National HIV Surveillance System (NHSS)

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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 Prevention (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 standard HIV/AIDS 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/AIDS surveillance over the next three years. A subset of these 59 areas are funded to report supplemental data elements for HIV Incidence Surveillance (HIS), Molecular HIV Surveillance (MHS) and Perinatal HIV Exposure Reporting (PHER). HIV surveillance 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 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 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).

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 periodically 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 staging of disease, 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 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.

CDC convened several workgroups from 2008 through 2009 to consider revision of various aspects of the HIV surveillance case definition. The topics addressed included 1) new HIV diagnostic testing algorithms that the current case definition might not recognize as valid; 2) criteria for differentiating HIV-2 infection from HIV-1 infection; 3) expansion of the staging system to include acute HIV infection; 4) the role of opportunistic illnesses in defining stage 3 HIV infection (AIDS); 5) use of CD4 T-lymphocyte counts for staging ; 6) The requirement of maternal HIV infection for diagnosis in children <18 months of age; and 7) Criteria for “physician-documented diagnosis” (when laboratory test documentation is insufficient).

CDC hosted a consultation to consider the recommendations of the workgroups on February 7 and 8, 2012. As in the workgroups, participants were experts in HIV case surveillance, laboratory testing, or clinical care. In addition, the consultation included representatives from relevant national and international organizations. The resulting recommendations from the consultation were submitted in a position statement to the June 2012 meeting of the CSTE. The position statement was modified based on further recommendations from the CSTE membership. We anticipate publishing the revised case definition in the Morbidity and Mortality Weekly Report (MMWR) in 2012 and implementing the revisions by 2013. This planned revision to the case definition will include modifications to testing categories

to accommodate new testing algorithms and modifications to staging criteria among other changes.

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 encrypted data network). 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 and Centers for Disease Control and Prevention and Council of State and Territorial Epidemiologists. *Technical guidance for HIV/AIDS surveillance Programs*; 2005. 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 enhanced HIV/AIDS reporting system (eHARS) has improved 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 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 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 was implemented in 2010. 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 HIS, MHS, and PHER 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 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 as well as

HIV recency results (STARHS result). Review and testing of statistical methods for incidence estimation 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**). Some refinements of these methods were published in 2011 (Prejean J, Song R, Hernandez A, Ziebell R, Green T, et al. (2011) Estimated HIV Incidence in the United States, 2006–2009. PLoS ONE 6(8): e17502.doi:10.1371/journal.pone.0017502) In September 2011, these methods were discussed in the context of anticipated changes in the HIV testing algorithm during a CDC consultation. After consideration of all presentations, discussions and commentary, consultants expressed that the impact of a revised HIV diagnostic algorithm seemed to be less problematic to current estimation methods than CDC had anticipated, and that blood specimens for recency testing would continue to be available. However, they did acknowledge that specimen collection could be more difficult in the context of "point-of-care HIV testing" and that surveillance programs would likely have to find alternative means of specimen collection. No single alternative to the current approach to incidence estimation emerged from the consultation. The agenda and participants listing from this consultation are provided in **Attachment 10**.

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

Several such consultations were held regarding the statistical methodology used to estimate HIV incidence. The most recent consultation did not focus on statistical estimation of HIV incidence but did include discussion about the impact of new testing algorithms on the current estimation methods. (**Attachment 10**) No single alternative to the current approach to incidence estimation emerged from the consultation.