

Evaluation of an Emergency Prevention Program for Mother to Child Transmission of HIV in British Columbia

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Abstract

Introduction: The objective of this study was to evaluate a province-wide program designed to identify HIV infection accurately and to prevent mother to child transmission among high-risk pregnant women of unknown serostatus.

Methods: Between 2000 and 2007, 347 high-risk women were identified through the Prevention of Mother to Child Transmission (PMTCT) program implemented in 27 hospitals across British Columbia. Rates of HIV transmission and details of the implementation of prophylaxis kits were assessed.

Results: Of the 346 high-risk mother-infant pairs identified and included in the provincial program, 35.4% of the mothers and 95.7% of infants received antiretroviral therapy for prevention of vertical transmission. Of 309 pairs who subsequently underwent HIV testing, five mothers were found to be HIV positive, an infection rate of 16.2/1000 in this cohort; the overall rate in BC is 0.68/1000 births. One of the five infants born to an HIV positive mother was infected with HIV.

Discussion: The program was successful in identifying a subgroup of pregnant women at increased risk of HIV infection; however, mother to child transmission occurred in one of five cases (20%). To reduce the risk of mother to child HIV transmission in BC to the lowest possible level, additional strategies such as increasing uptake of prenatal screening and point-of-care testing in labour and delivery may need to be explored.

Key Words: HIV in pregnancy, prevention of mother to child transmission (PMTCT), maternal child health

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Résumé

Introduction : Cette étude avait pour objectif d'évaluer un programme provincial conçu pour identifier l'infection au VIH de façon précise et pour prévenir la transmission mère-enfant chez les femmes enceintes exposées à des risques élevés dont l'état sérologique est inconnu.

Méthodes : De 2000 à 2007, 347 femmes exposées à des risques élevés ont été identifiées par l'intermédiaire du programme *Prevention of Mother to Child Transmission* (PMTCT) mis en œuvre au sein de 27 hôpitaux de Colombie-Britannique. Les taux de transmission du VIH et les détails de la mise en œuvre des trousseaux prophylactiques ont été évalués.

Résultats : Parmi les 346 paires mère-enfant exposées à des risques élevés identifiées et comprises dans le programme provincial, 35,4 % des mères et 95,7 % des nouveau-nés ont reçu une antirétrovirothérapie pour la prévention de la transmission verticale. Parmi les 309 paires qui ont par la suite été soumises au dépistage du VIH, une séropositivité pour ce qui est du VIH a été constatée chez cinq mères; en C.-B., le taux global est de 16,2/1 000 chez cette cohorte; en C.-B., le taux global est de 0,68/1 000 naissances. Un des cinq enfants issus d'une mère séropositive pour ce qui est du VIH présentait une infection au VIH.

Discussion : Le programme a réussi à identifier un sous-groupe de femmes enceintes exposées à un risque accru d'infection au VIH; cependant, une transmission mère-enfant a été constatée dans un cas sur cinq (20 %). Pour réduire le risque de transmission mère-enfant du VIH en C.-B. au plus faible niveau possible, il est possible que nous ayons à explorer des stratégies additionnelles, telles que des efforts visant à accroître la participation au dépistage prénatal et au dépistage au point d'intervention pendant le travail et l'accouchement.

INTRODUCTION

It is estimated that nearly 30% of people infected with human immunodeficiency virus in Canada are unaware that they are infected.¹ It is particularly important to know the HIV status of pregnant women, both for their own health and for preventing the transmission of HIV to their infant. In the absence of preventive interventions, the transmission rate of HIV from mother to child during pregnancy, delivery, or breastfeeding ranges from 15% to 40%.² Since 1994, the widespread use of antenatal, intrapartum, and neonatal antiretroviral therapy in developed countries, including Canada, has dramatically reduced this risk.^{3,4} With the advent of highly active antiretroviral therapy, it is now possible to suppress maternal viral loads to undetectable levels, allowing for vaginal delivery and vertical transmission rates of less than 2% in non-breastfeeding women.⁵⁻⁷

In British Columbia, HIV testing has been recommended as a routine component of antenatal care since 1994, and remarkable progress has been made in the last decade in identifying and managing HIV-positive pregnancies and preventing mother to child transmission.^{8,9} Ogilvie and colleagues reported that approximately 83% of pregnant women in the province underwent prenatal HIV testing in 2003/2004.¹⁰ All pregnant women known to be HIV positive in the province have access to a comprehensive program of HIV care, including expert consultation and administration of appropriate HAART regimens from the Oak Tree Clinic,¹¹ a tertiary referral centre for HIV-positive women and their children located at the Children's and Women's Health Centre of British Columbia. Since 1995, there has not been a single case of mother to child HIV transmission among the 401 singleton births to BC women engaged in HIV care at the Oak Tree Clinic.¹²

However, mother to child transmission of HIV still occurs, primarily among pregnant women who have not received adequate antiretroviral therapy.⁶ In many cases this is because these pregnant women have not been identified as HIV positive for several reasons: women may opt-

out of antenatal HIV testing, may not undergo prenatal testing due to limited or no prenatal care, or may acquire the infection or seroconvert in late pregnancy, after initially testing negative.¹³⁻¹⁵ The emergency Prevention of Mother to Child Transmission program was implemented in BC to identify and treat pregnant women who fall into these categories, using proven methods to prevent mother to child transmission of HIV. The BC PMTCT program, the first of its kind in Canada, coordinates the distribution, provision, and follow-up of short course prophylactic antiretroviral treatment for mother-infant pairs to 27 of the 53 obstetrical facilities across the province.¹⁶

The goal of this study was to evaluate the PMTCT program and its role in preventing vertical transmission of HIV over the years 2000 to 2007. Specific objectives were to describe the implementation and use of PMTCT kits, the characteristics of the population that accessed the kits, and the associated vertical transmission rates. To date, there have been very few published reports from developed countries, including Canada, evaluating PMTCT programs that provide antiretroviral treatment or prophylaxis to pregnant women with unknown or undocumented HIV serostatus. Ongoing evaluation of these initiatives is essential for the development of comprehensive prevention strategies to minimize vertical HIV transmission in BC, Canada, and beyond.

METHODS

We conducted a retrospective review of all mother-infant pairs with unknown HIV status at delivery who received peripartum prophylactic antiretroviral therapy as part of the emergency PMTCT program between September 1, 2000 and December 31, 2007. The emergency PMTCT program was initiated in September 2000 and now includes 27 hospitals across BC, with inclusion in the program based on geographic location and delivery volumes. Initially, 14 hospitals with more than 1000 deliveries per year were included in the program. In 2001 an additional 13 hospitals with more than 250 deliveries per year were added.

The program is a result of collaboration between the Centre for Excellence in HIV/AIDS Drug Treatment Program, housed at St. Paul's Hospital, Vancouver BC, and the Women and Family HIV Centre (Oak Tree Clinic), based at the Children's and Women's Health Centre of BC, also in Vancouver. The Drug Treatment Program oversees the centralized distribution of all antiretroviral agents to HIV positive individuals in BC. The Oak Tree Clinic coordinates clinical care and conducts surveillance of all births to HIV-positive women in BC. There is currently no enveloped

ABBREVIATIONS

HAART	highly active antiretroviral therapy
MTC	mother to child
NVP	nevirapine
PCR	polymerase chain reaction
ZDV	zidovudine
PMTCT	Prevention of Mother to Child Transmission

Characteristics of the five HIV positive mothers

Risk factors	Mode of delivery	Intrapartum ARVs to mother	ARVs to infant	Infant's HIV status
Drug use, sex trade work	Vaginal	ZDV	ZDV × 5 days,* NVP	Positive
Injection drug use, high-risk partner	Vaginal	None	ZDV, NVP	Negative
Injection drug use	Caesarean section	ZDV, NVP	ZDV, NVP	Negative
In correctional services	Caesarean section	ZDV, NVP	ZDV, NVP	Negative
Injection drug use	Vaginal	None	ZDV, NVP	Negative

ARV: antiretroviral; ZDV: zidovudine; NVP: nevirapine
 *Discontinued when infant tested HIV positive

funding for the PMTCT program; it is supported through the Oak Tree Clinic and Drug Treatment Program's base operational funding.

PMTCT kits containing intrapartum adult antiretroviral drugs, postpartum pediatric antiretroviral drugs, protocols for use of the prophylactic antiretrovirals, and requisitions for HIV testing were distributed to participating hospitals. Kits also included forms to order a replacement kit, which included a section to report additional information about kit implementation and maternal risk factor profiles.

Risk factor assessment in women presenting for delivery with unknown HIV status was performed by local health care providers. Distributed with the PMTCT kits were pre-printed checklists of the criteria for identifying individuals at high risk of HIV infection, a web address on which further guidelines could be found, and a telephone number for expert advice from Oak Tree Clinic personnel.¹⁷ On-site training for assessing risk was not provided to local health care providers because of the dispersed nature of the program across the province. Women were deemed at high risk if they self-identified as being at high risk for HIV infection, had a history of using injection drugs with needle sharing, had a sexual partner involved in high-risk activities, or had a sexual partner known to be HIV positive. High-risk women and their infants were assumed to be potentially HIV positive and eligible for the PMTCT program. Attending physicians or midwives then counselled these women on their risk of HIV infection, the nature and timing of HIV testing, and the schedule and side effects of antiretroviral medications. The PMTCT testing protocol recommended that high-risk women be tested for HIV infection using both HIV-PCR and enzyme immunoassay tests. Point-of-care test kits were not available for use during this study period.

At the time of this study, the PMTCT prophylaxis protocol recommended the following for women in

labour: a single oral dose of 200 mg NVP plus intravenous ZDV administered with a loading dose of 2 mg/kg over 1 hour, followed by an infusion of 1 mg/kg/hour until the umbilical cord was clamped. The protocol for infants born to an eligible mother comprised administration of a single 2 mg/kg dose of oral NVP and an oral regimen of ZDV at a dose of 2 mg/kg every 6 hours for up to 6 weeks. For infants who could not tolerate oral medications, intravenous ZDV was advised at a dosage of 1.5 mg/kg.⁶ Each time a kit was used, the centre was instructed to contact the multidisciplinary care team at the Oak Tree Clinic, who would follow up with the mother and infant. If maternal HIV serology and HIV-PCR indicated that the mother was HIV negative, infant ZDV prophylaxis was immediately discontinued in consultation with pediatric HIV specialists. For infants of HIV-positive mothers, further follow-up and testing was provided, and newly diagnosed HIV-positive women were referred to the Oak Tree Clinic for HIV care in the postpartum period. Funding for travel to these appointments was covered as needed by the provincial Travel Assistance Program, and further care was typically shared with the woman's and infant's local health care providers.

This study was a retrospective review of the data available from PMTCT kit replacement forms, which were submitted to the coordinating centre each time an emergency prophylaxis kit was used at a participating hospital. Data collected on these forms included basic demographic and clinical information such as HIV risk factors, pregnancy outcome, mode of delivery, use of antiretroviral drugs at delivery, use of antiretroviral drugs for the neonate, and HIV status of the mother and neonate.

Ethics approval for the study was provided by the BC Women's Hospital and Health Centre Research Review Committee and the University of British Columbia Clinical Research Ethics Board.

RESULTS

A total of 350 emergency PMTCT kits were used for women with unknown HIV status over the study period. This included three twin pregnancies and four instances of false labour in which antiretroviral drugs were administered but no birth was recorded during hospital admission. The average number of kits used per year was 49: six kits were used in 2000 (the program started in September), 40 in 2001, 56 in 2002, 39 in 2003, 52 in 2004, 41 in 2005, 45 in 2006, and 70 in 2007 (date of use was unknown for one kit). Kits were used by all health authorities in the province, and most kits, with site identified, were used by the Provincial Health Services Authority (n = 146), which includes BC Women's Hospital and Health Centre (the location of the Oak Tree Clinic), followed by the Fraser (n = 93), Vancouver Coastal (n = 46), Vancouver Island (n = 34), Interior (n = 19), and Northern (n = 7) Health Authorities.

Of the 347 pregnant women identified, the mean age at delivery was 28 years (range 15 to 42). Risk factors were documented for a subgroup of 169 women: 57% reported injection drug use (n = 96), 41% other drug use (n = 69), 17% sex trade work (n = 28), 14% hepatitis C infection (n = 24), and 8% had an HIV positive partner (n = 14). Approximately 17% of women reported multiple risk factors (n = 60).

Overall, 35.4% of the 347 women received intrapartum antiretroviral prophylaxis (n = 123), with 26.5% receiving both ZDV and NVP (n = 92), 6.0% receiving only ZDV (n = 21), and 2.9% receiving only NVP (n = 10). In contrast, 95.7% of the 346 infants received antiretroviral prophylaxis (n = 331): 85.3% received both ZDV and NVP (n = 295), 9.2% received ZDV only (n = 32), and 1.2% received NVP only (n = 4). Results of follow-up testing were available for 89% of the 346 mother–infant pairs (n = 309), and five mothers were subsequently found to be HIV positive, yielding a maternal HIV infection rate of 16.2 per 1000 in this high-risk cohort. The clinical characteristics of these women who tested HIV positive are described in the Table. The five women identified as HIV positive through this program were representative of the high-risk population that enrolled in the PMTCT program, with three of five women reporting injection drug use, and four of five residing in Greater Vancouver. Of the five women who were HIV positive, one case of vertical transmission was documented, indicating a risk of mother to child transmission of approximately 20% despite emergency prophylaxis.

DISCUSSION

The goal of this emergency prophylaxis program, as a supplement to the provincial treatment program for known HIV-positive pregnant women, is to identify women at high risk for HIV with unknown serostatus at delivery, and then to prevent potential MTC transmission of HIV by prophylactic treatment. Furthermore, identification of HIV-positive women through the PMTCT program promotes access to and engagement with comprehensive health care for both mother and child. This program was the first of its kind to be established in Canada, although a similar program (MaterniKit) has now been implemented in Ontario.¹⁸

Our results indicate that the program is effective in identifying pregnant women at high risk of HIV infection. The prevalence of HIV in the study cohort, 16.2 cases per 1000 women, is more than 20 times the background rate of HIV infection among pregnancies in BC that result in delivery (0.68 per 1000 births).¹² Geographic patterns in kit usage mirrored BC's population distribution, with all six health authorities represented.¹⁹ The relatively high prevalence of injection drug use highlights BC's unique population and the need for appropriate and targeted interventions.^{20,21}

Among the five women identified as HIV positive, there was one confirmed case of mother to child transmission. Given the small absolute number of HIV-infected women identified in this study, it is difficult to determine the overall effectiveness of the program in decreasing mother to child HIV transmission. The transmission rate in this cohort was 20%; in comparison, in the absence of any preventive intervention, HIV transmission risk during labour and delivery is approximately 25%.²² While initiation of antiretroviral drug therapy in the late intrapartum period and to the neonate postpartum is less than ideal for prevention of mother to child transmission, it remains a key component of prevention programs because it can still reduce transmission risk by up to 50%.²³ Clearly, it remains critical to identify HIV-positive pregnant women earlier in the prenatal period to maximize effectiveness of antiretroviral treatment and achieve transmission rates of less than 2%.

There were two major challenges associated with the PMTCT program. Most notably, many of the women identified as high risk did not receive the recommended prophylactic antiretroviral regimens. The PMTCT protocol recommended that mothers receive a single dose of oral NVP and intravenous ZDV until delivery. Only 35.4% of

mothers actually received antiretroviral therapy, and even fewer women (26.5%) received both ZDV and NVP as directed. Possible explanations for this are that women may have presented in late stages of labour or declined prophylaxis, or that care providers may have had insufficient time to assess risk, counsel women, and administer medications prior to delivery. This further emphasizes the need to increase uptake of prenatal HIV testing and care, and for risk assessment to be performed earlier in the pregnancy to ensure that optimal care is provided to pregnant women.

Another major challenge of the PMTCT program was that HIV test results were not reported for mother–infant pairs in all cases. A total of 37 mother–infant pairs (11% of the cohort) were lost to follow-up, meaning that local hospitals were not able to provide the Oak Tree Clinic with maternal or neonatal HIV test results, and that counselling, treatment, and care were not administered if required. The vertical transmission rate of 20% could potentially be under- or over-representative, given the unknown HIV status of these 37 mother–infant pairs.

It is difficult to determine the coverage of the PMTCT program because the denominator is not accurately known. Based on a prenatal screening rate of 83% in 2004, approximately 6800 women did not have an HIV test in that year as part of their prenatal panel. Therefore, over the eight-year study period, as many as 54 400 women may have presented at delivery with unknown HIV status, assuming that all those unscreened pregnancies resulted in a birth. This number undoubtedly includes women at low risk for HIV infection, although a limitation to the PMTCT program is a lack of universal and standardized risk assessment when a woman does present with unknown HIV status, which could be resolved with point of care HIV testing. From these figures of all comers with unknown status, the coverage of the PMTCT program was only 0.6%, but clearly captured high risk women. With improved knowledge translation strategies and standardization of risk assessment, more women with unknown HIV status may be properly assessed and, if deemed necessary, appropriately treated, increasing the coverage of the PMTCT program.

Point-of-care HIV testing in labour and delivery wards may offer a possible solution to a number of the challenges faced by the PMTCT program. The feasibility of such HIV testing during labour and delivery has been assessed, most notably in the MIRIAD study, which demonstrated that point-of-care testing can be implemented in a variety of labour and delivery settings using different models of implementation.²³ The MIRIAD study team found that

over 85% of women were willing to be tested, and that accurate results were available in less than 60 minutes and/or prior to delivery for the majority of women. Point-of-care testing of women with undocumented HIV status in the labour and delivery setting has been increasingly recommended as a public health strategy,²⁴ and has been successfully implemented in parts of the United States, Latin America, Africa, and Asia.²⁵ Point-of-care HIV testing may provide an important last opportunity to identify HIV-infected women, not only to intervene to prevent mother to child transmission, but also to encourage women to seek the care they need for their own health. It is noteworthy, however, that this is not an ideal time to implement the most effective prevention strategy of antenatal HAART, which can reduce maternal to child transmission to less than 2%, primarily through the suppression of maternal plasma HIV viral load. In BC, remarkable progress has been made in reducing mother to child transmission of HIV, particularly among known HIV-positive pregnant women actively engaged in prenatal and preventative care. However, it remains critical to reduce missed opportunities for screening and identifying women unaware that they are infected with HIV, particularly those women who do not report established risk factors. The results of this study suggest that although this emergency PMTCT program reliably identified and provided prophylaxis to a population of high risk women with unknown HIV status, additional strategies to prevent vertical HIV transmission need to be explored. Lessons learned from this trial program include the need for enhanced antenatal HIV testing, the promising role of point-of-care HIV testing in late pregnancy or the early stages of labour, and the need for greater resources to track and follow up HIV testing results. Further study exploring the feasibility and effectiveness of these strategies in reducing mother to child transmission in the province of British Columbia is warranted.

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