



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower

The Governor Nelson A. Rockefeller Empire State Plaza

Albany, New York 12237

Antonia C. Novello, M.D., M.P.H. Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

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Dear Colleague:

This letter provides important information related to the Maternal-Pediatric HIV Prevention and Care Program and the ongoing efforts in New York State to reduce perinatal HIV transmission to the lowest possible level. It serves to underscore the importance of the midwife's role and transmits new information related to advances in rapid HIV testing technology and emergency legislation targeted to promote prevention efforts.

IMPORTANCE OF PRENATAL HIV TESTING

HIV counseling with a strong clinical recommendation for voluntary testing is a standard of prenatal care recognized by the New York State Department of Health, the American College of Obstetrics and Gynecology (ACOG), the American Academy of Pediatrics (AAP), and the United States Public Health Service. The prenatal provider should counsel the mother about the benefits of knowing her HIV status, including her ability to make informed decisions about breastfeeding and, if she is HIV-infected, about medical interventions for her own health and for reducing the risk of HIV transmission to her baby. In New York State, counseling should also include information on the legal requirement that all newborns be tested for HIV and the fact that, if she declines to be tested during the prenatal period, she will receive additional HIV counseling and a recommendation for expedited testing during labor and delivery. If she declines testing for herself in both the prenatal and delivery settings, her newborn will be tested immediately after birth.

HIV counseling should be provided as early as possible in prenatal care. However, the Department has identified a small but significant number of cases where the mother tested negative early in pregnancy and became infected after testing. In these cases, the mother's infection and her infant's exposure were not identified until several weeks after the infant's birth, too late for therapy to prevent perinatal HIV transmission. For this reason, the Department encourages prenatal providers in areas of New York State where HIV seroprevalence is high to recommend repeat HIV testing in the third trimester of pregnancy.

EXPEDITED HIV TESTING IN LABOR AND DELIVERY

In 2003, over 94 percent of women presenting for delivery at hospitals in New York State had been HIV tested during their current pregnancies. Expedited HIV testing in the labor and delivery setting served as a safety net for the remaining six percent. Those who tested positive in labor and delivery had the opportunity to receive abbreviated antiretroviral regimens, which have been shown to be effective in reducing perinatal HIV transmission when initiated intrapartum or within the first twelve hours of life.

In light of the availability of a new generation of rapid HIV-1 antibody tests, which can be conducted at point of care, the Department has implemented an emergency amendment to the newborn HIV testing regulations [10NYCRR 69-1.3 (2)]. The amendment, which was effective on November 1, 2003, requires that the results of expedited HIV testing in labor and delivery be available as soon as possible, but no later than 12 hours after the mother consents to testing or after the birth of the child. The purpose of the amendment is to ensure that information on the mother's HIV status is available as soon as possible so that therapy to prevent perinatal HIV transmission can be initiated intrapartum or immediately after the birth of the child. (A copy of the New York State Register dated December 3, 2003 is enclosed as Attachment A.)

Protocol for Rapid Maternal/Newborn HIV Antibody Testing

New York State regulations [10NYCRR 69-1] require all birth facilities and birth attendants to provide expedited HIV testing of either mother (with consent) or infant (without consent) when the mother's prenatal HIV status is unknown or undocumented at the time of presentation for delivery. Effective November 1, 2003, the results of the expedited test be available as soon as possible, but in no event longer than 12 hours after the mother consents to testing of herself or 12 hours after the birth of the infant if the infant is tested [10NYCRR 69-1.3 (2)]. Please refer to Attachment C for detailed information.

The shortened turnaround time for test results is now feasible with the availability of a new generation of rapid HIV-1 antibody tests which can be conducted at point-of-care. For information about obtaining a CLIA number to provide rapid testing, please see the enclosed letter from the Wadsworth Center for meeting laboratory requirements. Currently, OraQuick is the only point-of-care rapid HIV test that has been CLIA-waived and may be performed outside of a laboratory setting.

Preliminary rapid HIV test results are available in 20-30 minutes. In the case of a negative rapid test result, no further confirmatory testing is required. The negative result should be reported to the mother as a final HIV test result in the context of post-test counseling.

A positive rapid HIV antibody screening test result is a preliminary result and should be reported to the mother as HIV-positive, unconfirmed. The midwife should counsel the mother regarding the meaning of a preliminary positive result, assess her risk to determine the likelihood that the result is true positive, discuss the risks and benefits of antiretroviral therapy (ARV) with the mother, and initiate ARV as soon as possible. The birth attendant is required to collect and process a specimen for confirmatory testing and to provide the mother with post-test counseling appropriate to the result of the confirmatory test, which must be available within four days. The birth attendant should also collect the first DNA PCR test specimen from the HIV-exposed infant within the first 48 hours and send it to Wadsworth Laboratory (see instructions included in Attachment E) for processing. These tests are free of charge for all HIV-exposed infants.

Maternal/ Newborn Management in the Absence of Antenatal ARV Therapy

The Department of Health has published clinical care guidelines for the management of HIV-infected pregnant women and the prevention of perinatal transmission. The guidelines, which were developed by a committee of experts convened by the AIDS Institute, include four options for the prevention of perinatal transmission when the mother has not received prenatal ARV therapy. Please ensure the ready availability of prophylactic ARV at the delivery site for administration to the mother and/or the newborn as appropriate upon (the unlikely) finding of a preliminary positive HIV test result.

Thank you for your ongoing efforts to reduce the transmission of HIV infection to New York's infants to the lowest possible level. Should you or staff at your facility have questions regarding the implementation of this emergency regulation, please contact Sheila Hackel, R.N., or Ellen Kowalski, R.N., in the AIDS Institute's Regulatory Unit, Bureau of HIV Ambulatory Care, at (518) 486-6048.

Sincerely,

Guthrie Birkhead, M.D., M.P.H.
Director, AIDS Institute