Adult and Pediatric HIV/AIDS Confidential Case Reports for National HIV/AIDS Surveillance

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Supporting Statement
Part B

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

The Division of HIV/AIDS (DHAP), CDC provides funding through cooperative agreements to all U.S. States, the District of Columbia and U.S. Dependencies to conduct surveillance for HIV/AIDS. Surveillance data collections are supported in 59 areas (the 50 states (including 6 separately funded cities), 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 Marianna Islands, and the Federates states of Micronesia) using a standard HIV/AIDS case report forms (Note the Marshall Islands, Palau 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/AIDS surveillance over the next three years. A subset of these 59 areas is funded to report supplemental data elements for incidence surveillance, surveillance for variant, atypical and resistant HIV surveillance (VARHS), and enhanced perinatal surveillance. HIV/AIDS case reports obtained through both active and passive methods 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 health care providers 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/AIDS is a reportable disease and, therefore, States routinely collect information on each reportable case, and data collected by the HIV/AIDS 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/AIDS in the United States and an absolute case count provides the best information on disease burden; and (3) reported HIV/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 HRSA.

2. Procedures for the Collection of Information

Persons meeting the CDC surveillance case definitions for HIV and AIDS are reported to the system based on clinical and laboratory criteria. These definitions have been updated several times to accommodate advances in diagnostic and therapeutic standards and to improve standardization and comparability of surveillance data regarding persons at all stages of HIV. The HIV case definition, including advanced stage of AIDS, was most recently updated in December 2008 (CDC. MMWR 57(RR10);1-8; 2008). See http://www.cdc.gov/hiv/topics/surveillance/resources/guidelines/index.htm#surveillance for all CDC case definitions for HIV and AIDS surveillance. CDC collaborated with the Council of State and Territorial Epidemiologists (CSTE) to develop the revisions in this report. CDC obtained additional input through consultations regarding the pediatric case definitions (April 2005) and adult and adolescent case definition (August 2005 and June 2006) 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. HIV testing is now widely available, and diagnostic testing has continued to improve; these changes are reflected in the 2008 revised case definition for HIV infection, which now requires laboratory-confirmed evidence of HIV infection to meet the case definition among adults, adolescents, and children aged 18 months to <13 years.

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 and 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 private network [VPN]). State Health Departments compile reported information and serve as respondents for this surveillance system. Health Departments use CDC provided software to manage surveillance data and report data to CDC on a monthly basis via a secure data network (SDN). Data include demographic and geographic information (e.g., sex, race, ethnicity, 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 and names are removed before data are sent to CDC.

There are no minimum sample size requirements. However, the local health jurisdictions routinely monitor the efficiency and performance of the system and the quality of data reported. Health departments conduct ongoing evaluations of system performance. Minimum performance standards for surveillance programs are outlined in the *Guidelines for National Human Immunodeficiency Virus Case Surveillance Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome. MMWR 1999 (No-13 (11-16*)) available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm. and Hall and Mokotoff,Journal of Public Health Management and Practice: September/October 2007 - Volume 13 - Issue 5 - p 519-523*: Setting Standards and an Evaluation Framework for Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome Surveillance* http://journals.lww.com/jphmp/Abstract/2007/09000/Setting_Standards_and_an_Evaluation_Framework_for.14.aspx. Minimum performance standards include completeness of reporting (>85%), timeliness of reporting (>66% of cases reported within 6 months of diagnosis), accurate case counts (less than or equal to 5% duplicate case reports) and 85% of cases should be reported with risk information. The revised electronic HIV/AIDS reporting system (eHARS), which will be completely deployed in 2009, will enhance health departments' capabilities to implement ongoing and systematic quality control procedures and evaluate system performance.

DHAP also performs periodic data quality checks and provides reports for areas to use in the investigation of incomplete, inconsistent, and unusual data and provides guidance for evaluating system performance. CDC is currently developing a national evaluation plan that includes a standardized approach to annually assess surveillance system performance using process and outcome standards. The process and outcome standards for the HIV core surveillance systems are based on the Technical Guidance for HIV/AIDS Surveillance Programs, Volume I and the evaluation standards and framework publication by Hall and Mokotoff published in the Journal of Public Health Management Practice in 2007. 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. The evaluations will include assessments according to outcome standards for completeness and timeliness, data quality, risk factor ascertainment, intrastate and interstate duplicate review, data reporting and dissemination and CD4 reporting and will be implemented over the next three years. Ultimately data obtained from these evaluations will be used to improve data quality and

increase completeness of reporting. Completeness of reporting of data elements collected for incidence, VARHS and EPS are also being evaluated and will continue to be assessed on an ongoing basis.

3. Methods to Maximize Response Rates and Deal with Nonresponse

This section is not applicable to the HIV/AIDS 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 the 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 must account for testing and medication use history. Review and testing of statistical methods for incidence surveillance was conducted according to the recommendations from consultation with statistical experts conducted in 2006 and 2007. These methods were published by Karon et.al. in Statistics in Medicine in 2008 (see publications listed in Attachment 5). Consultation materials for the 2006 consultation were provided in the last renewal application. The agenda and participants from the consultation on statistical methods conducted February 2007 is included in Attachment 11. The methods were reviewed through peer review by statisticians and surveillance experts, in compliance with the Office of Management and Budget requirements for the dissemination of influential scientific information.

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 HARS database, and transmitting data to CDC. CDC receives regular input from health departments through annual surveillance coordinator meetings (see Attachment 7 for listing of surveillance coordinators in state health departments). In addition, CDC has extensively collaborated with the Counsel of

State and Territorial Epidemiologists (CSTE) regarding the HIV surveillance case definitions and reported data elements. Additionally, outside (non-CDC) individuals or agencies are occasionally consulted on statistical aspects of the design, collection and/or analysis of HIV/AIDS data. Several such consultations were held regarding the statistical methodology used to estimate HIV incidence. The most recent consultation for statistical estimation of HIV incidence occurred in February 2007 (Attachment 11). 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.