

Because the interview will take approximately 45 minutes to complete, to increase response rates, patients will be offered reimbursement for their participation. Participants will be reimbursed approximately $25 in cash for participation in the interview. If local regulations prohibit cash reimbursement, equivalent reimbursement may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

Reimbursement was used in the SHAS project (described in #1 above), for persons who agreed to participate in the interview. Participants were offered $25 as reimbursement for their time.

A national provider advisory board, made up of providers of HIV care, provides input on the project to CDC regarding how data are collected and how to increase provider participation. A national community advisory board (CAB) made up of community members from each project area, serves as a link between MMP staff and patients who participate. The national CAB shares information about the project and provides feedback to CDC about patient recruitment, data collection, and how the project is seen by the community. Input from these two groups help to maximize provider and patient response and minimize patient non response.

4. Tests of Procedures or Methods to be Undertaken

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

Since these questions comprising the data collection instruments have been previously tested and used, only internal testing by CDC staff was needed. CDC staff tested the skip patterns and responses both electronically and using paper versions of the data collection instruments. CDC staff also conducted mock interviews of CDC staff members using the handheld computers to interview other CDC staff. Mock medical records were developed to serve as training aides to the data abstractors. CDC staff also used the mock medical records to test the data abstraction instrument.

Several project areas are currently piloting the data collection instruments on patients in care for HIV infection and community members who consented to be interviewed. Pilot testing was determined not to require OMB approval. The purpose of the pilot testing was to allow the pilot project areas to test facility and patient recruitment methods. This was done using elements from a previously OMB approved questionnaire (SHAS, OMB 0920-0262, exp. 06/30/2004). The SF-12 has been used as part of the Chronic Homelessness Initiative (OMB# 0990-0304) coordinated by the U.S. Interagency Council on the Homeless and involving the participation of three Council members: the Department of Housing and Urban Development (HUD), the Department of Health and Human Services (HHS), and the Department of Veterans Affairs (VA). It has also been used as part of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Disabled Veterans Survey (OMB 0930-0236).

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List of Attachments

Attachment 1

Section 301 of the Public Health Service Act

TITLE III - GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Sec301 (241.) a. Research and investigations generally

Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to -

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section. The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

substance; and (D) a description of (i) each request received during the year involved -

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Source: U.S. Code Title 42, Chapter 6A, Subchapter II, Part A