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Outcome of Different Nevirapine Administration Strategies in Preventin g Mother-to-Child Transmission (PMTCT) Programs in Tanzania and Uganda

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Abstract

Objective: Prevention-of-mother-to-child transmission (PMTCT) interventions based on single-dose nevirapine (NVP) are widely implemented in Africa, but strategies differ regarding how and when to administer the drug to women and infants. The aim of this study was to analyze the outcome of different strategies with regard to NVP intake in pregnant women and their infants in Tanzania and Uganda.

Methods: In an observational study carried out between March 2002 and December 2004, we compared a directly observed NVP administration strategy in Tanzania (supervised NVP intake for women and infants at a health unit) and a semi-observed administration strategy (self-administered NVP for women at home and supervised intake for infants at a health unit) in Uganda.

Results: The proportions of HIV-positive women accepting receipt of NVP from the health units were similar in the 2 countries (42.4% in Tanzania vs 45.6% in Uganda; $P = .06$). NVP intake in infants was significantly higher in Tanzania than in Uganda (43.7% vs 24.1%; $P < .001$). In a multivariate analysis, maternal age above 25 years, secondary education, Catholic faith, and having undergone PMTCT counseling at a hospital were independently associated with infant NVP intake.

Conclusion: In our settings, the directly observed administration strategy resulted in a higher NVP intake in infants. The semi-observed strategy, which implies that, after home delivery, the infant has to be presented to a health unit for NVP administration, was less successful.

Introduction

Vertical transmission is one of the most important routes of HIV-1 transmission in sub-Saharan Africa. Prevention-of-mother-to-child transmission of HIV (PMTCT) programs based on the administration of a single dose of nevirapine (NVP) to the mother and her infant at delivery have been adopted by many African countries as part of their national PMTCT policies and guidelines.[1,2] Due to the simplicity of NVP administration and low drug costs, this strategy is considered to be exceptionally appropriate

for resource-poor settings. Despite growing skepticism towards NVP because of the development of resistance in the mother and increasing use of combination antiretroviral therapy in PMTCT prophylaxis, the NVP-based intervention will remain the approach of choice in many resource-limited settings for some time because a feasible and affordable alternative is currently lacking.[3-8]

Most national PMTCT guidelines recommend the NVP-based single-dose drug regimen for PMTCT intervention, but national strategies of administering the drugs to the pregnant women and their infants differ. Although of high public health importance, the question of whether and in which way different drug administration strategies influence NVP intake has not yet been addressed.

Since 2001 the German Agency for Technical Co-operation and Development (GTZ) had supported NVP-based PMTCT programs in rural areas of Tanzania and Uganda. GTZ works in close cooperation with the Ministries of Health of the partner countries, and the programs are integrated into the existing governmental health facilities. Additionally, long-term antiretroviral treatment for the program participants and their families (PMTCT Plus approach) was started in 2003 in the Tanzanian and Ugandan sites.

The national PMTCT guidelines of the 2 countries recommend different NVP administration strategies. In this study we analyze the outcome of these different strategies with regard to NVP intake in pregnant women and their infants and factors possibly influencing the drug intake.

Methods

Study Population and Study Sites

An observational study design was used to compare NVP intake of PMTCT program participants in Tanzania and Uganda.

In Tanzania, the PMTCT intervention sites are in Mbeya Region (Mbeya Referral Hospital, Vwawa Hospital, Ruanda Health Centre, Igawilo Health Centre); in Uganda, in Kabarole, Kyenjojo, and Kamwenge Districts (Fort Portal Hospital, Virika Hospital, Kyenjojo Health Centre, Rukunyu Health Centre, Kibiito Health Centre).

Program Setting

The PMTCT programs comprise voluntary HIV counseling and testing for pregnant women and their husbands/partners, administration of NVP to the women and their infants, regular follow-up to counsel on infant feeding options, cotrimoxazole prophylaxis for children of HIV-positive mothers, management of infections and illnesses, and support to the HIV-affected family. Pregnant women are supposed to ingest a single tablet of 200 mg NVP at the onset of labor, and the newborn should receive 2 mg/kg of NVP syrup within 72 hours after birth.

The communities are continuously sensitized towards PMTCT measures in workshops, seminars, by brochures, leaflets, drama and theatre performances, and through radio spots in local languages. Integration of the PMTCT services into the existing health facilities demanded modification of space and reconstructions. Health personnel underwent comprehensive PMTCT and counseling training, including HIV rapid testing and training in antiretroviral treatment.

National NVP Administration Strategies

In Tanzania, women have to give birth at the intervention health units in order to receive the NVP tablet and syrup for the child. NVP is not handed out to the pregnant women in advance. The drugs are ingested under supervision of the health personnel (directly observed strategy) and the mother and her infant are not discharged before the drug is taken. In Uganda, the NVP tablet is handed to the pregnant woman at the antenatal care (ANC) clinic at week 28 of pregnancy. If she cannot deliver at an institution, she should take the NVP tablet at home. She is advised to present herself at the health facility with the newborn within 72 hours after birth in order to have the NVP syrup administered to her infant by health personnel (semi-observed strategy). In both countries NVP is administered to the infant within 72 hours after birth. In cases in which the mother did not take the NVP tablet within the recommended time frame (48 to 2 hours before delivery), the infant dose is given directly after birth.

Data Collection

Specific program indicators (such as the number of initial ANC visits, the number of ANC clients counseled for HIV/PMTCT, the number of ANC clients tested for HIV infection, the number of ANC clients testing positive, the number of ANC clients receiving NVP, and the number of clients and infants who ingested NVP under supervision of the health personnel or at home) were documented on a monthly basis and collected between March 2002 and December 2004 (observation period). For a subset of HIV-positive women, sociodemographic data such as age, educational level, occupation, marital status, religion, number of deliveries, and site of having undergone PMTCT counseling were collected on standardized documentation forms at the ANC visit of the women, at delivery, and at each follow-up visit. Due to logistic constraints, these data could only be collected from July to December 2003. During this period, the data were consist-

ently collected from all women of the observational cohort presenting at the health units without further selection.

NVP Intake and Acceptance of NVP Intervention

NVP intake was defined as the proportion of women or infants who ingested the NVP tablet or syrup, respectively, after they had received it from the health personnel.

Because NVP administration to women and infants in Tanzania and to infants in Uganda was supervised, exact figures on NVP intake were available and defined as true NVP intake. For women in Uganda, exact figures on NVP intake were not available because clients were allowed to self-administer NVP at home. For these clients, maximum NVP intake was defined as the proportion of all women to whom NVP was dispensed at the clinic at the ANC clinic over all women who tested HIV-positive; minimum NVP intake was defined as the proportion of women or infants for whom data on NVP intake was available over all women who tested HIV-positive.

Because the true intake in Tanzania and the maximum intake in Uganda corresponded to the proportion of HIV-positive women who were willing to receive the drug from their caregivers with the intention to take it, these numbers were used to describe the acceptance of the NVP intervention.

Statistical Analysis

Statistical analysis was performed using the SPSS program version 11.5 (SPSS Inc.; Chicago, Illinois).

Pearson's x^2 test was used to compare categorical data. Univariate analysis was performed to evaluate the sociodemographic variables: age, level of education, occupation, marital status, religion, number of deliveries, and PMTCT counseling site for the unadjusted association with the intake of NVP in the infant. Multivariate adjusted odds ratios were obtained from an unconditional logistic regression model. Those variables significant in the univariate analysis ($P < .1$) were included in the multivariate model and adjusted for the countries.

The association of sociodemographic variables with maternal NVP intake was not evaluated because, due to the different drug administration strategies, the maternal NVP intake was not comparable between the countries.

Ethical Considerations

This study was conducted according to the principles of the Declaration of Helsinki. It was approved as part of the evaluation protocol of the PMTCT programs by the national and regional health authorities in Tanzania and Uganda. Written informed consent for participation in the program and its evaluation was obtained from all participating pregnant women.

Results

PMTCT Program Uptake

The total number of ANC attendees in each country, the number of ANC attendees counseled and tested, and the number of ANC attendees who tested HIV positive are indicated in Figure 1.

True, Maximum, and Minimum NVP Intake

In Tanzania, 625 women and 645 infants of a total of 1475 HIV-positive women ingested NVP under supervision of the health personnel. The true NVP intake was therefore 42.4% for women and 43.7% for infants (Figure 2).

In Uganda, 979 of 2148 HIV-positive women received the NVP tablet at week 28 of pregnancy from the health personnel (Figure 2). Assuming that all women who received NVP also ingested it, the maximum NVP intake for women was therefore 45.6%. Of those women who tested HIV-positive, 490 reported back to the health unit and confirmed that they ingested the drug. The minimum intake was thus 22.8%. A total of 518 infants of 2148 HIV-positive mothers ingested NVP syrup. The true intake for infants in Uganda was therefore 24.1%.

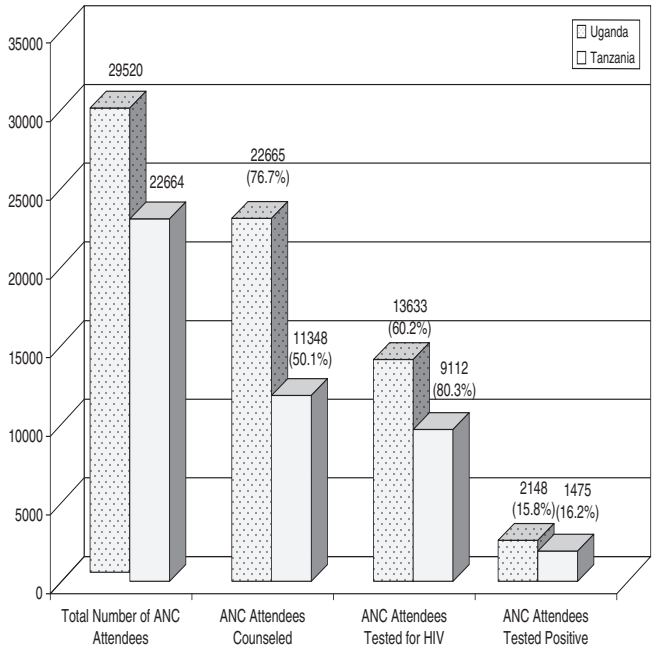

Figure 1
PMTCT program uptake in Tanzania and Uganda (March 2002December 2004).

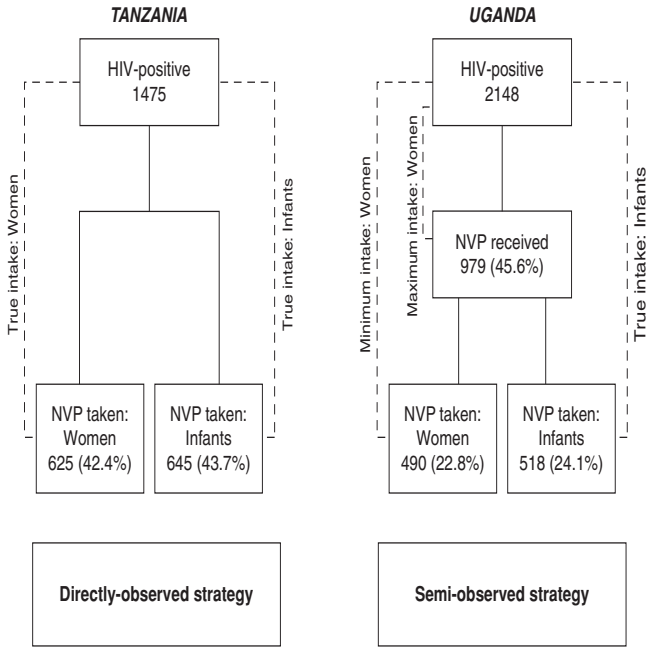

Figure 2
Comparison of true, maximum, and minimum NVP intake of PMTCT program participants in Tanzania and Uganda.

The acceptance of the NVP intervention (true intake in Tanzania and maximum intake in Uganda) did not differ significantly between the countries ($P = .06$).

With regard to true NVP intake in infants, significantly more infants in Tanzania than in Uganda ingested NVP syrup (43.7% vs 24.1%; $P < .001$).

Sociodemographic Data

Detailed sociodemographic data were available from 337 HIV-positive ANC attendees in Tanzania and from 282 in Uganda. The distribution of sociodemographic data differed significantly between the 2 countries (Table 1).

Maternal Factors Associated With NVP Intake in Infants

In univariate analyses, factors significantly associated with NVP intake in Tanzania were maternal age above 25 years ($P = .02$) and having undergone PMTCT counseling at a hospital (as compared with a health center; $P = .03$). In Uganda, age above 25 years ($P = .04$), secondary education (as compared with primary; $P = .01$), and having undergone PMTCT counseling at a hospital (as compared with a health center; $P = .03$) were associated with NVP intake. When adjusted for both countries, age above 25 years ($P = .005$), secondary education ($P = .02$), Catholic faith (as compared with Protestant faith; $P = .03$), and PMTCT counseling at a hospital ($P = .005$) retained significant influence in multivariate analysis (Table 2).

Discussion

The rates of women receiving NVP and the rates of women and infants ingesting the drug were relatively low in all of our settings and confirm the low uptake of the HIVNET 012 protocol in rural areas outside supervised research conditions. In other African settings, rates of women receiving the drug varied between 43% and 67%, and rates of women and infants ingesting it varied between 15% and 40%.[12-17]

In this study, we compared different NVP administration strategies in the GTZ-supported PMTCT programs in Tanzania and Uganda with regard to infant and maternal NVP intake. While the NVP intake in infants was directly comparable between the 2 countries, this was not true for the maternal NVP intake. Conclusions on how the different strategies might have affected maternal NVP intake in the 2 countries can therefore only be drawn with caution.

The proportions of HIV-positive women accepting to receive NVP from the PMTCT health units were similar in the 2 countries (42.4% in Tanzania vs 45.6% in Uganda). While it is unlikely that all women in Uganda who received the NVP tablet also ingested it, it did occur in the Tanzanian women due to the supervised drug administration strategy. Maternal NVP intake in the directly observed, health unit-based approach in Tanzania may therefore have been higher than under the semi-observed approach in Uganda, although this assumption cannot be proven from this study. Also, maternal NVP intake in Uganda may have been higher than the documented 22.8% because probably not all women who ingested the drug at home also reported back to the health units and may therefore not have been counted.

The NVP intake in infants was significantly higher in the directly observed approach in Tanzania than under the semi-observed Ugandan approach (44% vs 24%). This means that the different NVP administration strategies may not have affected the acceptance of the NVP intervention among the women as such, but presumably influenced the virtual NVP intake in women and infants. Of note, the access to the NVP intervention was more difficult for Tanzanian women because they had to come to deliver at an intervention site in order to receive the drug.

Factors positively correlated with the administration of NVP to the infants were: maternal age above 25 years, secondary education, Catholic faith, and undergoing PMTCT counseling at a hospital. The influence of education on PMTCT program uptake and NVP intake has been demonstrated previously. In a Zambian study, illiterate women were less likely to adhere to NVP intake, and in Côte d'Ivoire illiteracy was associated with low uptake of the PMTCT program package.[18,19] The latter study also

Table 1: Sociodemographic Data of HIV-Positive Clients per Country

Variable	Tanzania (n = 337)	Uganda (n = 282)	*P*
Age			.024
≤ 25 years	180 (53.4%)	125 (44.3%)	
> 25 years	157 (46.6%)	157 (55.7%)	
Education			< .001
None	30 (8.9%)	55 (19.5%)	
Primary	275 (81.6%)	159 (56.4%)	
Secondary	32 (9.5%)	68 (24.1%)	
Occupation			< .001
Housewife	169 (50.1%)	175 (62.1%)	
Farmer	111 (32.9%)	57 (20.2%)	
Business woman	47 (13.9%)	28 (9.9%)	
Other	10 (3.1%)	22 (7.8%)	
Marital status			< .001
Married	326 (96.7%)	239 (84.4%)	
Single	11 (3.3%)	43 (15.2%)	
Religion			< .001
Protestant	121 (35.9%)	90 (31.9%)	
Catholic	91 (27%)	145 (51.4%)	
Muslim	25 (7.4%)	12 (4.3%)	
Other	100 (29.7%)	35 (12.4%)	
Number of deliveries			.05
Primipara	25 (7.4%)	34 (12.1%)	
Multipara	312 (92.6%)	248 (87.9%)	
PMTCT counseling			< .001
Hospital	121 (35.9%)	238 (84.4%)	
Health center	216 (64.1%)	44 (15.6%)	

Table 2: Maternal Factors Associated With NVP Intake in Infants: Results of Univariate and Multivariate Analyses*

	Tanzania					Uganda					Multivariate Analysis		
Variable	**n**	**%NVP intake**	**OR**	**95% CI**	***P***	**n**	**%NVP intake**	**OR**	**95% CI**	***P***	**AOR**	**95% CI**	***P***
Age													
≤ 25 years	180	22.8	1.00			125	25.6	1.00			1.00		
> 25 years	157	34.4	1.78	1.102.87	.02	157	36.9	1.70	1.022.85	.04	1.68	1.172.42	.005
Education													
Primary	257	26.5	1.00			159	27.0	1.00			1.00		
None	30	40.0	1.85	0.854.02	.12	55	30.9	1.21	0.622.36	.58	1.28	0.742.20	.38
Secondary	32	31.3	1.26	0.572.78	.57	68	44.1	2.13	1.123.85	.01	1.83	1.123.00	.02
Occupation													
Farmer	111	27.0	1.00			57	29.8	1.00					
Housewife	169	29.0	1.10	0.651.88	.72	175	30.3	1.02	0.532.00	.95			
Business woman	47	29.8	1.15	0.542.43	.72	28	42.9	1.77	0.704.51	.23			
Other	10	20.0	0.68	1.143.36	.63	22	36.4	1.35	0.483.80	.58			
Marital status													
Single	11	9.1	1.00			43	34.9	1.00					
Married	326	28.8	4.05	0.5132.1	.15	239	31.4	0.85	0.431.70	.65			
Religion													
Catholic	91	34.1	1.00			145	37.2	1.00			1.60	1.052.43	.03
Protestant	121	27.3	0.90	0.541.49	.67	90	25.6	0.58	0.321.03	.06	1.00		
Muslim	25	28.0	0.88	0.372.10	.78	12	16.7	0.38	0.711.60	.15	0.82	0.351.90	.64
Other	100	24.0	0.78	0.461.33	.36	35	31.4	0.77	0.351.70	.52	0.85	0.491.47	.56
Number of deliveries													
Multipara	312	27.6	1.00			248	31.5	1.00					
Primipara	25	36.0	1.48	0.633.47	.37	34	35.3	1.19	0.562.52	.65			
PMTCT counseling													
Health center	216	24.1	1.00			44	18.2	1.00			1.00		
Hospital	121	35.5	1.74	1.072.83	.03	238	34.5	2.37	1.055.33	.03	1.86	1.202.89	.005

*Multivariate analysis adjusted for the countries (Tanzania and Uganda)
OR = odds ratio; AOR = adjusted odds ratio; CI = confidence interval

showed that women older than 25 years were more likely to accept post-test counseling, while no association between older maternal age or higher levels of education and adherence to NVP intake was found in a Kenyan study.[20] Reasons why maternal PMTCT counseling at a hospital as compared with counseling at a health center was associated with a higher NVP intake in infants may be manifold. Knowledge and motivation of staff are usually higher in a hospital, the setting more professional, and the medical infrastructure more developed. This may have positively influenced the quality of PMTCT counseling and care, including drug administration. In addition, the home distance of the clients to the urban hospitals may have been shorter than to the rural health centers, making women more likely to deliver at the hospital or to bring their newborn for the NVP intervention. Sociocultural factors and fear of disclosure of the HIV status in the countryside may have prevented women from delivering at the intervention health units and from bringing their infants for NVP administration.

Taken together, the factors associated with the administration of NVP to the infants remained independently associated with NVP intake in infants in a multivariate analysis after having adjusted for the countries. We therefore conclude that the differences in the sociodemographic maternal background in Tanzanian and Ugandan women did not explain the higher NVP intake in Tanzanian as compared with Ugandan infants.

The higher intake may thus be attributable to the different NVP administration strategy themselves. The current study, however, was not a randomized trial, and further possible confounders may not have been considered. One such confounder may be the quality of counseling. Counseling was performed by different counselors in at least 4 different PMTCT sites per country. Within the framework of the program, counselors in the 2 countries were trained uniformly and the counseling approach was standardized. Although we cannot exclude an influence of the quality of counseling on NVP acceptance and intake, we consider it to be unlikely. Furthermore, the detailed sociodemographic data on which the multivariate analysis was based were available from a subset of HIV-positive women of the observation cohort only. However, because this sociodemographic data were consistently collected for a specific period from all women of the observation cohort without any selection, we assume that the subset was representative for the entire cohort.

With regard to possible disadvantages of the 2 different NVP administration strategies studied, it is interesting that the more restricted approach, the directly observed NVP administration in Tanzania, neither impeded women from participating in the PMTCT intervention nor negatively influenced the NVP intake. It should be noted, however, that the majority of Tanzanian women delivered at home and had no access to the NVP intervention. The benefit of the directly observed approach is therefore limited. The semi-observed NVP administration strategy in Uganda which should facilitate the NVP intake in women did not result in a high NVP intake in infants. Possibly, once they have ingested the NVP tablet at home, women may not feel the necessity to bring their newborns to the health unit after delivery for the additional infant NVP dose. Furthermore, travel to the health unit shortly after delivery may be cumbersome for the women. The need to explain to the husband or family why it is necessary to take a healthy newborn to a health unit may be another barrier, particularly because disclosure of the HIV status may include isolation, expulsion from the family, and violence against women.[21] Nevertheless, the extent to which the efficacy of the NVP single dose is reduced when only the mother took the drug vs both mother and child receiving NVP is not known.

Conclusion

In our settings, the infant NVP intake in the directly observed Tanzanian approach was higher than in the semi-observed Ugandan approach. Furthermore, the Tanzanian strategy was possibly more beneficial regarding maternal NVP intake than the Ugandan strategy. In both countries, counseling activities, particularly for younger women and those with lower educational levels, need to be intensified in order to increase coverage of the PMTCT programs. Additional approaches to improve program uptake, such as "opt out" and intrapartum counseling and testing, are to be adopted.[12,22-24] Furthermore, complementary measures are necessary to better address women who prefer to deliver at home, such as NVP home administration by community volunteers or traditional birth attendants.[25]

Authors and Disclosures

Heiko Karcher, MD, has disclosed no relevant financial relationships.

Andrea Kunz, MD, MPH, has disclosed no relevant financial relationships.

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