Original Article

Feasibility of infant cord blood HIV testing for anti-retroviral post-exposure prophylaxis*

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Abstract

Background: Many maternity hospitals in developing country settings deliver women who are of unknown HIV status. The main objectives of this study were to evaluate the acceptability of post-partum infant cord blood HIV testing and the subsequent uptake of interventions to prevent mother-to-child transmission of HIV.

Methodology: This was a cross-sectional study among infants delivered to women of unknown HIV status at the maternity ward of the Kenyatta National hospital, Kenya. At the time of delivery, five milliliters of cord blood was collected from consecutive singleton-birth infants born to women with unknown HIV status. After delivery, the women were counseled and consent was sought for HIV antibody testing of the cord blood. Anti-retroviral post-exposure prophylaxis was provided for HIV exposed infants and their mothers counseled on infant feeding.

Results: Overall 220 (87%) of the 253 mothers gave consent for HIV testing. This included 35 (90%) of 40 mothers of babies with HIV positive cord blood and 184 (86.4%) of 213 with HIV negative cord blood. Seventeen (48.6%) of the 35 women who knew their status accepted to administer anti-retroviral prophylaxis to their infants, and 28 (80%) chose to breast-feed their infants.

Conclusions: Infant cord blood testing is highly acceptable among women who deliver with an unknown HIV status and provides an additional entry point for prevention of mother-to-child transmission of HIV.

Key Words: Maternity; cord; blood; HIV; testing.

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Introduction

Ninety percent (90%) of more than 600,000 annual new paediatric HIV infections worldwide result from mother-to-child transmission (MTCT) [1]. MTCT HIV takes place during pregnancy, labour and after delivery through breastfeeding [2]. Among anti-retroviral (ARV) naïve women, estimated rates of MTCT transmission of HIV are 15 to 25% in non-breastfeeding populations and 25 to 35% in breastfeeding populations [3,4]. HIV infected children have a nine-fold increased risk of dying in the first 2 years of life compared to uninfected children [5]. Prophylaxis with ARV drugs significantly reduces MTCT in breastfed and non-breastfed infants of HIV infected women by 41 to 63% [6-12]. In sub-Saharan Africa, where 90% of the MTCT takes place, many women do not access antenatal care (ANC) and even when they attend, HIV testing is not routinely available. Providing HIV testing during pregnancy is one method used to bridge the gap. HIV infected women are then able to benefit from the single-dose of Nevirapine (NVP) regimen, which is effective in preventing MTCT of HIV as long as the mother receives her dose one hour before delivery and the baby's dose is given soon after delivery [13].

Even with these measures there is a subset of women admitted in the active stages of labour for whom voluntary counselling and testing (VCT) during labour are not options and for whom post-exposure ARV prophylaxis is the only option for their infants with either one of the two following therapies: i) postnatal infant Zidovudine (AZT) prophylaxis for 6 weeks, which has been shown to significantly reduce the risk of infant HIV infection

when initiated within 48 hours of delivery [14]; or ii) a combination of a single dose of NVP 2mg/Kg given immediately after delivery plus Zidovudine 4 mg/Kg given twice a day for 7days, which has also been shown to reduce the rate of MTCT of HIV to 15.3% at six weeks of life in breastfeeding babies, which is close to the 12% reported for babies exposed to the 2-dose mother and infant NVP protocol [15,16]. In order to extend these benefits to the infant there is a need to rapidly identify HIV exposed neonates.

In Kenya as elsewhere in sub-Sahara Africa, antenatal HIV testing is not yet available at all service delivery points. At Kenyatta National Hospital (KNH), the teaching hospital for University of Nairobi, 67% of the annual 6,000 deliveries are to women who did not attend the hospital's antenatal clinic (non-booked women), and up to 20% having not attended any ANC [17]. If one assumes that "non-booked' women did not have access to VCT, and given the efficacy of 2-dose NVP, only 10% of the possible infant HIV infections among infants of positive women accessing antenatal and delivery care in this institution would be averted. An additional difficulty is that non-clinic attendees have many other untreated problems such as anaemia, vitamin deficiencies, and sexually transmitted illnesses, conditions that further increase the risk of MTCT of HIV.

Infants of HIV positive women will have passively acquired HIV specific antibodies and therefore cord blood testing for HIV-specific antibodies allows rapid identification of infants who could benefit from ARV post-exposure prophylaxis, and safer infant feeding practices. Establishing acceptability of infant HIV cord blood testing, post-exposure ARV prophylaxis, and appropriate infant feeding practices will help open an additional entry point into prevention of mother-to-child transmission (PMTCT) of HIV and long-term care for the mother-infant pair.

Materials and Methods

A cross-sectional descriptive study was conducted at the labour ward of KNH from July to September 2001, to determine the acceptance of post-partum infant cord blood rapid HIV testing, ARV post-exposure prophylaxis, and choices of infant feeding among HIV positive women. Secondary objectives of this study were to determine the prevalence of HIV among this group of women and to describe associated factors.

The study subjects were neonates in the labour ward delivered to "non-booked" mothers. Neonates were excluded from the study if their mothers were too sick to give consent, or if the mother was already participating in another HIV related interventional study. Consecutive eligible mother-infant pairs were recruited every day: Monday to Friday between 8:00 a.m. to 4:00 p.m. Five millilitres (5.0 mL) of cord blood were drawn from each neonate who met the inclusion criteria. The blood was labelled with name, file number, date, and mode of delivery. Pre-test counselling was provided to eligible women, 6 hours post-delivery. During this session consent for participation in the study was sought from the mother. Women were given the option of linked and unlinked cord blood HIV testing. The cord blood samples of women who refused to participate in the study were destroyed and no further information was sought from this group of women. Demographic identifiers that would link the blood sample to the women (name and in-patient file number) were removed from the cord blood samples for women who opted for unlinked testing.

As well as an HIV risk assessment, the pre-test counselling provided the mother with information on HIV infection, prevention, and modes of transmission and the meaning of HIV antibody testing. The post-test counselling entailed breaking the news of the HIV test results, reinforcing the preventive education with an emphasis on use of antiretroviral drugs, and providing information on infant feeding options and safer sexual practices.

The investigator (I.W.I.) examined all the neonates and recorded the birth weight, head circumference, and gestational age based on physical and neurological signs according to Dubowitz [18]. Data on maternal demographic and obstetric characteristics was abstracted from the labour ward records and participating women were interviewed on sexual risk taking by use of standardised pre-coded study instruments. Neonate cord blood specimens were then sent to the immunology laboratory of KNH for HIV testing. The results of the HIV test were available to the mothers within 2 hours of pre-test counselling.

Post-exposure prophylaxis (PEP) with AZT 4mg/Kg every 12 hours for six weeks was provided to HIV positive babies, the only PEP regimen with

demonstrated efficacy when this study was conducted [14].

PEP for all HIV positive babies was initiated within 12 hours from time of delivery. Infant feeding counselling was provided according to World Health Organization (WHO) and the Kenya Ministry of Health guidelines to the HIV positive women; however, free infant formula was not available.

At discharge, HIV positive women were invited to come back after 2 weeks for follow-up.

The health care providers in the study area were trained in PMTCT. During the study, regular meetings were held with providers and protocols were reviewed and reinforced.

Laboratory investigations

Screening for HIV IgG antibodies was done using Capillus® HIV-1/HIV-2 (Cambridge Diagnostics of Ireland) and confirmed with Immunocomb®II HIV 1 & 2 (Orgenics, Israel) according to the manufacturers' instructions.

Ethical Considerations

Written consent to conduct the study was obtained from the KNH ethics and research committee. Only those babies of mothers who gave a verbal informed consent were included. Laboratory results were provided to the clinician looking after the patient to assist in the management of the patients.

Data Analysis

Clinical and laboratory data were analysed using the Statistical Package for Social Sciences (SPSS) program. Simple proportions were used to determine the acceptability of neonate cord blood testing and subsequent uptake of PMTCT interventions. The characteristics of the women were described using means and medians for continuous variables and proportions for categorical ones. Women who tested HIV positive were compared to HIV negative women to determine demographic, behavioural, or clinical characteristics that would help identify women with a higher likelihood of being HIV positive and whose babies would then be prioritised for cord blood testing. A sub-analysis to determine factors associated with uptake of the PMTCT interventions was carried out.

Results

Cord blood samples were collected from 253 neonates of "non-booked" women, which included 134 (53%) males and 119 (47%) females. These neonates and their mothers formed the study population.

Demographic characteristics

Characteristics of the study population are shown in Table 1. The median age of the women was 23 years (range: 15 to 39 years), with 171 (70%) reporting that they are currently or have previously been married. Two hundred (79%) women lived in urban centres. Only 57 (23%) of the women reported that they had not completed 8 years of primary education.

Table 1. Characteristics of the Study Population.

	Median (range)/%
Maternal socio-demographic characteristics	
Median Age (years)	23 (range 15-39)
Previously or currently married	177 (70%)
Urban domicile	200 (79%)
Highest level of education achieved	
incomplete primary education (< 8 yrs)	57 (23%)
incomplete secondary education (8-11yrs)	58 (23%)
completed secondary education and beyond (≥ 12yrs)	73 (29%)
Median age of sexual debut (years)	18
One life time sexual partner	119 (47%)
Obstetric characteristics	
Primigravida	122 (48%)
At least one ANC attendance	181 (71%)
Timing of the 1st ANC visit	
< 6 months gestation	59 (23%)
6-7 months	102 (40%)
≥ 8 months	20 (8%)
Plans to have another baby	106 (42%)
Undecided about future pregnancy	84 (33%)
No plans for a future pregnancy	29 (4%)
Delivery and Infant Characteristics	
Mode of delivery	
SVD	182 (72%)
Emergency caesarean section	66 (26%)
Other*	5 (2%)
< 4 hours of ruptured membranes	144 (57%)
Median birth weight	2500gms
Male: female ratio	1.13:1

*Assisted vaginal delivery, breech.

Seventy-two (29%) of the 253 women reported that they did not receive any ANC; 36 (14%) attended once; and 145 (57%) had > 2 visits. Fifty-

nine (23%) started ANC before 6 months' gestation; 102 (40%) started at 6 to 7 months' gestation, and 20 (8%) attended at 8 months or later. Women in this study had a median number of two pregnancies. Women were interviewed regarding future fertility plans and 106 (42%) indicated that they wished to have another child in future; 84 (33%) were undecided; and 29 (4%) wanted no more children. Thirty-four women did not respond to this question.

The median age at sexual debut was 18 years with 23% of the women reporting first coitus between the ages of 13 and 16 years; 55% for 17 to 20 years; and 8% for 21 to 25 years. One hundred and nineteen (47%) women reported one lifetime sexual partner, and 100 (40%) more than one partner. Thirty-four (13%) of the women did not disclose their age of sexual debut or number of lifetime sexual partners.

The median gestation age of the 253 infants was 38 weeks (range: 26 to 42 weeks) and 182 (72%) babies were born via spontaneous vertex delivery. Overall the median duration of membrane rupture was 3 hours with 43% of the women having more than 4 hours of ruptured membranes.

Acceptability of cord blood HIV testing

Out of the 253 neonates who had cord blood collected at the time of delivery, 220 (87%) of their mothers gave consent to linked testing for HIV while 33 (13%) accepted unlinked testing. Forty (16%) of the 253 cord bloods were positive for HIV antibodies. Acceptance of testing was not influenced by HIV status with 184 (86%) of 213 seronegative women and 36 (90%) of 40 seropositive women accepting HIV testing (p = 0.5).

Comparison of mothers of babies with seropositive and seronegative cord blood

The 40 HIV positive women had a median age of 30 years with only 7 (17%) aged less than 20 years. In comparison, 78 (37%) of the 213 HIV negative women were aged less than 20 years [OR = 0.37 (95% CI 0.14, 0.92), p = 0.02]. The median age of HIV negative women was 21 years. A higher proportion of HIV positive women reported that they had less than 8 years of completed primary education, 17 (42%) of 40 versus 40 (19%) of 213, OR = 3.20 (95% CI 1.47, 6.93). HIV positive women were less likely to report non-attendance of antenatal clinics compared to seronegative women, 5 (12%) of 40 versus 67 (31%) of 213, OR=0.31 (95% 0.10, 0.88) p= 0.05. Eleven (31%) of the 36 seropositive women reported having only one lifetime partner compared to 108 (59%) of 183 seronegative women, a significant difference OR = 0.31 (95% CI 0.13, 0.70) P = 0.002. Only 8 (22%) of 36 positive women reported that they would like to have another baby compared to 98 (54%) of 183 seronegative women, OR = 0.25 (95% CI 0.1, 0.61) P= 0.006. HIV status was not associated with acceptance to testing, marital status, residence, or mode of delivery; nor was it associated with the, gender and gestational age of the baby. Data on the maternal and infant correlates of HIV positive cord blood is presented in Table 2. In a multivariate analysis, the mother's number of lifetime sexual partners was the only factor found to be significantly associated with HIV infection. Compared to women with one sexual partner, the risk of being HIV seropositive was OR = 3 (95% CI 1.5-8.9) for women reporting 2 to 3 lifetime partners and OR=10 (95% CI 2.03-47.7) for women with > 4 lifetime sexual partners.

Table 2. Maternal and infant correlates of HIV seropositive cord blood.

	HIV positive client N = 40		HIV negative client N = 213		P
Accepted HIV test	36	(90%)	184	(86%)	0.5
Age <20 years	7	(17%)	78	(37%)	0.02
Previously or Currently Married	29	(72%)	148	(69%)	0.7
Residence urban	30	(75%)	170	(80%)	0.49
< 8 years of education	17	(42%)	40	(19%)	0.001
Non-ANC Attendance	5/36	(12%)	67	(31%)	0.05
Spontaneous vertex delivery	27	(67%)	155	(73%)	0.5
Only one life time sexual partner	11/36	(31%)	108/183	(59%)	0.002
Would like to have another baby	8/36	(22%)	98/183	(54%)	0.006
Male to female ratio	1.5:1		1.1:1		0.33
Gestation <37weeks*	21/36	(58%)	83/183	(45%)	0.29

*Dubowitz criteria.

Acceptance of PMTCT interventions

Of 40 HIV positive mothers, four refused linked HIV testing, while one baby died soon after delivery and therefore these five mothers were not

offered prophylactic Zidovudine. So, the remaining 35 mothers of newborns who tested positive for HIV were offered neonatal Zidovudine and counselled on infant feeding. Seventeen (49%) of 35 women accepted to administer it to the infants. Two women left the drug in the ward at discharge and it was not clear whether they had administered any of the drug to the babies. Twenty-eight women (80%) chose to breast-feed; 3 (8.0%) formula fed; and 4 (4.4%) opted for cow's milk.

Mothers who accepted cord blood testing and whose infants tested HIV positive (36 including the one who lost her baby) were requested to come back after two weeks for follow-up and further counselling and 20 (56%) of them returned as requested. At this visit, 12 (60%) of the women indicated that they had informed their partners. Ten (83%) of the 12 women who informed their partners of the positive HIV seropositive status accepted to give their babies AZT compared to only 2 (25%) of the 8 women who did not inform their partners of the HIV sero-status. Women who had disclosed their HIV status to their partners were significantly more likely to give their infants AZT [OR = 15.0 (95% CI 1.18, 311.93) p = 0.019 by 2-tailed Fishers exact test)]. Six of the ten partners who were informed of their wives' HIV sero-positive status went for testing to determine their own status. None of the women could afford infant HIV PCR testing, which was not available in the hospital, and were therefore referred to the pediatric out-patient clinic for follow-up and diagnostic testing of their children at the age of 18 months. This study was not funded to conduct the HIV PCR testing.

Discussion

Infant HIV cord blood testing was highly acceptable to this group of "non-booked" women and provided an additional opportunity for prevention of MTCT of HIV and entry into long-term HIV care. The high HIV test acceptance probably means that these women would have been willing to be tested if VCT services were available at the antenatal clinic.

The challenge to cord blood testing is disclosure of the mother's HIV status. This scenario presents the classic situation where mother's need might be in complete conflict with her newborn's needs. Nevertheless, as women's rights to privacy are respected, there must be recognition that children have a right to health and implicit in this is a right to access interventions that will protect them from life-threatening conditions such as HIV infection. It is worth noting that HIV infection rates were high among this group of women as indicated by the prevalence rate of 15.8%; that is, approximately one in every six neonates delivered to in this health facility was HIV exposed and without an intervention, a third of the exposed infants would be infected. Since 68% of the deliveries in this institution are to non-booked women, a PMTCT program which focused only on identifying HIV infected women in the antenatal clinic would fall far short of the goals of preventing HIV infection among infants born to the women accessing antenatal and delivery services in the institution. After this study was completed, HIV counseling and testing during labor was introduced; however, only half of the women with unknown HIV status were eligible because the others arrived in advanced stages of labor highlighting the need for an additional strategy for identifying HIV exposed infants eligible for post-exposure prophylaxis.

HIV prevalence was higher among women who reported some antenatal clinic attendance compared to those who had not. This group of women would have benefited from a more efficacious ARV prophylactic regimen if HIV testing services had been available in the antenatal clinics that they first attended. In this study population, only 5 (12.5%) of the 40 women identified as HIV infected through infant cord blood testing were symptomatic, and all of them were non-clinic attendants. Without testing only these 5 women would have been clinically diagnosed as HIV infected at the time of delivery, and even then would probably not have benefited from PEP because this service was not yet part of routine care.

In this study, 49% of the 35 women who knew their HIV status accepted to give their babies AZT prophylaxis and 20% opted to do replacement feeding. The low uptake of replacement feeding is not unexpected since free infant formula was not available and infant feeding counseling was provided when breast-feeding had already been initiated. The study did not explore the reasons for the low acceptance of Zidovudine prophylaxis nor factors that women took into account when making decisions about infant feeding. Low uptake of

interventions to prevent mother-to-child transmission of HIV has been reported in both research and routine health care settings and one study found that concerns about MTCT of HIV ranked 6th in the immediate list of concerns [19-23]. We postulate that fear of stigmatization, denial of positive HIV status, inadequate knowledge of the benefits of infant ARV prophylaxis, and long duration of the regimen all contributed to the low uptake of the PMTCT interventions. The development of shorter but efficacious post-exposure prophylaxis regimens that are administered under direct observation before discharge from the maternity ward should significantly increase uptake and compliance of post-natal infant ARV post-exposure prophylaxis; however, efficacy of such regimens is eroded by breast feeding [24].

This study once again demonstrated that partner involvement significantly increases the likelihood of compliance with PMTCT interventions. Although this analysis is weakened by the fact that 15 (44%) of the 36 positive women did not return for the follow-up visit, there is a high likelihood that non-clinic attendants were also non-drug adherent and did not disclose HIV infection status to their partners. The importance of partner involvement is underlined by the results of a study carried out in the same time period in Nairobi which found a 15-fold increased likelihood of compliance with infant AZT prophylaxis following couple counseling[25]. In most instances women are accompanied or visited by their partners when they deliver in hospital. There is a need to evaluate feasibility of couple counseling in the maternity setting as another way of strengthening primary prevention of HIV in post-natal women as well as PMTCT.

Post-exposure ARV prophylaxis for prevention of MTCT of HIV is effective [15]. A mature PMTCT program should therefore include routine infant cord blood testing for infants of women who failed to access testing in the antenatal and intrapartum period to facilitate early identification of infants requiring PEP with ARV drugs. Women who refused the post-test counseling should be given an appointment to come back for additional counseling where extra effort should be made to get HIV infected women to take their results, since her own care and further care of the child is dependent on the mother's acknowledgement of the results.

Infant cord blood testing is highly acceptable among women who deliver with an unknown HIV status and provides an additional entry point for PMTCT. The modest uptake of PMTCT interventions by this group of women points to the need for continued health education and advocacy for PMTCT.

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