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.

CSTE Resolution 02-ID-04 – Surveillance for Perinatal HIV Exposure

CDC General Comments:

The overall goals of CDC's Enhanced Perinatal Surveillance are to monitor the implementation and impact of the Public Health Service recommendations for counseling and voluntary testing of pregnant women and the use of zidovudine to prevent perinatal transmission and to assist in timely evaluation of perinatal prevention efforts. One specific objective of the project is to assess short- or long-term adverse effects related to in-utero exposure to zidovudine and other antiretroviral drugs.

In January 1999, the Office of AIDS Research, National Institutes of Health; National Cancer Institute; Food and Drug Administration; and CDC sponsored a workshop on the detection of potential toxicities following perinatal exposure to antiretrovirals. A topic of discussion at the meeting was the use of surveillance systems and cohort studies to detect birth defects and cancers. Meeting participants decided that population-based surveillance studies linking perintally exposed children with antiretroviral information to cancer registries and birth defect registries would be an important component in discussions concerning adverse outcomes.

In addition, CDC sponsored a consultation in May 2001 to discuss the issue of adverse outcomes and the role of surveillance in this area. The group consensus was that health departments had an obligation to examine adverse outcomes using surveillance data.

CDC is very appreciative of CSTE's continued support in reiterating and strengthening its previous recommendation that all states conduct reporting of infants with perinatal HIV exposure, at birth or when first recognized in the first year of life. This type of surveillance aids in calculating and monitoring the rate of perinatal HIV transmission, determining risk factors for perinatal transmission, and targeting and evaluating perinatal prevention efforts.

CDC Comments on Specific Position Statements:

1 CSTE reiterates and strengthens its previous recommendations

CDC continues to provide support for surveillance of perinatal HIV exposure and transmission through funding of core pediatric HIV/AIDS surveillance, as well as supplemental funding of Enhanced Perinatal Surveillance (EPS). Commitment to the long-term continuation of this project was emphasized at the 2002 Perinatal Prevention Workshop held on February 12-14, 2002 in Atlanta, Georgia. This year CDC enhanced the data management dimensions of the EPS by revising the data collection form and developing a system to return on a quarterly basis state and area specific data that is submitted to CDC.

2 Conduct studies of adverse outcomes

CDC will continue to provide technical assistance and funding to states to assess the relationship between specific antiretroviral therapies (ART) and adverse outcomes. Also, CDC will periodically assist states in determining matches between their perinatal exposure database and birth defect and cancer registries. This collaborative effort will aid states in identifying short- and long-term adverse outcomes of perinatal ART using population-based surveillance data.

3 Fund long-term registries

CDC will continue to support Enhanced Perinatal Surveillance activities. This system establishes the necessary infrastructure for public health surveillance and for developing extended registries in areas that have sufficient morbidity and legal/regulatory safeguards to protect the confidentiality and security of data, as well as the technical capacity to maintain the registries. Local statutes and regulations and Human Subjects considerations should determine the need for informed consent to establish extended registries.