

National HIV Surveillance System (NHSS)

OMB # 0920-0573

**Supporting Statement
Part B**

June 3, 2019

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

The Division of HIV/AIDS Prevention (DHAP), CDC provides funding through cooperative agreements to all U.S. States, the District of Columbia, and U.S. dependent areas to conduct surveillance for HIV. Surveillance data collections are supported in 59 areas (the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, the Commonwealth of the Northern Mariana Islands, and the Federated states of Micronesia) using standard HIV case report forms (Note the Marshall Islands, and Federated State of Micronesia are in the process of establishing these systems). It is anticipated that all 59 jurisdictions will be fully implementing HIV surveillance over the next three years. HIV surveillance case reports are obtained through both active and passive methods and are reported from a variety of sources to state health departments who in turn report these cases to CDC. Cases are typically reported to state/local health departments by laboratories, physicians, hospitals, clinics, and other health care providers using standard adult and pediatric case report forms. Additionally, health departments also abstract medical records in hospitals and other health care facilities to complete HIV case reports.

No sampling methods will be used to select respondents. Absolute case count is preferred to sampling for the following reasons: (1) HIV is a reportable disease and, therefore, states routinely collect information on each reportable case, and data collected by the HIV surveillance system assist local areas by identifying populations that need immediate attention and trends that help focus valuable resources; (2) DHAP's goal is to reduce the burden of HIV in the United States and an absolute case count provides the best information on disease burden; and (3) reported HIV and stage 3(AIDS) cases are used for funding allocations for prevention and care programs by CDC and other federal agencies, for example the Ryan White HIV/AIDS Program administered by Health Resources and Services Administration (HRSA) and the Department of Housing and Urban Development (HUD) Housing Opportunities for Persons with AIDS (HOPWA) program.

2. Procedures for the Collection of Information

Persons with HIV meeting the CDC surveillance case definitions for HIV [all stages, including stage 3 (AIDS)] are reported to the system based on clinical and laboratory criteria. These definitions have been updated periodically to accommodate advances in diagnostic and therapeutic standards and to improve standardization and comparability of surveillance data regarding persons with HIV at all stages. The most recent HIV case definition, including staging of disease, was published in 2014 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1>). CDC collaborates with the Council of State and Territorial Epidemiologists (CSTE) to develop the revisions to the case definitions as necessary. Typically, CDC obtains additional input through consultations and through peer review by health-care professionals, in compliance with the Office of Management and Budget requirements for the dissemination of influential scientific information.

Following extensive consultation and peer review, CDC and the Council of State and Territorial Epidemiologists (CSTE) revised and combined the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case now accommodate new multitest algorithms, including criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Clinical (non-laboratory) criteria for defining a case for surveillance purposes have been made more practical by eliminating the requirement for information about laboratory tests. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition published in 2014 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1>).

Data collection and electronic submissions to CDC from the reporting areas are done by HIV surveillance programs in public health departments. Laboratories and care providers are required to report cases of HIV [all stages, including stage 3 (AIDS)] in accordance with local disease reporting laws, rules and regulations. These data are shared on hard copy case report forms and sent via U.S. mail, secure fax (CDC discourages transmission by fax), or secure electronic transmission (e.g., files are encrypted and sent via secure encrypted data network). State health departments compile reported information and serve as

respondents for this surveillance system. Health departments use CDC provided software [i.e. the enhanced HIV/AIDS Reporting System (eHARS)] to manage surveillance data and report data to CDC on a monthly basis via a Secure Access Management System (SAMS). Data include demographic and geographic information (e.g., sex, race, ethnicity, and residence), laboratory and clinical indicators of HIV infection and AIDS, and behavioral and other risk factors related to HIV transmission. Name and date of birth are collected and retained by state and local health departments but names are removed before data are sent to CDC.

There are no minimum sample size requirements. However, the local health departments routinely monitor the efficiency and performance of their local system and the quality of data reported to CDC. CDC also monitors the quality of data reported by health departments and the quality of data at the national level. DHAP performs periodic data quality checks and provides reports for areas to use in the investigation of incomplete, inconsistent, and unusual data and provides guidance and tools for evaluating system performance. CDC annually assesses surveillance system performance using process and outcome standards. The process and outcome standards for the HIV surveillance systems are outlined in the Technical Guidance for HIV Surveillance Programs. Obtaining health department and national outcome results is fully automated using programs designed and distributed by CDC. The goals are to develop a process for providing performance feedback to surveillance areas and to use evaluation findings to improve data quality, data interpretation, usefulness, and surveillance system efficiency. Ultimately, data obtained from these evaluations are used to improve data quality and increase completeness of reporting.

Health departments conduct ongoing evaluations of system performance. Minimum performance standards and recent assessments for surveillance programs are described in the "Standards Evaluation Report (SER) Form [Attachment 3 (e)]". Collecting information on data quality is critical for monitoring, evaluating and interpreting HIV surveillance data used to monitor the National HIV/AIDS prevention goals and estimate the impact of HIV at the local, state and national levels. Additionally, data quality assessments are useful for documenting the strengths and weakness of data for public consumption. Without assessing data quality any information released could be considered unreliable or invalid.

Since the last OMB approval, CDC revised some of the minimum standards. Currently, minimum performance standards include

completeness of reporting ($\geq 95\%$), timeliness of case reporting ($\geq 90\%$ of cases reported within 6 months of diagnosis), accurate case counts (less than 2% duplicate case reports), completeness of risk information ($\geq 80\%$), initial CD4 test result ($\geq 85\%$) and initial viral load test result ($\geq 85\%$), and data quality checks (passed by $\geq 97\%$ of cases for a diagnosis year). These same routine questions are asked each year. Completeness of reporting of data elements collected for perinatal HIV exposure reporting are also being evaluated and will continue to be assessed on an ongoing basis.

In 2015, CDC consolidated information gathered on evaluation outcomes and collection of laboratory data to reduce the burden on surveillance programs through elimination of duplicate questions. Programs report this information annually as part of the requirements of PS18 1802 SER. In addition, jurisdictions annually provide a narrative description of progress towards achieving program objectives including an implementation plan and timeline as part of their Annual Performance Report.

3. Methods to Maximize Response Rates and Deal with Nonresponse

This section is not applicable to the HIV surveillance system because of Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) which authorizes public health collection of this information.

4. Test of Procedures or Methods to be Undertaken

No additional tests of procedures or methods are proposed for this ongoing surveillance activity. Data collection instruments and data elements have been in use and have included extensive review and consultation with state and local health departments prior to implementation. Data reported through the surveillance system will be continually evaluated for data quality and completeness. For estimating HIV incidence, statistical methods do not require any information in addition to laboratory test results that are collected routinely (the CD4+ test results after HIV diagnosis).

The new method adopted by CDC for estimating HIV incidence is based on a well characterized and tested CD4+ depletion model [Time From Human Immunodeficiency Virus Seroconversion to Reaching CD4+ Cell Count Thresholds < 200 , < 350 , and < 500 Cells/mm³: Assessment of Need Following Changes in Treatment Guidelines (<http://dx.doi.org/10.1093/cid/cir494>), Using CD4 Data to Estimate HIV Incidence, Prevalence, and Percent of Undiagnosed

Infections in the United States
(<https://www.ncbi.nlm.nih.gov/pubmed/27509244>)], which uses the first CD4+ test result after HIV diagnosis to estimate the duration for which the person has been infected with HIV..

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Local and state health departments are responsible for collecting data on persons eligible to be reported, entering data into the electronic reporting system, and transmitting data to CDC. CDC receives regular input from health departments through annual surveillance technical assistance meetings . In addition, CDC has extensively collaborated with CSTE regarding the HIV surveillance case definitions and reported data elements. Outside (non-CDC) individuals or agencies are occasionally consulted on statistical aspects of the design, collection and/or analysis of HIV data. The individual consultant or agency from whom we request assistance depends on the problem being addressed and most often takes form as a multi-disciplinary panel.