CSTE Resolution 02-ID-07 – Surveillance for HIV Incidence

CDC General Comments:

CDC appreciates CSTE's strong support for the collection of surveillance information necessary to estimate the incidence of HIV. STARHS testing of newly reported HIV infections through the existing HIV reporting systems should enable these data to be useful at the local, state and national levels.

CDC Comments to CSTE Position Statements:

1 Supports goal of States and Territories being able to measure or estimate HIV

At the end of Fiscal Year 2002, CDC funded a total of twenty-four areas (3 Metropolitan Statistical Areas, 20 states and Puerto Rico) to begin implementation of population-based STARHS testing of newly reported HIV infections. CDC anticipates that this implementation will represent the first steps in a long-term commitment to a national system of surveillance of HIV incidence. Support for this activity will need to include federal and local resources.

2 CDC should work with FDA to obtain full licensure of tests for sero-conversion

On September 4-5, 2002, CDC held a consultation attended by laboratory directors, public health professionals, ethicists, and community leaders to discuss ethical and policy issues in the use of the technology needed to measure HIV incidence. One issue raised by the consultation participants concerned the complications of the methodologies and operations of STARHS because of its current investigational status. License of the test will require additional studies and involvement of the tool kit manufacturer, FDA, and CDC. CDC will also clarify with the FDA the restrictions placed on the use of this technology for surveillance purposes.

3 Recommends that CDC convene a consultation…to discuss the best programmatic approaches.

An executive summary from the September 4-5, 2002 consultation should be available by November 2002. Another consultation is scheduled for February 2003. This consultation will include state, local and non-government public health and clinical professionals who will need to collaborate to assure the effective functioning of a national system. The objective of the February consultation is to discuss and formally develop standards for the operational details regarding data collection and reporting.

4 Recommends CDC supply TA and funding

Technical assistance and funding are major priorities of the CDC. The initial funding of 24 areas (see #1 above) to implement STARHS testing has occurred. It is anticipated that a new cooperative agreement announcement for this surveillance activity will be released in 2003. This funding will provide opportunities for long-term funding to areas that have been previously funded and to additional areas with sufficient HIV/AIDS morbidity and mature reporting systems.

5. Recommends that base funding for HIV/AIDS surveillance be increased

The first HIV Incidence Consultation held on February 27-28, 2001 recommended that CDC implement HIV incidence estimation tied to the core activities of AIDS case surveillance and HIV infection reporting. However, the Health Resources and Services Administration, CDC, and other federal, state and local agencies continue to use AIDS surveillance to guide funding priorities and allocations. Therefore, until HIV reporting and incidence are widely available, and these data are utilized to determine the funding for other HIV/AIDS prevention, care, treatment and social service programs, substantial resources will still need to be devoted to AIDS surveillance activities. For example, as part of the most recent reauthorization of the Ryan-White Care Act, Congress mandated that HIV reporting, rather than AIDS, will be used to allocate these funds for treatment. The deadline for this change is the year 2007. During this transition, CDC continues to work with state and local surveillance programs to maximize the efficiency of the full spectrum of HIV/AIDS surveillance. However, we recognize that many states and local health departments have added or are in the process of adding HIV infection reporting and that increases in survival due to advances in treatment of HIV infection also result in increased HIV/AIDS case loads. This has occurred in the presence of level funding over the last few years. Increased resources will aid states in maintaining, evaluating and expanding core surveillance as the basis of efforts to incorporate the new activity of HIV incidence estimation.

Response submitted by email to Guthrie Birkhead from Sally Toye, CDC.

TO: CSTE National Office

From: Gus Birkhead, NY

Date: May 7, 2003

Subject: Follow up on 2002 Position Statement 02-ID-07: Surveillance for HIV Incidence.

Summary of statement: The statement 1) supported the goal of every state being able to measure HIV incidence, 2) recommended that CSTE work with FDA and the test kit manufacturers to obtain licensure of tests for recent HIV seroconversion (e.g. STARHS), 3) that CSTE convene a consultation on the best programmatic approaches to conduct HIV incidence surveillance and provide technical assistance to states, and 4) that funding for base HIV surveillance be increased.

CDC response: CDC 1) funded 24 areas to begin population-based STARHS testing, 2) held consultations in September, 2002, on policy and ethical issues, and in March 2003 on strategies and procedures for implementation, and 3) discussed licensure issues with FDA; at the March conference it was announced that the LS-EIA assay would continue to be classified as a research tool (the manufacturer is not pursuing FDA licensure). Thus, FDA IND rules and regs apply, and local IRB approval and patient consent will be necessary for any use of the test in which the patient identifying information will be maintained, 4) No additional base funds for surveillance were available.

Positive action: CDC is working with states collaboratively to determine the most effective ways to implement HIV incidence surveillance.

Recommendations: 1) The lack of a pathway for a test to be licensed for surveillance use even if it is not to be licensed for individual use makes undertaking population-based HIV incidence surveillance quite complicated; CDC should continue to pursue simplified means of obtaining such testing, 2) CDC should explore the impact of increasing use of oral fluid HIV tests which will decrease the number of blood samples available for STARHS testing. CDC should consider supporting development of a STARHS methodology for use with oral fluid tests. 3) CSTE should include the need for increased base funding for HIV surveillance in its annual federal budget recommendations.