

Issues Related to Rapid HIV Testing of Women in Labor and Delivery

Since the first case of pediatric HIV infection was documented in 1984, there have been tremendous medical and public health achievements in preventing mother-to-child transmission (MTCT) of HIV-1. When the recommended antiretroviral and obstetric interventions are used, the woman who knows her HIV infection status early in pregnancy now has a less than 2% chance of delivering an HIV-infected infant. Without intervention, the risk of MTCT of HIV in the United States is approximately 25%.

The Problem

In 2000, according to the Centers for Disease Control and Prevention (CDC), approximately 6,000 – 7,000 HIV-infected women gave birth in the United States, and approximately 280-370 HIV-infected infants were born. Approximately 40 percent of the mothers of these HIV-infected infants had not been diagnosed with HIV before labor and delivery.

The Solutions

Ideally, all women should be screened for HIV prior to delivery during an initial prenatal care visit. Preventive antiviral therapy is most effective when it is initiated early in pregnancy. However, starting antiretroviral treatment during labor and delivery and providing it to the newborn can reduce MTCT by half. To maximize the benefit of antiretroviral treatment, it is important to obtain HIV test results as soon as possible for women in labor. If rapid HIV tests are used, test results can be provided in less than 1 hour. Timely knowledge of the mother's HIV status provides opportunities for other interventions that reduce transmission, such as elective cesarean section, avoiding artificial rupture of membranes, and avoiding breastfeeding.

Timeliness of Testing a Barrier to Implementation

The Office of the Inspector General (OIG), Department of Health and Human Services, found that significant barriers prevented almost half of obstetricians from routinely offering HIV testing during labor and delivery. One barrier cited by 20% of obstetricians was the inability of available HIV testing technology to produce timely results, specifically “test results take too long” and “rapid or expedited HIV test results are not available.” State HIV/AIDS directors and the American College of Obstetricians and Gynecologists (ACOG) representatives identified the lack of rapid or expedited tests more frequently than any other barrier to testing during labor or delivery.

OIG Recommendation

Based on their findings, OIG recommended that CDC help develop and help States implement protocols for HIV testing during labor and delivery in order to promote testing in this setting as the standard of care.

Rapid HIV Testing of Women in Labor and Delivery: A Practical Guide and Model Protocol

CDC has been charged with the task of developing a model protocol for rapid HIV testing of women with unknown HIV status at labor and delivery. The protocol being developed will offer guidance to clinicians, laboratorians, hospital administrators, and policy makers. In conjunction with the model protocol, CDC is formulating practical tips for overcoming barriers to implementing a rapid testing program in a labor and delivery setting.

The MIRIAD Study:– Mother Infant Rapid Intervention at Delivery

CDC is also sponsoring the MIRIAD study – Mother Infant Rapid Intervention at Delivery – to learn more about the dynamics of MTCT, and how to use the available interventions to their best advantage by offering rapid HIV testing to women who do not know their HIV status late in pregnancy or at the time of delivery. The study will take place at 14 hospitals in 6 cities: Atlanta, Baton Rouge, Chicago, Miami, New Orleans, and New York City. The CDC secured a Treatment Investigational Device Exemption from the Food and Drug Administration to use the OraQuick rapid HIV test for women in the MIRIAD study because it is suitable for point-of-care use with whole blood, and offers rapid turnaround for test results. Women in the study are offered antiretroviral therapy on the basis of the OraQuick result. OraQuick results are also compared to standard EIA and Western blot results as soon as they become available. The table summarizes MIRIAD's experience with the OraQuick rapid test since the inception of the study in November 2001.

OraQuick Testing in MIRIAD Study 11/19/01 – 8/20/02

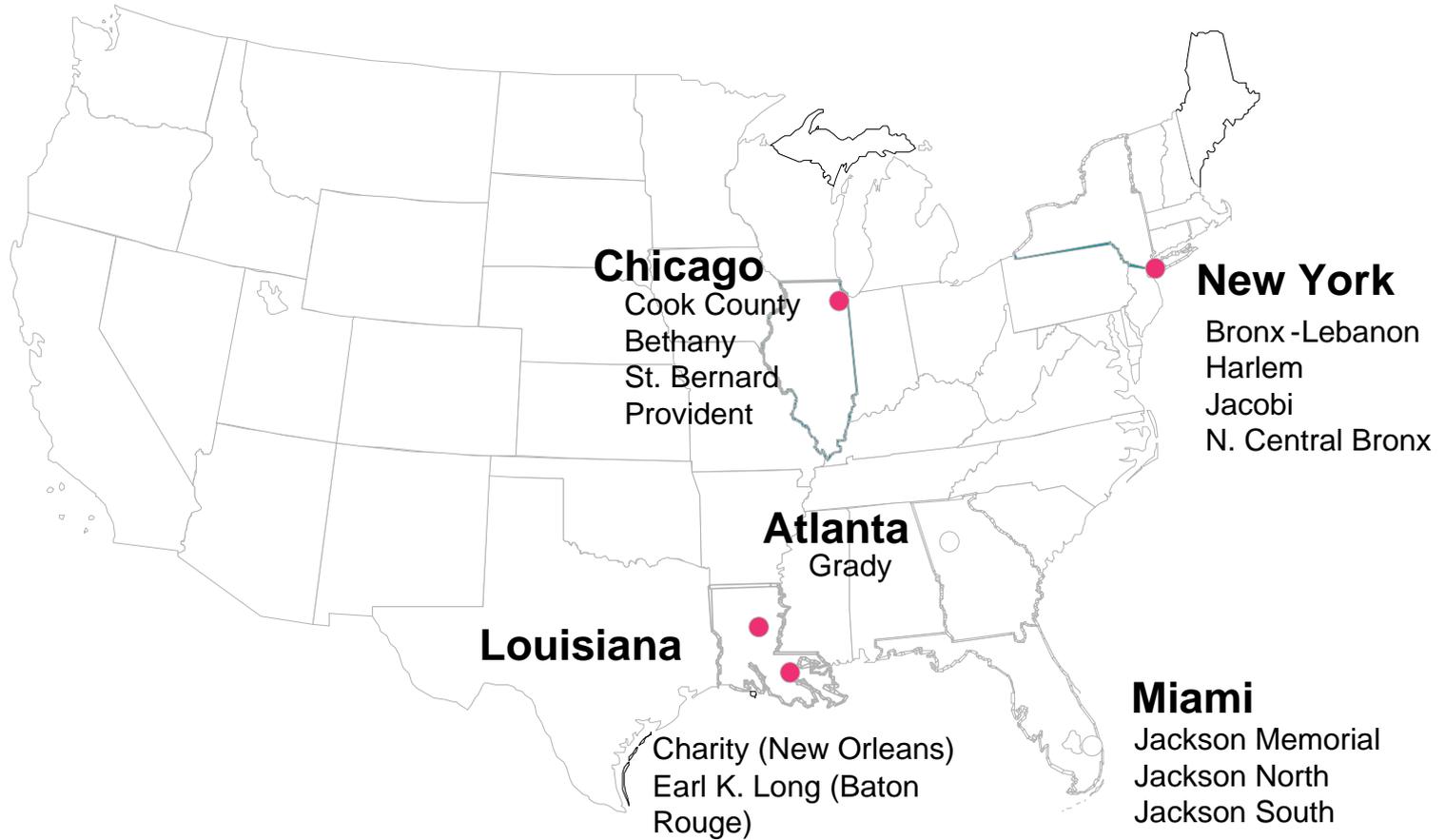
- Number of tests performed: 1308
- Number of HIV-positive tests: 8
- Number of false-negative tests: 0
- Number of false-positive tests: 0

MIRIAD: Mother Infant Rapid Intervention At Delivery

The MIRIAD Project

- Mother Infant Rapid Intervention At Delivery
- A 5 year, multi-site, CDC-sponsored project
 - Atlanta, GA
 - Chicago, IL
 - Miami, FL
 - Louisiana
 - New York City, NY

MIRIAD Sites and Hospitals



MIRIAD Study Aims

- 1) Assess innovative approaches to 24-hour counseling and voluntary rapid HIV testing program among women who present late to care or in labor with unknown HIV status
- 2) Assess the feasibility of obtaining informed consent during labor or soon after birth
- 3) Determine barriers to prenatal care and to HIV testing
- 4) Assess ART given at labor and delivery or to the neonate
- 5) Assess adherence to neonatal therapy
- 6) Determine subsequent receipt of ART and other services, as indicated, for women and their children.

Goals of MIRIAD

- Will offer voluntary rapid HIV testing, and ART if indicated, annually to 6000-8000 pregnant women with unknown HIV status late in pregnancy.
- The question of how best to provide rapid HIV testing, to perform urgent confirmatory testing in this setting, and how best to present women with risk/benefit information and treatment options will be investigated.

Summary of the MIRIAD Project

- Opportunity to provide rapid HIV testing for women who present to labor and delivery without documented HIV status
- Women identified as HIV-infected will receive comprehensive follow-up
- Opportunity to decrease number of cases perinatal HIV-1 transmission