

community-related and program data which can be used with HIV/AIDS surveillance data to track progress towards goals identified in CDC's HIV Prevention Strategic Plan ([http://www.cdc.gov/nchstp/od/hiv\\_plan/default.htm](http://www.cdc.gov/nchstp/od/hiv_plan/default.htm)).

#### *Part IV. Enhanced Surveillance for Perinatal Prevention*

The purpose of providing funds for this activity is to target and follow the progress toward maximal reduction of perinatal HIV transmission. Specifically, this support is to allow State and local health departments to evaluate (1) the impact of implementation of efforts to maximally reduce perinatal HIV transmission; (2) prevention failures for perinatal HIV transmission; (3) the efficacy of zidovudine (ZDV) and other antiretroviral medications in preventing perinatal HIV transmission; (4) potential adverse outcomes of perinatal and postnatal antiretroviral therapy; and (5) the Public Health Service recommendations for opportunistic infection prophylaxis by:

1. Conducting medical record reviews of mother/infant pairs and longitudinal follow-up of all HIV exposed children to ascertain knowledge of maternal HIV infection status before birth, HIV incidence, AIDS incidence, and death, the use of maternal and neonatal ZDV and its efficacy in preventing HIV transmission, and the use of other antiretroviral medications.
2. Conducting medical record reviews to evaluate recommendations for opportunistic infection prophylaxis and initiation of HIV evaluation and treatment in children.
3. Assessing potential adverse outcomes of exposure to antiretroviral medications among infected and uninfected children in the short term (e.g., birth defects, ascertained through record reviews and registry matches) and in the long term (e.g., by matching to tumor registries).
4. Matching HIV/AIDS registries to birth registries to ensure complete ascertainment of mother/infant pairs.
5. Collaborating with CDC to track progress towards the maximal reduction of perinatal HIV transmission.

#### *Part V. Laboratory Testing for Recent HIV Infection*

The Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) is the currently accepted method used for estimation of HIV incidence. With STARHS, confirmed HIV-positive samples are analyzed with a Less Sensitive HIV Enzyme-Linked Immunosorbent Assay (LS-EIA) which identifies antibodies at a point later in

the course of infection than the routine test. In performance of STARHS, the standard testing methodology for a commercially available HIV Enzyme-Linked Immunosorbent Assay (EIA) is altered by reducing the incubation time and increasing the dilution of the sample according to extremely precise criteria. Quantitative values from these tests are evaluated against control values and cut-off points to estimate the likelihood that that sample was collected from an individual who was infected with HIV within a finite period of time before the sample was collected. Because the testing procedures must be conducted with extreme precision, multiple control samples are run in tandem with each sample run. Other tests to identify recent HIV infection are currently being developed. In order to adopt those for more widespread use, new tests will need to be run on samples tested with the existing method to validate the new methodology.

STARHS has not been approved by the Food and Drug Administration (FDA) for routine use. STARHS is conducted under an Investigational New Drug/Device (IND) authorization from the FDA which allows for testing in controlled settings in which performance is closely monitored and data with regard to unforeseen adverse events and aggregate results are reported through CDC. All IND laboratories are required to participate in a quarterly proficiency testing program administered by CDC. A limited number of laboratories participate in the CDC-sponsored IND.

Since 1999, CDC has supported six health department laboratories to conduct the STARHS on stored, unlinked HIV-positive samples from HIV testing programs and research projects. This testing was for research purposes, therefore, it was not necessary to complete testing and return test results quickly. Laboratories were allowed to hold specimens, run them in batches, and schedule testing to accommodate the time requirements for their other work. For HIV Incidence Surveillance, laboratories will be required to return results to submitting health departments quickly. The current laboratory protocol allows for either manual or automated dilution and processing. For this activity, only laboratories that agree to use automated methods will be supported in order to maximize the number of tests they will be able to process and to optimize the accuracy and consistency of STARHS results. Laboratories will be selected to maximize efficiency, ensure timely availability of test results for all

geographic areas and to standardize methodology.

#### *Part VI. Behavioral Surveillance*

CDC's HIV/AIDS Strategic Plan has identified that monitoring behaviors that place people at risk for HIV infection is a key element of an integrated surveillance system. Measures of behavior are necessary to quantify progress in the plan's objectives. In addition, the plan identifies that studies of HIV incidence in special populations, including populations at high risk for infection, are an important strategy to provide locally relevant data for prevention resource allocation. The objectives of this program are to develop an ongoing surveillance system to ascertain the prevalence of HIV risk behaviors among groups at high risk for HIV infection for use in developing and directing national prevention services and programs; and to evaluate the impact of a variety of prevention efforts.

This announcement provides an opportunity to capitalize on experience recruiting at-risk individuals from non-healthcare community settings using a scientifically sound methodology to develop an ongoing system for surveillance of behaviors related to HIV acquisition. This system will assess risk behaviors and trends in behaviors over time among adults 18 years old and older at high risk for HIV infection through sexual behavior between men and injection drug use. These studies may be expanded to include high risk heterosexuals. In addition, access to and utilization of HIV prevention programs, including HIV testing, will be assessed. Each funded site will be expected to enroll at least 500 Men Who Have Sex with Men (MSM) and 500 Injection Drug Users (IDUs). Funded sites will also be expected to collaborate with CDC directly funded community-based organizations (CBOs) and CBOs funded by States/cities through the community planning process for allocating Federal HIV prevention funds, schools of public health, universities, ethnographers and behavioral scientists.

#### *Part VII. Core Surveillance in the Pacific Island Jurisdictions*

AIDS case surveillance is conducted in all U.S. dependencies, possessions, and independent nations that make up the six Pacific Island jurisdictions referred to as the Pacific Island Jurisdiction AIDS Advisory Group (PIJAAG). These islands and island groups are American Samoa, Guam, Marshall Islands, Palau, the Commonwealth of the Northern Mariana Islands and the Federated States of