

# Rapid HIV-1 Testing During Labor

## A Multicenter Study

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**T**HE CENTERS FOR DISEASE CONTROL and Prevention (CDC) estimates that between 280 and 370 infants are born infected with human immunodeficiency virus (HIV) annually in the United States despite recommendations for universal prenatal HIV screening and widespread use of antiretroviral drugs in pregnant HIV-infected women.<sup>1-4</sup> Perinatally acquired HIV infections may result from missed opportunities for prevention, such as inadequate prenatal care.<sup>4,5</sup> Ideally, all pregnant women should receive early prenatal care with voluntary HIV testing. However, for those who do not, rapid testing during labor could provide HIV-infected women with immediate access to antiretroviral prophylaxis.<sup>3,6</sup> Most women in the United States give birth in hospitals, presenting a crucial opportunity for systematically offering rapid HIV testing and, when indicated, interventions to decrease perinatal transmission.<sup>7</sup>

We sought to determine the feasibility of rapid HIV testing during labor,

**For editorial comment see p 269.**

**Context** Timely testing of women in labor with undocumented human immunodeficiency virus (HIV) status could enable immediate provision of antiretroviral prophylaxis.

**Objectives** To determine the feasibility and acceptance of rapid HIV testing among women in labor and to assess rapid HIV assay performance.

**Design, Setting, and Patients** The Mother-Infant Rapid Intervention At Delivery (MIRIAD) study implemented 24-hour counseling and voluntary rapid HIV testing for women in labor at 16 US hospitals from November 16, 2001, through November 15, 2003. A rapid HIV-1 antibody test for whole blood was used.

**Main Outcome Measures** Acceptance of HIV testing; sensitivity, specificity, and predictive value of the rapid test; time from blood collection to patient notification of results.

**Results** There were 91 707 visits to the labor and delivery units in the study, 7381 of which were by eligible women without documentation of HIV testing. Of these, 5744 (78%) women were approached for rapid HIV testing and 4849 (84%) consented. HIV-1 test results were positive for 34 women (prevalence=7/1000). Sensitivity and specificity of the rapid test were 100% and 99.9%, respectively; positive predictive value was 90% compared with 76% for enzyme immunoassay (EIA). Factors independently associated with higher test acceptance included younger age, being black or Hispanic, gestational age less than 32 weeks, and having had no prenatal care. Lower acceptance was associated with being admitted between 4 PM and midnight, particularly on Friday nights, but this may be explained in part by fewer available personnel. Median time from blood collection to patient notification of result was 66 minutes (interquartile range, 45-120 minutes), compared with 28 hours for EIA ( $P<.001$ ).

**Conclusions** Rapid HIV testing is feasible and delivers accurate and timely test results for women in labor. It provides HIV-positive women prompt access to intrapartum and neonatal antiretroviral prophylaxis, proven to reduce perinatal HIV transmission, and may be particularly applicable to higher-risk populations.

*JAMA.* 2004;292:219-223

www.jama.com

and assess barriers to HIV testing, and facilitate comprehensive care for HIV-infected mothers and their infants. A US Food and Drug Administration treatment investigational device exemption permitted the use of a rapid test before its approval in November 2002.<sup>8,9</sup> This test yields HIV results in 20 minutes, making it ideally suited for point-of-care use. This report describes the experience of performing rapid HIV testing during labor and the factors associated with acceptance of rapid testing.

### METHODS

The CDC funded 16 hospitals in 6 US cities (Atlanta, Ga; Baton Rouge, La; Chicago, Ill; Miami, Fla; New Orleans, La;

and New York, NY) to participate in the MIRIAD (Mother-Infant Rapid Intervention At Delivery) study, which offered HIV counseling, voluntary rapid testing, and, if indicated, antiretroviral prophylaxis to women with undocumented HIV status late in pregnancy. Counseling, voluntary rapid testing, and antiretroviral prophylaxis (as well as study enrollment) were offered by la-

**A List of the Other Members of the MIRIAD Study Group, Author Affiliations, and Financial Disclosures** appear at the end of this article.

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bor and delivery nurses, midwives, and obstetrics/gynecology residents in most hospitals. MIRIAD staff performed study interviews (usually post partum) and medical record reviews for the study at each hospital. Women were offered enrollment if they were in active labor (defined as having regular strong contractions and ruptured membranes or cervical dilation  $>4$  cm) at a minimum of 24 weeks' gestation (potentially viable neonate). Women not in active labor were enrolled only if they presented at 34 weeks' gestation or later to the labor and delivery unit (standard HIV testing could be offered at  $<34$  weeks per hospital protocol).

We developed a standardized procedure for obtaining written informed consent for rapid testing and study participation during labor that included use of a flipchart, which pictorially reviews the main study aspects.<sup>10</sup> The study was approved by institutional review boards of the CDC and each participating institution. One MIRIAD study hospital did not allow collection of variables (cervical dilation, membrane status, frequency of contractions, gestational age, number of prenatal care visits, age, years of education, Hispanic ethnicity, and race) on the eligibility form (all other study hospitals permitted this) from women who were not approached or who declined rapid testing and study participation (but this hospital did allow collection of time of admission). Thus, this hospital is not represented by variables from this group in relevant analyses herein.

Blood was collected for both rapid testing and enzyme immunoassay (EIA) and, when indicated, Western blot confirmatory testing. Laboratory technicians and labor and delivery staff performed rapid test proficiency panels for quality assurance. The EIA, and if needed, Western blot testing, was performed immediately following rapid HIV testing in the MIRIAD protocol. Nine institutions used the Abbott HIV-1/HIV-2 EIA (Abbott Laboratories, Abbott Park, Ill) and the Genetic Systems HIV-1 Western blot (BioRad Laboratories, Hercules, Calif); 7 institutions used the Genetic Systems HIV-1/HIV-2 Pep-

tide EIA (BioRad Laboratories) and 4 of these used the Genetic Systems HIV-1 Western blot (BioRad Laboratories) and 3 used the Cambridge Biotech HIV-1 Western blot (Calypte Biomedical, Rockville, Md). In all institutions, initially reactive EIAs and rapid tests were repeated in duplicate; specimens with repeatedly reactive EIA or rapid tests were tested using Western blot. Women identified as HIV-positive by the Ora-Quick Rapid HIV-1 Antibody Test (Orasure Technologies Inc, Bethlehem, Pa) or EIA, and those with discordant rapid test and EIA/Western blot results were followed up together with their infant for at least 6 months. The infants were tested using HIV DNA polymerase chain reaction (PCR) at less than 48 hours, 2 weeks, 6 weeks, and 3 months, and if having an indeterminate status, at 6 months.

To determine factors associated with acceptance of HIV testing, odds ratios (ORs) and 95% confidence intervals (CIs) were estimated using unconditional logistic regression, adjusting for study site and other covariates. Reported ORs should not be misinterpreted as relative risks.<sup>11</sup> Sensitivity, specificity, and positive and negative predictive values were determined using the EIA/Western blot algorithm as the gold standard. For each of these measures, CIs were estimated using exact binomial methods.<sup>12</sup> Median turnaround times were compared using the Wilcoxon rank-sum test. We used SAS statistical software version 8 (SAS Institute Inc, Cary, NC) and S-Plus version 6.1 (Seattle, Wash). All *P* values reported are 2-sided and  $P \leq .05$  was considered statistically significant.

## RESULTS

Between November 16, 2001, and November 15, 2003, there were 91 707 visits to the labor and delivery units of the 16 participating hospitals and 7381 women (8% of all visits recorded) were eligible for rapid HIV testing. Of these, 1637 women (22%) were not approached for rapid HIV testing for reasons that included no staff member being available or verification for HIV testing

during pregnancy still pending. Every attempt was made to have continuous labor and delivery coverage but some hospitals were less successful (implementation issues are being addressed in separate analyses). The remaining 5744 women were offered rapid HIV testing. Data on frequency of visiting the units were not collected and some women may have visited the units more than once. Written informed consent for both rapid testing and study participation was obtained from 4849 (84%) women.

Thirty-four women tested HIV-1 positive with both rapid test and EIA, and all were confirmed by Western blot (prevalence=7/1000). There were 4 false-positive and no false-negative rapid test results. All 4 patients presented in active labor and were given antiretroviral prophylaxis, which was stopped when clinicians were notified that the rapid test result was false-positive. Sensitivity of the rapid test was 100% (95% CI, 90%-100%) and specificity was 99.9% (95% CI, 99.78%-99.98%). Negative predictive value was 100%; positive predictive value was 90% (95% CI, 75%-97%). The EIA had 11 false-positive results: 5 in women with an indeterminate Western blot result (usually a single p24 band) and 6 others with negative Western blot results. All 11 women had negative rapid test results. No false-negative EIA results were identified. The specificity of EIA was estimated to be 99.8% (95% CI, 99.6%-99.9%); positive predictive value was 76% (95% CI, 61%-87%).

In analyses adjusted for study site, acceptance of HIV testing during labor was associated with younger age, Hispanic ethnicity, gestation of less than 32 weeks, time of admission, and no prenatal care (TABLE 1). In multivariate analysis, black as well as Hispanic women were more likely than white women to accept testing. Younger age, gestation less than 32 weeks, and no prenatal care also remained significant (Table 1). Hospital admission between 4 PM and midnight was associated with lower HIV test acceptance (adjusted odds ratio [AOR], 0.7; 95% CI, 0.5-0.9); acceptance was lowest on Friday nights ( $P = .001$ ).

Median time from blood collection to patient notification of rapid test result was 66 minutes (interquartile range, 45-120 minutes). In contrast, the median time from blood collection to receipt of EIA results was 28 hours ( $P<.001$ ), with more significant delays for specimens obtained on weekends vs weekdays (39 vs 25 hours;  $P<.001$ ).

Among women tested during active labor ( $n=4073$ ), the factor most strongly associated with receipt of test results after delivery was the number of hours the woman spent in the labor and delivery unit before delivery (TABLE 2). Women who arrived 2 or fewer hours before delivery were more likely to receive rapid test results post partum than women who arrived 12 or more hours before delivery (AOR, 34.5; 95% CI, 24.9-47.9).

Twenty-seven of the 34 HIV-infected women identified were in active labor when they first arrived. Of those, 18 received intrapartum zidovudine (8 of these also received intrapartum single-dose nevirapine). The remaining 9 women who arrived in active labor did not receive intrapartum prophylaxis because they arrived near the time of delivery and could not receive the rapid test result in time to start prophylaxis. The median time between receipt of rapid test result and zidovudine dosing was 33 minutes; zidovudine was started on average 6 hours prior to delivery (range, 1-18 hours). All HIV-exposed infants received zidovudine prophylaxis soon after birth (median, 3.8 hours); 17 infants also received single-dose nevirapine (prophylaxis protocols<sup>3</sup> varied by institution). Two foreign-born HIV-infected women presenting late in pregnancy but who were not in active labor could not be followed up (they may have returned to their home country).

Of the remaining 32 HIV-exposed infants in the study, 17 were delivered vaginally and 15 by cesarean delivery (none of these 32 infants were breastfed). Three infants were found to be HIV-infected: 2 were already DNA-PCR positive at birth and the other infant was negative at birth but positive by 6 weeks of age. The mother of this infant arrived too late for intrapartum prophylaxis. Two of the 3

infected infants had a vaginal delivery. The infant who was DNA-PCR negative at birth but positive by 6 weeks was delivered vaginally. Of the 32 infants, 27 were followed up for 6 months. Many of the women have started highly active antiretroviral therapy for their own health (follow-up of women testing positive is continuing and being addressed in separate analyses). Of the 34 HIV-infected women identified, 30 were black, of whom 21 (70%) were born in the United States and 9 (30%) were immigrants from

Africa and the Caribbean. Regarding test performance with non-clade B HIV-1, there was 100% sensitivity in use of the rapid test with whole blood and no indication in the MIRIAD study that specificity was decreased in African women.

## COMMENT

We found that rapid HIV testing yielded accurate and timely results to women in labor and that implementing rapid testing was acceptable and feasible. Overall test acceptance was nearly 85%. Lower

**Table 1.** Odds of Accepting if Approached for Rapid HIV Testing During Labor, by Characteristics ( $n = 5744$ )

Characteristic	No./Total (%)	Odds Ratio (95% CI)*		
		Adjusted for Study Site	Adjusted for Age and Study Site	Full Model†
<b>Age, y</b>				
<20	881/976 (90.3)	1.8 (1.4-2.3)‡		1.9 (1.3-2.6)‡
20-24	1512/1730 (87.4)	1.4 (1.1-1.7)‡		1.5 (1.2-2.0)‡
25-29	1004/1164 (86.3)	1.2 (0.98-1.5)‡		1.4 (1.0-1.8)‡
≥30	1157/1394 (83.0)	1.0		1.0
Not reported	295/480 (61.5)			
<b>Race</b>				
White	1313/1544 (85.0)	1.0	1.0	1.0
Black	3042/3503 (86.8)	0.9 (0.8-1.1)	0.9 (0.86-1.2)	1.8 (1.2-2.7)
Other	312/346 (90.2)	1.1 (0.8-1.7)	1.2 (0.8-1.8)	1.1 (0.6-1.9)
Not reported	182/351 (51.9)			
<b>Hispanic ethnicity</b>				
No	3195/3715 (86.0)	1.0	1.0	1.0
Yes	1494/1704 (87.7)	1.6 (1.3-1.9)	1.5 (1.2-1.8)	2.4 (1.6-3.5)
Not reported	160/325 (49.2)			
<b>Duration of gestation, wk</b>				
<32	395/438 (90.2)	1.4 (1.0-2.0)	1.6 (1.1-2.2)	2.0 (1.2-3.3)
32-36	976/1154 (84.6)	0.8 (0.7-0.96)	0.8 (0.7-1.0)	0.9 (0.7-1.2)
>36	3184/3686 (86.4)	1.0	1.0	1.0
Not reported	294/466 (63.1)			
<b>Time of admission</b>				
Midnight-8 AM	1529/1805 (84.7)	1.0 (0.8-1.2)	1.0 (0.8-1.2)	0.8 (0.7-1.1)
8 AM-4 PM	2057/2414 (85.2)	1.0	1.0	1.0
4 PM-midnight	1262/1523 (82.9)	0.8 (0.7-0.99)	0.8 (0.7-1.0)	0.7 (0.5-0.9)
Not reported	1/2 (50.0)			
<b>Prenatal care visits, No.</b>				
0	1299/1451 (89.5)	1.5 (1.2-2.0)	1.7 (1.3-2.2)	1.7 (1.3-2.3)
1-5	839/959 (87.5)	1.2 (0.95-1.6)	1.4 (0.98-1.6)	1.3 (0.98-1.7)
>5	1350/1578 (85.6)	1.0	1.0	1.0
Not reported	1361/1756 (77.5)			

Abbreviations: CI, confidence interval; HIV, human immunodeficiency virus.

\*Reported odds ratios should not be misinterpreted as relative risks.<sup>11</sup>

†Logistic regression model containing study site, study year, rapid testing procedure, and all variables listed in the table; individuals with missing data were excluded from the model. It should be noted that 1 study hospital did not allow collection of variables (cervical dilation, membrane status, frequency of contractions, gestational age, number of prenatal care visits, age, years of education, Hispanic ethnicity, and race) on the eligibility form (all other study hospitals permitted this) from women who were not approached or who declined rapid testing and study participation (but this hospital did allow collection of time of admission). Thus, this hospital is not represented by variables from this group in relevant analyses herein. Missing data for 35 women were due to this hospital not collecting the information on women who declined testing (translating to 3%-11% of all missing data, depending on the variable).

‡Test for trend,  $P<.001$ .

acceptance during evening shifts may be explained in part by fewer available personnel. Informed consent was obtained not only for rapid HIV testing but also for participation in a research study.

Based on the feasibility of rapid testing demonstrated in MIRIAD, the CDC now recommends routine rapid HIV testing using an opt-out approach (ie, a woman is informed that HIV testing will be routinely done during labor if her HIV status is unknown but she may decline testing).<sup>8,13</sup> Each woman should be informed that a preliminary positive rapid test result means that she is likely HIV infected but that this result will need to be confirmed. If her rapid test result is positive, she should be notified that antiretroviral drugs will be offered to her and

to her newborn. If her rapid test result is negative, she should be notified that she is almost certainly not HIV infected. One practical approach to implementing routine rapid testing would be for each hospital to put in place standing orders to immediately inform any woman in labor whose HIV status is unknown that she will be tested unless she declines.<sup>8,13</sup>

The rationale for focusing on women in labor is that there is a brief window of opportunity for interventions to decrease HIV transmission to the newborn.<sup>6,14-16</sup> This rationale is related to the pharmacokinetics of the antiretroviral drugs used for prophylaxis.<sup>3</sup> In decision analysis modeling, rapid HIV testing during labor is cost-saving to the medical system.<sup>17</sup> Our study demon-

strates that, in general, results are timely and that antiretroviral prophylaxis can be provided promptly to HIV-infected women and their infants. In addition, we have previously shown that point-of-care rapid testing has the potential to save valuable time compared with sending specimens to the laboratory.<sup>18,19</sup>

Appropriate training of staff and quality assurance processes are essential to ensure accurate rapid HIV test results.<sup>9,20</sup> Despite high test performance, there were still instances in which preliminary HIV-1 screening tests (rapid test or EIA) yielded false-positive results. The decision to recommend antiretroviral prophylaxis on the basis of an unconfirmed test result will continue to require clinical judgment and knowledge about HIV prevalence and the performance characteristics of each test. Although EIA has been the mainstay of HIV screening, the rapid test demonstrated a higher positive predictive value in the present study.

Several study caveats should be considered. First, clinical interventions were not standardized but left up to individual practitioners following US Public Health Service guidelines.<sup>3</sup> Second, the total number of encounters recorded included some women who visited the labor and delivery unit more than once. Therefore, the percentage of eligibility reported in this study (8%) is likely an underestimate of the true proportion of women with undocumented HIV status. Third, our findings about acceptance rates and the informed consent process may not directly translate to a nonresearch setting. Fourth, the utility of the program is in part contingent on accurate and accessible documentation of the HIV status to avoid redundancy of effort.

The MIRIAD findings are important both in the United States and internationally. In many settings, including in the developing world, pregnant women with unknown HIV status are often seen by clinicians for the first time during labor.<sup>16,21,22</sup> Rapid testing during labor can enable pregnant women with undocumented HIV status to learn their HIV infection status so they can

**Table 2.** Multivariate Analysis of Factors Associated With Receipt of Rapid HIV Test Results After Instead of Before Delivery in 4073 Women in Active Labor\*

Characteristic	Univariate No./ Total (%)	Multivariate Logistic Regression	
		Adjusted Odds Ratio (95% CI)†	χ <sup>2</sup> P Value for Test of Overall Effect
Time between arrival and delivery, h (hours)			
0-2	723/856 (84.5)	34.5 (24.9-47.9)	<.001
3-5	349/696 (50.1)	5.2 (4.0-6.9)	
6-8	179/506 (35.4)	2.2 (1.6-3.0)	
9-12	146/474 (30.8)	2.0 (1.5-2.7)	
>12	206/1124 (18.3)	1.0	
Time between blood collection and patient notification, min			
≤90	1021/2624 (38.9)	1.0	<.001
>90	766/1437 (53.3)	2.2 (1.8-2.6)	
Prenatal care visits, No.			
0-5	780/1738 (44.9)	1.0	.002
>5	623/1217 (51.2)	1.4 (1.1-1.7)	
Time of admission			
Midnight-8 AM	717/1403 (51.1)	1.9 (1.5-2.3)	<.001
8 AM-4 PM	614/1645 (37.3)	1.0	
4 PM-midnight	461/1024 (45.0)	2.3 (1.8-3.0)	
Admission on weekend‡			
Yes	622/1263 (49.3)	1.6 (1.3-2.0)	<.001
No	1171/2810 (41.7)	1.0	
Duration of gestation, wk			
<32	97/359 (27.0)	1.0	.002
32-36	254/675 (37.6)	1.2 (0.8-1.9)	
>36	1336/2809 (47.6)	1.7 (1.2-2.6)	

Abbreviation: CI, confidence interval.

\*Of 4073 women in active labor with information on receipt of rapid test results, 417 had missing data on time between arrival and delivery, 12 had missing data on time between blood collection and rapid test notification, 1118 had missing data on prenatal care, 1 had missing data on time of admission (and weekend), and 230 had missing data on gestational age. Overall, 1510 of 4073 women were excluded from the model due to 1 or more missing explanatory variables.

†Odds ratios were adjusted for all other variables listed as well as for study site and study year; analysis was restricted to women tested during active labor (those tested post partum were excluded). Reported odds ratios should not be misinterpreted as relative risks.<sup>11</sup>

‡Weekend considered from Friday at 5 PM to Monday at 6 AM.

receive antiretroviral prophylaxis and be referred for comprehensive medical care and follow-up.

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**Financial Disclosures:** Dr O'Sullivan had a CDC-funded HIV project (MIRIAD), a Title III Primary HIV Care grant, and an NHLBI WHI study, for which she was the principal investigator in Miami. Dr Maupin was a consultant member of the US Public Health Service Perinatal Guidelines Working Group (nonfunded position, 1999-present), coinvestigator for the Tulane-LSU Pediatric AIDS Clinical Trial Unit (the site is a DAIDS-NIAID-supported clinical trials site [1996-present]), obstetric cochair of the Pediatric AIDS Clinical Trials Group Perinatal Research Agenda Committee (contract-funded position since July 2003), clinical trainer with the MTCT-Plus Program sponsored through the Columbia University School of Public Health (honoraria provided for training activities, January 2004), and working group member for the CDC Guide and Model Protocol for Rapid Testing During Labor and Delivery (nonfunded position, 2003). Dr Van Dyke received honoraria for speaking from Boehringer Ingelheim and GlaxoSmithKline. Drs Bulterys and Branson do not have any financial relationship with any company involved with the manufacture of HIV diagnostic tests but have presented lectures and continuing medical education programs on HIV diagnostic testing during the last 5 years, all of which were supported only by the CDC and performed as part of job responsibilities. No other authors have any such affiliations.

**Author Contributions:** As principal investigator, Dr Bulterys had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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**Funding/Support:** The MIRIAD Study is coordinated and funded by the National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC) under cooperative agreements U64/217724, 417719, 417735, 517715, and 617734. Assay kits for the MIRIAD investigation were made available by the manufacturer at a price determined in accordance with the FDA requirements of 21 CFR 812.36, "Treatment Use of an Investigational Device" (this included a statement indicating that the price was based on manufacturing and handling costs only). None of the MIRIAD investigators received funding from Orasure Technologies, nor did any investigator receive funding for this study from any other source.

**Role of the Sponsors:** The CDC coordinated the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, and approval of the manuscript. Orasure Technologies had no input into the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, and approval of the manuscript.

**Previous Presentation:** This work was presented in part at the 11th Conference on Retroviruses and Opportunistic Infections, San Francisco, Calif, February 2004. Abstract 95.

**Acknowledgment:** We gratefully acknowledge Susie Danner, BA, Siva Rangarajan, MA, and Shawn Wei, MS, for superb assistance with project coordination and data management at CDC. Mary Glenn Fowler, MD, MPH, Alan Greenberg, MD, MPH, Lillian Lin, PhD, and Ida Onorato, MD (at CDC) provided guidance and support throughout the study and critically reviewed the manuscript. We especially thank our project coordinators: Renata Dennis, RN, MPH (Atlanta, Ga), Yolanda Olszewski, MPH (Chicago, Ill), Yvette Rivero, BA (Miami, Fla), Angela Bradley-Byers, RN (New Orleans, La), and Rosalind Carter, PhD (New York, NY). Margaret Lampe, RN, MPH (CDC) and Pat Garcia, MD, MPH (Northwestern University) provided critical input into protocol development and Carol Fridlund, BS (CDC) provided training on rapid testing at each of the participating sites. David Shapiro, PhD, and Ruth Tuomala, MD (Harvard University) provided helpful comments on an earlier draft of the manuscript.

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