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Factors Associated with Declining a Rapid Human Immunodeficiency Virus Test in Labor and Delivery

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Abstract The Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists recommend routine rapid HIV testing in labor and delivery (L&D) for women with undocumented HIV status using an opt-out approach. Identifying factors associated with declining a rapid HIV test in L&D will be helpful in developing strategies to improve rapid HIV testing uptake. Data from the Mother-Infant Rapid Intervention at Delivery study were analyzed. Women $\geq$24 weeks gestation, in labor, with undocumented HIV status were offered rapid HIV testing using informed consent. Women who declined rapid HIV testing (decliners) but agreed to be interviewed were compared to women who accepted testing (acceptors). 102 decliners and 478 acceptors met inclusion criteria for analysis. Decliners of rapid HIV testing were more likely to have had prenatal care (PNC), after adjusting for age, Hispanic ethnicity, high-school education and city of enrollment (adjusted OR 2.4, 95% CI 1.06–5.58). Having had PNC was collinear with prior HIV education and previous offer of an HIV test during the current pregnancy, so these factors were not part of the model. During PNC, standard informed consent may involve discussions that negatively affect later uptake of testing in L&D. Therefore an opt-out approach to testing may improve testing rates. Furthermore, decliners may have felt that testing in L&D was redundant because of previous testing during PNC; however, if previous testing occurred, this was undocumented at L&D. Documentation and timely communication of HIV status is critical to provide appropriate HIV prophylaxis.

Keywords HIV · Pregnancy · Rapid HIV testing · Labor and delivery

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Introduction

In the United States (US) in 2005, acquired immunodeficiency syndrome (AIDS) cases diagnosed in children <13 years of age were attributed to mother-to-child transmission of human immunodeficiency virus (HIV) in 99% of cases [1]. Data from 28 states with name-based reporting showed 323 children with perinatally-acquired HIV infection between 2001 and 2004 [1]. Among the mothers of these children, about one-third had an unknown HIV status during delivery and 41% did not receive intrapartum antiretroviral prophylaxis [1]. These data reflect critical missed opportunities for timely HIV diagnosis and intervention. While preconception or early prenatal HIV screening provides the best opportunities to identify women who should receive the full range of interventions to reduce perinatal HIV transmission, providing rapid HIV testing to women presenting to labor and delivery (L&D) with unknown HIV status during pregnancy will allow for transmission-reducing interventions during and after delivery. Therefore, optimizing acceptance of HIV testing in L&D among women with unknown HIV status is key to appropriate delivery of care.

Until recently, an informed consent process was standard for HIV testing. In informed consent, patients are counseled on the benefits and risks of testing, and if the patient decides to accept testing, a consent form is signed. In several studies that offered rapid HIV testing using an informed consent process to all women who presented to L&D, 10–20% of women declined HIV testing [2, 3]. Additionally, in the Mother-Infant Rapid Intervention at Delivery (MIRIAD) Study which examined feasibility and acceptance of rapid HIV testing in the L&D setting, preliminary analysis showed that 15% of women with unknown HIV status rejected rapid HIV testing [4].

In 2006, the Centers for Disease Control and Prevention (CDC) and in 2008, the American College of Obstetricians and Gynecologists (ACOG) recommended rapid HIV testing for women who present to L&D with undocumented HIV status using an opt-out approach [5, 6]. However, implementing these recommendations can be difficult due to pre-existing state laws [7, 8]. One study reported that as of 2006, 33 states required an oral or written informed consent process [8].

The objective of this study was to examine factors associated with declining the rapid HIV test by doing a secondary analysis of MIRIAD data. Identification of these factors will be helpful in examining strategies, such as the opt-out process, for improving the uptake of rapid HIV testing among women in the L&D setting.

Methods

Mother-Infant Rapid Intervention at Delivery was a multicenter CDC-funded prospective study conducted from November 2001 through February 2005. Women with undocumented HIV status (defined as no available HIV test result from the current pregnancy at the time of the woman's presentation to L&D), in active labor (regular strong contractions and ruptured membranes or cervical dilation >4 cm), and ≥24 weeks gestation were offered enrollment. Women with undocumented HIV status and not in active labor were enrolled only if they presented at ≥34 weeks gestation. These women were offered a rapid HIV test using an informed consent process, and a subset of women were offered interviews. Rapid HIV testing was done via OraQuick Rapid HIV-1 Antibody Test. All women also received conventional testing which consisted of screening by enzyme immunoassay (EIA) and confirmatory Western blot. Reactive rapid tests and EIAs were repeated and if still reactive, confirmatory Western blot was done. Discordant rapid and conventional test results were resolved using an algorithm. Detailed methods of this study have been described elsewhere [4, 9]. Institutional Review Board approval was obtained from CDC and all participating sites.

A screening form, which collected basic demographic information and determined a woman's eligibility for MIRIAD, was completed for all women who presented to the L&D units. Eligible women were approached and asked to participate in MIRIAD. Women who agreed to participate were consented for HIV testing. Some of the women who accepted testing (acceptors) were offered a postpartum baseline interview. In the anticipation of future analyses that could involve comparisons of women by HIV status, the selection process for interviews was as follows: for every woman who tested HIV-positive, the next three consecutive women who tested negative were selected as controls. To increase sample size, an additional 500 postpartum interviews were conducted with a convenience sample of women who tested HIV-negative. Additional information such as course of labor and type of delivery was obtained through review of participants' medical charts.

During the entire enrollment process (including the time additional interviews were conducted), women who declined a rapid HIV test (decliners) were asked if they would complete a decliner interview. If the woman agreed, informed consent for an interview was obtained. Information gathered from interviews included demographics, prenatal care history, HIV education and testing history, and past and present HIV testing experience. The women were also asked to share limited medical information which included number of

pregnancies, use of pain medication during labor, and method of delivery. Medical records for these women were not reviewed.

All women who participated in an interview received financial compensation in the form of cash ($20–25) or gift card (worth $20–$25) in exchange for their time.

This secondary analysis used data collected from MIRIAD. Following a case–control design, rapid HIV test decliners who completed a decliner interview (cases) were compared to rapid HIV test acceptors (controls) who agreed to an interview. Participants included in this analysis were women enrolled in Chicago, New York, or Miami, and were ≥24 weeks gestation, in active labor, and with undocumented HIV status during the current pregnancy. Women from Miami were excluded if their information was collected after June 14, 2004, because a separate MIRIAD sub-study was initiated at this site after this date. Additionally, women who declined to participate due to "refusal to be part of research" ($n = 10$) were excluded in order to examine only those who declined participation due to the test rather than those who objected to participating in research.

Analysis was done using SAS v9.1. Factors of interest were maternal characteristics such as demographics, prenatal care experience, past and present HIV testing experience, and course of labor.

Decliners and acceptors of the rapid HIV test were characterized and described using univariate analysis. Characteristics of the two groups were compared using Mantel–Haenszel chi-square tests for categorical variables and a Wilcoxon rank-sum test for continuous variables. Then, bivariate analysis was done to identify factors possibly associated with declining rapid HIV testing. Crude odds ratios (ORs), *P*-values, and 95% confidence intervals (CI) were calculated.

A descriptive logistic regression model then identified independent factors associated with declining a rapid HIV test. Data were assessed for effect modifiers and confounders using stratified analysis. Candidates for the main effect variables were chosen based on significant ($P < 0.05$) results in the crude analysis. Then, a full model that included all confounders and effect modifiers was developed and further refined through a hierarchical backward elimination method [10]. Adjusted ORs, *P*-values, and 95% CIs were calculated.

To assess if the decliners interviewed were representative of those not interviewed, demographic and limited obstetrical characteristics of these two groups were compared. For continuous variables that were normally distributed a *t*-test was used, otherwise a Wilcoxon-rank sum test was used. For categorical variables the chi-square test was used. ORs for dichotomous variables were calculated.

Results

Characteristics of Decliners and Acceptors

Data from 102 decliners and 478 acceptors were examined. A description of decliners and acceptors can be found in Table 1. A majority of the participants were non-Hispanic blacks and most were single, but decliners and acceptors differed by city of enrollment, median age, and education. Decliners were from primarily Miami (42%) and New York (40%), had a median age of 27 (range 15–44) years, and only 33% had at least a high-school education. The acceptors were primarily from Chicago (30%) and Miami (41%), had a median age of 24 (range 15–45, *P*-value 0.036) years, and 47% had at least a high-school education.

Crude analysis of the association between patient demographics and declining a rapid HIV test revealed significant differences between the decliner and acceptor groups (Table 2). Decliners were slightly more likely to be black (OR 1.7, 95% CI 1.0–2.8), less likely to be Hispanic (OR 0.5, 95% CI 0.3–0.9), and less likely to have at least a high-school education (OR 0.6, 95% CI 0.4–0.9).

In the crude analysis, having received prenatal care (OR 2.6, 95% CI 1.2–5.5), being offered an HIV test during prenatal care in the current pregnancy (OR 1.9, 95% CI 1.1–3.3), and receiving HIV information prior to L&D but during the current pregnancy (OR 2.2, 95% CI 1.3–3.8) were associated with later declining the rapid HIV test (Table 2) in L&D.

Table 1 Demographics of decliners and acceptors of the rapid HIV test in L&D, MIRIAD, November 2001 through February 2005

Demographic	Decliners *n* (%) ($N = 102$)[a]	Acceptors *n* (%) ($N = 478$)[a]	*P*-value
Median age (range)	27 (15–44)	24 (15–45)	0.036
Race/ethnicity			
White, non-Hispanic	3 (3)	12 (3)	0.039
Black, non-Hispanic	67 (67)	256 (54)	
Hispanic	29 (29)	203 (43)	
Marital status			
Married	21 (21)	96 (20)	0.755
Not married	80 (79)	378 (80)	
City of enrollment			
Chicago	18 (18)	146 (30)	0.0143
Miami	43 (42)	194 (41)	
New York	41 (40)	138 (29)	
Education			
<High school	67 (66)	253 (53)	0.015
≥High school	34 (33)	224 (47)	

[a] Missing values were not included in the analysis

Table 2 Factors associated with declining a rapid HIV test in L&D, MIRIAD, November 2001 through February 2005

Factor*	Unadjusted odds ratio (95% confidence interval)	Adjusted odds ratio (95% confidence interval)
Age category		
15–20	1.1	1.2 (0.60–2.37)
21–25	Ref	Ref
26–31	1.8	1.7 (0.89–3.28)
≥32	1.8	1.6 (0.82–2.95)
Race—Black	1.7 (1.0–2.8)	
Ethnicity—Hispanic	0.5 (0.3–0.9)	0.4 (0.21–0.60)
Education ≥ high school	0.6 (0.4–0.9)	0.7 (0.41–1.09)
Prior HIV testing	1.8 (0.8–3.9)	
Received prenatal care (PNC)	2.6 (1.2–5.5)	2.4 (1.06–5.58)**
HIV test offered at PNC	1.9 (1.1–3.3)	
HIV/AIDS information provided during pregnancy	2.2 (1.3–3.8)	
HIV testing recommended strongly during pregnancy	1.0 (0.6–1.6)	
HIV testing received during pregnancy	1.1 (0.6–1.9)	
Felt reassured with test offer	0.3 (0.2–0.5)	
Felt pressured with test offer	1.7 (0.9–3.4)	

* Other factors examined and found to be not significantly associated: single marital status, ≥3 pregnancies, pain medication not used during labor, unplanned Cesarean

** *P*-value 0.030

When asked about their experiences with being offered the rapid HIV test in the L&D setting, those who declined the rapid test were less likely to express feelings of reassurance (OR 0.3, 95% CI 0.2–0.5) when the test was offered.

Factors in the pregnancy history and current delivery circumstances were not associated with declining the rapid HIV test. Factors that might indicate a difficult birth process such as use of anesthetic and unscheduled Cesarean delivery were also not associated with declining the rapid HIV test.

Based on the crude analysis, the likely candidates for the main effect variable in the model were: having had prenatal care (PNC); receiving HIV/AIDS information during pregnancy; and having had a previous offer of HIV testing during the current pregnancy prior to presentation at L&D. However, analysis showed collinearity between these three factors. Because having had prenatal care will likely result in the woman receiving HIV/AIDS information and being offered an HIV test, having had PNC was chosen as the exposure of interest for the model.

In the stratified analysis, having at least a high-school education confounded the relationship between having had PNC and declining a rapid HIV test. Effect modification was suspected due to age, Hispanic ethnicity, and city of enrollment, but comparisons of the full and reduced model showed that this was not significant. Other ways of coding ethnicity were examined, such as white non-Hispanic, black non-Hispanic, and Hispanic, but due to small strata size (93% of whites were Hispanic), Hispanic ethnicity was the most feasible variable to include in the model. The resulting full model is shown in Table 2. When controlling for age, Hispanic ethnicity, high-school education, and city of enrollment, those who rejected the rapid HIV test were 2.4 times as likely to have had PNC as those who accepted the test (adjusted OR 2.4, 95% CI 1.06–5.58).

Acceptors and decliners provided their reasons for their decision to accept or refuse rapid HIV testing, and were allowed to choose more than one reason. The three most common reasons for refusing a rapid HIV test include: previous testing during pregnancy (44%), previous testing prior to pregnancy (27%), and believing herself to not be at risk for HIV (26%). Among acceptors, the most common reasons for accepting a rapid HIV test include: the desire to "know HIV status now" (50%), "doctor or nurse recommended it" (23%), and "being worried about the baby" (14%).

The percentage of HIV rapid test decliners who participated in the decliner interview was between 7 and 9%, about the same for each city of enrollment. The interviewed and non-interviewed decliners differed non-significantly in terms of Hispanic ethnicity, and educational level. The obstetrical characteristics of the two groups also did not differ significantly in terms of receipt of prenatal care, gravida, use of pain medication during delivery, and type of delivery. While the two groups differed in their reasons for declining the rapid HIV test, they had the same top reasons for declining the rapid HIV test at L&D: previous testing prior to this pregnancy and previous testing during this pregnancy.

Discussion

Those who declined the rapid HIV test were more likely to have received prenatal care, after controlling for potential confounders such as age, education level, city of enrollment, and co-predictors such as Hispanic ethnicity. Over half of the decliners cited "previous testing during the current pregnancy" as one reason for declining and so L&D testing was seen by many as being redundant. Having had previous testing during PNC as a primary reason for declining repeat rapid testing at L&D brings up three issues: HIV testing at L&D may be perceived to be part of the PNC testing package; undocumented HIV status was an eligibility requirement so while participants reported previous HIV testing at PNC, their records had no documentation of these test results at L&D; and women may not be aware of the benefit of repeat testing.

The perception of having already received HIV testing during PNC may not be accurate. Not all PNC providers offer an HIV test, and women who received PNC may believe that having gone through PNC means that they have been tested thoroughly and so reported "previous testing" as the reason for declining rapid testing at L&D.

There was also a lack of documentation and timely communication of a woman's HIV status between PNC providers and L&D. A requirement to be eligible for MIRIAD was undocumented HIV status, yet a high percentage of participating women reported previous testing during the current pregnancy. A previous study looking at MIRIAD data from the New York City site found that among women who accepted rapid testing in L&D, 63% reported previous testing in the current pregnancy but their test results were not available at the time of delivery [11]. Anecdotally, some women who were enrolled in MIRIAD with missing HIV status documentation had their PNC records arrive postpartum. Knowing a woman's HIV status at L&D in a timely manner is key to the appropriate delivery of preventive measures for the transmission of HIV from mother to infant. Implementing measures, such as an electronic medical record could improve documentation and availability of PNC HIV test results.

Women also may not have been informed about the benefits of repeat testing because at the time of MIRIAD, repeat HIV testing was not routinely recommended in L&D. So, women who had been previously tested and knew their HIV status may not have seen the need for repeat testing. Women can become infected during pregnancy [12]. While it is unknown if HIV education during PNC covered the possibility of seroconversion during pregnancy, it should be noted that seroconversion was not discussed when the rapid test was offered to women in the MIRIAD study. However, discussions of HIV testing in PNC such as the offer of a test and HIV education associated with the test make a woman more likely to decline rapid HIV testing at L&D.

The association between discussions involved in a standard informed consent process (such as the offer of a test and HIV education associated with the test) and declining rapid HIV testing has been reported in the literature. One study found that most women had pre-formed decisions about HIV test acceptance prior to their prenatal appointment, and that after their appointment 36% changed their decision from accepting the test to declining the test [13]. One study found that HIV education in the antenatal setting did not increase uptake of HIV testing [14]. This study looked at discussion of HIV testing and acceptance of testing during the same PNC appointment while this analysis of MIRIAD data examined the attendance at PNC and the declining of rapid testing much later in L&D. There is also evidence in the literature that in the PNC setting, the strength of a doctor's or nurse's recommendation of the HIV test is associated with patient acceptance of HIV testing [15–17]. Those who accepted testing commonly cited doctor or nurse recommendation at L&D as a reason for accepting rapid testing in the L&D setting (25%). However, in the MIRIAD study, strong health care provider recommendation of HIV testing earlier in pregnancy was not significantly associated with uptake of the rapid HIV test later in L&D. It should be noted that the MIRIAD study did not define the meaning of "strongly recommended an HIV test" and did not collect information about magnitude of the strength of recommendation for the L&D rapid HIV test. Since discussions involved in the active consent process during PNC were counterproductive towards uptake of later testing in L&D, the opt-out approach (i.e., as part of routine screening without explicit consent) could result in more women being tested in L&D.

The importance of getting women tested when presenting to L&D with an undocumented HIV status is emphasized by an Institute of Medicine (IOM) report that found that late or missed HIV diagnosis was the major contributor to continued perinatal transmission in the US [18]. A few studies have noted that HIV seroprevalence may be higher among pregnant women who refuse HIV testing than those who accept testing [19–21]. Furthermore, one study showed that 20% of pregnant women in New York with HIV lacked PNC [22]. Rapid HIV testing in the L&D setting using an opt-out approach would make HIV testing routine and increase testing rates among all women, including those who would not have been tested otherwise.

It should also be noted that MIRIAD was implemented in New York City after state laws were passed that mandated HIV testing of newborns whose mothers were not previously tested. While the final model controlled for location of enrollment, the New York City mandate may have affected participants' decision to decline or accept a

rapid HIV test in L&D. Since refusing HIV testing would result in their infants being tested, women may have been inclined to accept testing. However, when New York City patients were left out of the analysis, the results were the same.

There are a few limitations to this study. As a secondary analysis, this study uses data from patients enrolled using a sampling scheme appropriate for other MIRIAD objectives. Intentional enrollment of women based on their HIV status, such as the convenience sample of 500 HIV-negative women may affect the characteristics of the group of acceptors. Therefore, the acceptors examined in this analysis may differ from all women who accept rapid HIV testing. Decliners were enrolled throughout the enrollment process, so this sampling scheme may not affect representativeness of decliners. However, self-selection bias may exist in the decliner group. Women who participated in the decliner interview may not necessarily be representative of all women who declined rapid HIV testing since only a small percentage of decliners accepted the interview. Interviewed decliners had several demographic differences (i.e., median age, Hispanic ethnicity, and education) from un-interviewed decliners. The interviewed versus un-interviewed decliners had comparable obstetrical characteristics and had similar odds of having had prenatal care. Another potential source of bias may have been different styles of offering the test and providing informed consent since MIRIAD staff often knew whether or not women received PNC prior to offering the rapid HIV test. There was also no information about the type of services and quality of PNC received as well as the content of discussions regarding HIV education and testing during PNC. Therefore, the generalizability of the findings may be limited by the assumptions made about HIV education and testing during PNC and representativeness of the women in the decliner and acceptor groups.

The findings of this study support 2006 CDC HIV screening guidelines and ACOG guidelines that recommend offering all women who present to L&D with undocumented HIV status a rapid HIV test using an opt-out approach. Rapid testing would not only provide a safety net for women with undocumented HIV status (whether due to no prior PNC or lack of testing during PNC), but offers a chance to repeat HIV testing on women at high risk for HIV seroconversion. The current findings question the contribution of PNC-associated experiences such as the offer of HIV testing and HIV education to the uptake of rapid HIV testing during L&D. An opt-out approach to providing HIV testing would make testing more routine without the influence of these PNC-associated events and may result in higher testing rates. Furthermore, all women who participated in MIRIAD lacked HIV status documentation (a requirement for eligibility) despite reporting to have already received HIV testing. Therefore, documentation and timely communication of a woman's HIV status between PNC providers and L&D units is critical to provide appropriate HIV prophylactic measures when appropriate.

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