Preventing Mother-to-Child Transmission of HIV in Western Kenya

Operational Issues

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Objectives: To improve uptake in a program to prevent mother-to-child HIV transmission and describe lessons relevant for prevention of mother-to-child transmission programs in resource-poor settings.

Methods: Implementation of a pilot project that evaluates approaches to increase program uptake at health facility level at New Nyanza Provincial General Hospital, a public hospital in western Kenya, an area with high HIV prevalence. Client flow was revised to integrate counseling, HIV testing, and dispensing of single-dose nevirapine into routine antenatal services. The number of facilities providing PMCT services was expanded to increase district-wide coverage. Main outcome measures were uptake of counseling, HIV testing, nevirapine, and estimated program impact.

Results: Uptake of counseling and testing improved from 55 to 68% ($P < 0.001$), nevirapine uptake from 57% to 70% ($P < 0.001$), and estimated program impact from 15% to 23% ($P = 0.03$). Aggregate reports compare well with computer-entered data.

Conclusion: Addressing institutional factors can improve uptake, but expected program impact remains low for several reasons, including relatively low efficacy of the intervention and missed opportunities in the labor room.

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Programs to prevent mother-to-child transmission of HIV (PMCT) are being scaled up in many resource-poor settings. Many countries and programs have adopted nevirapine according to the HIVNET012 protocol[1] as the antiretroviral regimen of choice, because of its simplicity, low cost, and feasibility.[2] Several programs, however, report low uptake of counseling, HIV testing, and prophylactic nevirapine,[3–6] which translates into low program impact at a population level. It is crucial to determine factors that result in low program uptake and to evaluate strategies to increase HIV testing and nevirapine uptake, to improve the effectiveness of services.

The approach used to offer HIV testing to antenatal clients influences test acceptance; uptake is higher when HIV testing is performed routinely on all women as part of antenatal care with women reserving the right to refuse testing ("opt-out" approach), when compared with the "opt-in" approach that requires women to approve HIV testing.[7,8] Recently UNAIDS and the World Health Organization recommended that HIV testing be routinely offered to all pregnant women.[9] Other facility-level considerations such as client flow and user friendliness of the service may also contribute significantly to program success. We describe our experience in implementing a PMCT program at a public health facility in an area with high HIV prevalence in western Kenya, from its start in May 2001 till July 2003, focusing on a facility-level strategy aimed at increasing uptake.

METHODS

Background

The PMCT program was introduced at the New Nyanza Provincial General Hospital (NNPGH), in Kisumu, a city of 300,000 people in western Kenya. NNPGH is a government hospital with a total of 400 beds, 5000 annual antenatal clinic

(ANC) attendees, and 2500 deliveries. It serves both as a major primary care provider for the city's low-income population and as a referral hospital for Nyanza Province.

National HIV prevalence in Kenya was estimated at 6.7% in 2003[10] but over the past 5 years HIV seroprevalence measured through sentinel surveillance among ANC attendees at NNPGH has been 26%–35%.[11] In Nyanza Province as a whole, 85% of pregnant women receive antenatal care from a health professional, of whom two-thirds attend ANCs at government facilities and one-third through missions or private providers. Another 5% receive antenatal care from traditional birth attendants. The majority of women deliver at home, assisted either by a traditional birth attendant or a relative, and only 36% of deliveries are in a health facility.[10] Therefore ANCs have the largest potential to reach women for PMCT services. Women frequently access antenatal care, maternity care, and pediatric follow-up and preventive services from different facilities, which compromises continuity of care and follow-up. Cost plays a role in choice of facility for each service. Provincial infant mortality and under-5 mortality rates are 133/1000 live births and 206/1000 live births, respectively.[10]

Program Description

The PMCT program at the NNPGH was started in May 2001, with the aim to provide services that could subsequently be replicated throughout Kisumu District. Before services started, 32 facility staff members (mainly nurses and nurse-midwives working in ANC, maternity, and pediatric wards) were trained regarding PMCT to equip them with the clinical, programmatic, and counseling knowledge and skills required to implement PMCT in their facility. By August 2002, 94 service providers in the facility and 215 in the entire district were trained. No additional staff were added to the facilities for program purposes.

Changes in Services in ANC and Counseling Strategies

Original Services

Services provided to all women attending ANCs included a strengthened package of antenatal care, including provision of ferrous sulfate, folic acid, and sulfadoxine-pyrimethamine (presumptive malaria treatment) according to Ministry of Health guidelines, as well as routine syphilis testing. During the first 16 months HIV testing and counseling in the ANC were presented as an optional service to which pregnant women could "opt in." General information on HIV and PMCT was provided to nearly all women, but counseling was provided in a separate location within the hospital complex. Pretest and test-decision counseling emphasized an informed and voluntary decision; HIV testing was not considered an essential part of antenatal care.

Because HIV testing was considered as a separate activity and conducted in an off-site laboratory, client flow was cumbersome and required excessive movement of the clients. Starting from registration, women underwent routine ANC physical examinations followed by pretest counseling. Thereafter women were sent to the general hospital laboratory for routine antenatal tests, which included HIV testing if they consented. Women then returned to the counselor for posttest counseling. The counselor collected laboratory result slips, provided posttest counseling usually on the same day, and recorded HIV test results on the ANC card, using codes that were known to trained health workers but did not directly reveal HIV status for laypersons.

Women who tested HIV positive were requested to see a counselor again at 34 weeks gestation, at which time maternal and infant nevirapine doses were dispensed, and infant feeding counseling was provided. Women were asked to keep the drug at home and take it at the onset of labor independent of the place of delivery. The infant suspension was provided in a dispensing Luer-lock syringe. On admission in labor a woman's HIV test result was checked on her ANC card. For women known to be HIV positive, the midwife verified intake of nevirapine, reminded the client to take the dispensed dose, or offered her a (new) dose if necessary. Children born to women known to be HIV infected were given nevirapine suspension before discharge, usually within 24–48 hours of delivery.

The nationally recommended HIV testing algorithm consisted of 2 rapid whole-blood HIV tests (Determine HIV 1/2, Abbott Laboratories [Dainabot Co., Tokyo, Japan] and Unigold HIV 1 & 2, Trinity Biotech [Bray, Ireland]), which provide results within 20 minutes.[12,13] If discrepant, a 3rd rapid whole-blood test served as tie-breaker. Syphilis testing was also done using a rapid whole-blood assay (Determine syphilis, Abbott Laboratories), making all test results available within half an hour, to facilitate same-day results and reduce the number of women tested but never returning for follow-up appointments to receive results.

All women were encouraged to bring their spouses for counseling and HIV testing. Safer obstetric practices such as the judicious use of episiotomies and avoidance of artificial rupture of amniotic membranes were encouraged in the maternity ward for all women.

Infant feeding counseling was provided during posttest counseling and upon dispensing of nevirapine. Appropriate options were discussed, with emphasis on exclusive breast-feeding for 6 months if replacement feeding was not feasible. The PMCT package did not include free formula. Women were advised to attend postnatal clinics at the hospital's child health clinic. Attendance at ANC, including laboratory tests, cost approximately $1, and an uncomplicated delivery $7. PMCT services are free of charge, meaning that the existing fee structure did not change with the introduction of the program.

Revised Services

During the period September–November 2002, a more integrated approach to service delivery was adopted that required facility renovations, including establishment of a "side" laboratory in the ANC to conduct routine antenatal tests and HIV testing. All first-time ANC clients received ANC examinations and pretest HIV counseling from an ANC nurse-counselor. The same nurse-counselor also provided posttest HIV counseling and routine ANC preventive interventions like tetanus toxoid and sulfadoxine-pyrimethamine upon collection of laboratory results. Nevirapine was dispensed at any time from the 2nd trimester following a report on drug stability.[14]

Between July and November 2002, PMCT services were introduced in the district hospital and 6 public health centers within 30 km of Kisumu City. Together with NNPGH these services reach >80% of ANC clients and facility-based deliveries in the district.

Evaluation Method

Routine service data were collected from registers specifically designed for collecting PMCT monitoring data at the service delivery points. Nurses and laboratory personnel were instructed on how to complete the registers. To ensure data quality and evaluate the appropriateness of paper-based aggregate monitoring systems, 2 separate methods of data collection were used: a hospital nurse responsible for monthly reports did manual counts from the registers to compile aggregate data, and data from individual patient records were entered from the registers using Epi Info 2000 (Centers for Disease Control and Prevention, Atlanta, GA). Computer-entered data on all women attending the ANC for a 1st visit during the period May 15, 2001–June 30, 2002 were compared with results of manually counted aggregate data. To control for seasonal variations in evaluating the impact of integrating HIV testing more fully with ANC care, the period of November 2001–August 2002 was compared with the period of November 2002–August 2003 (after changes were introduced). Sentinel surveillance data were obtained from the National AIDS/STD Control Program of the Ministry of Health.

Analysis and Statistical Methods

Aggregate data comparison between groups was done using the χ^2 test for proportions (Epi Info 2002). Line-listed data were analyzed using SAS, version 8.0 (SAS Institute, Cary, NC). A P value of ≤ 0.05 was considered statistically significant for all tests.

RESULTS

Uptake of Counseling, Testing, and Nevirapine

Service uptake during the 2 periods under evaluation is shown in Table 1. The proportion of ANC clients who learned their HIV status was 55% in the 1st period and 68% in the 2nd period, a 24% increase ($P < 0.001$). This improvement was primarily the result of more comprehensive pretest counseling, from 77% when the pretest counseling was conducted in a separate part of the hospital to 92% when integrated into the examination ($P < 0.001$). There was also a small improvement in the acceptance rate of HIV testing among those who received pretest counseling, from 80 to 83% ($P < 0.001$). The main reasons for declining the HIV test were recorded in the register by the counselors. "Not ready" or "undecided" were the most common reasons, given by 65% of the women who refused. The wish to consult the husband first or to return with the husband was expressed by 11%. Fear, either of the result or of the husband's reaction, was also commonly mentioned (20%). Less than 1% of partners came for partner or couples counseling, in both periods. Nevirapine uptake was higher in the 2nd period, 70% compared with 57% in the 1st period ($P < 0.001$). Those reported as receiving nevirapine included women who collected nevirapine in the ANC and women who received their dose in maternity.

Women Delivering in Maternity

In 2002, when only this hospital provided PMCT services, 31% of women presenting for delivery at the hospital had learned their HIV status in the ANC, and 20% were of unknown status despite access to PMCT during antenatal care. The others either never attended the ANC (18%) or attended elsewhere (31%) and had not had access to PMCT services. Since PMCT services had expanded to more facilities and uptake of counseling and testing in ANC increased, we expected the proportion of women delivering with a known HIV status to be higher in 2003 than in previous years. This was, however, not the case. The proportion varied per quarter between 10% and 30%, which may be explained by a human resource shortage, but no significant differences were observed between the 2 program periods.

Although no further information on infant feeding and follow-up is provided here, of HIV-infected women who delivered in the hospital in the 2 periods, 95 and 100%, respectively, elected to breast-feed their infants. A PMCT postnatal follow-up visit was reported for only 5 and 2%, respectively, of HIV-infected women receiving antenatal PMCT services.

Comparison of Data Capture Methods

A comparison of computer-entered data with hand-counted data is shown in Table 2. No significant differences

TABLE 1. Uptake of Counseling and HIV Testing in ANC Per Stage and Nevirapine Uptake (November 2001–August 2002 and November 2002–August 2003)

	Nov. 2001–Aug. 2002 Hand-Counted Data		Nov. 2002–Aug. 2003 Hand-Counted Data		
	Women	%	Women	%	*P* Value
1st ANC visits	4142		4089		
Pretest counseled	3206/4142	77	3743/4089	92	<0.001
Accepted	2551/3206	80	3101/3743	83	<0.001
Posttest counseled	2278/2551	89	2799/3101	90	0.233
Overall: 1st ANC visits learning HIV results	2278/4142	55	2799/4089	68	<0.001
NVP uptake*	302/534	57	471/673	70	<0.001

*Denominator is the number of HIV-positive women who learned their status.
NVP indicates nevirapine.

TABLE 2. Comparison of Computer-Entered and Analyzed With Hand-Counted Data on Uptake of Counseling and HIV Testing in ANC Per Stage and Nevirapine Uptake (May 2001–June 2002)

	May 2001–June 2002 Computer-Entered Data		May 2001–June 2002 Hand-Counted Data		
	Women	%	Women	%	*P* Value
1st ANC visits	5501		5501		
Pretest counseled	4391/5501	80	4318/5501	78	0.087
Accepted HIV testing	3568/4391	81	3514/4318	81	0.883
Learned status	2971/3568	83	2983/3514	85	0.062
Overall: 1st ANC visits learning HIV results	2971/5501	54	2983/5501	54	0.818
NVP uptake*	369/683	54	356/625	57	0.286

*Denominator is the number of HIV-positive women who learned their status.
NVP indicates nevirapine uptake.

are noted between the 2 types of data at each service delivery point.

Accuracy of calculating nevirapine uptake from aggregate data was biased by nevirapine dispensing and posttest counseling occurring in different months. We assumed that on average over a longer, stable period, dividing numbers of nevirapine doses dispensed in ANC and maternity by the number of posttest-counseled HIV-infected women in the same period gave reliable trends in uptake. For the starting period, we excluded women testing HIV positive in the first 2 months of the program, to correct for the interval between HIV testing and nevirapine dispensing. In comparison to computer-analyzed data, the aggregate method slightly overestimated the number of women receiving nevirapine, though the difference was not significant. In aggregate counts women receiving more than one dose (eg, because of false labor) were counted twice.

The proportion of women testing HIV positive was not significantly different in the 1st and 2nd period of evaluation (23 vs. 24%, respectively, $P = 0.6$). The number of HIV-positive women receiving results was calculated from aggregate data by multiplying the number of women testing HIV positive in the laboratory with the proportion of tested women who received posttest counseling. Further analysis of computer-entered data showed that women who did not return for posttest counseling did not differ significantly in terms of HIV status and age from women who did return. Age patterns in women testing HIV positive were similar to those observed elsewhere;[15] however, sentinel surveillance usually reports slightly higher HIV prevalence among ANC attendees than obtained by the program.[11] Specific comparison between sentinel surveillance (testing all ANC attendees for up to 2 months per year) and computer-analyzed program data for the same period (June/July 2001) showed a significant difference (21.9% among named vs. 28.5% in anonymous unlinked testing, $P = 0.04$). This could reflect a tendency of HIV-infected women to exclude themselves from HIV testing.

To illustrate the potential effect of our intervention, we calculated hypothetical program impact, defined for this purpose as the extent to which the intervention reduced early (3-month) MCT of HIV in women attending the hospitals' ANC clinic during the observed periods from these data. The efficacy of single-dose nevirapine in the HIVNET 012 trial, compared with single-dose zidovudine, in reducing early MCT was 47%.[1] During the initial period of the program in Kisumu, an estimated 31% of all HIV-infected women accessing ANC care at the hospital received nevirapine. This translates into 15% effectiveness in reducing early mother-to-child transmission, assuming 47% efficacy of the intervention. In the 2nd service period, 48% of the target population was reached with testing and nevirapine, translating into a significantly increased program effectiveness of 23% ($P = 0.03$).

DISCUSSION

Our experience shows that integration of PMCT into routine ANC services is possible and that the way PMCT is implemented in the ANC can make a difference in uptake of counseling and testing, which increased by 24% after implementing an integrated approach. The proportion of women receiving nevirapine also increased significantly. Loss of ANC clients between stages and low return for nevirapine, we believe, were due at least in part to institutional factors that can be changed. Integration of HIV counseling and testing with other antenatal services by using the same location and staff is compatible with current policies of a routine offer of HIV testing in the context of pregnancy.[9,16]

The proportion of women refusing HIV testing after pretest counseling, however, decreased only slightly after implementing an integrated approach. Reasons given for refusing testing denote stigma and fear, though health worker attitudes may also affect women's decisions to accept the program,[17,18] but will not be expressed directly. Results of a qualitative study further exploring program perceptions and barriers at this facility have been reported elsewhere.[19] Addressing stigma and the attitudes of health workers who feel overburdened and strongly underpaid requires approaches that cannot be addressed by individual health institutions or PMCT programs alone.

Despite improved uptake, the estimated impact of the program remains low, and calculated effectiveness ignores late transmission through breast-feeding and incomplete ANC coverage. The relatively low efficacy of the nevirapine regimen limits potential program impact and highlights the need to implement more efficacious protocols, like highly active antiretroviral therapy (HAART), which would in addition increase the survival of mothers with low immune status.[20,21]

Contrary to our expectations, the proportion of women delivering in the institution with a known HIV status remained low despite wider geographical program coverage and increased testing uptake. It will be important to address PMCT strategies in maternity wards, to reduce missed opportunities for preventing HIV transmission to infants. In a US-based study, rapid HIV testing during labor appeared feasible and effective in reducing perinatal HIV transmission.[22]

Since many primary health facilities in resource-poor settings lack computers, the favorable comparison between aggregate reports from routinely collected service data and computer-entered line-listed data reassures us about the usefulness of aggregate reports for program monitoring.

Under program conditions, follow-up of HIV-infected mothers and infants was poor, since women in this urban setting tend to attend child health services at other (smaller) health units and tend not to reveal their HIV status at child health clinics, while incentives and resources for home visits are not applied as in research settings. Poor routine follow-up also compromises opportunities for ongoing infant feeding counseling and prophylaxis of opportunistic infections; this deserves more attention within PMCT programs. The introduction of special programs like MTCT-Plus provides opportunities for improved follow-up, partner involvement, and more efficacious antiretroviral regimens, thus addressing an important shortcoming of nevirapine programs only, requiring, however, substantially more resources. Male involvement has been associated with increased adherence to PMCT regimens[18] but is counteracted by many cultural attitudes and beliefs.[19]

Limitations of our report are that we describe experiences of one program only and focus on one of many issues that compromise the success of PMCT programs. Uptake of counseling, HIV testing, and nevirapine are similar, however, to reports from other programs within the region.[2–6] Program reports from various African sites show a wide range of uptake[23] with "opt-out" strategies being more successful.

Program effectiveness was calculated to show potential impact of our intervention but may be lower in reality. We were not able to verify whether nevirapine dispensed to women who delivered was taken as indicated. Follow-up data were insufficient to verify transmission and the efficacy of the intervention, and special cohort analyses to assess program efficacy have not yet been performed.

The assumed 47% reduction in early transmission was measured under clinical trial conditions, and effectiveness may differ under program conditions and in different populations. Early vertical transmission rates earlier observed in Kisumu were 20% in a study recruiting from the same hospital, but excluding pregnant women with symptoms of malaria or HIV,[24] and we consider rates of 26% from neighboring Uganda[1] closer to the overall transmission rate in the entire ANC population.

Recommendations

We wish to emphasize the role of programmatic aspects in PMCT. Low uptake of testing and counseling and of antiretroviral drugs undermines public health impact. Mothers who do not learn their HIV results during pregnancy, whether by choice or program failure, have received substandard health care. When scaling up PMCT programs, strategies to maximize program uptake in ANC and to increase the proportion of women delivering with known HIV status should be implemented. We recognize, however, that the success of PMCT program implementation is multifactorial, depending on institutional, community, as well as policy factors. The recent release of guidelines on HIV testing in clinical settings by the Kenya Ministry of Health,[16] strongly endorsing routine testing of pregnant women, should constitute a better program coverage and uptake.

To improve program impact we recommend better patient flow to minimize inconvenience; routine HIV testing in ANC using rapid tests; repeated education concerning nevirapine administration; routine testing for women of unknown status in labor, or of their infants postnatally; expansion of PMCT Plus to improve follow-up and involve partners and families; and expansion of treatment efforts to provide HAART as a more efficacious regimen for women with low immunity, the most likely to transmit including through breast-feeding. More data are needed on HAART to prevent postnatal transmission.

There has been inadequate emphasis on program monitoring and evaluation to assess program effectiveness. Collection of routine data on site is feasible to monitor process, but evaluation through periodic surveillance of HIV infection in infants or through cohort analyses will be necessary to assess population impact. With currently reported uptake and efficacy of interventions, the proportional reduction of transmission of HIV from mothers to their children in Africa remains low.

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