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.

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

TO: CSTE National Office

From: Gus Birkhead, NY

Date: May 1, 2003

Subject: Follow up on 2002 Position Statement 02-ID-04: Surveillance for Perinatal HIV Exposure.

Summary of statement: The statement called 1) for states to require reporting of newborns with perinatal HIV exposure, 2) for states with large numbers of HIV-exposed births to consider undertaking studies of possible adverse pregnancy outcomes related to antiretroviral exposure (CDC provide technical assistance), and 3) for CDC, NIH, FDA and other federal agencies initiate appropriately designed long term perinatal exposure registries with informed consent.

CDC response: CDC continues 1) to support surveillance for perinatal HIV exposure and supplemental Enhanced Perinatal Surveillance, and 2) to provide technical assistance to states, e.g. on studies matching perinatal exposure data base with birth defect data base.

Positive action: The statement was past in part to support a few states which had legal barriers to requiring reporting and maintaining records of perinatal HIV exposure in changing their legal requirements. It is not known whether those states have successfully overcome those barriers. There has been no movement on a federal initiative to fund perinatal exposure registries.

Recommendation: CSTE does not need to take any further action on this issue at this time.