

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.

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.

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 ($n_{\text{fac_tot}} = n_{\text{fac_large}} + n_{\text{fac_medium}} + n_{\text{fac_small}}$)
- the number of patients to be sampled in each stratum adds to the total number of patients to be sampled ($n_{\text{pat_tot}} = n_{\text{pat_large}} + n_{\text{pat_medium}} + n_{\text{pat_small}}$)

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 ($n_{\text{fac_tot}} = 50$)
- the assigned patient sample size for the project area ($n_{\text{pat_tot}} = 750$)
- 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 $(100/n_{\text{fac_tot}})\%$ 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., $n_{\text{fac_large}} = 3$). 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 = $1,500 \times 0.10 = 150$ 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., $n_{\text{fac_medium}} + n_{\text{fac_small}} = n_{\text{fac_tot}} - n_{\text{fac_large}} = 50 - 3 = 47$). The number of patients to be sampled from the small and medium facilities is 600 patients (i.e., $n_{\text{pat_medium}} + n_{\text{pat_small}} = n_{\text{pat_tot}} - n_{\text{pat_large}} = 750 - 150 = 600$). The average cluster size is 13 (i.e., $(n_{\text{pat_medium}} + n_{\text{pat_small}}) / (n_{\text{fac_medium}} + n_{\text{fac_small}}) = 600/47 = 12.8 \sim 13$). 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 $1.0 \times .75 \times .75 = .56$ 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.

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.

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. Methods for constructing patient lists may vary based on the type of facility. 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. 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. 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.

Patients recruited through 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 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.

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% (see Second Stage Sampling).

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.

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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