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Rapid intrapartum or postpartum HIV testing at a midwife obstetric unit and a district hospital in South Africa

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Abstract

Objective—To compare the prepartum and postpartum feasibility and acceptance of voluntary counseling and rapid testing (VCT) among women with unknown HIV status in South Africa.

Methods—Eligible women were randomized according to the calendar week of presentation to receive VCT either while in labor or after delivery.

Results—Of 7238 women approached, 542 (7.5%) were eligible, 343 (63%) were enrolled, and 45 (13%) were found to be HIV infected. The proportions of eligible women who accepted VCT were 66.8% (161 of 241) in the intrapartum arm and 60.5% (182 of 301) in the postpartum arm, and the difference of 6.3% (95% CI, −1.8% to 14.5%) was not significant. The median times (44 and 45 minutes) required to conduct VCT were also similar in the 2 arms. In the intrapartum arm, all women in true labor received their test results before delivery and all those found to be HIV positive accepted prophylaxis with nevirapine before delivery.

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Conflict of interest

The authors have no conflicts of interest.

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Conclusions—Rapid testing in labor wards for women with an unknown HIV status is feasible and well accepted, and allows for a more timely antiretroviral prophylaxis than postpartum testing.

Keywords

Labor; Rapid testing; Unknown HIV status

1. Introduction

The prevalence of HIV infection among women attending public antenatal clinics in South Africa was 28.0% in 2007 [1]. Without an antiretroviral intervention, the rate of mother-to-child transmission (MTCT) is about 40%, with 50% of the transmissions occurring intrapartum. Many women enter labor with unknown HIV status. Although rapid HIV testing is offered in antenatal clinics in South Africa, it is not routinely offered in labor and delivery settings owing to a shortage in obstetrics staff. Yet, the national Prevention of MTCT (PMTCT) guideline for health care providers advises that “unbooked women reporting in labor should be offered voluntary counseling and testing (VCT) for HIV during the first stage of labor and offered a PMTCT intervention, if possible” [2].

In 2001, the US Centers for Disease Control and Prevention recommended the use of rapid HIV testing for women in labor with unknown HIV status [3]. In 2004, a study conducted in the United States with 4849 women drew attention to the potential efficacy of rapid intrapartum HIV testing in reducing MTCT [4]. In Sub-Saharan Africa, studies have focused on either intrapartum or postpartum VCT [5,6,7,8,9,10], but there are no published randomized controlled trials comparing the feasibility and acceptance of intrapartum and postpartum VCT. We conducted such a trial.

2. Materials and methods

This prospective, cluster randomized trial (Protocol P1031A of the International Maternal Pediatric and Adolescent AIDS Clinical Trials Group) was conducted at Macassar Midwife Obstetric Unit (MCC) and Helderberg Hospital (HH), in the Somerset West district of Western Cape Province, South Africa. It compares (1) the feasibility as well as the acceptance, by women in labor, of intrapartum and postpartum VCT for HIV infection and (2) the acceptance, by the women, of antiretroviral prophylaxis for themselves and their newborns if they test positive for HIV infection. The trial was approved by the research ethics committee of the Faculty of Health Sciences of Stellenbosch University, Stellenbosch, South Africa, and each participant provided written informed consent.

The eligibility criteria were the following: being at least 14 years old and, based on clinical estimate, at least 28 weeks pregnant; being admitted for delivery because of active labor, rupture of membranes with expected delivery, planned induction of labor, planned cesarean delivery, or obstetric/medical complications for which delivery was indicated; and being of unknown HIV status, defined as no mention of HIV status in the antenatal record for the current pregnancy and no previous record of a positive HIV test result.

The exclusion criteria were the following: taking or having taken antiretroviral drugs; progressing to the second stage of labor or having a clinical indication for immediate delivery; being in an obstetric emergency and/or medically unstable; and a fetal diagnosis of death or anomaly incompatible with life.

The eligible women were cluster randomized according to their calendar week of presentation to receive VCT either while in labor (the intrapartum arm) or following

delivery but prior to hospital discharge (the postpartum arm). The randomization schedule, which was generated prior to study initiation by the method of permuted blocks, was used concurrently at both sites. The block size of 2 ensured that no more than 2 consecutive weeks were assigned to the same arm.

Trained research counselors and study nurses determined eligibility and the reasons for exclusion were recorded. Because the women were considered to be vulnerable, the study staff avoided recruitment approaches that could be perceived as coercive or misleading. The women could decline testing at any time during counseling. Selected characteristics such as age, membrane status, cervical dilation, frequency of contractions, and whether the woman had received prenatal care were extracted from the delivery log.

After counseling, each participant underwent 2 fingerstick HIV tests. These were rapid antibody assays (OraQuick [supplied by the US Centers of Disease Control] and Determine; Abbott Laboratories, Roodepoort, South Africa). A blood specimen was also taken for an enzyme-linked immunosorbent assay, performed at the PathCare Reference and Clinical Trial Laboratories, Cape Town. If both rapid test results were positive, the participant was considered HIV positive. If both rapid test results were negative, the participant was considered HIV negative. Discordant rapid tests and immunosorbent assay results were resolved by means of a Western blot.

In the intrapartum arm, women with at least 1 positive rapid test result immediately received a single, 200-mg dose of nevirapine orally and their newborns received antiretroviral prophylaxis within 72 hours of birth prior to discharge. In the postpartum arm, the newborns of women with at least 1 positive rapid test result received antiretroviral prophylaxis as soon as possible. Moreover, the newborns of women with at least 1 positive rapid test result in both arms took zidovudine twice daily for 7 days. The antiretroviral drugs were used according to the national guideline and supplied by the hospital's pharmacy [2]. All women received post-test counseling prior to discharge.

The women with at least 1 positive rapid test result underwent laboratory assessment and were followed up until for 6 to 12 weeks. Those with a positive result to the immunosorbent test were referred for clinical HIV care and their newborns were followed up until they were 8 to 12 weeks of age. Polymerase chain reactions (PCRs) were performed at birth and between 6 and 10 weeks of age to detect HIV-1 DNA. The infants were considered infected if the results of the first and second PCR were positive, or if the result of the PCR at birth was negative but those of the second and a third PCR, done between 8 and 12 weeks of age, were both positive. The infants were considered not to be infected if the results to the first and second PCRs were both negative, and their infection status was reported as unknown if the result to the first PCR was negative and the result of the second was missing.

Using a 2-sided χ^2 test with a continuity correction and a type I error of 0.05 we determined that a sample size of 400 women would provide 80% power to detect differences between 7% and 14% in acceptance of rapid testing and between 29% and 36% in acceptance of antiretroviral prophylaxis between the 2 arms. All analyses of acceptance of testing were intent-to-treat and included all women approached for enrollment.

Groups were compared using the χ^2 test or the Fisher exact test for categorical variables and the Wilcoxon rank sum test for continuous variables. Logistic regression was performed to identify prognostic factors of acceptance and adjust for potential confounding. All *P* values were 2-sided, with *P*<0.05 considered to indicate statistical significance. The software used for statistical analysis was SAS version 9.1 (SAS Institute, Cary, NC, USA) and StatXact version 1.0 (Cytel, Cambridge, MA, USA).

3. Results

From October 27, 2004, to September 30, 2006, a total of 7238 women were screened for study eligibility, 3596 in the intrapartum and 3642 in the postpartum arms (Fig. 1). Of the 1041 women (14%) whose HIV status was undocumented, 499 were excluded, leaving 542 (7.5%) eligible for the study (Fig. 1). The 2 main reasons (25.7%) for exclusion were presentation in advanced labor and clinical indication for immediate delivery.

A comparison of available baseline maternal characteristics of the eligible women showed that those who had received no prenatal care were in significantly higher proportion in the intrapartum arm, and that those who were delivered at HH were significantly more likely to present with ruptured membranes and a greater dilation of the cervix (Table 1). Of the 542 eligible women, 199 declined. The reasons for declining were similar across study arms and sites. The most frequent reason (36.7%) for declining rapid testing was knowing the result of a prior test that, however, was undocumented.

Overall, 343 women (63.3%) accepted enrollment and rapid HIV testing (Fig. 1 and Table 2). No significant differences in the rate of acceptance were observed between the intrapartum (66.8%) and postpartum (60.5%) arms or between the HH (61.8%) and MCC (64.8%) sites. However, compared with the HH site, there was a significantly larger difference between the intrapartum and postpartum acceptance rates at the MCC site (60.2% vs. 62.8% and 71.7% vs. 57.4%, respectively; interaction $P=0.04$). This difference at the MCC site remained statistically significant in the logistic regression analysis. Overall, older maternal age was associated with significantly lower acceptance (odds ratio [OR], 0.34; 95% confidence interval [CI], 0.13–0.81 for ages 26 to 34 years and OR, 0.23 [95% CI, 0.08–0.66] for age 35 years and older, compared with ages 14 to 17 years ($P=0.01$). Membrane status, cervical dilation, and frequency of contractions were not significantly associated with acceptance. Significantly more women presented with intact membranes in the intrapartum than in the postpartum arm, but no significant differences were observed regarding the other studied factors (Table 3). Of the 343 women who enrolled, 25 (7%) were lost to follow-up or withdrew from the study.

In the intrapartum and postpartum arms, respectively, the women agreed to participate in the study after median times of 14 minutes (interquartile range [IQR], 11–17 minutes and 15 minutes (IQR, 12–19 minutes), and the median times between initiation of VCT and availability of the rapid HIV test results were 44 minutes (IQR, 38–58 minutes) and 45 minutes (IQR, 37–60 minutes). In the intrapartum arm, all rapid HIV test results were available prior to delivery and all women but 1 received a single dose of nevirapine (the woman who did not receive the dose was in false labor). In the postpartum arm, all rapid HIV test results were available prior to hospital discharge.

Among the 343 enrolled women, 45 (13.1%; 95% CI, 9.7%–17.2%) were HIV positive (Table 4) and the infection rates did not significantly differ between arms or sites. The baseline characteristics of the HIV-infected and uninfected women were similar (Table 3). Maternal demographics and clinical characteristics did not differ significantly between the arms. In 96% of cases the infection was WHO stage I. At diagnosis the median maternal CD4⁺ count was 414 cells/ μ L and the median maternal viral load was 10,500 copies/mL.

In the intrapartum arm, all 16 women in true labor and with a positive result to at least 1 of the rapid HIV tests accepted prophylaxis with nevirapine. The median time between nevirapine administration and delivery was 2 hours and 8 minutes, excluding 3 women who first presented in false labor. Those who took a dose of nevirapine while in false labor did not receive another dose when they were readmitted in true labor. Eighteen of the 19 newborns exposed to HIV in the intrapartum arm were prophylactically treated with

nevirapine and zidovudine prior to hospital discharge, and the treatment was initiated within 12 hours of birth in 17 of these newborns (89.5%). The median time between birth and initiation of the prophylactic treatment was 1.28 hours (range, 0.25–20.18 hours).

In the postpartum arm, 1 of the 27 women with a positive result to at least 1 of the rapid HIV tests was later found to be uninfected. Twenty-six of the newborns were prophylactically treated with nevirapine and zidovudine, including the newborn whose mother had a false-positive result. The treatment was initiated within 12 hours of birth in 21 (81%) of the 26 newborns. The median time between birth and treatment initiation was 6.5 hours (range 2.5–19 hours).

The characteristics of the 45 newborns with HIV-infected mothers did not differ significantly between the 2 arms of the study (Table 5). Follow-up ranged between 8 and 26 weeks for 15 (79%) of the 19 newborns in the intrapartum arm and 19 (73%) of the 26 in the postpartum arm, and the follow-up duration allowed their infection status to be determined. Overall, 5 (15%) of the 34 newborns were diagnosed as being HIV infected, and 4 (12%) had been infected in utero. The time of transmission could not be determined for the fifth one. The infection rates among newborns and (later) infants were not statistically different in the intrapartum and postpartum arms (13% [2 of 15] and 16% [3 of 19], respectively).

4. Discussion

Women are often admitted to labor wards with an unknown HIV status. Postpartum counseling and testing, followed by neonatal prophylaxis, appears to be the most feasible and best accepted method to reduce MTCT [7,9,10]. This policy, however, excludes the benefit of intrapartum prophylaxis with a single dose of nevirapine [11].

Comparing the acceptance rates of VCT and possible prophylactic treatment in the 2 study arms was the primary aim of this study. The rates in the 2 study arms did not differ significantly (Table 2). However, although the rates were similar in both arms at the HH site and in the postpartum arm at the MCC site, they were higher in the intrapartum arm at the MCC site (interaction $P=0.04$) and the reason for the difference at the MCC site is unclear. Nevertheless, our results suggest that offering intrapartum VCT to women admitted in labor with an unknown HIV status will result in acceptance rates similar to or higher than those obtained when VCT is offered postpartum.

As much as 36.7% of the women declined participation, and their knowing their HIV status was the most common reason for declining. The acceptance rate of intrapartum VCT was reported to be 74.2% in Rwanda and two thirds of the women who declined VCT reported previous testing as the reason [5]. A study in Malawi with women in early labor reported a 41% acceptance of intrapartum VCT [8]. In that study, 31% of the women approached refused to speak with a counselor about VCT, and this refusal was the most common reason for the low overall acceptance rate. This and other studies investigating intrapartum testing did not include postpartum control groups [4,5,6,8].

The participants in our younger group (aged 14–17 years) were significantly more likely to accept VCT than those in our older groups (women aged 26–34 years and women aged ≥ 35 years). In the Rwanda study, significantly more women 35 years and older accepted to be tested [5]. In our study, women with intact membranes in the intrapartum group were significantly more likely to accept testing ($P=0.01$) (Table 3), but frequency of contractions and cervical dilation were not associated with accepting VCT. None of the other studies reported a possible association between acceptance of VCT and either rupture of the membranes or cervical dilation [5,6,8]. The Rwanda study only included women with a

cervical dilation of less than 7 cm on admission [5] and the other 2 studies only included women in early labor [6,8].

Implementing facility-based VCT was successful at both sites. The overall median time from initiation of VCT to availability of test results was 45 minutes, with no significant differences between arms or sites. In the intrapartum arm the results were available prior to delivery and a dose of nevirapine could be administered prior to delivery in all cases. None of the other studies reported on time to test results [5,6,8].

The time between nevirapine intake and delivery is important. The median time of 2 hour 8 minutes (excluding the participants initially admitted in false labor) allowed for sufficient maternal and fetal levels of nevirapine during delivery [12]. The median time between nevirapine intake and delivery was 4.2 hours in the study conducted in Malawi [8]. Only women in early labor and expected to be delivered 4 or more hours after presentation were included in that study, and the other 2 studies did not report time intervals [5,6].

In summary, our results suggest that intrapartum HIV testing is feasible and acceptable to a large proportion of women, and that it allows most of these women to receive a dose of nevirapine prior to delivery. The benefit of reducing intrapartum transmission with nevirapine was illustrated by the HIVNET 012 study and could be offered even in resource-poor settings [11]. While HIV testing during prenatal care is optimal, programs to prevent MTCT should suggest intrapartum VCT as the preferential option for women admitted in labor with an unknown HIV status.

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Figure 1.
Number of women randomized, screened, found to be eligible, enrolled, and found to be HIV positive.

Table 1Baseline characteristics of eligible women by study arm and delivery site^a

Characteristic	Intrapartum arm (n=241)	Postpartum arm (n=301)	P value	HH site (n=302)	MCC site (n=240)	P value	Overall (n=542)
Age at randomization, y	(n=241)	(n=301)		(n=302)	(n=240)		(n=542)
14-17	19 (8)	26 (9)		34 (11)	11 (5)		45 (8)
18-25	134 (56)	155 (51)	0.47	140 (46)	149 (62)	0.15	289 (53)
26-34	68 (28)	87 (29)		87 (29)	68 (28)		155 (29)
≥35	20 (8)	33 (11)		41 (14)	12 (5)		53 (10)
Membrane status	(n=210)	(n=256)		(n=239)	(n=227)		(n=466)
Intact	148 (70)	161 (63)	0.08	129 (54)	180 (79)	<0.001	309 (66)
Ruptured	62 (30)	95 (37)		110 (46)	47 (21)		157 (34)
Cervical dilation, cm	(n=207)	(n=249)		(n=229)	(n=227)		(n=456)
0-3	106 (51)	111 (45)	0.30	86 (38)	131 (58)	<0.001	217 (48)
4-6	62 (30)	92 (37)		82 (36)	72 (32)		154 (34)
≥7	39 (19)	46 (18)		61 (27)	24 (11)		85 (19)
Frequency of contractions	(n=235)	(n=286)		(n=288)	(n=233)		(n=521)
None	13 (6)	10 (3)	0.18	21 (7)	2 (1)	0.39	23 (4)
Irregular	115 (49)	131 (46)		118 (41)	128 (55)		246 (47)
Labor type	107 (46)	145 (51)		149 (52)	103 (44)		252 (48)
Prenatal care	(n=195)	(n=230)		(n=212)	(n=213)		(n=425)
Yes	130 (67)	179 (78)	0.01	156 (74)	153 (72)	0.68	309 (73)
No	65 (33)	51 (22)		56 (26)	60 (28)		116 (27)

Abbreviations: HH, Helderberg Hospital; MCC, Macassar Midwife Obstetric Unit.

^aValues are given as number (percentage) unless otherwise indicated.^bWomen with unknown values for a characteristic were excluded from analyses involving the characteristic.^cThe χ^2 test was used for nominal variables and the Mantel-Haenszel χ^2 test for trend was used for ordinal variables.

Table 2

Acceptance of voluntary counseling and rapid HIV testing by eligible women^a

Variable	Percentage of participants who accepted enrollment and rapid HIV testing (95% CI)		Difference between randomization arms(95% CI)	P value for site and study arm interaction
	Intrapartum	Postpartum	Overall	
Overall	66.8 (161 of 241) (60.5–72.7)	60.5 (182 of 301) (54.7–66.0)	63.3 (343 of 542) (59.1–67.4)	–6.3 (–14.5 to 1.8)
By site ^a				
HH	60.2 (62 of 103) (50.1–69.7)	62.8 (108 of 172) (55.1–70.0)	61.8 (170 of 275) (55.8–67.6)	2.6 (–9.3 to 14.5)
MCC	71.7 (99 of 138) (63.4–79.1)	57.4 (74 of 129) (48.4–66.0)	64.8 (173 of 267) (58.7–70.5)	–14.4 (–25.7 to –3.0)
Difference between sites	11.5 (–0.5 to 23.6)	–5.4 (–16.6 to 5.8)	3.0 (–5.1 to 11.1)	0.04

Abbreviations: CI, confidence interval; HH, Helderberg Hospital; MCC, Macassar Midwife Obstetric Unit.

^aSome women who presented at MCC were transferred to HH prior to delivery. Women among these probably declined participation, but it is unknown whether they were approached at MCC or HH. These analyses were performed assuming that, in each arm of the study, the proportion of those who declined after they were approached at MCC but were delivered at HH was the same as the proportion of women who, in the same situation, accepted to enroll. Otherwise, the actual site of approach and enrollment was used. In a sensitivity analysis, acceptance was also compared according to actual site of delivery, which was available for all women, with similar results (interaction $P=0.02$).

Table 3
Baseline characteristics of enrolled women by randomization arm and true HIV serostatus^a

Characteristic	Study arm		True HIV status		Overall
	Intrapartum	Postpartum	Positive	Negative	
Age at randomization, y	(n=161)	(n=182)	(n=45)	(n=298)	(n=343)
14–17	21 (13)	20 (11)	2 (4)	39 (13)	41 (12)
18–25	85 (53)	100 (55)	27 (60)	158 (53)	185 (54)
26–34	44 (27)	48 (26)	13 (29)	79 (27)	92 (27)
≥35	11 (7)	14 (8)	3 (7)	22 (7)	25 (7)
Membrane status	(n=149)	(n=162)	(n=40)	(n=271)	(n=311)
Intact	112 (75)	100 (62)	29 (73)	183 (68)	212 (68)
Ruptured	37 (25)	62 (38)	11 (28)	88 (32)	99 (32)
Cervical dilation, cm	(n=145)	(n=155)	(n=41)	(n=259)	(n=300)
0–3 cm	79 (54)	70 (45)	17 (41)	132 (51)	149 (50)
4–6	41 (28)	57 (37)	18 (44)	80 (31)	98 (33)
≥7	25 (17)	28 (18)	6 (15)	47 (18)	53 (18)
Frequency of contractions	(n=161)	(n=177)	(n=44)	(n=294)	(n=338)
None	10 (6)	6 (3)	1 (2)	15 (5)	16 (5)
Irregular	81 (50)	84 (47)	21 (48)	144 (49)	165 (49)
Labor-type	70 (43)	87 (49)	22 (50)	135 (46)	157 (46)
Prenatal care	(n=127)	(n=126)	(n=35)	(n=218)	(n=253)
Yes	84 (66)	93 (74)	25 (71)	152 (70)	177 (70)
No	43 (34)	33 (26)	10 (29)	66 (30)	76 (30)
Gestational age at birth, wk	(n=161)	(n=182)	(n=45)	(n=298)	(n=343)
≤33	3 (2)	7 (4)	1 (2)	9 (3)	10 (3)
34–36	35 (22)	37 (20)	15 (33)	57 (19)	72 (21)
≥37	123 (76)	138 (76)	29 (64)	232 (78)	261 (76)

^aValues are given as number (percentage) unless otherwise indicated. Women with an unknown value for a given characteristic were excluded from analyses of that characteristic.

^bThe χ^2 test was used for nominal variables and the Mantel-Haenszel χ^2 test for trend was used for ordinal variables.

Table 4

Seroprevalence among enrolled women by site of approach for enrollment ^a

Delivery Site	HIV prevalence (95% CI)		Difference between arms (95% CI)	P value for difference between arms	P value for site and arm interaction
	Intrapartum arm	Postpartum arm			
Overall	11.8 (19 of 161) (7.3–17.8)	14.3 (26 of 182) (9.6–20.2)	13.1 (45 of 343) (9.7–17.2)	2.5 (–4.6 to 9.6)	0.50
HH	12.7 (8 of 63) (5.7–23.5)	12.0 (13 of 108) (6.6–19.7)	12.3 (21 of 171) (7.8–18.2)	–0.7 (–10.9 to 9.6)	0.37
MCC	11.2 (11 of 98) (5.7–19.2)	17.6 (13 of 74) (9.7–28.2)	13.9 (24 of 172) (9.2–20.0)	6.3 (–4.3 to 17.0)	0.23

* Values are given as percentage unless otherwise specified. We used cord blood specimens with complete site and treatment arm information. The 2 women with a positive result to the immunosorbent test but an indeterminate Western block result were excluded from this analysis.

Table 5Characteristics concerning the newborns/infants^a

Characteristic	Intrapartum arm	Postpartum arm	Overall	P value
No. of newborns	19	26	45	
Male sex	10 (53)	10 (38)	20 (44)	0.34 ^b
Type of delivery				
Vaginal	17 (89)	25 (96)	42 (93)	0.56 ^c
Cesarean	2 (11)	1 (4)	3 (7)	
Median gestational age at birth, wk	38	38	38	0.85 ^d
Median birth weight, g	2930	3193	3150	0.41 ^d
Received antiretroviral prophylaxis	16 (100) ^e	25 (96)	41 (97)	>0.99 ^c
Had follow-up visits between 5 and 24 wk	15 (79)	19 (73)	34 (76)	0.74 ^c
Feeding method chosen at delivery				
Bottle exclusively	13 (68)	19 (73)	32 (71)	0.73 ^b
Breast exclusively	6 (32)	7 (27)	13 (29)	
Adhered to chosen feeding method ^f	11 (73)	15 (79)	26 (76)	>0.99 ^c
Had infection status defined	15 (79)	19 (73)	34 (71)	0.73 ^b
Were found to be infected	2 (13)	3 (16)	5 (15)	>0.99 ^c
Infected in utero	2	2	4	
Infected, time unknown	0	1	1	

^aValues are given as number (percentage) unless otherwise indicated.^bBy the χ^2 test.^cBy the Fisher exact test.^dBy the Wilcoxon rank sum test.^eThese were the newborns of the women who were in true labor and had at least 1 positive rapid HIV test result.^fThese were the infants who had follow-up visits.