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Prevalence of HIV among women entering labor who accepted or declined voluntary counseling and testing

Gerhard B. Theron^{a,*}, Mae P. Cababasay^b, Russell B. Van Dyke^c, David E. Shapiro^b, Jeanne Louw^d, D. Heather Watts^e, Marc Bulterys^f, Linda M. Styer^g, and Robert Maupin^h

^aDepartment of Obstetrics and Gynaecology, Faculty of Health Sciences, Stellenbosch University and Tygerberg Hospital, Cape Town, South Africa

^bCenter for Biostatistics in AIDS Research, Harvard School of Public Health, Boston, USA

^cDepartment of Pediatrics, Tulane University Health Sciences Center, New Orleans, USA

^dKidCru, Department of Pediatrics and Child Health, Faculty of Health Sciences, Stellenbosch University and Tygerberg Hospital, Cape Town, South Africa

^ePediatric, Adolescent and Maternal AIDS Branch, Centre for Research for Mothers and Children, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, USA

^fGlobal AIDS Program, Beijing, China

^gBloodborne Viruses Laboratory, Wadsworth Center, New York State Department of Health, Albany, USA

^hHealth Science Centre, Louisiana State University, Pediatric ACTU, New Orleans, USA

Abstract

Objective—To assess whether there was a difference in HIV seroprevalence between eligible women who declined and those who agreed to participate in a study of voluntary counseling and testing among women entering labor with unknown HIV status in South Africa.

Methods—Anonymous cord blood specimens were collected—as dried blood spots—from all women approached for participation in a cluster-randomized trial. No patient identifiers were included on the cord blood specimens. The dried blood spots were analyzed for HIV antibody via enzyme immunoassay and western blotting.

Results—Of 7238 women screened for study participation, 1041 (14.4%) had undocumented HIV status; of these women, 542 were eligible for inclusion and 343 enrolled. Based on 513 evaluable samples, the overall seroprevalence was 13.3% (95% confidence interval [CI], 10.4–16.5), which was similar to the 13.1% (95% CI, 9.7–17.2) seroprevalence among the 343 enrolled women.

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*Corresponding author: Gerhard B. Theron, Department of Obstetrics and Gynaecology, Faculty of Health Sciences, PO Box 19063, Tygerberg 7505, South Africa. Tel.: +27 21 9389209; fax: +27 21 9322455. address: gbth@sun.ac.za.

Conflict of interest

The authors have no conflicts of interest.

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Conclusion—Seroprevalence among eligible women was similar to that among enrolled women, which indicates that study participation did not select for a group with an HIV seroprevalence substantially different from that among women who declined to enroll.

Keywords

Anonymous testing; HIV prevalence; Study participation; Voluntary counseling and testing

1. Introduction

During 2006, the National Department of Health in South Africa estimated that only 47% of pregnant women in the public health sector were tested for HIV [1]. More recently, lack of HIV testing was estimated to account for 46% of missed opportunities to intervene with antiretrovirals to reduce the risk of mother-to-child HIV transmission in Western Cape, South Africa [2]. Many women in South Africa enter labor with an undetermined HIV status. Protocol P1031A of the International Maternal Pediatric and Adolescent AIDS Clinical Trials Group (IMPAACT) was a cluster-randomized study of the feasibility and acceptance of intrapartum versus postpartum voluntary counseling and testing (VCT) for women who presented for delivery with undetermined HIV status [3].

There is a paucity of knowledge about the prevalence of HIV among women declining testing [4,5]. The aim of the present study was to determine the prevalence of HIV among eligible women who met the IMPAACT P1031A inclusion criteria in order to enable assessment of whether seroprevalence among eligible women who chose not to participate in the study differed from that among women who agreed to participate.

2. Materials and methods

In the present study, the HIV status of all women eligible for enrollment in IMPAACT P1031A [3] was determined in a blinded fashion. The original study was a prospective, cluster-randomized trial carried out between October 1, 2004, and September 30, 2006, to determine the feasibility and acceptance of intrapartum versus postpartum VCT, and the acceptance of antiretroviral prophylaxis by HIV-infected women for themselves and their infants [3]. Both studies were conducted at the Macassar Midwife Obstetric Unit and Helderberg Hospital, Somerset West, Western Cape, South Africa. The clinical trial—including anonymous testing of all eligible women—was approved by the Research Ethics Committee of the Faculty of Health Sciences of Stellenbosch University (N04/04/081).

Women were eligible for the study if they fulfilled the following criteria: 14 years of age or older; undocumented HIV serostatus; at least 28 weeks pregnant; and admitted for delivery based on a diagnosis of active labor or rupture of membranes with expected delivery, planned induction of labor/cesarean delivery, or obstetric/medical complications for which delivery was indicated.

Women were ineligible if there was documentation of previous or current maternal antiretroviral therapy; progression to the second stage of labor or clinical indication for immediate delivery; an obstetric emergency in which the woman was medically unstable; or a diagnosis of fetal death or fetal anomaly incompatible with life.

Research counselors and study nurses determined eligibility. Because pregnant women approached for participation were considered to be vulnerable, study staff avoided recruitment approaches that could be perceived as coercive or misleading. Women were able to decline testing at any time during counseling. Selected characteristics of all eligible women were abstracted from the delivery log. Eligible women were cluster randomized—

according to calendar week of presentation—to undergo either intrapartum or postpartum VCT; the testing algorithm has been reported in full elsewhere [3].

Cord blood specimens were collected in an anonymous, unlinked fashion from all eligible women, regardless of whether they participated in the original study. This anonymous sampling was conducted in a similar manner to that used in the South African national annual prenatal HIV seroprevalence survey, where an additional blood specimen is obtained, without consent, when blood is taken for syphilis serology and blood grouping during the booking appointment [1,6]. Cord blood was collected as dried blood spots (DBS) on filter paper and stored at 4°C. No patient identifiers were included on the cord blood specimens; only the site name, the date and time of collection, and the study arm assigned for that week were documented. This information enabled HIV prevalence among all eligible women to be compared with that among the women who enrolled. Comparisons by randomization group and site of delivery could also be made. Evaluable DBS specimens were those from eligible women and had complete information regarding site and randomization arm.

Stored DBS specimens were tested via enzyme immunoassay (EIA) and western blot analysis at the Bloodborne Viruses Laboratory, Wadsworth Center, New York State Department of Health, Albany, NY, USA. The EIA (Genetic Systems rLAV; Bio-Rad Laboratories, Hercules, CA, USA) was run according to the manufacturer's instructions with 3 additional controls: Centers for Disease Control and Prevention (CDC) DBS high positive; CDC DBS low positive; and CDC DBS negative. Reactive specimens were retested with EIA. Repeatedly reactive specimens were tested with a western blot kit (GS HIV-1 Western Blot; Bio-Rad Laboratories) according to the manufacturer's instructions. Specimens were considered HIV positive if they were repeatedly reactive on EIA and had positive western blot results.

The randomization groups were compared using the χ^2 test for categorical variables and the Cochran–Armitage trend test for ordinal variables. The Zelen test for homogeneity of odds ratios was used to assess potential differences in acceptance over time by site, and seroprevalence by randomization group. All *P* values were 2-sided, with *P* < 0.05 considered to indicate statistical significance. Exact binomial methods were used to calculate 95% confidence intervals (CIs). Statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC, USA) and StatXact version 1.0 (Cytel, Cambridge, MA, USA).

3. Results

Of 7238 women screened for study participation from October 1, 2004, to September 30, 2006, 1041 (14.4%) had undocumented HIV status, of whom 542 (7.5%) were eligible for participation. Of the eligible women, 343 (63.3%) accepted VCT and were enrolled in the study [3]. The most common reason (92.5%) for ineligibility was documented HIV status (Table 1).

The most common reason (36.7%) for women declining VCT was knowledge of their HIV status, despite it not being documented in their patient records. Women who knew their HIV status were not asked to disclose it. The overall acceptance rate decreased significantly (*P* = 0.004) from 75.4% to 61.5% to 57.6%, respectively, during the accrual periods October 1, 2004, to July 27, 2005; July 28, 2005, to February 28, 2006; and March 1 to September 30, 2006. A decrease was observed at both study sites: from 72.0% to 66.4% to 62.9% at Macassar Midwife Obstetric Unit; and from 76.2% to 56.5% to 51.6% at Helderberg Hospital. The association between delivery site and accrual period was not significant (*P* = 0.27). The characteristics of women who enrolled and those who declined have been reported previously [3].

Anonymous DBS samples with complete information regarding study site and randomization arm were available for 513 (94.6%) of the 542 eligible women. The overall seroprevalence among these 513 women was 13.3% (95% CI, 10.4–16.5), which was similar to the seroprevalence of 13.1% (95% CI, 9.7–17.2) among the 343 enrolled women (Table 2). Comparison by randomization group and by site did not reveal any significant differences in seroprevalence (Table 2).

4. Discussion

The general perception is that women who know that they are HIV positive may choose not to undergo VCT. A Canadian study found a 3.3-fold higher seroprevalence among women opting out of prenatal HIV screening in a country with a low HIV prevalence [4]. In a study from South Africa, where there is a higher HIV prevalence, women who initially declined prenatal HIV screening had a seroprevalence rate of 44%, compared with a background rate of 29% [5]. Among Ugandan women attending a prenatal clinic, those who accepted VCT had a similar or higher HIV prevalence compared with those who underwent anonymous testing [7]. During periods with a high uptake of VCT, seroprevalence was similar (13% vs 14%), whereas it was significantly higher among women who underwent VCT (17% vs 8%) when uptake was less than 70%. Other studies investigating intrapartum HIV testing for women entering labor with unknown HIV status did not report the HIV prevalence among women declining VCT [8–13]. The rate of acceptance ranged from 69% to 90% in these studies [8–11]. The rate of acceptance in IMPAACT P1031A was 63.3% [3]. The present study included anonymous cord blood samples from all women eligible for enrollment in IMPAACT P1031A and provides important information on the HIV status of women declining VCT. The proportion of women who declined participation increased during the study period, possibly because increasing numbers of women knew their HIV status.

The overall seroprevalence among the 513 anonymous samples was 13.3%, which was similar to the 13.1% seroprevalence among the 343 enrolled women (Table 2). The social and medical interventions that accompany an advancing epidemic will increase the proportion of the population with a known HIV status. The decrease in acceptance rate over the 2-year study period probably reflects this evolving process.

During the past 30 years, the evolving HIV pandemic has resulted in an unprecedented quantity of research into perinatal HIV. However, knowledge of HIV prevalence among women declining to participate in studies of perinatal HIV transmission is of critical importance in interpreting the results of such investigations.

In the present study, HIV seroprevalence among women who were eligible for enrollment in an investigation of VCT among parturients with unknown HIV status was similar to that among women who enrolled. The inference is that study participation did not select for a group with a seroprevalence substantially different from that among women who declined to enroll.

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Table 1Reasons for ineligibility and declining participation in IMPAACT P1031A [3] by accrual period ^a

	October 1, 2004, to July 27, 2005 ^b	July 28, 2005, to February 28, 2006	February 29 to September 30, 2006	Overall
Reasons for ineligibility	n=1321	n=2567	n=2808	n=6696
Documented HIV status	1186 (89.8)	2386 (92.9)	2625 (93.5)	6197 (92.5)
Progressed to second stage of labor/indication for immediate delivery	54 (4.1)	106 (4.1)	108 (3.8)	268 (4.0)
Private patient	33 (2.5)	41 (1.6)	52 (1.9)	126 (1.9)
Planned cesarean delivery or induction	24 (1.8)	11 (0.4)	3 (0.1)	38 (0.6)
Intrauterine fetal death	9 (0.7)	6 (0.2)	7 (0.2)	22 (0.3)
Obstetric emergencies	8 (0.6)	8 (0.3)	6 (0.2)	22 (0.3)
Other ^c	7 (0.5)	9 (0.4)	7 (0.2)	23 (0.4)
Reasons for declining	n=31	n=84	n=84	n=199
HIV status known but not documented	1 (3.2)	32 (38.1)	40 (47.6)	73 (36.7)
Did not want to know status	6 (19.4)	13 (15.5)	28 (33.3)	47 (23.6)
Did not want to participate in study	7 (22.6)	14 (16.7)	9 (10.7)	30 (15.1)
Thought they were not at risk for HIV	3 (9.7)	3 (3.6)	1 (1.2)	7 (3.5)
Labor too painful	0 (0.0)	0 (0.0)	3 (3.6)	3 (1.5)
Other ^d	14 (45.2)	22 (26.2)	3 (3.6)	39 (19.6)

Abbreviation: IMPAACT, International Maternal Pediatric and Adolescent AIDS Clinical Trials Group.

^aValues are given as number (percentage).^bThe first accrual period is 2 months longer than the other 2 periods (9 vs 7 months), so chosen because initial accrual restrictions were lifted on July 27, 2005.^cIncluding the following: less than 28 weeks pregnant; younger than 14 years of age; not in active labor; previous antiretroviral treatment; delivery before arrival at hospital; fetal distress; and language barrier.^dNo additional information was collected.

Table 2HIV prevalence by randomization group and delivery site among eligible and enrolled women ^a

	Intrapartum	Postpartum	Overall	P value
Eligible	29/227 (12.8)	39/286 (13.6)	68/513 (13.3)	0.78 ^b (0.79 ^c)
Macassar	13/100 (13.0)	14/113 (12.4)	27/213 (12.7)	
Helderberg	16/127 (12.6)	25/173 (14.4)	41/300 (13.7)	
Enrolled	19/161 (11.8)	26/182 (14.3)	45/343 (13.1)	0.50 ^b (0.19 ^c)
Macassar	8/82 (9.8)	14/75 (18.7)	22/157 (14.0)	
Helderberg	11/79 (13.9)	12/107 (11.2)	23/186 (12.4)	

^aValues are given as number (percentage) unless otherwise indicated.^b χ^2 test.^cTest for interaction between delivery site and randomization group using the Zelen test of homogeneity of odds ratios.