

Title: HIV Incidence Surveillance

Statement of Problem:

Since the HIV/AIDS epidemic was first recognized, HIV surveillance has been limited to monitoring prevalence while no direct measures of incidence were possible. Understanding trends in new HIV infections is increasingly important so that public health officials can more effectively and completely monitor the epidemic, allocate resources, and plan and implement programs, particularly those designed to prevent the spread of HIV. Over the last few years, new serologic testing methods have become available that can distinguish recent from long-standing infections on a population level. The most studied of these methods is the serologic testing algorithm for recent HIV seroconversion, or STARHS. Once HIV diagnoses have been confirmed, STARHS can determine, on a population level, whether newly diagnosed HIV infections are likely to represent recent infections (within the last six to twelve months) or long-standing infections (ref 1).

From 2001 through 2004, CDC hosted five expert consultation meetings to determine how best to generate population-based HIV incidence estimates in the United States. Surveillance, biostatistics, infectious disease, bioethics, and laboratory experts discussed the best possible methods to derive a national incidence estimate. Consensus indicated that implementing HIV incidence surveillance as part of the current HIV/AIDS Reporting System (HARS) would be the best method for obtaining incidence estimates. Furthermore, information about individuals' HIV testing behaviors would be required to determine the likelihood that individuals were tested during the STARHS window period, that is, during the period after they began to produce antibodies in response to HIV antigens but before the relative concentration of those antibodies reached a detectable level using the STARHS assay. Thus, persons newly diagnosed with HIV infection who tested confidentially (i.e., with name) would be reported to HARS per routine case reporting requirements which include demographic, clinical, and risk factor information. To arrive at a population-based estimate of HIV incidence, requisite testing history data would also be collected and a remnant of the blood specimen used for the diagnostic HIV test would be submitted from the testing laboratory to the CDC STARHS laboratory for STARHS testing.

In response to CSTE recommendations, at the 2001 CSTE Annual Meeting, CDC initially funded five surveillance areas to conduct HIV incidence surveillance; by 2004 this number was increased to 34 areas, accounting for approximately 85% of new HIV diagnoses in the United States. Additionally, a single laboratory was selected and designated as the CDC STARHS laboratory. However, full implementation of national HIV incidence surveillance was delayed by regulations for using the initial assay used in STARHS, the LS HIV EIA. The assay was governed by FDA's Investigational New Drug (IND) rules that mandated informed consent and IRB approval to maintain information that could identify a specimen. Because of these requirements CDC disseminated three model protocols to surveillance areas in September 2003. Most surveillance areas chose one of two protocols to implement based on local factors and submitted their protocols to their local IRB and the FDA for approval. A few well-established programs obtained IRB and FDA approval and implemented a third protocol designed to assess the bias of informed consent; consent normally is not obtained for purposes of routine public health surveillance.

Thirteen surveillance areas had implemented HIV incidence surveillance when a new assay, the BED HIV-1 Capture EIA, was put into use in spring of 2005. The assay was named "BED" because it uses a branched peptide with gp41 immunodominant sequences from HIV-1 subtypes B, E, and D, however, its use has been validated for subtypes A, B, C, D, and E (ref 2). The FDA labeled the BED HIV-1 Capture EIA: "For Surveillance use only. Not for diagnostic or clinical use." The labeling eliminated the FDA's IND requirements of obtaining informed consent and IRB approval. However, the BED HIV-1 Capture EIA is not FDA approved as a diagnostic test and the results are only useful as part of a population-based incidence estimate, and for tracking of

population-level transmission patterns of HIV including atypical subtypes and drug resistant strains. Therefore STARHS results cannot be returned to individual patients or their providers.

As a result of the availability of the BED HIV-1 Capture EIA standard surveillance operating procedures were written and disseminated by CDC in March 2005 to all surveillance areas participating in HIV incidence surveillance (ref 3). Areas that had already implemented protocols under the IND were asked to close them through their standard IRB closure protocol and change to the standard procedures as soon as possible. (ref 4). We recognize that some states may choose to supplement the STARHS protocol by using Nucleic Acid Amplification Testing (NAAT) testing on EIA negative specimens.

The ultimate goal of HIV incidence surveillance is to expand nationwide and derive incidence estimates for use at local, state, and national levels. In order to be truly population based this expansion must include specimens from both public and private laboratories as well as testing history information on all individuals newly diagnosed HIV-positive and reported to HARS by all providers who administer HIV testing including public and private health care providers and testing facilities. The availability of HIV incidence data will fulfill the recommendation of the Institute of Medicine to base funding for HIV prevention and health care programs on HIV incidence (ref 5).

It is important that CSTE and CDC assist states and territories to address the legal, ethical, policy, logistical, and fiscal considerations necessary to conduct surveillance for HIV incidence and to provide guidelines for the appropriate uses of such data in surveillance and public health practice. This position statement will enable CDC to mobilize funding and technical assistance resources and will offer support to states and territories to address any regulatory changes that will facilitate the implementation of surveillance for HIV incidence.

Statement of desired action(s) to be taken:

CSTE:

1. Supports the goal of states, territories and local health departments being able to estimate HIV incidence in their jurisdictions in a manner that will allow aggregation of local and state data to estimate national HIV incidence. Each state should ultimately determine its approach to this issue within the framework of CDC's standard procedures for conducting HIV incidence surveillance that were issued on March 16, 2005 to participating surveillance areas, updated on March 30, 2005 to include laboratory transport guidance, and revised on June 16, 2005 to describe statistical methods (ref 2);
2. Recommends that CDC provide guidance, technical assistance and increased, ongoing and stable funding to all States and Territories for these activities;
3. Recommends that CDC hold annual meetings of state, territorial, local and national surveillance practitioners to discuss remaining barriers and significant feasibility issues involved in establishing routine HIV incidence surveillance;
4. Recommends that CDC, states and laboratories take steps necessary to ensure the availability of remnant HIV-1 Western Blot positive blood specimens for additional public health assessment such as testing for HIV incidence estimation, viral resistance surveillance and surveillance of atypical HIV subtypes;
5. Recommends that CDC set as a priority and accelerate the process to minimize the number of essential testing history questions collected as a part of the incidence surveillance standard procedures (ref 3) by working with surveillance and statistics experts. These questions should be those that are most likely to determine the probability

of individuals being tested during the seroconversion period. These efforts should be coordinated with data collected by CDC in HIV counseling and testing programs;

6. Recommends that CDC explore methods to ensure that testing history is collected in the most efficient and comprehensive way, including the possibility of applying adjustments for missing values based on data that are collected;
7. Recommends that CDC continue to coordinate efforts to obtain specimens for incidence surveillance from major national labs to facilitate submission of remnant blood specimens to the STARHS testing laboratory;
8. Recommends that CDC incorporate the standard guidance for HIV incidence surveillance (ref 3) into the web-based HIV/AIDS Surveillance Technical Guidance to increase the ability of the states, territories and local health departments to incorporate the requirements for STARHS into HIV reporting rules, laws and regulations;
9. Recommends that CDC pursue additional options for conducting STARHS testing using oral fluid and dried fluid spot specimens (blood, plasma or serum);
10. Recommends that CDC conduct and publish additional evaluations of STARHS, including comparisons using alternative methods of incidence calculations. Due to the high importance placed on having national and state/local HIV incidence estimates, alternative incidence calculations will help assure the accuracy and validity of STARHS incidence calculations.

Fiscal Impact on CSTE:

None.

Public Health Impact:

Public health programs will benefit from available incidence data by more accurately describing trends in HIV incidence for epidemiologic monitoring and improving prevention program planning and evaluation.

References

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2. Parekh BS, Kennedy, MS, Dobbs, T, et. al. "Quantitative Detection of Increasing HIV Type 1 Antibodies after Seroconversion: A Simple Assay for Detecting Recent HIV Infection and Estimating Incidence." AIDS Research and Human Retroviruses, 18(4); 2002; p295-307.
3. CDC. HIV Incidence Surveillance: Estimating National and Local HIV Incidence Using a Population-based Serologic Method to Detect Recent HIV-1 Infection. March 14, 2005.
4. Janssen RS. March 11, 2005. Letter to HIV Incidence Surveillance Colleagues.
5. Institute of Medicine. No Time To Lose: Getting More from HIV Prevention. 2000.

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