

National HIV Surveillance System (NHSS)

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**Supporting Statement
Part B**

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Contact Information

**Project Officer: Patricia Sweeney, MPH
HIV Surveillance Branch
Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop E-US8-2
Atlanta, GA 30329**

**Voice: (404) 639-2047
Fax: (404) 639-2980
Email: pas3@cdc.gov**

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The Division of HIV Prevention (DHP), 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) DHP'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 cases (all stages) 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

State, local, and territorial laws and regulations require the reporting of HIV to health departments and health departments voluntarily share HIV case information with Centers for Disease Control and Prevention (CDC) as part of nationally notifiable disease reporting. 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 (<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>). The Council of State and Territorial Epidemiologists (CSTE) and health-care professionals provided valuable input through consultations and peer review, in compliance with the Office of Management and Budget requirements for the dissemination of influential scientific information.

The current case definition combines 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 accommodates multitest algorithms, criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Additionally, clinical (non-laboratory) criteria for defining a case in the absence of HIV laboratory tests results. 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 (<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>).

State health departments compile reported information from laboratories and care providers and serve as respondents for this surveillance system. CDC Technical Guidance for HIV Surveillance Programs describes practices and standards for conducting surveillance activities. Health departments use CDC provided software 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, gender, sexual

orientation, race, ethnicity, and residence), laboratory and clinical indicators of HIV infection (all stages), 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. As a reportable disease all diagnosed cases should get reported making sampling unnecessary. However, the local health departments routinely monitor the efficiency and performance of their local system and the quality of data reported to CDC. Whereas CDC monitors the quality of data at the national level, providing feedback to reporting 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 outlined in the Technical Guidance for HIV Surveillance Programs.

The minimum performance standards and recent assessments for surveillance programs are described in the "Standards Evaluation Report (SER) Form [Attachment 3 (d)]". Data quality assessments are 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 all levels, as well as for documenting the strengths and weakness of data for public consumption.

The minimum performance standards include completeness of case 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).

Programs will continue to report this information annually as part of the SER.

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 for the next cycle have been thoroughly reviewed and revised in consultation with state and local health departments.

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 method in use 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

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 depending upon the problem being addressed and most often takes form as a multi-disciplinary panel.