

Prevention of mother-to-child transmission of HIV in Haiti

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ABSTRACT

Objectives. To describe the effectiveness of a program designed to reduce the rate of mother-to-child transmission (MTCT) of HIV at the primary HIV testing and treatment center in Haiti between 1999 and 2004.

Methods. All pregnant, HIV-positive women who attended the major HIV testing and treatment clinic in Port-au-Prince, Haiti, between March 1999 and December 2004 were asked to participate in an MTCT prevention program. Of the 650 women who participated, 73.3% received zidovudine (AZT), 2.9% received nevirapine (NVP), and 10.1% received triple-drug therapy when it became available in 2003 and if clinical/laboratory indications were met. Approximately 13.8% received no antiretroviral medication. All participants received cotrimoxazole prophylaxis and infant formula for their children. Kaplan-Meier survival analysis and the log rank test were used to evaluate program impact on child survival.

Results. Complete data were available for 348 mother-infant pairs who completed the program to prevent MTCT of HIV. The rate of MTCT in the study was 9.2% (95% CI: 6.14–12.24), in contrast to the historical mother-to-child transmission rate of 27% in Haiti. HIV-positive infants were less likely to survive than HIV-negative infants at 18 months of follow-up ($\chi^2 = 19.06$, $P < .001$, log rank test). Infant survival improved with early pediatric diagnosis and antiretroviral treatment.

Conclusions. The MTCT prevention program described proved to be feasible and effective in reducing vertical HIV transmission in Haiti. The authors emphasize the need to expand testing, extend services to rural areas, and implement early HIV diagnosis to reduce infant mortality.

Key words

Anti-HIV agents; disease transmission, vertical; HIV infections; prenatal care; Haiti.

An estimated 120 000 adults (15 years old and above) and 6 800 children (14

years old and younger) live with HIV/AIDS in Haiti (1). Recent national HIV seroprevalence surveys among women visiting antenatal clinics show a prevalence rate of 3.2%,⁵ the highest in the Region of the Americas and a rate very similar to that in countries in sub-Saharan Africa (2). An estimated 260 000 infants

are born each year in Haiti, and approximately 6 400 of these are born to HIV-infected women.⁶ The majority (76%) of Haitian women deliver outside of a health care setting (3).

Studies conducted at the *Groupe Haïtien d'Étude du Sarcome de Kaposi et des Infections Opportunistes* (Haitian Group for

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⁶ Ministry of Health and Population, Haiti. Guide for the prevention of mother to child transmission of HIV in Haiti, First Revision [internal report]; 2005. Port-au-Prince, Haiti.

the Study of Kaposi's Sarcoma and Opportunistic Infections—GHESKIO), the main referral site for HIV testing and integrated services in Haiti, suggest that mother-to-child transmission (MTCT) of HIV was as high as 27% prior to the availability of antiretroviral therapy (4). In the industrialized world, a greater emphasis on prenatal HIV testing and comprehensive HIV therapy with highly active antiretroviral therapy (HAART) has reduced MTCT of HIV to levels at or below 1% (5). More recently, simplified regimens adapted to developing country treatment protocols have reduced HIV transmission rates by 50% or more (6). While this has led to targeted antiretroviral programs to reduce MTCT, there has been increasing recognition of the importance of including the broader mandates of family planning, treatment of co-existing infections, and primary obstetrical and pediatric care within programs to prevent MTCT (7, 8).

In March 1999, in collaboration with the Haitian Ministry of Health, a program to prevent mother-to-child transmission of HIV (PMTCT) was implemented at GHESKIO. This program includes the progressive introduction of antenatal, perinatal, and postnatal care for mothers and infants; "short course" zidovudine monotherapy (9); provision of infant formula and cotrimoxazole prophylaxis; and early pediatric diagnosis of HIV. HAART was introduced in 2003 for mothers and infants who met clinical or laboratory indications. We present the evidence for acceptance of the program, document the effects of an ongoing effort to integrate PMTCT with comprehensive maternal/infant care, discuss limitations, and suggest future directions for growth in the effectiveness of the program.

MATERIALS AND METHODS

Program description

GHESKIO is the primary center for voluntary counseling and testing (VCT) and care of HIV patients in Port-au-Prince, Haiti. It serves as a model for determining the feasibility of introducing care for HIV-infected persons in urban Haiti. The program integrates VCT for HIV and syphilis services, reproductive health services (family planning), treatment for sexually transmitted infections, screening, treatment, and prophylaxis for tuberculosis, and care for moth-

ers and infants. A detailed description of this model has been documented (10). Based on successful Thai and South African protocols, the Ministry of Health in Haiti developed national guidelines to provide antiretroviral therapy to all pregnant women with HIV infection starting in 1999 (9, 11, 12). The treatment protocol was incorporated into the program at GHESKIO.

Enrollment and consent procedures

This study was approved by the Institutional Review Boards of the GHESKIO center and the Government of Haiti. All women attending the GHESKIO clinic and seeking HIV testing signed a written consent form, which was witnessed by a nurse. Once a woman was determined to be HIV-positive and pregnant, she was asked to participate in the PMTCT program. If she agreed, she was asked to sign a second consent form. Women were told that they could refuse to participate and that their care would not be affected if they chose not to participate. This informed consent initiated participation in the study and authorized home visits by outreach workers for follow-up in case any woman was unable to return to the clinic for antenatal and postpartum care. Home visits were necessary in this context since most women did not have phones. Additionally, home visits allowed outreach workers to deliver medications to the women if they were too ill to attend the clinic. One field worker was assigned for every 50 women.

All pregnant women were provided with same-day HIV testing and syphilis screening. All pregnant, HIV-positive women were individually counseled, informed of their HIV status, and referred to the antenatal clinic.

Antenatal care

A physical exam with emphasis on stage of pregnancy was conducted along with a laboratory evaluation that included complete blood count (CBC), CD4 test, urine test, and Gravindex pregnancy test.

Following national guidelines, HIV-positive pregnant women received 300 mg of oral zidovudine (AZT), twice daily, at 36 weeks of gestation. Women were given a one-month supply of medication and vitamins and followed on a monthly basis, or more frequently if warranted

by health/medical complications. Compliance was monitored via self-report and monthly pill counts. AZT was administered orally (300 mg) every three hours at the onset of labor. Women who presented for care too late in pregnancy for effective AZT therapy were instructed to self-administer a single dose (200 mg) of nevirapine (NVP) at the onset of labor.

Since 2003, with the introduction of triple-drug antiretroviral therapy in Haiti, women who presented with a CD4 count < 250/ μ L were administered zidovudine/lamivudine/nevirapine (AZT/3TC/NVP) or stavudine/lamivudine/nevirapine (d4T/3TC/NVP) if the mother presented with anemia. All mothers participating in the program were given access to condoms at the clinic, and oral or injectable hormonal contraception after delivery.

Women were provided ferrous sulfate and folic acid supplements and tetanus toxoid vaccination in accordance with the Haitian Ministry of Health guidelines. A counselor reviewed past and current HIV signs and symptoms and pregnancy related information with participants. Each woman was assigned a unique identification number to maintain confidentiality. The majority of deliveries occurred in the home setting.

Postnatal care

The mothers attended the clinic with their infants within 72 hours of birth and were followed until the infants reached 18 months of age. Starting immediately after birth, newborns received 2mg/kg of AZT every six hours for seven days. Screening to determine HIV status of the infant was initiated at the age of two months. Beginning in 2004, infants diagnosed with HIV infection were started immediately on HAART. Infant formula was provided for those mothers who chose not to breastfeed. All immunizations recommended by the Ministry of Health, including pneumococcus and Haemophilus influenzae type B vaccinations, were provided. The infant's weight was obtained at each visit. Treatment with cotrimoxazole prophylaxis (Bactrim) was initiated at six weeks and continued until the infant's HIV status was resolved. The baby received a unique identification number linked to the mother's number, facilitating correlations between mother and infant data. A standardized questionnaire was administered to the mother at each visit to identify outcomes.

Laboratory diagnosis

HIV status was determined by two enzyme-linked immunosorbent assays (ELISA) from Abbott Laboratories (Abbott Park, Illinois, U.S.A.) and Sanofi Pasteur (Chaska, Minnesota, U.S.A.). Same-day testing for pregnant women was done using two rapid whole-blood HIV tests: Determine HIV 1/2 (Abbott Laboratories, Abbott Park, Illinois) and Capillus HIV 1/HIV 2 for specificity (Trinity Biotech, Bray, Ireland) (13, 14). The diagnosis of HIV infection was dependent on consecutive, positive Determine and Capillus results. If the Determine and Capillus results were discrepant, the laboratory performed a Western blot for final designation of HIV status. Routine syphilis testing was provided using rapid plasma reagent (RPR—Becton Dickinson, Sparks, Maryland, U.S.A.). CD4 cell counts were measured by the manual cytosphere method using a hemocytometer.

HIV infection in children born of HIV-infected mothers was determined by nucleic acid sequence-based amplification (NASBA—BioMerieux Boxtel, Netherlands) for the first three years of the study. Currently, DNA polymerase chain reaction (PCR) testing (Roche Amplicor HIV-1 DNA PCR test) is performed on HIV-exposed infants at birth and at 3 and 6 months of age. An HIV antibody test (ELISA) was also performed at 15 or more months of age (after maternal antibodies waned).

Stage of HIV infection in pregnant women was determined according to WHO guidelines (15). Criteria for determining infant HIV status were based on serology, nucleic acid detection, and clinical signs and symptoms as described by Noel and colleagues (16).

Data analysis and statistical methods

All clinical, demographic, and laboratory data on mothers and their infants were incorporated into an integrated data management system. Analysis utilized SPSS 13.0 (SPSS for Windows, Release 13.0, SPSS Inc., Evanston, Illinois, U.S.A., 2004). Descriptive analyses were applied to examine trends in enrollment and the distribution of socio-demographic and program-related characteristics. Pearson chi-square analysis was used to examine the relationship between syphilis serology of mothers and the HIV status of their infants for the

women who received PMTCT services. Kaplan-Meier survival analysis and the log rank test were used to evaluate program impact on child survival.

RESULTS

While the PMTCT program is ongoing in Haiti, results presented here are for data collected during the 1999–2004 study period.

Of the 45 259 women who presented at GHESKIO between March 1999 and December 2004, 43 173 women agreed to undergo screening for HIV. This number represents a 227% increase in annual screening: from 4 256 in 1999 to 9 682 in 2004. There was a 443% increase in the number of pregnant women enrolled in the program during the study period: from 286 in 1999 to 1 266 in 2004 (see Figure 1).

Of the 43 173 women tested in the study period, 7 890 (18.3%) tested HIV-positive and 3 732 (8.6%) had a positive serologic test for syphilis. Women with positive syphilis serology were more likely to be HIV-infected than those without syphilis (odds ratio [OR]: 3.0; 95% confidence interval [CI]: 2.68–4.47). Of the 5 270 pregnant women screened at GHESKIO during the study period, 650 (12.3%) were HIV-infected and 437 (8.3%) had a positive serology for syphilis. Of the 650 pregnant, HIV-positive women, 596 delivered during the study period. Of these, only 158 (24.3%) knew their HIV status prior to pregnancy. The majority of women (74%) were self-referred. In cases where women left Port-au-Prince to return to a rural area, field staff used a standardized questionnaire to establish

reasons why women did not return for follow-up. The questionnaire was used in home visits in Port-au-Prince where household members were interviewed.

One hundred and sixty-six (25.5%) of the 650 pregnant, HIV-positive women were lost to follow-up. Reasons noted were the following: 74 of the women opted to deliver in rural areas, 32 delivered prior to expected date, 27 did not return for fear of being abandoned or stigmatized, 29 could not be located, and 4 died of AIDS before delivery. The final analyses included 348 mother-infant pairs.

The demographic and program-related characteristics of the 348 pregnant, HIV-positive women who were enrolled in the PMTCT program are shown in Table 1. The majority (64.5%) were between 25 and 39 years of age, had no income (60.2%), were either married or in a common-law relationship (78.4%), and had a primary school education or less (62.8%).

In our sample of pregnant, HIV-positive women, 72 (21.1%) had a positive syphilis test. Approximately 70% had CD4 counts of 350 or more. Over 85% of the women in the sample had abnormal baseline hemoglobin levels (less than 11 g/dL), indicating high levels of anemia. Almost 90% of the women in our sample chose to feed infant formula exclusively, and at the 18-month follow-up visit, 73.9% (257) were using family planning services. Although our clinic staff encouraged women to bring in their partners for testing, 86% were unable to do so due to power disparities and/or lack of interest or resistance from partners.

The majority of women received AZT medication (73.3%), 10.1% received triple therapy, 2.9% received nevirapine, and

FIGURE 1. Enrollment of women for HIV screening at GHESKIO in Haiti, 1999–2004

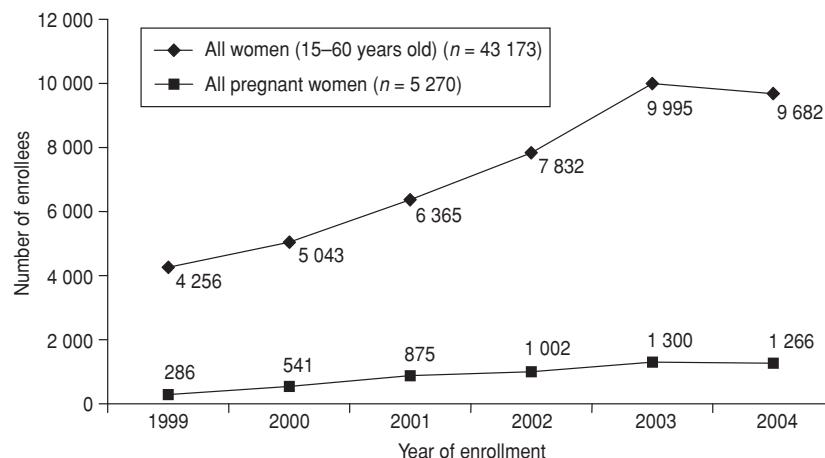


TABLE 1. Characteristics of pregnant, HIV-positive women included in study sample (*n* = 348) at GHESKIO in Haiti, 1999–2004

Participant characteristics	No.	%
Mother's age at enrollment (years)	12–17	11
	18–24	97
	25–39	223
	40–49	15
	Mean age	28
Marital status	In union	269
	Separated	14
	Widowed	15
	Single	45
Education	Primary or less	216
	Secondary	122
	Superior/technical	6
Annual income (US \$)	None	207
	Less than \$150	15
	\$150–1 000	68
	\$1 001–5 000	46
	\$5 001–10 000	8
Residence	Port-au-Prince	335
	Rural Haiti	13
Infant feeding	Replacement	305
	Breastfeeding	14
	Mixed	23
Family planning after delivery RPR (syphilis) testing	Total participation	257
	Positive	72
	Negative	269
Baseline CD4 count	≥ 350 cells	237
	< 350 cells	105
Baseline hemoglobin level	4–8 g/dL	110
	9–10 g/dL	158
	≥ 11 g/dL	45
Mother's antiretroviral therapy protocol during pregnancy	AZT	255
	Tri-therapy	35
	NVP	10
	Not treated	48
Prevalence of mother-to-child HIV transmission by type of antiretroviral therapy	AZT	24
	Tri-therapy	0
	NVP	0
	Not treated	8
	Total	32
Note: Categories may not sum to 348 due to missing data points.		

the remaining 13.8% received no antiretroviral treatment. The latter group is comprised of the women who either arrived too late at the clinic to receive treatment or who went to the countryside after delivery and refused follow-up. While nevirapine was provided with instructions for self-administration during labor, clinic staff was unable to ascertain whether the medication was properly used.

The rate of HIV transmission to infants was 9.2% (95% CI: 6.14–12.24). The infants were followed for 18 months after birth. A Kaplan-Meier survival analysis (see Figure 2) showed that the HIV-positive infants survived for a shorter

period of time than the HIV-negative infants ($\chi^2 = 19.06$, $P < .001$; log rank test). Twelve mothers died while their infants were young which may have been a factor in poor infant survival. Improvement in overall infant survival coincided with the introduction of early HIV diagnosis and antiretroviral therapy for infants (see Figure 3).

To trace the operational outcome of the program in a different way, the percentages of mother-infant pairs receiving complete antiretroviral therapy (mothers for four weeks and infants for one week), incomplete, and no therapy were plotted by year. Across the entire study period, an average of 50% of the mother-infant

pairs received complete antiretroviral therapy (see Figure 4).

DISCUSSION

Of the more than 43 thousand women who were evaluated as part of this five-year program, 18.3% were HIV-positive. This figure is higher than the national figure of 3.2% because GHESKIO acts as the primary referral site for higher-risk individuals in Haiti. This discrepancy limits the generalizability of our observations, which we discuss below (see limitations section). Nevertheless, the fourfold increase over the five-year study period in the number of pregnant women seeking services at GHESKIO as well as the relatively greater increase in pregnant compared to non-pregnant women presenting for screening, reveal the need for a PMTCT program among women in Haiti.

Although enrollment increased substantially over the study period, it is discouraging that 162 (28.7%) of the women in our sample did not participate in the PMTCT program. The primary reason given for not participating in the program was the desire of women to return to rural areas for family support. Another obstacle to participation in the program was the delay in seeking prenatal care by some of the women due to poor knowledge of conception date and time to delivery. It may be possible to overcome these barriers by: 1) promoting early presentation for care through education which would result in earlier initiation of antiretroviral therapy, and 2) extension of PMTCT services through a national referral network.

Fear of partner reaction, including abandonment and violence, was another significant deterrent to program participation. GHESKIO and other researchers in Haiti and in several African countries have documented the prevalence of partner violence and higher levels of domestic violence upon notification of HIV-positive status, as well as the impact of partner violence on limiting participation in PMTCT programs (17, 18). These factors speak to the need to integrate partner violence services into reproductive health care (19). In addition, public health messages directed toward men and the general public, targeting the reduction of stigma and discrimination surrounding HIV, may increase the likelihood that more women will get tested and increase program participation.

Nearly 75% of women evaluated in our study used family planning services after delivery in contrast to national data indicating that contraceptive use in Haiti is only 23% (20). Family planning in our sample at the 18-month follow-up (73.9%) is comparable to the 71% rate found among the general population of women in the United States (20).

There was a critical need for comprehensive care among the women in our sample, including nutrition and treatment of co-existing infections, a requirement that has been emphasized by the United Nations (21). However, structural, financial, and leadership barriers prevent the realization of comprehensive care in low resource contexts (22). Nutrition assistance has been identified as a potential component in the care of pregnant, HIV-positive women since malnutrition is an important factor in the declining health status of these individuals (23–25). In addition, the high incidence of syphilis (21%) and low hemoglobin levels in 86% of the sample, as well as the need to provide free infant formula, require that these and other health needs of the women be effectively addressed to improve their health as well as that of their infants.

Several critical observations speak of the success of the PMTCT program at GHESKIO, not the least of which is the effectiveness of linking research and service together in an effort to promote the PMTCT program (26). Studies conducted at GHESKIO suggest that MTCT of HIV was as high as 27% in Haiti prior to the availability of the PMTCT program, compared to the study's overall rate of 9.2% (4). This rate is similar to studies of PMTCT programs in several African countries (27–30) where transmission rates are comparable for mixed interventions and range from 9% to 15%. For the purposes of this study, we chose to compare the Haitian experience to that of several African countries, since the prevalence, interventions, and effectiveness most closely mimic countries in several regions of Africa.

With regard to effectiveness of the program for infants, the overall mortality rate of children born to HIV-positive mothers was over twice the national average but it is now decreasing with the PMTCT program. There is a high early mortality rate in this population, which emphasizes the need for early pediatric diagnosis and immediate initiation of antiretroviral therapy

FIGURE 2. Mother-to-child transmission of HIV and infant survival (%) in GHESKIO program in Haiti, 1999–2004

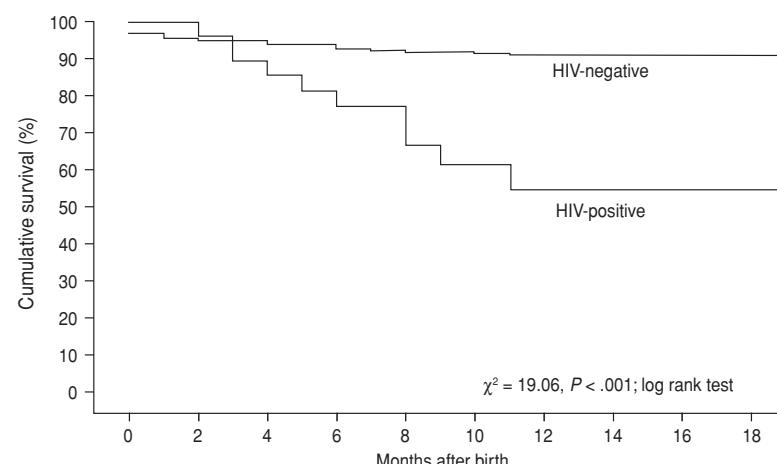


FIGURE 3. Mortality of infants born to HIV-infected mothers within first 15 months of life in GHESKIO program in Haiti, 1999–2004

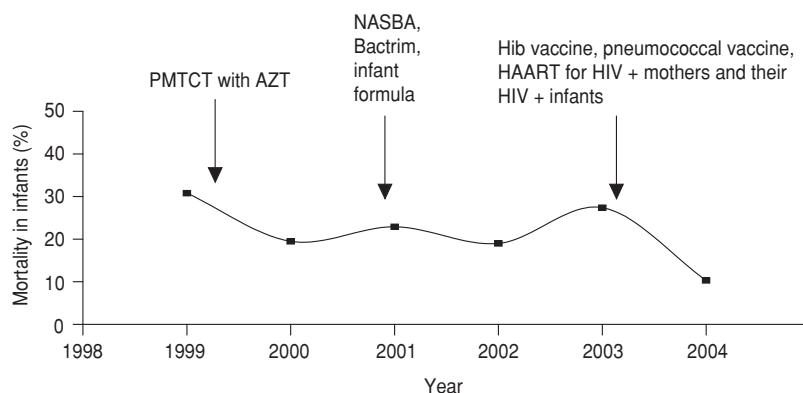
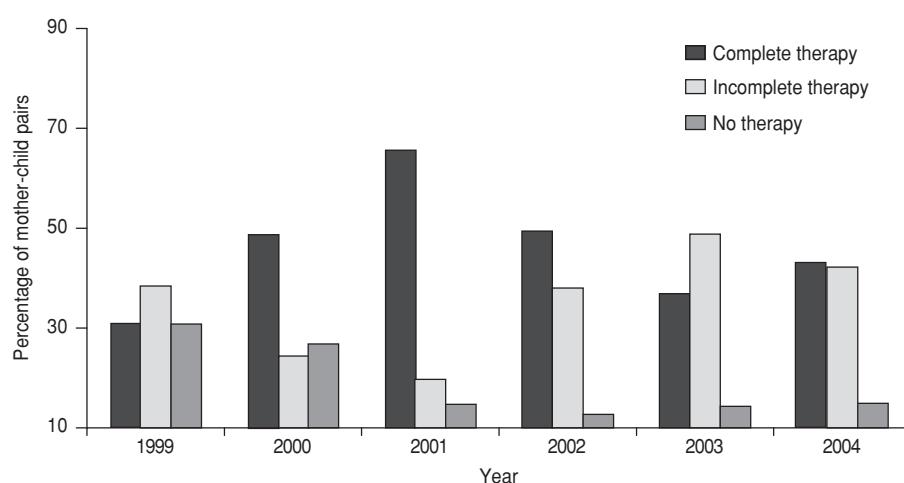


FIGURE 4. Implementation of antiretroviral therapy for HIV+ women and their infants enrolled in GHESKIO program in Port-au-Prince, Haiti, 1999–2004



upon confirming the diagnosis (4, 8). Studies show that combinations of zidovudine and lamivudine or neviripine will further decrease transmission; this

therapy protocol is being incorporated into the GHESKIO regimen (28, 31).

There are many challenges to administering any program in Haiti given the

sociopolitical context. Collecting data and conducting follow-up in a systematic fashion is hindered by simple logistics such as the lack of transportation in the midst of persistent violent conflict. These problems, along with severe resource limitations, may limit large-scale implementation of national PMTCT programs. In addition, nationwide testing rates are low due to these factors. Techniques such as the "opt-out" approach to testing have increased testing rates to 99% in studies conducted in Malawi and Zimbabwe, and are under consideration for Haiti (32, 33). With this strategy, an HIV test is one of a myriad of tests administered as part of standard antenatal care. After receiving information on HIV, a woman would have to explicitly refuse or "opt-out" of being tested for HIV.

Limitations

Our study was negatively affected by the large number of women lost to follow-up, a fact that reduces our ability to draw definitive conclusions about our sample and to generalize the findings. We are investigating options to address this issue, including more intensive follow-up efforts and encouragement of earlier presentation for prenatal care.

The 18.3% rate of HIV found in the women attending GHESKIO is significantly higher than the estimated 3.2% national rate, and is not representative of Haitian women of reproductive age. Nonetheless, the findings of our study regarding the acceptability of formula feeding and family planning, and the high level of acceptance of the PMTCT program among pregnant, HIV-positive women, support the advisability of implementing similar programs nationwide.

Conclusions

Despite numerous challenges, the vital need for PMTCT in Haiti, as well as the success of GHESKIO in reducing transmission of HIV to infants, cannot be overstated. In addition to addressing infrastructural barriers, results of this study reveal several areas of intervention that could be implemented. Our experience has shown the importance of integrating family planning, VCT, and HIV treatment services.

This study highlights important needs and future directions for PMTCT in Haiti. It is vital that HIV testing be implemented nationwide and that trained staff be available to care for those who reside in and those who return to rural areas for support and care. It is also important that

women be encouraged to present earlier in their pregnancy for services. A comprehensive care program that integrates family planning, VCT, nutrition services, and support for women affected by domestic violence, along with HIV treatment services initiated early in pregnancy appears to be justified. Despite the absence of advertisements or publicity, a large number of women presented for testing at GHESKIO, a fact that speaks to the understanding of the need for, and acceptance of these services, at least within the capital city of Port-au-Prince. In combining services for these women, GHESKIO has provided a model for prevention and treatment that may be replicated throughout the country and in other developing nations with limited resources.

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RESUMEN

Prevención de la transmisión del VIH de madre a hijo en Haití

Objetivos. Describir la eficacia de un programa diseñado para reducir la tasa de transmisión del VIH de madre a hijo (TMH) en el principal centro de diagnóstico y tratamiento de esa infección en Haití entre 1999 y 2004.

Métodos. Se invitó a participar en un programa para la prevención de la TMH a todas las embarazadas positivas al VIH que asistían a la clínica principal de diagnóstico y tratamiento de la infección por el VIH en Puerto Príncipe, Haití, entre marzo de 1999 y diciembre de 2004. De las 650 mujeres que participaron, 73,3% recibieron zidovudina (AZT), 2,9% nervirapine (NVP) y 10,1% tripleterapia cuando esta se hizo disponible en 2003 y cumplían los indicadores clínicos y de laboratorio requeridos. Aproximadamente 13,8% no recibió medicamentos antirretrovirales. Todas las participantes recibieron el tratamiento profiláctico con cotrimoxazole y fórmula infantil para sus hijos. Para evaluar el impacto del programa sobre la supervivencia infantil se aplicó el análisis de supervivencia de Kaplan-Meier y la prueba de rangos logarítmicos.

Resultados. Se obtuvieron los datos completos de 348 parejas madre-hijo que terminaron el programa de prevención de la TMH del VIH. La tasa de TMH en el estudio fue de 9,2% (intervalo de confianza de 95%: 6,14 a 12,24), frente a una tasa de TMH histórica en Haití de 27%. A los 18 meses de seguimiento, los niños positivos al VIH presentaron una menor probabilidad de supervivencia que los negativos ($\chi^2 = 19,06$; $P < 0,001$; prueba de rangos logarítmicos). La supervivencia de los niños aumentó con el diagnóstico y el tratamiento antirretroviral pediátricos tempranos.

Conclusiones. El programa de prevención de la TMH descrito demostró su factibilidad y eficacia para reducir la transmisión vertical del VIH en Haití. Los autores subrayan la necesidad de extender el tamizaje y los servicios a áreas rurales, así como de implementar el diagnóstico temprano del VIH para reducir la mortalidad infantil.

Palabras clave

Agentes anti-VIH, transmisión vertical de enfermedad, infecciones por VIH, atención prenatal, Haití.