

Mobile Clinic Voluntary Counseling and Testing and Prevention of Mother-to-child Transmission of HIV in Rural

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Summary

We describe an innovative program for diagnosis and treatment of HIV among pregnant women in rural Haiti. Mobile clinic (MC) testing and treatment by directly observed therapy with antiretrovirals (DOT-ARV) was introduced to a registered population of 175,000 people. The intervention improved access to testing and care for rural women with 3191 women tested in 10 months (92% coverage) and 76% enrolled in a prevention of mother-to-child transmission (PMTCT) program. A high infant mortality rate (IMR) not attributable to diarrheal illness or explained by HIV infection may be related to the loss of protective immunity of breast milk among formula fed infants. Missed and late diagnoses were documented during a period of political instability but the DOT-ARV intervention ensured continuity of care for enrolled patients. This MC DOT-ARV program linked to an equitable food relief program improved access to HIV testing and care for pregnant women in rural Haiti.

Introduction

In resource-poor settings where innovative strategies for HIV disease management are essential, the benefits of ARV are restricted by limited access to voluntary counseling and testing (VCT) services, limited access to healthcare and stigma.

Haiti has the highest HIV seroprevalence in the Western Hemisphere, with an estimated 160,000 HIV-infected persons at year-end 2003 (UNAIDS). The Ministry of Health (MoH) has recently established a policy of HIV testing, and efforts to expand access to ARVs are underway.

Management and Resources for Community Health (MARCH) provides hospital and community-based services in four geographic zones with the support of the MoH. An innovative PMTCT program was introduced at the Lower Central Plateau site in June 2003. The entire population of 175,000 was registered in 2002-2003 in a door-to-door census. A community outreach system has existed for many years using community health workers and monthly MC visits to 25 fixed healthcare delivery sites. There is a referral hospital in Mirebalais with an obstetrician trained in HIV management and nurse midwives trained in VCT. According to CDC, sentinel HIV seroprevalence data for the region was 6% in 1996 (N=275), 4% in 1999-2000 (N=240) and 2% in 2003 (N=400).

With CDC, UNICEF and MoH support, MARCH implemented a program of VCT and DOT-ARV for PMTCT to serve over 4000 pregnant women annually with an estimated 100 HIV-positive women per year. The Tulane University Division of Infectious Diseases provides clinical consulting and monitoring support. A Burroughs Wellcome-American Society of Tropical Medicine and Hygiene Fellowship supports monitoring and evaluation.

Methods

VCT and PMTCT is offered free of charge to all pregnant women presenting to MCs or fixed health facilities along with routine prenatal services and a monthly food ration. Laboratory testing for HIV-1 antibody is performed with a rapid field test,

Determine (Abbott) (1). Results are confirmed with a second rapid field test, Capillus (Cambridge Diagnostics) (2). In case of discordant results a third rapid test, OraQuick (Abbott) is performed (3). CD4+ T cell counts are performed by two methods: an antibody-coated, bead-based, manual assay using only a light microscope (Beckman Coulter, Fullerton, CA) is performed in Mirebalais and a CD4 count by flow cytometry (Beckman) is performed at a near-by hospital, PIH (Partners in Health, Cange) as part of a collaborative agreement.

Same-day post-test counseling is provided at MCs and fixed delivery points where HIV-positive women are prescribed ARV. At that time, they select an *accompagnateur* (accompanying person) who may be a family member, friend or a community health worker who receives training on the PMTCT protocol (4). The *accompagnateur* is expected to make daily home visits beginning at 34 weeks gestation, to be present during delivery to monitor drug administration and to ensure that the infant is brought to the hospital to initiate weight-based ZDV prophylaxis. The *accompagnateur* monitors medication adherence and makes daily visits during the post-partum period to supervise medication administration and to coordinate safe feeding. The treatment regimen is based on the national protocol using a short-course three-part ZDV regimen beginning at 28-34 weeks gestation, with oral ZDV intrapartum and one week of ZDV to the infant. Patients qualifying for HAART (the locally available regimen is zidovudine/lamivudine plus nevirapine) are those who present later than 34 weeks or those with CD4 count below 350. Mothers are counseled about safe feeding choices and select either exclusive breastfeeding or artificial feeding. In the latter situation, formula and all necessary supplies for safe feeding (charcoal, pots for boiling water, bottles, nipples) are provided for the duration of formula feeding, a minimum of 9 months.

All women are tested for anemia, syphilis, and sexually transmitted infections and counseled about partner referral, condom use and family planning. All HIV-infected patients are tested for malaria with a blood smear and for TB in Mirebalais with purified protein derivative (PPD), sputum for acid fast bacillus staining, and referred to PIH for a chest radiograph. In addition to routine prenatal labs, all women on ZDV are retested for anemia with a complete blood count and all patients on HAART have a baseline chemistry including transaminases and creatinine, repeated quarterly while on therapy.

HIV-exposed infants are weighed within 24 hours of birth and treated with ZDV syrup (four times daily for seven days) as defined in the MoH protocol. At 12-48 hours, 1-2 months, and 4-6 months, heel stick blood is collected on FTA minicards (Life Technologies, Rockville MD) and sent to New Orleans for a qualitative nested PCR assay to determine the presence or absence of HIV viremia. All infants are tested by serology (Determine, Capillus) at 12 and 18 months and followed for 24 mos.

Data collection includes *clinical*, *laboratory*, and *behavioral* data sets at pre-enrollment, enrollment, and follow-up. Indicators are designed to measure baseline characteristics of the cohort, acceptance of the intervention by patients and accompagnateurs, adherence, completion, and outcomes. Social service questionnaires identify patients eligible for monthly financial assistance.

Results

In the first 10 months of the program, VCT was introduced at 24 of 25 MC sites with 3191 women tested, representing 92% coverage. HIV seroprevalence was 2% by rapid field tests, a result which has been independently corroborated by a concurrent

ELISA-based CDC seroprevalence study. Of the HIV-screened population, 2969 women were tested for syphilis (seroprevalence 3.6%). In April-May 2004, 100% of women tested received same-day test results and 73% enrolled in the PMTCT program.

To date, 98 HIV-infected individuals have been identified, including 82 women (72 during pregnancy and 10 breastfeeding mothers), 14 men (9 partners of pregnant women and 5 men presenting with clinical AIDS) and 2 infants (diagnosis confirmed by PCR). Currently, 99 patients are in care (71 HIV-positive and 28 HIV-exposed infants) and 76% of qualifying patients are receiving or have received ARV.

The CD4+ T cell count mean and median for women in the PMTCT program is 489 and 476 respectively (range 132-1156); for male patients and non-pregnant women the mean and median CD4 cell counts are 441 and 383 (range 160-791). Overall, 32% of patients qualify for HAART due to a low CD4 count. The rate of TB infection is 35%.

Twenty-one patients are being treated with HAART and reported medication adherence is 100%. ARV treatment was deferred for both HIV-infected infants because of TB coinfection. Five patients are currently being treated for active TB.

Only 31% of partners (n=18) have presented for testing; 9 (50%) are HIV positive; 2 are currently receiving HAART. Of seven men not receiving treatment, 5 had CD4 cell counts greater than 350 cells/microliter, one was placed on TB therapy and moved to the capital, and one declined therapy.

All women surveyed are living in a state of absolute poverty; 9% have been educated beyond the 5th grade (UNICEF, 2003). Over 70% have experienced the death of at least one child; 50% have lost a child in the first year of life. Only 6% are currently married and 30% have experienced the death of a partner in the last 5 years; 12% have a current partner with a positive HIV test result.

Thirty-eight women enrolled in the PMTCT program have delivered infants. Ten women have not received any ARV due to either late presentation for testing or premature delivery; six of whom delivered in February or March 2004. Another 10 women were diagnosed with HIV while breastfeeding for a total of 48 HIV-exposed infants. HIV viremia was documented by PCR in 5% (2 of 38) of infants.

Among HIV-exposed infants, there have been 11 deaths, resulting in a calculated infant mortality rate (IMR) of 230 per 1000. Causes of death for infants include: fever and cough (3), fever without cough (1), diarrhea (1), neurological symptoms or meningitis (2), vomiting and aspiration (2), AIDS/failure to thrive (1), unknown (1). Of the deaths determined to be non-diarrheal in nature, one infant had diarrhea in addition to respiratory symptoms. The corresponding IMR for HIV-negative infants in the MARCH catchment area during the same time period was 39 per 1000 infants; nationwide, reported IMR is 79 per 1000 infants (UNICEF, 2003). Of the observed infant deaths: 7 of 11 infants received ZDV, 3 of 11 infants received cotrimoxazole, 10 of 11 infants were formula fed, 1 of 6 infants tested was HIV-positive by PCR, 1 of 11 infants had a mother with AIDS. The median age of death was 43 days (range 12 days to 12 months).

Conclusions

We have improved access to HIV testing for destitute pregnant women in rural Haiti and linked HIV care to antenatal and postpartum care. Unique strengths of the program include a monitored population registry allowing for prospective comparison of IMR for infants born to HIV-positive and HIV-negative women, provision of food aid and social service relief to people living with HIV without stigma, and MC DOT-ARV.

Barriers to HIV diagnosis, treatment, and care are not unique to Haiti and challenge HIV programs elsewhere in resource poor settings. Economic and political instability, extreme poverty, lack of access to improved water sources, and a high IMR in HIV-exposed infants are some of the problems encountered.

Early in program implementation the need for social service support including safe water was recognized. Home visits to document poor living conditions with demonstrations in safe formula preparation have become a cornerstone for safe feeding and identification of destitute patients requiring additional assistance for housing or food.

Political turmoil in Haiti has challenged HIV treatment efforts nationwide (5). For the MARCH program, late and missed HIV diagnoses were a direct result of the conflict resulting in missed opportunities for care. Because of food shortages directly resulting from the political situation as well as safety issues, MCs were reduced and often without food rations. These shortages have since tapered and MCs have resumed at full capacity reflected in the increase in number of patients served in April, after peacekeeping troops had arrived (n=429 women) relative to March, during the turmoil (n=168 women).

Excess IMR in HIV-exposed infants compared to HIV-unexposed children has previously been reported in Haiti (6). As in our experience, HIV infection did not explain the discrepancy. Despite maternal HIV treatment and ZDV prophylaxis to infants, daily house visits by a trained accompagnateur, and aggressive efforts to ensure safe feeding, infants are dying at 6 times the rate of HIV unexposed infants in our community. The paucity of deaths attributed to diarrhea suggests that contaminated water sources do not explain the IMR, though loss of protective immunity from breastfeeding may play a role. Current efforts to improve infant survival include cotrimoxazole prophylaxis, intensified instruction in safe preparation of infant formula and earlier intervention for infant illness. A study is underway to prospectively assess the determinants of survival for HIV-exposed and HIV-unexposed infants and to determine the relationship of infant deaths to feeding choice.

Efforts to develop innovative methods to expand VCT for men, to ensure partner referral and testing without stigmatizing women, to validate the filter paper PCR method and apply this technology to identify viral resistance are future directions.

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