Project Determination

Medical Monitoring Project Facility Survey

Project ID:	0900f3eb81b47ee2
Accession #:	NCHHSTP-CST-5/13/20-47ee2
Project Contact:	Beer_Linda (gur0)
Organization:	OS/OS/OSI
Status:	Pending Regulatory Clearance
Intended Use:	Project Determination
Estimated Start Date:	09/17/20
Estimated Completion Date:	03/14/22
CDC/ATSDR HRPO/IRB Protocol#:	
OMB Control#:	

Description

Priority

Standard

Determination Start Date

05/13/20

Description

The Medical Monitoring Project (MMP) Facility Survey will survey approximately 1,500 HIV medical care facilities at which clinical data were abstracted for the Medical Monitoring Project (MMP; OMB # 0920-0740). Surveying the entire universe of facilities at which an MMP abstraction took place is preferable to surveying a sample because the total number of facilities is relatively small and employing sampling would unnecessarily complicate MMP Facility Survey methods. Surveys will be developed by CDC staff and data will be collected by contractors. Participants may complete the survey online, by mail, or by telephone. No person-level data, including any personally identifying information or sensitive information, will be collected; the data elements will be limited to facility characteristics, services, and policies. The survey will take approximately 30 minutes to complete. This survey does not involve human subjects□□ research because it is an MMP surveillance activity. It will require OMB approval; an OMB PRA ICR has been submitted to the DHAP PRA Coordinator for review.

IMS/CIO/Epi-Aid/Chemical Exposure Submission

No

IMS Activation Name

Not selected

CIO Emergency Response Name

Not selected

Epi-Aid Name

Not selected

Assessment of Chemical Exposure Name

Not selected

Goals/Purpose

The Medical Monitoring Project (MMP) is a public health surveillance project implemented by local and state health departments. The goal of the MMP HIV Facility Survey is to document the capacity of HIV medical care facilities to support the initiative to End the HIV Epidemic (EHE). Despite the development of biomedical tools to stop transmission of HIV, including effective antiretroviral therapy and HIV pre-exposure prophylaxis, the incidence of HIV in the United States has plateaued in recent years. Substantial proportions of people with HIV remain undiagnosed. Many others, who have been diagnosed, are not engaged in HIV medical care that could effectively eliminate the chance of transmitting HIV to others. Similarly, many people at risk for acquiring HIV are not receiving treatment that is known to be highly effective at blocking transmission. Barriers to engagement in care include lack of insurance coverage, inadequate housing and transportation, food insecurity, mental health and substance use disorders, and HIV-related stigma and discrimination. EHE has received initial funding to support efforts to address these barriers in highly affected areas. Many of the strategies recommended by EHE are to be carried out by health care facilities, including rapidly enrolling people who are newly diagnosed and immediately starting antiretroviral therapy, providing onsite support services including case management, navigation services, and treatment for substance use and mental health disorders, using apps and text messaging to increase retention in care and adherence to treatment, and using clinic and pharmacy data to systematically motor retention in care and identify patients requiring more support. Data describing the extent to which facilities of varying sizes and types have implemented these strategies are required by DHHS and state and local health departments to inform allocation of EHE resources. These data are not available elsewhere.

Objective

The objectives of the project are to describe the characteristics of HIV care facilities, scope of clinical services provided, and alignment of those services with the goals, objectives, and strategies of EHE.

Activities or Tasks

New Collection of Information, Data, or Biospecimens

Target Population to be Included/Represented

Other-HIV medical care facilities

Tags/Keywords

HIV: Health Services

CDC's Role

Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition

of any funding provided

Method Categories

Survey

Methods

Approximately 1,500 medical care facilities at which medical records were reviewed during the 2019 MMP data collection cycle (June 1, 2019 through May 15, 2020) will be eligible to be surveyed. MMP uses a 2-stage sample design that results in annual cross-sectional probability samples of HIV-diagnosed adults in the United States. During the first stage of sampling, geographic primary sampling units (PSUs) were selected. During the second stage of sampling, persons in each PSU are randomly sampled directly from the National HIV Surveillance System. Most MMP participants are in care for their HIV and provide the name of their care facility, at which their medical records are abstracted. The facilities at which the participants received care are eligible to be surveyed. Survey domains will include facility characteristics (e.g., size, type, and funding sources including the Ryan White HIV/AIDS Program), onsite clinical and support services (e.g., case management, navigation services, and adherence support), systems for rapidly enrolling new patients and starting antiretroviral therapy, participation in HIV telemedicine to serve patients in rural and other areas with limited access to HIV specialty care, the use of technology to retain patients in care (e.g., text messaging and apps to remind patients about upcoming appointments and to take their medications), and the use of clinical and pharmacy data to identify patients not receiving consistent care. Staff in the 23 MMP project areas will create lists of names of eligible facilities in their jurisdiction and the name and contact information of a facility administrator or other key personnel at each facility. This information will be transferred to the contractor through a secure data portal maintained by the contractor. The contractor will compile the information into a single database, assigning a unique facility identification number to each facility. The contractor will use the facility names and contact information to create individualized recruitment packets on CDC letterhead, including recruitment materials and the paper version of the survey as well as a link to the web-based version. The contractor will deliver these packets electronically and by mail to each facility.

Collection of Info, Data, or Bio specimens

Surveys will include not more than 100 questions, requiring up to 30 minutes to complete. Facilities will have the option of completing the survey 1) on paper and mailing it to the contractor, 2) through a web-based application developed and maintained by the contractor, or 3) during a telephone call with the contractor. The contractor will follow-up with nonresponders using the Dillman Method. The contractor may ask staff of health departments in MMP jurisdictions to contact nonresponding facilities and encourage their participation. The contractor will provide de-identified final datasets to CDC and the project areas. No person-level surveillance data, including any personally identifying information or sensitive information, will be collected. The survey will not contain specific identifiers of facilities or facility employees, (names, Employer Identification Numbers, physical or email addresses, or phone numbers). No aggregate patient information that could potentially identify a facility, e.g. demographic characteristics of patients, will be collected. All data that will be collected are publicly available. A stamped return envelope addressed to the contractor will be included in the recruitment packet. After the contractor has entered the paper survey responses into the web-based application, they will send the paper surveys to CDC. The contractor will not be permitted to make copies of these completed paper surveys. Paper surveys will be destroyed at the CDC six months after survey activities are completed. The Web-based software, which will be used as one form of collecting data, will support the ability to encrypt response data and password-protect surveys so that unauthorized users are unable to view, export, or modify collected data. The contractor will not save IP addresses of survey respondents who complete the web-based survey. Participation in the facility survey presents negligible risk of harm to facilities or facility staff members. Participation involves the completion of a voluntary, self-administered questionnaire. Respondents may decline to answer any of the questions in the survey, and, if they choose, can end the survey at any time.

Expected Use of Findings/Results and their impact

MMP Facility Survey data will be used to describe the characteristics of HIV care facilities, scope of clinical services provided, and alignment of those services with

the goals, objectives, and strategies of EHE.
Could Individuals potentially be identified based on Information Collected?
No
Will PII be captured (including coded data)?
No
Does CDC have access to the Identifiers (including coded data)?
No
Is an assurance of confidentiality in place or planned?
No
Is a certificate of confidentiality in place or planned?
No
Is there a formal written agreement prohibiting the release of identifiers?
No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award
CDC Contract	APHIR IDIQ		2020	1

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office:
No

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
HANNA DEMEKE	12/13/2021				Project Officer	mln7@cdc.gov	404-639-6230	CLINICAL SURVEILLANCE TEAM
John Weiser	11/16/2021				Project Officer	eqn9@cdc.gov	404-639-8405	CLINICAL SURVEILLANCE TEAM
Linda Beer	12/11/2021				Project Officer	gur0@cdc.gov	404-639-5268	CLINICAL SURVEILLANCE TEAM
Roy Shouse	12/11/2021				Principal Investigator	zxz3@cdc.gov	404-639-4678	CLINICAL SURVEILLANCE TEAM

DMP

Proposed Data Collection Start Date	09/17/20
Proposed Data Collection End Date	03/14/22
Proposed Public Access Level	Non-Public
Reason for not Releasing the Data	Other- Facility level data collected within a surveillance system that collects non-public data
Public Access justification	NA
How Access Will Be Provided for Data	Data will be available upon request from CDC and contingent on meeting the requirements of the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs.
Plans for archival and long-term preservation of the data	The Contractor will not retain any copies of data generated under the contract. During or after the life of the contract, no data may be released except after CDC approval. All requests which the Contractor receives from third parties for access to the data must be referred to CDC. Six months before the end of the contract the Contractor and CDC will determine a data disposition plan. The data disposition plan may include several actions including purging or destroying data, moving data to less expensive or more secure storage like the cloud or offline, copying files to legal hold

	archives, or encrypting sensitive content to protect against breaches.

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States		

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research	05/21/20	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		05/22/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator
ICRO: **Returned with No Decision**		05/22/20	Zirger_Jeffrey (wtj5) ICRO Reviewer