MEDICAL MONITORING PROJECT

Protocol

2021-2023

Clinical Outcomes Team
CDC/NCHHSTP/DHAP/BCSB

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ABBREVIATIONS, ACRONYMS, AND DEFINITIONS

ART	Antiretroviral therapy
CAPI	Computer assisted personal interview – A method of administering interviews using a computer, typically a laptop or tablet device.
CDC	Centers for Disease Control and Prevention
Computed variables	Computed variables have values that are the result of arithmetical or logical manipulations performed using values from other pre-existing variables.
CSTE	Council of State and Territorial Epidemiologists
DCC Portal	The Data Coordinating Center (DCC) Portal allows field staff the ability to securely exchange data with the CDC that are considered sensitive or critical in nature. The DCC Portal also functions as a tracking mechanism and provides reports.
Delayed sampling frame	Process in which the initial sampling frame used to draw the sample is updated with the most recent information available after the end of data collection in order to address reporting delays and allow for more complete and accurate data
Design effect	Design effect is the increase in statistical variance that is introduced by using a complex sampling design to obtain patient or other samples. Mathematically, design effect is the variance obtained using a complex sampling design divided by the variance that would have been obtained from a simple random sample of the same size. A design effect of 2 means that the variance obtained using a complex sampling design was twice as large as the variance that would have been obtained from a simple random sample of the same size.
DMS	Data management system
eHARS	Enhanced HIV/AIDS Reporting System
FISMA	Federal Information Security Management Act of 2002
HHS	Health and Human Services
IRB	Institutional review board
MMP	Medical Monitoring Project
MRA	Medical record abstraction

NAM	National Academy of Medicine (formerly known as the Institute of Medicine, or IOM)
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NHAS	National HIV/AIDS Strategy
NHSS	National HIV Surveillance System
Observation period	For the MRA component of MMP, the observation period is the 24 months prior to patient interview.
OMB	Office of Management and Budget
PWH	People with HIV
PPS	Probability proportional to size – A method of sampling in which the probability of selection for each unit on the sampling frame is proportional to some measure of size. For the 2021-2023 MMP data collection cycles, the measure of size for first stage sampling of project areas was the number of reported living AIDS cases as of December 2002.
PSU	Primary sampling unit – The element, or entity, that is sampled in the first stage of sampling. For MMP, the 50 states, plus the District of Columbia and Puerto Rico, were the 52 primary sampling units.
Sampling date	Refers to the reference date used by the sample draw program for determining eligibility, e.g. to be eligible persons must have been diagnosed with HIV and aged greater than 18 on the sampling date.
Sampling frame	A list of NHSS population elements from which a sample is selected.
STATENO	NHSS's unique patient identification number
US	United States

1. INTRODUCTION

1.1. BACKGROUND

The U.S. Centers for Disease Control and Prevention (CDC) National HIV Surveillance System (NHSS) collects a core set of data on the characteristics of persons diagnosed with HIV infection in all 50 states and dependent areas. Domestic HIV surveillance projects, such as the Medical Monitoring Project (MMP), provide complementary information about clinical outcomes of HIV infection, care seeking and care utilization of persons living with HIV, and ongoing transmission risk behaviors. From 2005 to 2014, MMP's study design relied on a probability sample of HIV-diagnosed persons sampled from HIV facilities to generate nationally representative estimates of clinical outcomes and HIV-related behaviors [1-3]. MMP has provided high-priority national HIV prevention indicators, such as the number of HIV-positive persons receiving care for HIV infection and the proportion of HIV-positive persons receiving care who have achieved viral suppression. In 2015, MMP implemented new methods to include all HIV-diagnosed persons both receiving and not receiving HIV care.

When MMP was first proposed in 2004, the importance of antiretroviral therapy (ART) for HIV treatment was clear—ART had already been shown to dramatically reduce the probability of AIDS or death[4, 5]—but the role of ART in HIV prevention had yet to be firmly established. Since that time, strong evidence has emerged that ART can reduce the amount of HIV in the blood to undetectable levels[6-10]. As a result, people living with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners. Mathematical models show the potential for halting the HIV epidemic through an aggressive program of universal testing and immediate ART initiation, a strategy dubbed "test and treat"[11-13]. In its National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS), the White House identified two key areas for critical focus: "broad support for people living with HIV to remain engaged in comprehensive care, including support for treatment adherence" and "universal viral suppression among people living with HIV"[14].

There is compelling evidence that prompt ART is beneficial for both individuals and public health. However, HIV-positive persons must be linked to and retained in HIV care to initiate and maintain ART. Linkage to care is necessary for reducing transmission of HIV infection and improving health outcomes. As such, differential access to, and utilization of, care contributes to health inequities. In a report discussing implementation of NHAS, the National Academy of Medicine (NAM, formerly the Institute of Medicine [IOM]) concluded, "Primary barriers to optimal outcomes for people living with HIV include late diagnosis, delayed linkage to care for HIV, poor retention in care, delayed initiation of ART, and poor adherence to ART…"[15].

Just as the prevention potential of ART had not been established when MMP was launched in 2004, at MMP's inception, comprehensive rosters of persons living with HIV from which a sample could be drawn did not exist in all states, because name-based HIV reporting had not been legally mandated. However, it was possible to generate HIV patient lists at the facility level, so MMP employed a facility-based sampling method. The facility-based multistage sampling approach employed by MMP from 2005-2014 allowed collection of interview and medical record data from

a national probability sample of persons receiving HIV medical care. However, this sampling method had limitations. Construction of comprehensive lists of facilities was expensive and time-intensive. Collecting data through facilities also depended upon their voluntary participation and resulted in lower than desired response rates. Most importantly, recruiting persons through HIV care facilities excluded those who had not been linked to or retained in HIV care. This limited MMP's capacity to monitor progress toward current linkage and retention objectives and its ability to elucidate barriers to care for those not receiving HIV medical care.

In its review of national HIV data systems, the NAM highlighted the exclusion of marginalized groups from existing data collection, stating, "most of the data systems are not fully representative of the population of PWH in the United States [US]." Of MMP specifically, it went on further to advise that "steps might be taken either to make the population more representative of the national population of people living with HIV or to include groups…who are less apt to be represented in other data systems"[15].

To address the information gaps described above regarding progress with linkage and retention in care and early initiation of ART, MMP revised its methods in 2015 to expand the target population to all persons diagnosed with HIV, including those receiving and not receiving HIV care. This has increased MMP's capacity to monitor and guide efforts to prevent HIV infection and its clinical outcomes through available treatment and other clinical interventions. MMP provides information on HIV-related health outcomes and disparities among PWH that supports the goals of the United States' Ending the HIV Epidemic Initiative[16] and informs the strategies of the Initiative's roadmap, the HIV National Strategic Plan[17].

1.2. PURPOSE AND SCOPE

The primary objectives of MMP are to:

1. Provide locally and nationally representative estimates of risk behaviors and clinical outcomes of persons receiving HIV care
2. Describe health-related behaviors
3. Determine accessibility and use of prevention, care, and support services
4. Increase knowledge of the care and treatment provided
5. Examine variations of above factors by respondent characteristics

The primary purpose of this protocol is to provide a consistent method for state and local health departments to use in collecting data on behaviors and clinical outcomes from a probability sample of HIV-diagnosed adults. The method involves the selection of adults diagnosed with HIV from NHSS, an informed consent process, telephone or, in some cases, in-person interviews of eligible persons, and abstraction of HIV-related medical records for persons who are interviewed and have ever received HIV medical care.

Collection of data from interviews with persons diagnosed with HIV provide information on current behaviors that may facilitate HIV transmission; seeking of, access to, and use of HIV-related prevention services; utilization of HIV-related medical services; and adherence to medication regimens. Through medical record abstractions (MRAs) and interviews with eligible

persons, MMP provides information on clinical conditions that result from illness or the medications they take, as well as the HIV care and support services they receive and the quality of these services. MMP data also provide estimates of met and unmet needs for HIV care and prevention services. These estimates can be used to evaluate services and to direct future resources for persons living with HIV.

MMP generates national and state or local estimates of characteristics and behaviors that are generalizable to adults living with HIV in the US. MMP also generates estimates of the proportion of persons diagnosed with HIV who have not been linked to HIV care and who have not been retained in care. For those not engaged in care, MMP data describe the barriers to linkage and engagement identified by HIV-positive persons, as well as the demographic and behavioral factors that are associated with linkage and retention.

1.3. COLLABORATING AGENCIES AND STAKEHOLDERS

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

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

In addition to CDC and its funded recipients, other stakeholders include:

- Non-funded state and local health departments

- National Institutes of Health (NIH)
- Health Resources and Services Administration (HRSA)
- National Association of AIDS Education and Training Centers (AETCs)
- National Alliance of State and Territorial AIDS Directors (NASTAD)
- American Academy of HIV Medicine (AAHIVM)
- Communities Advocating Emergency AIDS Relief (CAEAR)
- Association of Nurses in AIDS Care (ANAC)
- Council of State and Territorial Epidemiologists (CSTE)
- HIV Medicine Association (HIVMA)
- National Alliance of State and Territorial AIDS Directors (NASTAD)
- National Minority AIDS Council (NMAC)
- National Alliance for HIV Education and Workforce Development (NAHEWD)
- HIV prevention planning groups
- Ryan White HIV/AIDS Program planning councils and consortia
- Providers of HIV medical care and prevention services
- Persons living with HIV

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

State and local HIV surveillance programs, which have been operating for more than 30 years, have a history of collaboration with the medical providers and PWH in their jurisdictions on projects involving both interview and MRA. MMP staff need to build on these collaborations to ensure high participation rates for sampled persons.

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

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

At the national level, CDC has convened community and provider advisory boards for MMP, which include one community representative and one provider representative from each of the project areas. These boards also include members of national organizations (e.g. NMAC, HIVMA,

AAHIVM, and others). These boards provide input on the data collection instruments, operational considerations, barriers to participation, usefulness of collected data, and optimal methods for data dissemination. The community members and providers who serve on the national boards are the designated contact persons at the local level and serve as a resource to HIV-positive persons who are approached about participating, but who wish input from a peer or health care provider before deciding whether to do so.

CDC has also engaged 2 contractors to develop and provide data management support for the Data Coordinating Center (DCC) and the secure, web-based electronic application that collects and processes MRA data. The scope of the work for both contracts, as they pertain to MMP, consist of the contractors independently furnishing all necessary personnel, facilities, supplies, and equipment to achieve each of the following objectives:

- Receive data from the CDC designated project areas
- Process data for quality assurance
- Create and transfer cumulative and final data sets to CDC and to project areas
- Provide ad-hoc technical assistance to MMP project areas
- Provide formal training sessions for MMP project areas
- Communicate with and report to CDC

1.4. INITIATION, DURATION, AND PROJECT PERIOD

Data Collection Cycles*	Number of Grantees	Project Area Names
2004-2005	13	Delaware; Florida; Illinois; Los Angeles, California; Maryland; Michigan; New Jersey; New York City, New York; Philadelphia, Pennsylvania; South Carolina; Texas (including the separately funded jurisdiction of Houston), and Washington
2006-2008	26	California (including Los Angeles County and San Francisco); Delaware; Florida; Georgia; Illinois (including Chicago); Indiana; Maryland; Massachusetts; Michigan; Mississippi; New Jersey; New York State (including New York City); North Carolina; Oregon; Pennsylvania (including Philadelphia); Puerto Rico; South Carolina; Texas (including Houston); Virginia; and Washington
2009-present	23 (randomly dropped 3 project areas due to budget constraints)	California (including Los Angeles County and San Francisco); Delaware; Florida; Georgia; Illinois (including Chicago); Indiana; Michigan; Mississippi; New Jersey; New York State (including New York City); North Carolina; Oregon; Pennsylvania (including Philadelphia); Puerto Rico; Texas (including Houston); Virginia; and Washington

*MMP cycles typically begin in June of the cycle year and end the following May

2. METHODS

2.1. POPULATION OF INFERENCE

The national population of inference for MMP is all adults diagnosed with HIV aged ≥ 18 years living in the US on the date of sampling. For each project area, the population of inference is all HIV-diagnosed adults aged ≥ 18 years living within the project area on the date of sampling.

The date of sampling for a given data collection cycle is December 31 of the prior calendar year. For example, the date of sampling for the 2021 data collection cycle is December 31, 2020.

2.2. SAMPLING FRAME

MMP employs a two-stage sample design. The first stage sampling frame consists of all 50 states, the District of Columbia and Puerto Rico.

At the second project area-level stage, the sampling frame includes persons reported to NHSS who meet the following inclusion criteria on the date of sampling:

- Is present in the national case surveillance dataset within eHARS (the Enhanced HIV/AIDS Reporting System for NHSS)
- Meets the HIV case surveillance definition
- Diagnosed with HIV
- Aged ≥ 18 years
- Has their most recently reported address located in the project area in NHSS
- Has no death documented in NHSS

2.3. ELIGIBILITY CRITERIA

2.3.1. *State and Local Health Departments*

The goal of MMP is to obtain a national probability sample of adults diagnosed with HIV in the US; therefore, all 50 states, plus the District of Columbia and Puerto Rico, were eligible to participate. Six of the states sampled have large cities that have been funded separately from their states to conduct HIV surveillance activities and were funded separately for MMP. These cities are Chicago, Houston, Los Angeles County, New York City, Philadelphia, and San Francisco.

2.3.2. *Adults Diagnosed With HIV*

Eligibility for inclusion in the sampling frame is discussed in section 2.2. At the time of recruitment, eligibility will be verified according to the following criteria as of the date of sampling:

- Diagnosed with HIV

- ≥ 18 years of age
- Alive (persons who died before the sampling date are ineligible; persons who died on or after the sampling date, but before recruitment are part of the population of inference and will be considered eligible non-respondents)
- Living in an MMP project area on the sampling date

The most recently recorded address in NHSS is used to allocate persons to MMP project areas to facilitate operations. However, as long as the person fulfills the inclusion criteria stated above, the person continues to be eligible regardless of whether their project area assignment was correct. In addition, a person may have duplicate NHSS records and may be sampled twice. In this case, the person is eligible for MMP but can only participate once.

In order to define a sampling frame of current project area residents using data in NHSS, it is critical that the best available address information be included in local eHARS. In particular, CD4 and viral load reports, which often include patient address information, are useful for ascertaining current residence. As was required of all case surveillance jurisdictions in the NHSS funding opportunity announcement that took effect in January, 2018, MMP project areas must develop and implement plans to include all available CD4 and viral load data in eHARS.

Persons who have participated in MMP in a prior data collection cycle are still eligible to participate. The interview is offered in both English and or Spanish in all project areas.

Interviews may be conducted in languages other than English or Spanish if a qualified interpreter is available. If a qualified interpreter is unavailable or if the person is unable to provide informed consent, they will not be interviewed, but will still be considered part of the population of inference and will therefore be considered eligible for response rate calculation purposes.

2.4. SAMPLING METHODS

MMP uses a two-stage sampling design resulting in annual cross-sectional probability samples of adults diagnosed with HIV living in the US.

2.4.1. *First-Stage Sampling*

For the first stage of sampling, geographically stratified random sampling with selection probabilities proportional to a known measure of size was used. Because the goal of MMP is to obtain a series of national probability samples of adults diagnosed with HIV in the US, all 50 states, the District of Columbia, and Puerto Rico were eligible for selection. Although 6 cities (Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco) were qualified to receive separate funding for MMP, these separately funded cities were included with their respective states for the purposes of first-stage sampling. Therefore, the first-stage sampling frame consisted of 52 primary sampling units (PSUs): the 50 states, the District of Columbia, and Puerto Rico.

First-stage sampling for MMP was conducted in early 2004. During this stage of selection, systematic probability proportional to size (PPS) sampling was used in which the measure of size

for each PSU was the estimated total number of persons living with AIDS, as reported to the National HIV/AIDS Reporting System (NHSS) at the end of 2002. Although the target population for MMP is all persons diagnosed with HIV in the US, at that time, HIV non-AIDS diagnoses were not reportable in all states, so the estimated number of persons living with AIDS was used for sampling as the best available proxy. Using an indirect measure of size at any given sampling stage does not affect the validity of the statistical estimates derived from the overall sample.

On the basis of available funding, 20 PSUs were selected during the first stage of sampling. All 20 state and 6 local (for the separately funded jurisdictions within the states) health departments in areas selected for the first stage sample agreed to participate in MMP, resulting in 26 project areas. Because the first stage of MMP sampling was conducted using probabilities proportional to the measure of the number of persons living with AIDS associated with each PSU, it is estimated that this first stage sample included more than 80% of the persons living with AIDS in the US during 2002. See Appendix A for more information regarding first stage selection.

Due to budget restrictions, beginning in 2009, Massachusetts, South Carolina, and Maryland were dropped from the MMP project area sample through a random selection process. The 23 remaining project areas include approximately 73% of all persons living with HIV in the US during 2015.

2.4.2. *Second-Stage Sampling*

Within each project area, persons meeting the inclusion criteria specified in section 2.2 will be sampled. Random samples will be selected from each project area sampling frame.

I. Project Area Sample Sizes

A combined total of 9,700 persons per year will be sampled from the project area sampling frames (see Appendix B). To determine a minimum sample size, the expected precision of estimates derived from the entire sample and from subpopulations were considered for different sample size options. A sample size of approximately 400 persons per state or 9,700 persons overall has both acceptable precision and feasibility.

In calculating the precision of estimates from project area samples of 400 persons and a total combined sample of 9,700, the impact of weighted data analysis on precision was taken into account. Weighted analysis is necessary, because the use of two-stage sampling and adjustment for non-response bias will cause unequal selection probabilities. Both unequal selection probabilities across project areas and correlation of observations within project areas produce variance estimates that are larger than they would be for a simple random sample of the same size. This variance inflation is called the design effect. A design effect of 2 is used in the calculations, because a design effect of this magnitude is commonly encountered in national surveys.

The following table shows an example of the expected precision of any given estimate from MMP data, e.g., the proportion of persons who identified insufficient financial resources as a barrier to receiving care. The level of precision to be expected (i.e. the confidence interval (CI) half-widths)

is what would be expected for estimates based on sample sizes of 400 and 9,700 for project area and aggregated estimates, respectively. Column 2 shows the estimates for the entire population and columns 3, 4, and 5 show the estimates for the subpopulations that comprise 50%, 33%, and 10% of the total population, respectively.

N	CI half-width total	CI half-width subpopulation = 50%	CI half-width subpopulation = 33%	CI half-width subpopulation = 10%
400	6.93%	9.81%	12.09%	22.06%
9,700	1.41%	2.00%	2.45%	4.45%

II. Locating and Contacting Sampled Persons

The authority of public health to collect and use data on individual health relies on public trust that the information will not be used in a way that threatens the dignity or well-being of those individuals[18, 19]. Given the history of discrimination against HIV-positive persons in the US, HIV surveillance systems bear an even greater responsibility of safeguarding the confidentiality of their participants than other disease surveillance systems. The sharing of information between HIV case surveillance, MMP, and other partners who assist in locating or contacting sampled persons is critical for the success of the project, but MMP staff should be aware that it may raise concerns for sampled persons about the protection of their confidentiality. Both HIV-positive persons and HIV providers tend to support electronic data sharing when it is clear that sharing is ultimately intended to benefit HIV-positive persons themselves, as it is in this case[20]. Therefore, MMP staff should always be clear about the intended uses of the data when obtaining informed consent and be sensitive to a sampled person's concerns about confidentiality.

It is also critical that MMP staff make initial contact with a sampled person in a way that safeguards the confidentiality of the sampled person's HIV status and raises no concerns that surveillance data are being mishandled. MMP staff should anticipate the possibility that persons initially believed to be the sampled person may have been misidentified. MMP staff must respect the right of the sampled person to decline participation in the project.

Locating Sampled Persons. Project areas are expected to comply with local rules and regulations concerning permissible procedures for locating and contacting sampled persons. The most recent contact information should be used as a starting point. In some cases this information may be up to date in eHARS, but in many instances, project areas will need to consult other sources of information. The following is a list of resources that may be useful for obtaining recent contact information for the sampled persons:

- Health provider at the time of HIV or AIDS diagnosis identified through eHARS
- Current HIV care provider identified through eHARS
- Contact information associated with laboratory data in eHARS or local surveillance databases

- Ryan White database (CAREWare)
- ADAP list
- Pharmacy records
- Medicare database
- Medicaid database
- Integrated disease surveillance database
- Partner services database
- Prison or jail database
- People search engines, i.e., LexisNexis Accurint, TLO, Clear
- Department of Motor Vehicles (DMV) records
- Phone directory
- Reverse phone directory, i.e. a directory that uses phone numbers to identify addresses associated with the phone number entered

Additional resources may be available locally. Project areas will need to determine which of these sources staff will be permitted to use, and if permitted, how feasible it will be to use them. MMP staff should follow their agency guidelines for the use of these resources.

Contacting Sampled Persons. The order in which sampled persons are contacted may be influenced by logistical considerations. Local operating procedures should be used to establish and document a systematic ordering of lead searches and contact attempts. In addition, project areas should document the method for recruiting certain subgroups, e.g. those with no evidence of having received HIV care or the homeless. Such documentation will aid in the interpretation of variations in response rate by subgroup.

MMP staff will attempt to directly contact and recruit sampled persons. For this form of direct contact, sampled persons will be initially contacted using letters or e-mail and telephone-contact scripts developed using CDC templates (see Appendices C.1-C.4). Messaging features available on social media and dating websites (e.g. Facebook, Grindr) **should not be used** for contacting sampled persons.

As an adjunct to direct contact by MMP staff, staff from the sampled person's HIV care facility may introduce the project to the sampled person to maximize the likelihood of participation. HIV care facility staff may be used to encourage sampled persons to initiate contact with MMP staff to the extent allowed by local regulations and/or institutional review boards (IRBs). HIV care facility staff should be given contact scripts based on CDC templates for these purposes (see Appendix C.3).

When an individual who is sampled for MMP is first contacted, the staff member should establish rapport and take the following steps:

1. Identify him or herself and his or her association with the project area health department
2. Establish the identity of the person contacted using at least 2 identifiers, e.g. full name and date of birth

3. Engage the person in a private conversation
4. Confirm the person is eligible for MMP
5. Recruit the person for participation in MMP
6. Conduct the interview immediately or arrange a later interview time, according to the sampled person's preference; informed consent must be obtained immediately prior to the interview
7. If needed, provide referrals for linkage to or re-engagement in care and other ancillary services (following the interview in cases where the person consents to participate in MMP)

In addition, project areas must develop and implement procedures to identify whether persons who are not aware of their HIV status have been sampled for MMP and to manage the situation appropriately. Project areas may wish to consider different recruitment approaches for sampled persons with CD4 and viral load tests or other information indicating that they may have received HIV care, versus those with no indication of HIV care. In the latter case, project areas should ascertain whether or not the sampled person is aware of his or her HIV status after confirmation of identity. Persons who are unaware of their HIV status should not be recruited for the MMP interview until they have been notified according to the standard operating procedures within the jurisdiction.

In practice, documentation that a person has been informed of his or her HIV status in eHARS is rare and may vary by health department. When possible, project areas should consult supplementary sources of information about whether the sampled person has been informed of his or her HIV status, e.g. information collected by partner services staff or present in HIV medical databases.

However, it is possible that MMP staff may inadvertently contact sampled persons who are unaware of their status. Such instances are opportunities to assist sampled persons by letting them know their HIV diagnosis and by facilitating their entry into HIV care. However, these interactions must be approached with sensitivity, because of the emotional impact of learning of one's HIV diagnosis.

If the contacted person was previously unaware of his or her HIV status, MMP staff must be prepared to immediately perform the following:

- Directly provide post-test counseling or assist the person in obtaining those services, e.g. assistance with transportation and offering to have the person accompanied to the post-test counseling location
- Refer the contacted person for or directly provide help coping with the emotional consequences of learning his or her HIV status, if needed

Persons notified of their HIV status through MMP should not be recruited as MMP participants at that time. If circumstances allow, MMP staff may provide contact information so that the person can contact MMP staff if he or she wants to participate at a later date. MMP staff should report to their CDC Project Officer the fact that staff contacted a person unaware of his or her HIV status

and consider whether the event meets the criteria for adverse event reporting (discussed in section 5.4 below).

Jurisdictional Issues. Recruitment of eligible persons who have relocated outside of the project area is necessary to ensure that the MMP sample represents the population of all HIV-diagnosed persons in the US. Sampled persons may be recruited for participation in MMP wherever they currently reside, conditional on local law and policy, and in a manner specified by a written, project-specific agreement with the HIV surveillance unit at the health department in the jurisdiction of current residence. The HIV subcommittee of the Council of State and Territorial Epidemiologists (CSTE), working with CDC staff and HIV surveillance coordinators, has coordinated the development of a template for interagency agreements regarding cross-jurisdictional recruitment for MMP that specify whether and how cross-jurisdictional recruitment of persons sampled for MMP will be done. The agreement specifies 1 of 4 options selected by the jurisdiction of current residence of the sampled person:

1. Recruitment by the project area from which the sampled person was selected, with no notification of the health department in the jurisdiction to which the person has relocated
2. Recruitment with notification to the health department in the jurisdiction where the person currently resides after contact with the sampled person
3. Recruitment with notification to the health department in the jurisdiction where the person currently resides before contact with the sampled person
4. Cross-jurisdictional MMP recruitment activities are not permitted (see Appendix D for a copy of the agreement form).

If through the process of conducting MMP more current address information is obtained, project areas should add this information to eHARS.

Linkage to Care and Re-engagement. In the course of MMP, project area staff may identify people who have never been linked to HIV care, as well as people who have previously received HIV care, but have not been retained in care. Local protocols must be developed to link or re-engage these people.

Project areas will develop written linkage and re-engagement protocols that specify how persons in need of these services will be linked to or re-engaged in care. In some cases, it will be most appropriate and/or feasible for MMP staff to address these issues directly, and in others, MMP staff may collaborate with partners inside or outside the health department to offer engagement in care services. In either case, written procedures must be established to ensure that the required linkage and re-engagement activities take place.

Project areas must either develop active linkage and re-engagement referral protocols that include 1 or more of the following services or partner with service providers that do:

Linkage Services	**Re-Engagement Services**

Educate persons about the importance of regular care to treat symptoms, maintain health, and prevent HIV transmission, even if they are feeling well	Educate persons about the importance of regular care to treat symptoms, maintain health, and prevent HIV transmission, even if they are feeling well
Assess readiness to enter care and barriers to entering care	Assess barriers to care and motivate the person to overcome barriers
Motivate the person to overcome barriers to care	Assess the need for ancillary and supportive services
Investigate ways to pay for HIV medical care (on behalf of the person)	Offer care navigation
Make the first HIV medical care appointment with the person and transporting or accompanying the person to the appointment, whenever feasible	Make the first HIV medical care appointment with the person and transporting or accompanying the person to the appointment, whenever feasible

2.5. DATA COLLECTION

All project areas will conduct interviews of sampled persons who consent and will perform MRAs for sampled persons with a completed interview who have received HIV care. Participants are free to withdraw consent to participate in the project at any time, but are not given the option to participate in only 1 part of the project (e.g. interview, but not MRA).

2.5.1. *Personal Interview*

The MMP interview is a structured interview administered via telephone or in some cases in person to sampled persons who consent. Interviews and recruitment may be conducted via video subject to the project area's CDC project officer's approval. Interviews should not be audio- or video recorded. Interviews for a given data collection cycle should begin and end on the date established by CDC. All interview data should be sent to the DCC according to the DCC submission schedule. Sampled persons should only be interviewed once each cycle.

I. Interview Instruments and Application

The MMP interview takes approximately 40 minutes to complete and is available in English (Appendix E.1) and Spanish (Appendix E.2). The 2021–2023 questionnaire consists of 17 modules to be administered in all project areas:

- Preliminary Information
- Eligibility Criteria
- Basic Demographics
- Disability

- Financial
- General Medical Care
- HIV Care
- HIV Treatment and Adherence
- Sexual Behavior
- Violence
- Depression and Anxiety
- Alcohol, Smoking, and Drug Use
- Stigma and Discrimination
- Gynecological and Reproductive History
- Met and Unmet Needs
- Prevention Activities
- Interview Completion

CDC will provide an electronic application of the survey. Project areas will administer the interview by means of a computer-assisted personal interview (CAPI) via a laptop computer, tablet, or other device that meets project specification requirements. CDC will also provide PDF versions of the questionnaires, so that project areas may print paper copies in the rare event that a device malfunctions and the survey application cannot be administered. In these cases, the data will be entered using the survey application as soon as it is feasible and the paper forms will be destroyed no later than 12 months after the end of the data collection cycle.

II. Local Questions

Project areas may choose to develop questions for local use. These questions are not part of the CDC MMP. However, because the addition of local questions can affect MMP, CDC requires the following:

- If local questions pertain to subject matters that are sensitive or have potential legal implications (e.g. child or sexual abuse, suicide), the project area must ensure that interviewers are properly trained to deal with adverse events, comply with all local laws, and are knowledgeable about and able to offer appropriate referrals
- Local questions must not exceed 40 variables and cannot take longer than 10 minutes to administer. The 40 variable limit does not include calculated variables that are not asked directly to respondents.
- Local questions must be administered at the conclusion of the MMP interview after all other interview questions have been completed. Interviewers must indicate that the CDC portion of the interview has ended and that the local questions were developed by the state or local health department
- A courtesy copy of all local questions in use by a project area must be provided to the CDC Project Officer
- Local questions and data from local questions that are presented at scientific meetings, shared with colleagues for scientific input, used for publication in abstracts or journals, or disseminated in any other format should include a disclaimer indicating that such

questions were developed by the respective state or local health department and are not part of the CDC MMP

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

III. Respondents

Informed Consent. All interview respondents must provide informed consent immediately before participating in the interview, in compliance with all state and local, and when necessary, area-specific IRB guidance. See section 5.5, "Informed Content," for more information.

Interviewing Special Populations

- If a respondent requires an interpreter, project areas should administer the interview using a qualified interpreter (see section below entitled "**Interviews Using an Interpreter**"). Project areas should follow their state or local guidance regarding any consent forms or confidentiality agreements necessary for circumstances in which translation is required.
- **Persons who are ill**: If a respondent who is ill is willing and able to consent and attempt to do the interview, then they are eligible for MMP
- **Pregnant women**: Administration of the MMP interview does not pose any special risk to pregnant women
- **Incarcerated persons**: There is no reliable method of excluding incarcerated persons from a sampling frame that is based on cases reported to HIV surveillance. The feasibility of interviewing and conducting MRAs for incarcerated persons will be determined by the project areas according to local regulations and requirements.

As is true for all MMP participants, persons who face challenges in completing the entire MMP interview should be allowed to discontinue participation at any time during the interview. Persons who discontinue the interview should receive a token of appreciation and their interview file should be submitted to the DCC.

IV. Interviews Using an Interpreter

Interviews should be offered via interpreters to all non-English, non-Spanish speaking sampled persons and to Spanish speaking persons in project areas if a Spanish speaking MMP interviewer is not available. Health department standards and state or local IRB requirements for interpreters will apply. At a minimum, the interpreter must meet all project area security and confidentiality requirements.

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

Project areas should anticipate what non-English, non-Spanish languages they are likely to encounter, and what resources and arrangements they may need to make to secure an effective interpreter. The sampled person's country of birth may be available in the project area's local NHSS data and may help these areas anticipate interpretation needs.

Below are some general guidelines for identifying appropriate interpreters:

- The interpreter needs to be proficient in both English and the other language
- The interpreter should be culturally competent and demonstrate that he or she is capable of accurately conveying information in both languages, including information on sensitive subjects, such as sexual behaviors and drug use
- The interpreter should be provided orientation and training that includes interpretation/interviewing skills, ethical considerations, and confidentiality considerations
- Family members or friends of the person should not be used as interpreters for MMP

If substantial numbers of non-English, non-Spanish speaking participants are anticipated, project areas should consider preparing written translations of the questionnaire and/or conduct training to ensure consistent interpretation.

V. Interview Locations

Interviews will be conducted over the telephone. If a potential respondent is unable or refuses to participate in the interview over the telephone, then a project area may offer to meet the respondent in person. When arranging an interview over the phone, interviewers should suggest a telephone interview first and then follow up with an offer of an in-person interview if the sampled person declines a telephone interview. An in-person interview may be conducted in a variety of settings, including in medical facilities, in the person's home, in a hospital, and at other mutually agreed-upon locations where security and confidentiality can be guaranteed. Interviews should be conducted in private. For example, partners, friends, and family members should not be present during the interview. If the interview location is not private, then the interview should be moved to a secure location or rescheduled.

VI. Concluding the Interview

At the end of the interview, participants will receive prevention materials and referrals to local prevention and care services, as needed. They will also be given the opportunity to ask the MMP staff questions about prevention methods.

VII. Tokens of Appreciation

After the conclusion of the interview, participants will receive a token of appreciation. Participants will be given no more than $50, either in cash or a cash equivalent, in appreciation for their participation in the interview regardless of whether the interview was completed. All participants within a project area will be given the same amount, but the exact amount may differ between project areas according to local standards and cost of living. If local regulations

prohibit cash tokens of appreciation, an equivalent amount may be offered in the form of gift items or gift certificates.

VIII. Interviewer Training

CDC will provide participating state and local health departments with a manual containing detailed instructions on conducting MMP interviews. CDC will convene meetings in which lessons learned throughout the interview process are discussed by staff from all project areas. In addition, training will be provided on methods to locate and recruit sampled persons.

Interviewer training at the state and local health departments is required prior to data collection. Suggested topics for the interviewer training are: protocol changes, security and confidentiality, comportment, recruitment procedures, consent process, locally-specific terminology, referrals and prevention messages, adverse events, interviewer evaluation, and interviewer practice. Interviewers should conduct practice interviews to prepare for each data collection cycle. Experienced MMP interviewers should complete a minimum of 3 full practice interviews using mock data with mock respondents before conducting an MMP interview. New interviewers should complete a minimum of 4 practice interviews and obtain supervisory approval before conducting an MMP interview. Potential mock respondents are local health department staff, community advisory board members, or CDC staff. Mock respondents should be instructed to not provide real data. In addition, ongoing interviewer training should occur throughout the data collection period. Mid-cycle trainings should be based on monitoring and evaluation findings from field observations and data review.

IX. Interview Quality Control and Assurance

Automated edit checks will be built into the survey software applications used to conduct MMP interviews to ensure that high quality data are collected. For additional quality assurance purposes, a minimum of 10% of interviews will be observed to ensure data quality and completeness. Periodic review of interviews will also ensure that all interviewers use the same techniques when administering the interview.

X. Cross-jurisdictional Interviews

Because NHSS data may not always contain updated contact information, the MMP sample is likely to include persons who have moved out of the jurisdiction where they were presumed to be living when they were sampled. If an eligible sampled person has moved to a jurisdiction that permits MMP recruitment (see the Jurisdictional Issues section above), the project area should attempt to do a telephone interview with the person. If the sampled person refuses to do a telephone interview and has moved to another MMP project area, the project area of current residence may conduct an in-person interview with the person. It is the project area of sampling's responsibility to ensure that all local and national protocols are followed and to inform their CDC Project Officer of the situation.

2.5.2. *Medical Record Abstraction (MRA)*

I. Eligibility and Determination of the MRA Site

If the sampled person has never received outpatient HIV care, then no MRA will be conducted. If the sampled person is currently receiving HIV care or has previously received HIV care, an MRA will be conducted from the sampled person's most often visited source of HIV care, defined as the place he or she went to for the most outpatient HIV medical care visits in the 24 months prior to the interview date.

Sampled persons who consent to be interviewed in MMP will be interviewed first, and their medical records will be abstracted after the interview is completed. This is necessary because the surveillance period used for an MRA is defined as the 2 year period prior to the date of interview. Even if the project area has authority to conduct an MRA without the sampled person's consent, interviewed persons who refuse to have their medical records abstracted, and thus withdraw their informed consent to participate in MMP, will have no MRA performed.

II. Conducting MRAs

Trained staff will abstract clinical data from medical charts using the web-based electronic MRA application developed by CDC and its contractor (see Appendix F). MMP will capture clinical data documented in the medical record from the HIV care facility the participant identified as their most often visited source of care during the observation period. The information includes all diagnoses, provision of preventive care, prescription of antiretroviral and other medications, laboratory results, and health services utilization.

Information will be collected on an electronic form with multiple sections as follows:

- Demographics
- Health care encounters (outpatient and inpatient)
- Diagnoses
- Medications
- Prophylaxis
- Laboratory and screening

Medical records may be obtained through 1 or more of the following methods:

- Mail or secure fax from the HIV care facility
- Physically visiting the HIV care facility
- Secure, remote access (if available)

Access to medical records may be secured by a number of methods, including direct review of the patient's physical or electronic chart (whether in person or remotely) or by obtaining a copy of the medical record (whether by physically visiting the HIV facility or by mail or fax). Copies of medical records may be provided in paper or electronic format (e.g. CD, DVD, flash media).

Whenever possible, electronic media should be encrypted and/or secured by biometric security devices, such as a fingerprint reader. When obtaining medical records by mail, project areas must

develop systems to ensure that only project area staff may open and read these records. When receiving faxed medical records, project area staff should adhere to CDC guidelines on the use of fax for surveillance data, including developing systems to ensure that only project area staff may receive and read the faxes. Paper and electronic copies of medical records will be destroyed as soon as they are no longer needed and no later than 12 months after the end of the data collection cycle.

MRA data will be collected on a web-based electronic application using a computer or tablet device. In certain instances, such as device failure or lack of internet connectivity, data may be collected using a paper form. In these cases, the data will be entered into the web-based application as soon as is feasible and the paper forms will be destroyed no later than 12 months after the end of the data collection cycle.

MRA data received by CDC will be identified only through the use of the participant ID.

III. MRA Training

CDC, in conjunction with its contractors, will provide training sessions on conducting MRAs using the web-based data collection application. Detailed, written instructions and guidance are provided in an abstraction manual given to abstractors by CDC.

CDC will routinely convene conference calls in which lessons learned throughout the abstraction process are discussed by staff from all project areas.

IV. MRA Quality Control and Assurance

MRA data must be checked for completeness and accuracy by project area supervisory staff. For quality assurance purposes, a minimum of 5% of medical records must be re-abstracted each cycle by a second, more experienced, independent reviewer. Re-abstraction records will be entered in the web-based data collection application and comparison of the abstracted records will be done using a re-abstraction report produced within the application. As soon as possible after the original abstraction, the reabstraction report will be reviewed by the more experienced abstractor and the original abstractor. Discrepancies due to incorrect information in the original abstraction will be corrected in the original abstraction.

V. Cross-jurisdictional MRAs

If a participant reported during the interview that they received most of their HIV care outside of the jurisdiction of sampling, the MRA can be conducted by the jurisdiction of sampling after obtaining a written medical record release from the participant allowing his or her medical record to be mailed or securely faxed to the project area. If it is not possible to obtain mailed or faxed records and the jurisdiction of care is an MMP jurisdiction, the jurisdiction of care may complete the MRA by filling out a paper form and sending it to the jurisdiction of sampling to enter into the web-based application. In this case, it is the jurisdiction of sampling's responsibility to ensure that the jurisdiction of care adheres to the protocol and, if applicable, IRB requirements of the project area of sampling. Non-MMP jurisdictions should not conduct MRAs for MMP.

2.5.3. *Sampling Frame Data*

The NHSS data that is used to construct the second-stage sampling frame provides information on every patient person who was eligible to be selected to participate in MMP and informs the weighting of the data. In addition, CDC uses STATENOs (NHSS's unique patient identification number) to prospectively monitor MMP respondents' care utilization and treatment. Along with interview and MRA data, sampling frame data on participating persons become a part of the final MMP datasets. Sampling frame data may be used to update missing information in the interview and medical record data and are used as the primary source of information on HIV disease stage and diagnosis date.

Because NHSS is a dynamic system and the data are continually being updated by local surveillance jurisdictions and sent to CDC for de-duplication, CDC will update the initial sampling frame (section 2.2, sampling frame) used to draw the sample with the most recent information available after the end of data collection in order to address reporting delays and allow for more complete and accurate data. This updated sampling frame is called the delayed sampling frame. The delayed sampling frame also allows for an assessment of persons who should have been included in the initial sampling frame but were not due to reporting delays and those who were on the initial sampling frame but are no longer on the delayed sampling frame due to corrections to the data made by the local surveillance jurisdictions. In instances where sampled persons are no longer present on the delayed sampling frame due to de-duplication, project area and CDC staff should make every effort to trace back which cases were combined, so that the appropriate data may be incorporated into the delayed sampling frame.

The delayed sampling frame data are also used to assess potential non-participation bias and help to provide an adjustment to the weighting methods for MMP. The delayed sampling frame also provides demographic information used to construct population data that informs the weighting process.

The NHSS data elements in the initial and delayed sampling frames are provided in Appendix G.

3. DATA MANAGEMENT AND ANALYSIS

Four types of data are collected for MMP:

Tracking data	Consist of project operational information collected in order to recruit persons for participation in MMP. The data are used to inform project staff regarding progress of data collection and provide dispositions to CDC to create statistical weights for data analysis.
Contact data	Consist of data involving how and when project areas contact sampled persons, as well as the outcome and responses to these contact attempts. These data are used to monitor the burden of locating sampled persons on project area staff and to determine best practices for locating and recruiting sampled persons.

Interview data	Described in a prior section.
Abstraction data	Described in a prior section.

The tracking, interview, and abstraction data are also used by the contractor to create analytic data files that are used by CDC and the project areas to describe the populations of persons diagnosed with HIV and address project-related questions. Contact data are not sent to CDC.

CDC contracts with the DCC to implement a data management system (DMS) to provide MMP project areas with a secure, web-based data portal system through which project areas can submit data to CDC, revise submitted data sets, and receive final data from CDC. The DCC server is a secure environment that meets all of CDC's security and confidentiality guidelines and specifications, as well as federal standards for data security. The system also allows the project areas and CDC staff to track critical respondent and MRA activities. The DCC data portal is equipped with an access control system that supports different levels of access, so that the project areas can see only their own data and unauthorized use can be prevented. The 3 main features of the DMS and their major functions are listed below.

Feature	Major Functions
Data portal	Enables data to be uploaded and downloaded and provides project areas with a secure, web-based mechanism through which they can submit interview data and data changes. MRA data will initially be submitted to the data portal by the MRA web-based data collection application contractor after preliminary data cleaning and reconciliation are performed. Project areas will either submit data changes directly into the web-based application or use the data portal to submit changes to MRA data as needed. The data portal provides access to the respondent tracking component.
Tracking component	Allows project areas and CDC to track the status of data submissions, provide transfer of data error reports between the DCC and project areas, and enable project areas and CDC to download the most recent data sets. The respondent tracking component of the DMS assists project areas in managing contact attempts with sampled participants, interview assignments, respondent dispositions, and MRA assignments.
Reporting component	Provides the project areas and CDC with management-level reports that include information on data collection status at each project area, such as the number of completed interviews and MRAs, number of refusals, number of persons unable to be located, and number of persons ineligible for participation. Reports are available by project area and in aggregate.

3.1. DATA MANAGEMENT

3.1.1. *Tracking Data*

Tracking data provide information on project area progress in MMP activities, including project area sampling, person sampling, recruitment, interview, and MRA.

Tracking data are collected and stored by each project area via the DCC data portal, as described above. The data tracking component is accessed using a secure digital identification system by only a limited number of users at each project area and at CDC. CDC users will only have read-only access to the tracking data. Personal identifiers, such as names or patient medical record numbers, are not available to CDC or its contractors. The DCC contractor is responsible for providing any technical assistance to project areas on how to use the tracking system.

3.1.2. *Contact Data*

Project areas will collect and store data documenting all attempts to contact sampled persons. CDC will provide a database to be used to collect and store these data. Project areas may use this database to collect personally identifying information (e.g. telephone numbers or addresses) collected as they locate sampled persons. CDC will not have access to this personally identifying information.

The contact attempt tracking database must be stored on electronically and physically secure data drives at the project area and should only be accessed by a limited number of users at each project area. Project areas will be responsible for maintaining and securing this database.

The data will not be shared with CDC except in aggregate reports. Project areas should destroy identifying information from the contact attempt tracking database no later than 24 months after the end of each MMP data collection cycle.

3.1.3. *Personal Interview Data*

Interview data will be stored in, and uploaded from, the electronic devices as 2 data files: 1) the questionnaire (including the completion module) and 2) the local questions (if applicable). Multiple interview records may be contained in each data file. The local question data files will be kept only at the project area for local use – this local question data file will not be sent to CDC or the DCC.

The file names of the interview data files are automatically generated by the survey software and include the project area abbreviation, data collection cycle, type of data, and the date and time when the data file was created. To uniquely identify each file, each file name also includes the identification number of the electronic device with which the data were collected, as specified below.

- Project area abbreviations for state and local project areas are provided in Appendix B
- Device codes are a 3-digit code unique to the device used to collect the data (e.g. 073)
- The date part of the file name is the 8-digit date when the file was created (e.g. 02152013 for February 15, 2013)

- The time part is the hour, minute and second the file was created (e.g. 172347 for 5:23:47 pm)

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

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

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

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

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

3.1.4. *MRA Data*

MRA data are entered into the web-based application and are automatically stored on the contractor's server each time the data are saved. The server is a secure environment that meets all of CDC's security and confidentiality guidelines and specifications.

MRA data from the web-based application will first be processed by the contractor for preliminary data cleaning and error checks. The contractor will upload all MRA data to the DCC data portal via the secure network using approved encryption software. Once at the DCC, the data will be decrypted, cleaned, and processed according to CDC guidelines. The processed data will be provided to CDC and to the project areas in a timely manner following the close of data collection.

The contractor will upload clean and processed datasets to the DCC portal on a monthly and quarterly basis. Once MRAs are completed, project area staff will perform quality assessment reviews of each data record, including checks for duplicate records, incomplete records, and inappropriate data values. Through its web-based application, the contractor provides up-front tools, including validations and reflexive logic, that allow project areas to identify many of the errors prior to final data entry and submission. The application generates a log for the contractor that automatically stores all changes made to the data. In addition to up-front checks, the contractor will perform monthly quality assessments on abstracted data to identify additional data errors and inconsistencies. Data-related changes that are made as a result of these quality assessments will be incorporated into the clean datasets that will be uploaded to the DCC portal on a monthly or quarterly basis. No facility or personal identifiers, other than participant IDs, will be transmitted to the contractor, CDC, or DCC.

Once the data files are received by DCC, additional quality assessment checks will be implemented that link MRA data with individual interview data and compare overlapping data elements. DCC will then produce error reports specifying any discrepancies found. These reports will be provided to the project areas on a monthly basis. Project areas will be required to address each discrepancy by making changes to MRA data in the web-based application, the interview error log, or the DCC tracking system, as applicable. Each subsequent error report will reflect the changes made to the data based on the previous report. For information on the standard naming conventions for MRA data, please refer to the MMP Data Management Manual.

3.1.5. *Analytic Data*

The interview and MRA are linked by the DCC using the MMP participant ID. Selected data from the sampling frame may be used to supplement missing information in the interview and MRA data.

Both SAS and text analytic files containing each project area's data will be created by the DCC. The appropriate SAS and text analytic files will be made available to each project area via the DCC data portal after the data collection cycle has ended. The SAS and text analytic data files for all MMP project areas will be used to create MMP national analytic files. The project area files, as well as the national files, will contain both "raw" and selected "calculated variables." "Raw" variable values represent the direct untransformed responses to items on the questionnaire, MRA forms, and sampling frame. Calculated variable values are the result of calculations performed on "raw", selected variables form the NHSS, or other computed variables. All project areas will receive un-weighted and weighted data.

3.2. DATA ANALYSIS

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

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

4. SECURITY AND CONFIDENTIALITY OF MMP DATA

MMP data will be subject to the same security and confidentiality requirements as those implemented for HIV surveillance data at state and local project areas, as well as at CDC. These requirements include adherence to CDC's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. Specifically, all MMP staff will undergo the same security and confidentiality training as that required for health department staff who conduct HIV case surveillance. While conducting MMP, protocols will be strictly followed at the project area and national level to ensure the integrity, confidentiality, and security of all MMP data.

Security and confidentiality of MMP data is within the scope of the DCC contract and the MRA web-based data collection application contract. The contractors will also adhere to CDC's data security and confidentiality guidelines.

HIV case surveillance data are currently collected according to the Assurance of Confidentiality, under Sections 306 and 308(d) of the Public Health Service Act (42 U.S.C. Sections 242k and 242m(d)). Information collected in the surveillance system that would permit identification of any individual or establishment is collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual or the establishment in accordance with Section 306 and 308(d) of the Public Health Service Act. Because data collected for MMP constitute data collected for an enhanced surveillance activity, these data will be reported to and maintained by CDC in the same manner as are current HIV surveillance data, and accordingly, are covered by the existing Assurance of Confidentiality.

MMP interview and abstraction data records do not contain specific personally identifiable information (e.g. name, date of birth, address, social security number). They are linkable to eHARS only through the STATENO.

The table below summarizes the storage requirements and schedule for destruction of paper data collection forms and materials containing personally identifiable information. Signed

consent forms, interviews, MRAs, and sampling frame data will be retained for the duration specified by the state or local surveillance policies.

Data type	**Storage method**	**Destroy as soon as no longer needed, but no later than:**
Paper interviews and MRAs	Under lock and key	12 months after end of data collection cycle
Paper or electronic copies of medical records	Under lock and key	12 months after end of data collection cycle
Paper or electronic lists containing specific identifiers (e.g. name, phone number) used for locating or recruiting sampled persons or other MMP activities	Under lock and key with strict, limited access	Destroy once no longer needed (e.g. when all the eligible persons on the list have been dispositioned, contacted, or determined to be unlocatable), but no later than 24 months after the end of data collection
Contact attempt tracking database records	Secure server with strict, limited access	24 months after end of data collection cycle
Informed consent forms (if required)	Securely stored separate from the data collection instruments (preferably at the main HIV Surveillance office) and under the same security procedures as those for HIV case surveillance forms	N/A – retain for the duration specified by state or local surveillance policies

The survey software that will be used to collect the interview data supports the ability to encrypt response data and password-protect interviews, so that unauthorized users are unable to view, export, or modify collected data. The web-based application that will be used to collect MRA data is similarly password-protected, so that unauthorized users are unable to view, export, or modify collected data.

Portable electronic data collection devices, such as laptop computers or tablets, used to store interview and other data related to sampled persons must be protected through use of individual passwords, which are known only to the user and to Data Managers at the project area. The security of the system must meet all Federal Information Systems Management Act (FISMA), Office of Management and Budget (OMB), HHS, and CDC IT Security requirements, which ensure the confidentiality, integrity, and availability of data on federal information systems. The hard drives of all electronic data collection devices must be encrypted. Data should be uploaded frequently to office computers kept in an area behind a locked door. Portable electronic data

collection devices should always be stored in a secure locked location. They should never be stored for extended periods of time (e.g. overnight) in a car.

When traveling into the field to recruit sampled persons, MMP staff may need to carry identifying and contact information for sampled persons. In doing so, staff should take care to limit the amount of information carried to the minimum necessary and to keep the data secure, e.g. in a locked briefcase or other method described in CDC's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs. Electronic information should be maintained on a password-protected, encrypted device. Additional protections, such as biometric authentication, are encouraged whenever they are deemed to increase the security of the data.

The interview data warehouse, contact attempts tracking database, and sampling frame data for each project area will be stored on a secure server with limited access. Frequent backup of the interview records will be performed by the project area using protocols developed by CDC. Project areas should also upload interview data on a monthly basis to the DCC data portal. The MRA data will automatically be stored on the secure server as it is entered and saved, and the contractor will upload MRA data on a monthly and quarterly basis to the DCC portal. The DCC has 1 month from receipt of project area data to upload a cumulative project area specific dataset to the data portal. Project areas will be able to download the interview and MRA data from the data portal on a monthly basis. The DCC will also post project area specific reports.

5. HUMAN SUBJECTS CONSIDERATIONS

5.1. NON-RESEARCH DETERMINATION

The CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has determined that MMP is not research and that it is a routine disease surveillance activity with data being used for disease control program or policy purposes (Appendix H). Because NCHHSTP has determined that MMP is not research, it is not subject to human subjects regulations, including federal IRB review and approval. However, all federal, state, and local MMP staff must adhere to the ethical principles and standards by respecting and protecting the privacy, confidentiality, and autonomy of participants to the maximum extent possible.

MMP project areas should follow state and/or local procedures to determine whether the MMP protocol is subject to state or local human subject regulations. If MMP is determined to be research and is submitted for IRB review, the outcome of the IRB review should be kept on file locally. Project areas should report to CDC if their local MMP is considered surveillance or research and, if it is considered research, should submit documentation of the IRB's review and decision to their Project Officer.

5.2. ANTICIPATED RISKS AND BENEFITS

Participation in MMP presents some risk of inadvertent disclosure of the sampled person's HIV status to others. This is similar to that which may arise from case reporting of HIV infection to NHSS, participating in HIV prevention activities, or seeing an HIV care provider. The project

employs multiple safeguards to minimize this risk, such as providing guidance and model scripts for recruiting participants (Appendices C.1-C.4) and through requiring strict adherence to security and confidentiality guidelines (Section 4, "Security and Confidentiality of MMP Data").

Participants who are aware of their status, but are not receiving HIV care at the time of interview, may benefit from learning about the advantages of HIV care and from assistance with linkage to or re-engagement in HIV medical care. Defined protocols for linkage and re-engagement are required of project areas participating in MMP. Persons diagnosed with HIV may benefit from participating in MMP by better recognizing their own risks for transmitting HIV or transmitting or acquiring other sexually transmitted infections, talking with trained staff about how to reduce those risks, learning more about local HIV prevention efforts, and obtaining prevention materials and referrals for health care, social, and prevention services. MMP participation benefits communities by helping HIV prevention and care planners more appropriately allocate federal, state, and local HIV prevention resources and care services.

Although MMP samples persons whose HIV diagnosis has been reported to surveillance, it is possible that a small number of people who are unaware of their HIV diagnosis may be inadvertently contacted, and MMP staff may disclose HIV test results to some sampled persons for the first time. In such cases, the sampled person may benefit from the encounter by learning about his or her HIV status and being linked to care. However, such encounters are likely to involve substantial emotional stress. Procedures and staff training to maximize the benefit (education and linkage to care) and minimize the harm (emotional stress) in such encounters will be required of all project areas. For persons previously unaware of their HIV status, the MMP staff member's responsibility is to focus on the implications of this disclosure; such persons will not be recruited for participation in MMP at that time, although MMP staff may provide contact information so that the sampled person can participate at a later time if he or she so chooses.

5.3. VULNERABLE POPULATIONS

Persons under the age of 18 will not be included in MMP. Pregnant women may be included in MMP if they are sampled. Persons with mental disabilities may be included in the sample; however, any person alive at the time of interview who cannot provide informed consent will be excluded from participation in the project. Incarcerated persons may be interviewed for MMP if they provide informed consent. As do all sampled persons, incarcerated persons have the right to refuse participation without penalty. All participants will be afforded the same human rights protections.

If local regulations allow, MMP staff will approach correctional facilities to determine those that are willing to allow access to inmates for interview and/or to medical records. MMP staff will meet with appropriate administrative, corrections, and health care providers to explain the surveillance activity and collaborate to determine a feasible method of conducting the activity specific to each participating facility. If persons sampled through MMP methods are determined to be incarcerated, local MMP staff will contact the correctional facility to arrange to meet the sampled persons, e.g. at a subsequent visit to a health care provider. At that subsequent visit, the MMP interviewer should be on site to present the surveillance activity, obtain informed consent,

and conduct the interview in a private (but secure) location in the clinic. A mechanism for providing a token of appreciation should be arranged (e.g. a deposit into an inmate's commissary or employment account). Project areas must have documented permission from the correctional institution, as well as any necessary IRB determination (with participation of a prisoner advocate, if needed) prior to recruiting and interviewing prisoners for MMP. The participants' HIV status will not be disclosed to prison or jail guards, health care providers, or parole department staff, except as needed to obtain permission to conduct the interview. Inmates recruited for MMP will be informed that participation has no effect on his or her parole and that all information from the interview is confidential and not communicated with anyone outside the local health department and CDC.

5.4. ADVERSE EVENTS

Adverse events are expected to be rare. However, possible serious adverse events in this project may result from contacting persons unaware of their HIV status, as discussed above in "Contacting Sampled Persons" and "Risks and Benefits." The emotional impact of learning that one is HIV-positive is significant, and project areas must develop procedures to handle this situation sensitively, as described in the recruitment guidance document (Appendix C.2). Although only persons who have been diagnosed with HIV and whose diagnosis has been reported to the surveillance systems will be sampled for MMP, in rare instances, persons unaware of their HIV status may be sampled. In such cases, the sampled person should be informed of his or her positive HIV test and procedures to address the emotional impact of the information. Facilitation of subsequent linkage to HIV care should be followed.

Emotional distress may also result from concerns about confidentiality. Although unlikely, it is possible that participants may experience anxiety or emotional distress when responding to interview questions on sensitive topics, such as their health status or sexuality.

Potential adverse experiences are most likely to be identified during initial contact with sampled persons or during the consent and interview process. Sampled persons will first be contacted by mailing, telephone, text message, e-mail or in person, depending on the availability of contact information. The wording of the contact scripts will be developed by MMP staff in local project areas and should use language that includes Assurance of Confidentiality. Model contact scripts are given in Appendices C.1-C.4. Local informed consent forms will incorporate the language used in the model informed consent form approved by CDC and, as appropriate, the local IRB, which also includes Assurance of Confidentiality and the person to contact should an adverse event occur.

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

Project areas should develop procedures for dealing with adverse events and protocol breaches that meet the requirements of their governing institutions or IRBs, which should include procedures for reporting adverse events and protocol breaches. Project areas should report all severe adverse events to CDC within 24 hours of occurrence. All adverse events and protocol breaches, regardless of severity, should be reported to CDC within 2 weeks. Detailed guidance on reporting of and development of procedures to address adverse events and protocol breaches are provided in Appendices I.1 and I.2.

5.5. INFORMED CONSENT

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

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

Even in cases of oral consent, project areas should offer a copy of the consent form to the participant. If oral consent is given via telephone, staff can offer to mail or email a copy of the consent form. When consent is obtained for the interview, participants should be advised that information from their medical records will also be collected and analyzed along with their answers to the interview questions.

Example Statement of Informed Consents (Model Consent Forms) in both English and Spanish are available for local area use and modification (Appendices J.1 and J.2, respectively). Project areas should follow their own regulations regarding any consent forms or confidentiality agreements necessary for an interpreter.

Project areas should modify the templates of the consent forms to fulfill the requirements of their IRBs, if applicable. These consent forms should also be modified for use by hearing and visually impaired participants.

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

6. DATA DISSEMINATION

6.1 NOTIFYING PROVIDERS, PERSONS LIVING WITH HIV, AND THE COMMUNITY OF FINDINGS

Data from MMP are expected to improve surveillance activities, contribute to prevention programs and treatment services, provide information about unmet needs in HIV care, and increase knowledge about medical care for persons with HIV. Results are also expected to guide national surveillance efforts. Because MMP is a surveillance system that represents persons with

diagnosed HIV in the US, it is imperative to disseminate findings from the project as soon as they are available.

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

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

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

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