

Factors Influencing the Utilization of Zidovudine and Nevirapine among HIV Positive Perinatal Women at Pumwani Maternity Hospital in Nairobi, Kenya.

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Abstract

Prevention of Mother to Child Transmission (PMTCT) of Human Immunodeficiency Virus (HIV) is a key strategy aimed at protecting babies from being infected with HIV by their mothers. Treatment with combination rather than single Antiretroviral (ARV) drugs has been found to be more effective in PMTCT. The objectives of this study were: 1. To determine the rates of utilization of single drug and combinations of Zidovudine (AZT) and Nevirapine (NVP) for PMTCT and 2. To determine the factors that influence the choice of treatment among HIV positive perinatal women at Pumwani Maternity Hospital (PMH) in Nairobi, Kenya. This was a cross-sectional descriptive study. The study site was Pumwani Maternity Hospital, which is a public health facility on the eastern suburbs of Nairobi County. A total of 326 post natal HIV Positive women were sampled and administered with questionnaires either at the Postnatal Clinic (PNC) or postnatal ward in Pumwani Maternity Hospital. Among the 326 HIV positive women, 299 (91.7%) acknowledged having been given ARV's for PMTCT where 160 (53.5%) and 139 (46.5%) of them were given single and combination drug treatments respectively. Single dose NVP was used by 132 (44.1%) of the women while AZT alone was prescribed in 28 (9.4%) of the women. The other 139 (46.5%) of the women received a combination of NVP and AZT. The frequency of Antenatal Clinic (ANC) visits was significantly related to the number of ARV's dispensed ($p=0.001$). Late ANC attendance and health problems were given as reasons why AZT was not dispensed while the main reason that was cited for NVP not being used was the lack of its availability. More than half of the HIV positive women delivering at PMH received single drug PMTCT. Availing combination PMTCT therapy should be enhanced. Success could be realized by encouraging frequent ANC attendance, availing alternative ARV treatment options and addressing health conditions that contribute to the use of monotherapy.

Key words: HIV, Positive perinatal women, Pumwani Maternity Hospital, Prevention of Mother to Child Transmission (PMTCT), Antiretroviral (ARV), NVP and AZT.

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HEALTH & MEDICAL EDUCATION

Introduction

More than 120,000 children under the age of 5 years are living with HIV/AIDS in Kenya of whom more than 90% acquired it through Mother to Child Transmission (MTCT) (NACC, 2006). Over 30% of these HIV positive children die within the first 6 months of life while by the 2nd birthday, 50% of them will be dead (MoH, 2005). Gains that had been previously made in reducing deaths of infants have now been lost following an increase of 30% in the infant mortality rate due to Acquired Immune Deficiency Syndrome (AIDS) related deaths (NACC, 2006). Majority of this maternal child HIV transmission occurs during labor and delivery and in the breastfeeding period (De Cock et al, 2000). In an urban set up study at Kibera, Bukonya et al (2005) established an Antenatal HIV Sero prevalence rate of 15.9 %. Reports show that the HIV prevalence rate among females of birth giving age in Nairobi stands at 12.3 % (NACC, 2007).

In Western countries the use of ARVs has drastically reduced MTCT rates to below 2% (Cooper, 2002 and Dorenbaum, 2002)). In keeping with the global trend, the Kenyan Ministry of Health (MoH) has developed and implemented PMTCT guidelines that are backed with a comprehensive strategy and policy framework (NASCO, 2002). Through these efforts close to 2,000 PMTCT sites have been operationalized countrywide where expectant women receive Counseling and Testing (CT) and Prophylactic ARV treatment among other ANC services. Nevirapine (NVP) is accessed by the national PMTCT programme via the free Viramune Donation Programme.

Single dose NVP (sdNVP) is a simple and cheap PMTCT regimen with high efficacy

and minimal side effects that reduces MTCT rates by close to 50% (Guay, et al 1999 and Musoke et al 1999). Adding Zidovudine (AZT) to NVP improves the efficacy of the regimen while reducing the possibility of viral resistance from developing to sdNVP (McIntyre, 2005). A local knowledge gap currently exists as to what extent the HIV positive antenatal clients are exposed to single or combination PMTCT prophylactic regimens and the underlying factors that influence their treatment options. It was the purpose of this study to determine the rates of single versus dual (combination) PMTCT regimen usage in the study group. The study further evaluated the underlying factors that lead to the use of single rather than dual PMTCT therapy.

Ethical approval of the study protocol was obtained from Kenyatta University, Ministry of Science and Technology and the Pumwani Hospital Ethical Committee. All the information obtained from the study was treated confidentially without taking down patient's identification or divulging their personal details.

Pumwani is the largest maternity hospital in the East and Central Africa region with a client base exceeding 30,000 annually. The hospital caters specifically for maternity cases and therefore serves as a role model to be emulated by other hospitals in the region. Women who seek ANC and delivery services at PMH are routinely counseled and upon agreement tested for HIV. Those who test positive are offered appropriate doses of NVP, AZT or both drug regimens. A large proportion of the women who deliver at PMH will usually have received ANC services at alternative health facilities within Nairobi City Council clinics in various parts of Nairobi County.

HEALTH & MEDICAL EDUCATION

Materials and Methods

HIV positive women whose serostatus had been previously determined through antibody tests were identified according to their hospital records. They were recruited into the study either while in the postnatal ward or when visiting the PNC at Pumwani Maternity Hospital during the period of this study. The sample size was calculated using Fisher et al (1998) formula

$$\text{Where } n = \frac{Z^2 pq}{d^2}$$

$Z = 1.96$ corresponding to a confidence interval of 95%

$P =$ the proportion of target population who are estimated to be having the characteristic of interest. (In this case 0.159 as earlier determined by Bukenya et al, 2005).

$$q = 1.0 - p = 0.841$$

$d =$ Degree of precision of 0.05

$$n = 202$$

Inclusion criteria: -HIV positive women attending the PNC or those that were in the postnatal ward after delivery.

-Willingness to participate in the study.

Exclusion Criteria:-HIV negative women

- Women on Highly Active Antiretroviral Therapy (HAART)

- Unwillingness by the women to participate in the study.

The participants were recruited into the study using the convenience sampling

method since the entry characteristic of the seropositive status was the exception rather than the norm with few cases being available for evaluation. They were counseled, informed the purpose of the study and given the opportunity to accept or decline to participate. Those who accepted signed informed consent forms that guaranteed confidentiality of their personal information. No coercion, inducement, intimidation or manipulation was used to enlist their cooperation. A structured questionnaire was administered to collect the data. The place where the data collection took place was noted on the questionnaire either as PNC or ANC by the researchers. The ARV dispensing history including the type and quantity of each drug that had been dispensed were also noted from the women's hospital records onto the questionnaires by the investigators. The women were then asked to complete the questionnaires with the options of responding to all, some or none of the questions. Those who experienced difficulties in understanding the questions were aided by the investigators and their assistants. The questions were set in English with back translation into Kiswahili to enable the participants to use their preferred language.

To control for bias the questionnaire was pre-tested on a sample of 30 women before being adjusted and standardized for the final data collection. Further control of bias was achieved by increasing the precision which was adjusted to 0.04 which consequently raised the number of participants from the calculated sample size of 202 to 326 and adhering to the inclusion and exclusion criteria. The participants were required to answer questions on their socio-demographic characteristics by providing

HEALTH & MEDICAL EDUCATION

information on their Age, Marital status (categorized as Single, Married, Widowed and Divorced), Highest level of education reached (categorized as no education at all, Primary School, Secondary School, College and University). Religion was categorized as Christian, Muslim, no religion and other. Data was also collected on monthly household expenditure (in Kenya shillings) on food, rent, clothes and other household needs. Data on occupation (categorized as none, employed, self-employed, housewife and other) was also collected. The questionnaire further elicited information on the hospital where the women delivered and the reasons for choosing to deliver there; the ANC attendance history (whether they attended ANC, where they attended ANC, gestation age when they made the first ANC visit, the total number of ANC visits that were made, reasons why ANC was not attended), ARV dispensing history (whether they were offered ARV's, number of ARV's that they were given, reasons why only one ARV was dispensed).

Data was cleaned, coded and entered into the computer where the Statistical Package for Social Sciences (SPSS) version 13 was used to process and analyze it. Descriptive statistics were used to analyze the data while Chi square test was applied to determine significance of relationships with statistical significance being based on p values < 0.05 .

Results

A total of 326 eligible women participated in the study. Out of these 206 (63%) were seen in the PNC while the other 120 (37%) were recruited through the postnatal ward at Pumwani Maternity Hospital. Their

age ranged from 15 to 42 years with 142 (43.6%) falling in the age group of 25 – 29 years. Most of the women (72.7%) were married while 15.7% were still single and the rest either separated or widows. Over half of the women (58.9%) had Secondary School Education, while the rest had tertiary or no education at all. Housewives formed 38% of the participants while the rest were employed (20.9%) or owned small businesses (31.3%). The maximum reported monthly household expenditure was Ksh. 35,000/=, the minimum was Ksh. 1,000 with a mean of Ksh. 8,187 (Table 1).

The main reasons the women gave for choosing to deliver at Pumwani Hospital were cost effectiveness (62.7%), referral from other healthcare centers (32.9%) and Pumwani being the nearest health facility (4.4%) as shown in Fig. 1 below.

ANC was attended by 310 (95%) of the women of whom majority (92.4%) received their ANC services in other health facilities and only 7.6% actually attended ANC at Pumwani Hospital (Tables 2 and 3). Most women (66%) started attending ANC in the 5th to 7th month of gestation with the number of visits averaging 4 to 6 in 50.4% of them (Table 4 and Fig. 2). Regarding ARV treatment 299 women reported having been given prophylactic ARV's for PMTCT out of whom 160 (53.5%) and 139 (46.5%) received single and combination drug therapy respectively. Where single drug treatment had been prescribed sdNVP was most commonly used (44%) compared to treatment with AZT alone (Fig 3).

Among the women who received single ARV treatment 32.2% cited health problems such as low blood and low CD4

HEALTH & MEDICAL EDUCATION

Table1: Socio-demographic characteristics of HIV positive postnatal women at Pumwani Maternity Hospital, Nairobi County.

VARIABLE	NUMBER(n=326)	%
Age(years)		
15 – 19	12.....	3.7
20 – 24	51.....	15.6
25 – 29	142.....	43.6
30 – 34	74.....	22.7
35 – 39	28.....	8.6
40 – 44	10.....	3.1
No response	9.....	2.7
Marital Status		
Single	51.....	15.7
Married	237.....	72.7
Separated	15.....	4.6
Widowed	22.....	6.7
No response	1.....	0.3
Education Level		
None	10.....	3.1
Primary	192.....	58.9
Secondary	92.....	28.2
College	32.....	9.8
University	0.....	0
Household Expenditure in Kenya shillings per month		
< 5,000	106.....	32.5
5,000 to 10,000	143.....	43.9
> 10,000	55.....	16.9
No response	22.....	6.7
Religion		
Christian	295.....	90.5
Muslim	30.....	9.2
No religion	0.....	0
No response	1.....	0.3

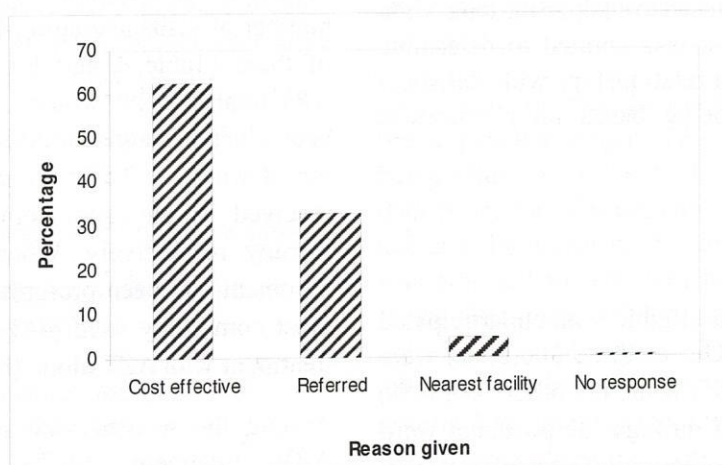


Fig.1: Reasons for delivering at PMH

HEALTH & MEDICAL EDUCATION

Table 2: ANC attendance behavior of the study participants

	frequency	%	Valid %
Attended	310	95.0	97.5
Did not Attend	8	2.5	2.5
No Response	8	2.5	-

Table 3: Facilities where participants attended ANC

	frequency	%
PMH	23	7.6
Other facilities	279	92.4
Total	302	

Table 4: Facilities where participants attended ANC

visits	frequency	%
1 – 3	142	46.6
4 - 6	154	50.4
7 - 10	9	3.0

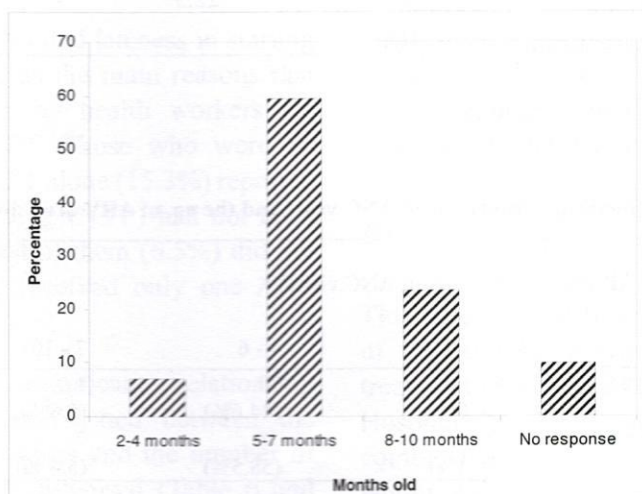


Fig. 2: Gestation age when participants began ANC attendance

HEALTH & MEDICAL EDUCATION

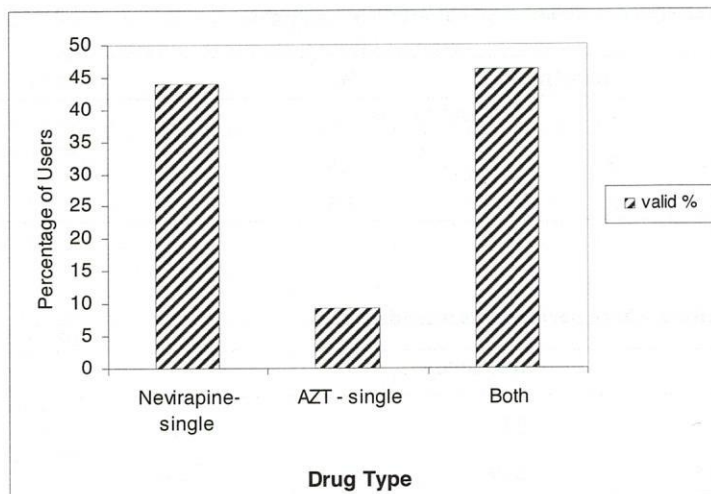


Fig. 3: Percentage of Women that were issued with each drug by type.

Table 5: Reasons offered by Participants for taking only one instead of two ARV's for PMTCT

	freq	%	Valid %
Don't Know	8	5	6.5
One drug not available	19	11.9	15.3
Late clinic attendance	57	35.6	46
Health problems	40	25	32.2
No response	36	22.5	-
Total	160		

Table 6: Relationship between no. of ANC visits and the no. of ARV drug dispensed

Number of ARV's	Number of ANC visits		
	1 - 3	4 - 6	7 - 10
Only one type	86 (54.8%)	70 (44.6%)	1 (0.6%)
Both NVP and AZT	48 (36.1%)	78 (58.5%)	7 (5.4%)

$\chi^2 = 13.8169$ $p = 0.001$

HEALTH & MEDICAL EDUCATION

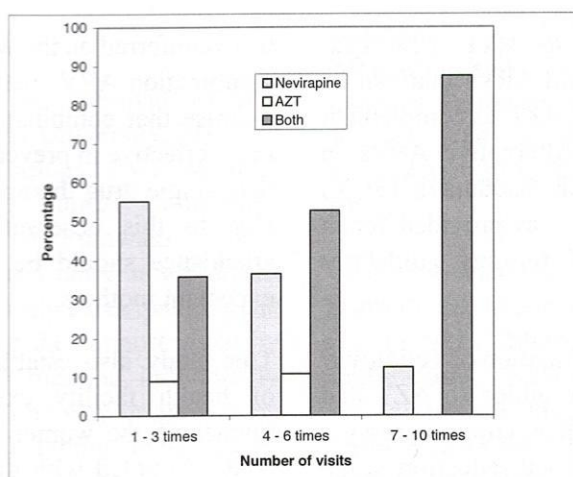


Fig. 4: Relationship between number of ANC visits and use of NVP and AZT alone or in combination

Table 7: Relationship between the no. of ANC visits and the facility that was attended

Facility	Number of ANC visits		
	1 - 3	4 - 6	7 - 10
Pumwani Hospital	9 (34.6%)	13 (50%)	4 (15.4%)
Other facilities	133 (49.1%)	133 (49.1%)	5 (1.8%)

$$F = 15.39 \quad p = 0.00045$$

counts while 46% cited lateness in starting ANC attendance as the main reasons that they were given by health workers for not receiving AZT. Those who were on treatment with AZT alone (15.3%) reported that the second drug (NVP) had not been available. The rest of them (6.5%) did not know why they received only one ARV (Table 5).

A statistically significant relationship ($P=0.001$) was established between the number of ANC visits and the number of ARV's that were dispensed (Table 6 and Fig.4). The type of health facility also had a significant effect on the clinic attendance in

that women who attended ANC at Pumwani Hospital visited the clinic significantly more frequently ($p=0.00045$) than those who visited other facilities (Table 7).

Discussion

This study established that more than half of the HIV positive women on PMTCT treatment who delivered at Pumwani Hospital received single rather than combination ARV regimens. Women to whom AZT could not be dispensed for health reasons or due to late attendance to ANC were not offered any alternative

HEALTH & MEDICAL EDUCATION

ARV's in addition to NVP treatment. Clearly, a need to avail ARVs that can be dispensed in place of AZT to complement NVP was exposed. Alternative ARVs in this case could include Saquinavir (SQV) and Lamivudine (3TC) as provided for in the national PMTCT training guidelines (MoH, 2005).

Additionally the combination of Tenofovir/ Emtricitabine may be added to AZT and NVP resulting in excellent viral suppression coupled with a significant reduction in the Non Nucleoside Reverse Transcriptase Inhibitor (NNRTI) viral resistance (Chi et al 2007). Where NVP was not available the women delivering at Pumwani were given AZT alone which they used as a single drug. This calls for further investigation to establish where the causative factors are originating from the supply chain with a view to improving NVP's availability. Similarly, collaboration between the Ministry of Health and the private sector or non-governmental organizations can be enhanced in order to avail alternative ARVs for the women who need them.

A large proportion (95%) of the women that were evaluated in this study had attended ANC mostly in health institutions other than Pumwani. This ANC attendance pattern is consistent with the national statistics which estimate that 90% of the pregnant women in Kenya usually attend ANC (NASCO, 2005). The number of ANC visits impacted positively on the PMTCT treatment options since the study established that the women who made more visits to the ANC were likely to receive dual rather than single ARV treatment. This in turn implies that higher treatment efficacy with greater chances of protecting the babies from contracting HIV

were conferred on the women who received combination ARV treatment based on the premise that combination ARV therapy is more effective in preventing MTCT of HIV than single drug therapy (McIntyre, 2005). Due to this observation frequent ANC attendance should be encouraged among expectant mothers.

This study also established that the type of health facility exerted a significant impact on the women's attendance to the ANC. Coupled with the finding that 32% of the women visited Pumwani Hospital after being referred there implies that the peripheral health structures need specialist services. This could be partly addressed by availing specialists and improving the diagnostic and treatment facilities within the peripheral health clinics. The access by ANC clients to such facilities and personnel has been shown to increase through providing mobile specialist coordinated PMTCT services to the peripheral health facilities (Odey et al 2006).

Conclusion

More than half of the women seen in this study received single rather than combined PMTCT ARV regimens. The uptake of combination treatment regimens should be enhanced. Health problems, late ANC attendance and lack of alternative ARVs were identified as reasons that contributed to the use of monotherapy and they therefore need to be addressed. This may be partly achieved through collaborating with private or non-governmental organizations to avail optional drug regimens, encouraging frequent ANC attendance and establishing mobile PMTCT clinics.

HEALTH & MEDICAL EDUCATION

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