LOS ANGELES COUNTY STANDARDS FOR PERINATAL HIV PREVENTION AND CARE

Abstract

Recent successes in the prevention of perinatal HIV transmission have prompted development of national, state and local guidelines for prevention of perinatal transmission. The goal is to reduce perinatal HIV transmission to the lowest possible level through a comprehensive approach that includes:

- Universal access to prenatal care
- Universal mandatory HIV counseling, along with voluntary offering of HIV testing
- HIV counseling, risk assessment, and testing of women presenting for labor and delivery with: no prenatal care, no prior HIV testing, or no evidence of a negative HIV test result
- Established standards for centers caring for HIV+ pregnant women and their newborns
- Referral of all HIV+ women to centers with expertise in HIV, perinatal and women's specialty care, and pediatric HIV
- Access to antiretroviral therapy during pregnancy, at delivery and postpartum
- Education related to treatment and adherence of regimens offered
- Provision of support services necessary for family well being and to sustain adherence to treatment and compliance with care, including, but not limited to, social work, case management, and mental health services

Purpose

This document will review current national and state recommendations and present guidelines for the identification, diagnosis, treatment and follow-up care of HIV+ women during pregnancy and at delivery and for their newborn infants postpartum. These recommended guidelines are intended to establish minimum requirements necessary for the provision of care of the HIV+ pregnant woman and her newborn in facilities in Los Angeles County that provide care for these patients. An additional goal of this document is to suggest guidelines that may be utilized for establishment of a network of sites providing HIV specific care to this population by a "carve out" mechanism. This document is not intended to be exhaustive; and appropriate references and Internet resources that include national published guidelines are included.

Background

Perinatal transmission can occur prenatally, intrapartum, and postpartum through breast-feeding. A landmark study, the AIDS Clinical Trials Group 076 Study, demonstrated that zidovudine given to the HIV+ pregnant woman prenatally, during labor, and to the neonate for 6 weeks, reduces perinatal transmission by two thirds from 22.6% to 7.6%.[1] As a result, the United States Public Health Service (PHS) recommended that all pregnant women receive HIV counseling and voluntary testing, and those identified to be HIV-1 infected receive ZDV prophylaxis.[2-4] These recommendations were quickly implemented, and the number of children found to be HIV infected or to develop AIDS has decreased dramatically. In the state of California, perinatal transmission has decreased by 78% between 1992 and 1999, and the number of new pediatric perinatal AIDS cases was only 12 in 1999.

Most recently, results from several international trials using simple, short course regimens were published.[5-8] A joint Uganda-U.S. study, known as HIVNET 012, demonstrated that a single oral dose of nevirapine given during labor and to the newborn within the first 72 hours of life resulted in a 47% decrease in the perinatal transmission of HIV.[8] Another study that used oral zidovudine plus lamivudine during labor and for 1 week to the newborn has also been shown to decrease transmission by 38%.[7] Additionally, the availability of highly active antiretroviral therapy (HAART) and tests to monitor HIV RNA levels have resulted in a remarkable decrease in the morbidity and mortality of HIV infected patients. In turn, formal recommendations for antiretroviral therapy for adolescents and adults as well as for the pediatric population have been published.[9] With the expanded access to potent antiretroviral therapy for all HIV infected patients, including pregnant women, perinatal transmission has decreased to 4-5% nationally and as low as 0% to 2% at some centers where pregnant women are treated aggressively with HAART.

Although the rate of transmission in Los Angeles County is low, there is evidence that the rate of test acceptance among HIV+ pregnant women varied from 57% TO 100% in selected County prenatal facilities. Statistics from 6 County health centers who report directly to Acute Communicable Disease Control showed an overall test acceptance rate of 83% in 2000.

Universal Availability of HIV Counseling and Testing

Given our current state of knowledge, the elimination of perinatal transmission of HIV has become potentially possible. Even a very short course of treatment can prevent perinatal transmission, if given to the mother identified at delivery. These findings increase the urgency of adoption of universal perinatal testing and treatment on the national level. In 1998, the Institute of Medicine (IOM) proposed that "the United States adopt a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care," regardless of risk. With this approach, extensive pretest counseling is not required, and testing will be done unless the patient actively refuses. The recommendations also included measures to improve coordination of care and access to high-quality interventions and treatment for HIV+ pregnant women. Finally, the proposal emphasized that a comprehensive infrastructure is essential if the recommendations are to prove successful. The American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and other organizations formally support these recommendations.

In 1995, the State of California and Los Angeles County formally mandated that all pregnant women be offered HIV information, counseling and testing with informed consent.

Guidelines

HIV Counseling and Testing

- All pregnant women must be referred to a prenatal care facility so that adequate prenatal care is provided starting from the first trimester of pregnancy.

- All women in prenatal care must receive HIV counseling and testing according to the CDC

guidelines and California Senate Bill 998, regardless of risk factors and as early in pregnancy as possible. This includes all pregnant women followed in Los Angeles County, whether in private offices, County clinics, or through Managed Care and Health Maintenance Organizations (HMOs).

- HIV pre-test counseling, informed consent for testing, and HIV-positive post-test counseling should be provided at, or coordinated by, the testing site and provided by a person who has been certified as an HIV Counselor.

- All pregnant women should receive a clinical recommendation for testing and information concerning the relevance of HIV testing including: information about medical interventions and treatment for her own health and for reducing the risk of HIV transmission to her baby.

- Counseling should be provided in a manner that is sensitive to the language and cultural norms of the patient.

- Repeat testing should be offered later in pregnancy for women who have a continued risk for HIV infection but test negative or refuse testing early in pregnancy.

- HIV counseling and testing should be encouraged upon admission to the hospital for women without prenatal care, or who were not tested during prenatal care. The use of rapid testing should be encouraged.

- If a patient refuses testing for herself in both the prenatal and delivery settings, she should be offered HIV testing for her newborn infant.

- All prenatal care providers should have a plan of action for patients who test positive, including those who are identified as HIV positive in labor; if specialized knowledge and expertise in maternal-pediatric HIV and related services are not available on site, the plan should include a Memorandum of Understanding (MOU) with an HIV Specialized Care Center for consultation and referral.

- For women who test positive, HIV post-test counseling should include: information about the availability of antiretroviral therapy for treatment of HIV and prevention of perinatal HIV transmission; psycho-social support, including information about resources for the follow-up and testing of other family members; and immediate referral to an HIV Specialized Care Center that provides family-centered care, including prenatal, obstetric, perinatal and pediatric services for women and their family members who test positive, and follow-up of HIV-positive women lost to prenatal care.

- Providers who have limited expertise in maternal-pediatric HIV care should immediately consult with an HIV Specialized Care Center for interim management and refer the HIV-infected pregnant woman to a Center within her geographic area.

- A Continuous Quality Improvement (CQI) plan should be developed and implemented, to ensure that appropriate national, state and local guidelines for counseling and testing are followed.

Network of Specialty Providers for Perinatal HIV Medical Care:
Qualifications for HIV Specialized Care Center:

HIV infection is a complex disease that affects all organ systems. Therefore, all HIV positive patients must be referred to centers with expertise in treating HIV. Studies in peer-reviewed journals have demonstrated better outcomes for patients managed by HIV specialists. The need for this high level of clinical expertise has become more obvious with the advent of complex antiretroviral regimens, the toxicities and long-term complications related to these medications, the additional complex regimens necessary to treat superimposed opportunistic infections and the close follow-up necessary to maintain adherence of these complex drug regimens.

An **HIV Specialized Perinatal Care Center** must include the following *minimum* requirements:

- Fully developed therapeutic guidelines for antiretroviral therapy, prevention of perinatal transmission, and the prophylaxis and treatment for opportunistic infections that are updated as new information is available
- Family-Centered Care, integrated to include adult, pediatric and obstetric and gynecologic providers who can provide from primary to tertiary care for all aspects of HIV infection
- A family-centered model of care including culturally competent and bilingual staff as needed
- A case management model with a team of providers, to include**:** physicians, nurses, social workers, psychologists, dieticians, and other mental health providers and health care professionals as needed; the team develops a service plan for the continuum of care of each individual member of the family, as well as the family as a unit, including both psychosocial and medical aspects.
- Extensive outreach with linkages between the Center and community resources including but not limited to linkages such as drug and alcohol treatment centers
- Adult and Pediatric Infectious Disease physicians with expertise in HIV care who are available 24 hours a day for consultation and follow-up
- Obstetricians with expertise in Maternal-Fetal Medicine and the care of HIV+ women, and gynecologists with knowledge of HIV-related gynecologic abnormalities
- Pediatric Care, to be provided at one of the state approved California Children's Services HIV Specialty Care Centers (Infectious Disease and Immunology Centers); these centers have established minimum requirements necessary for the care of the child born to an HIV- infected woman and they require a case management model.
- Consultations available in the areas of pulmonology, cardiology, neurology, gastroenterology, and ophthalmology
- Access to state-of-the-art HIV-specific laboratory testing, including HIV RNA monitoring, diagnostic testing and resistance testing
- A pharmacy with 24-hour availability for antiretroviral agents necessary for HIV prophylaxis during pregnancy, in labor and at delivery and postpartum and to the neonate in the newborn nursery as well as other medications necessary to treat acute HIV complications and opportunistic infections
- Access to Clinical Trials
- A level III nursery for all deliveries
- Fully-developed procedures for follow-up of complex patients, such as those with substance abuse, those in the juvenile justice system, probation, or jails, and children and adolescents in foster care
- Expertise in the management and treatment of adolescents
- Case Management, including expertise in biannual updating of the service plan that is done by the team of providers in close association with the family
- Access to the State AIDS Drug Assistance Program (ADAP)
- Attention to treatment adherence, which may include adherence counseling and other supportive

services to overcome barriers to adherence
- A Continuous Quality Improvement Program, to ensure that national guidelines for testing, counseling and treatment are followed
- A continuing medical education and training program for staff, to update new information and guidelines for HIV

All Medi-Cal Managed Care HMOs Organizations must strictly adhere to these guidelines**,** specifically with regard to universal offering of HIV testing and counseling, and access to specialized care for all patients who test positive. If services are not available internally HIV+ patients must be cared for by specialized HIV centers with expertise in HIV and family centered management.

References:

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