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**Nguefack Félicitée**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

**Fonguazi Mary-Madaline N**  
Faculty of Health Sciences,  
Université des Montagnes,  
Bangangté, Cameroon

**Dohbit Julius Sama**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

**Dongmo Tsopfack Félicie Cindy**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

**Mekone Isabelle**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

**Epee Jeanette**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

**Kago Tague Daniel**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

**Fotsing Kwetche Pierre René**  
Faculty of Health Sciences,  
Université des Montagnes,  
Bangangté, Cameroon

**Corresponding Author:**  
**Nguefack Félicitée**  
Faculty of Medicine and  
Biomedical Sciences,  
University of Yaounde,  
Cameroon

## Adherence to anti-retroviral therapy in mothers with HIV infection and its relation to infants' status

**Nguefack Félicitée, Fonguazi Mary-Madaline N, Dohbit Julius Sama, Dongmo Tsopfack Félicie Cindy, Mekone Isabelle, Epee Jeanette, Kago Tague Daniel and Fotsing Kwetche Pierre René**

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### Abstract

Effective Prevention of Mother-to-Child-Transmission (PMTCT) of HIV depend on the adherence to Anti-Retroviral Therapy (ART) by pregnant and lactating mothers. This prospective cohort study aims to determine the adherence of infected mothers to ART and its relation to infant's contamination at 6 weeks. We recruited 110 HIV pregnant mothers during pregnancy and their 6 to 8 weeks old infant with their DNA/PCR test performed. Fisher's test was used to search factors associated with the level of adherence to ART considering  $p < 0.05$ . The mean age of mothers was  $31.2 \pm 6.2$  years. Their overall level of adherence was 97.6% out of which 97.3% had a score  $\geq 95\%$ . Four infants were infected among which 3 from non-adherent and one from an adherent mother. We conclude that perfect adherence to ART greatly had an effect on the infant's status with mother-to-child HIV transmission rate relatively low.

**Keywords:** Prevention, mother-child, transmission, HIV, adherence, ARV

### Introduction

Adherence to antiretroviral therapy (ART) is the extent to which a patient takes his or her treatment according to the prescribed doses, dosing intervals, and other medication instructions. Option B+ according to World Health Organization (WHO) is a life-long regimen of a combination of three antiretroviral drugs (ARVs) for pregnant and breastfeeding women, commencing at the time of HIV diagnosis no matter the 4 (CD4) count or clinical stages <sup>[1]</sup>. It is estimated to 1,400,000 the number of HIV infected women giving birth to about 330,000 HIV infected babies annually <sup>[2]</sup>. Mother-to-child transmission (MTCT) accounts for greater than 10% of HIV infections worldwide and also contributes to more than 90% of HIV infection among infants and young children <sup>[3]</sup>. Each day in 2023, it is estimated at 685, the number of children becoming infected with HIV and approximately 250 of them died from AIDS related causes, mostly due to inadequate access to HIV prevention, care and treatment services <sup>[3]</sup>. In Cameroon, it is estimated new infections per hour, approximately 141 per day; the total number of children infected through Mother-to-child transmission (MTCT) was 3,308 in 2019, representing the essential source of pediatric infections coming from women who have discontinued ARV treatment during pregnancy and from women who have not received ART at all <sup>[4]</sup>. In view of the foregoing, the World Health Organization (WHO) recommended Option B plus as an intervention for PMTCT of HIV, for which all pregnant and breastfeeding women are on lifelong ART <sup>[5]</sup>. Option B+ poses as problem in that as a life-long regimen, it creates a source of drug interruption for those that have begun thus leading to virologic failure, and progresses the disease to advanced stage leading to an increased risk of MTCT of HIV <sup>[6]</sup>. Optimal adherence to antiretroviral therapy (ART) among people living with HIV is critical for maintaining viral suppression and preventing HIV transmission <sup>[7]</sup>. Adherent definition refers to Mother taking HIV medicines every day and exactly as prescribed. There is no consensus about the definition of adherence, meanwhile, five main ways adherence to ART are used: self-report, medication event monitoring systems, pill count, pharmacy refill, and therapeutic drug monitoring <sup>[8]</sup>. Non adherence to ART of mothers is very crucial in that it increases the mortality and morbidity of children; the survival probability of children born to women with

HIV infection is high (93.0%) among children whose mothers received ART before, 87.8% when ART starts during pregnancy, and low 53.4% when mothers did not receive any ART during pregnancy [9]. Not only does non adherence have as complication at the infant level but over time, it becomes a burden due to the risk of developing opportunistic infections which becomes very costly financially [10]. However, adherence to ART remains an unsettled problem. Looking into this situation that prevails our setting, we conducted a study on the level of adherence to anti-retroviral therapy in women and its relation on infants' HIV status.

### Materials and Methods

It was a consecutive and exhaustive method in a prospective cohort study carried out in three health facilities at Yaoundé-Cameroon. All HIV positive pregnant women in their third trimester and their future exposed infants followed up from birth to at least 6 weeks of age were included. The loss to follow-up mothers were excluded.

### Data collection procedures

The first interaction with mothers was during the antenatal visit and consisted of an interview lasting 10-20 minutes. After delivery, they were then followed up. Using the HIV psychosocial health workers, they were recalled with the system in place in order to access their level of adherence to the ART. To determine the status of their infant, blood sampling was collected for HIV DNA/PCR test between 6 and 8 weeks post-delivery. In the study sites, blood samples for HIV PCR testing are sent free of charge to the reference laboratory of the Centre Pasteur of Cameroon or to the International Reference Centre of Chantal Biya. We monitored and collected the results of the infant included. The questionnaire comprised socio-demographic, economic, clinical and paraclinical characteristics. Socio-demographic variables consisted of age, residence, marital status, religion, education, profession and the sex of infant. Clinical variables included counseling on drug side effect, the number of antenatal care (ANC) visit, the gestational age, knowledge of HIV status, the ART upon the diagnosis, knowledge on option B+, mode of delivery, infant feeding option and the result of HIV PCR test in infant.

As for the operational definition of adherence, two indirect methods were used including the self-report and the pill count [11]. The self-report method was accessed using four fundamental questions initially prepared in English and translated into French to overcome any language barrier. This included difficulty to remember to take medication, or break from medication when feeling better, missing any of doses over the past four days or stop taking ARV when feeling worse or when taking the medicine. A mother who did not miss any antiretroviral (ARV) drugs in the last four days prior to the interview and who responded correctly to two or more of the four self-report measurement questions had good adherence; if not, she was considered to have poor adherence.

The number of current pills were registered and the mothers

were asked for how long a container stay, knowing how many pills a container has. Pill-count adherence was assessed by counting the remaining doses of medication and assuming that the remaining pills in excess of the expected number represented missed doses. The adherence expressed in percentage was therefore calculated by subtracting the number of remaining pills from the number of dispensed one, divided by the expected number of pills to be taken and the result multiplied by 100. A mother was said to be non-adherent if she rates <95% and adherent  $\geq 95\%$ .

### Data analysis

Qualitative variables were expressed as numbers and percentages. Quantitative variables were expressed as mean and standard deviation or median and interquartile range depending on the distribution of the data. The search for associated factors was done using the chi-square or Fischer test: the measure of association used was the relative risk. Data were being considered statistically significant at  $p < 0.05$  with 95% of confidence of interval.

**Ethical consideration:** this study received the approval of the ethical Committee of the Yaounde Gynaeco-Obstetric and Pediatric Hospital.

### Results

#### Mothers' characteristics upon recruitment

The mother's age ranges from 15 to 45 years with 47.3% between 25-35years, followed by the 35-45% (38.2%). Those married represented 79.1% and 89.1% of the mothers had gone through secondary and university levels. Almost all (99.1%) were Christians, most of the participants originated from the center region 69 (62.7%) while almost all 107 (97.3%) were living in urban areas. The majority of the participants were unemployed 40.0% followed by those working at the informal sector 38.2% (table1).

**Table 1:** Socio-demographic characteristics of pregnant women

Variable	Modalities	Number (N=110)	Percentage
Age (years)	15 – 24	16	14.5
	25 – 34	52	47.3
	35 – 45	42	38.2
Marital status	Single	87	79.1
	Married	23	20.9
Level of education	Primary	12	10.9
	Secondary	62	56.4
	University	36	32.7
Profession	Unemployed	44	40.0
	Working in informal sector	42	38.2
	Working in formal sector	24	21.8
Religion	Christian	109	99.1
	Muslim	1	0.9
Residence	Urban	107	97.3
	Rural	3	2.7

#### Gynecological characteristics and knowledge on option B+ treatment and PMTCT

**Table 2:** Gynecological characteristics and knowledge on option B+ treatment and PMTCT

Variable	Modalities	Number (N=110)	Percentage
Antenatal consultation	< 4	11	10.0
	≥ 4	99	90.0
Duration of information on HIV positive status	<5 years	61	55.5
	≥5 years	49	44.5
Start ART on diagnosis	Same day	107	97.3
	≥ 1 month	3	2.7
Knowledge on Option B+	Good	108	98.2
	Poor	2	1.8
Mode of delivery	Vaginal	104	94.5
	Cesarean	6	5.5
Infant feeding option	Exclusive breastfeeding	87	79.1
	Artificial feeding	23	20.9
Counseling received on side effects of drug ART	Yes	110	100.0

The table 2 shows that 99 mothers (90.0%) had more than 4 ANC. Almost half 61 (55.5%) had been tested HIV positive for less than 5 years and 107 (97%) of these mothers began their treatment just after. More than half 108 (98.2) had good knowledge on option B+, 104 (94.5%) went through vaginal delivery and 87 (79.1%) opted for exclusive breastfeeding. With regards to the counseling on side effect of drug, all 110 participants were being counseled before the onset of the treatment.

#### Infant's characteristics

The infants were aged between six and eight weeks and females infants represented 69.1%.

Their mean birth weight was  $3155.73 \pm 500$  grams; it was  $5336.36 \pm 715$  between six and eight weeks of age (table 3)

**Table 3:** clinical characteristics of the infants

Variable	Mean ± SD	Min	Max
<b>Weight</b>			
Birth	$3155.73 \pm 500.556$	2000	4300
At 6 to 8 weeks	$5336.36 \pm 715.431$	2440	6600

The mean (SD) birth weight was  $3155.73$  ( $500 \pm 556$  g with a minimum being 2000g and maximum 4300g. The mean (SD) weight of these infants after 6 weeks of age  $5336.36 \pm 715.431$ g with a minimum being 2440g and maximum being 6600g.

#### Adherence on ARV drugs of the mothers during pregnancy and post-partum period

The overall level of adherence of the mothers was 97.6% using both the self-report and the pill count methods. There was no difference in level of adherence using both the self-report and pill count method.

#### Proportion of exposed and infected infants with regard of the level of adherence on ART

Table 4 shows that among the exposed infants, 106 issued from mothers with good adherence to ART were non-infected. Of the 4 infected, 3 were from those who had poor adherence to their ART and 1 infected despite the good adherence to ART of the mother ( $P < 0.001$ ).

**Table 4:** Relationship between the level of adherence in mothers and infants' status

Variable	PCR-DNA result		p- value
	Positive n=4 (%)	Negative n=106 (%)	
Poor Adherence	3 (75)	0 (0)	< 0.001
Good Adherence	1 (25)	106 (100)	< 0.001

#### Discussion

##### Limitations of our study

Most of the mothers were recruited during the first and second, but less in the third trimester of gestation. Additionally, the self-report method used could have been prone to social desirability, thereby leading to overestimate of our results. Recall and information bias could also have influenced the result. Exclusive breastfeeding even with the ART, could have represented an additional risk of contamination of the exposed infant postnatally. In spite of these limitations, the present study analyzed the HIV status of the exposed children with regards of the adherence on ART of the HIV infected mothers in the course of the PMTCT. Mean self-report adherence was 73.77% and mean pill count adherence 77.36% [12]. The overall level of adherence was 97.6% using the self-report and the pill count methods of evaluation. This level was same both during pregnancy and post-partum, result similar to that of Khreichmann *et al.* 2012 in Latin America [13]. It could be explained by the delivery of drugs free of charge, the proximity of the health care units and also the means used by the units to recall mothers for their appointments in our setting. In Ethiopia, social and financial support, disclosure of HIV status to partners, easily access a health facility, counseling on drug side effects and its experience influenced adherence to the Option B+ program [14]. In rural Uganda, upgrading and providing full time HIV services improved by 100% of retention of HIV positive pregnant and breastfeeding mothers on option-B+. [15]. In the northeast Ethiopia, adherence to option B+ PMTCT drugs was 87.9%; women who received in-hospital treatment, who lived in rural areas and faced challenges in initiating lifelong option B+ treatment on the same day of diagnosis of HIV were less likely to adhere to the treatment [15]. In the present study, a greater number started their ART the same time they had been enrolled in the process of diagnosis-treatment and were more adherent (99.1%). This was similar to the results of a study performed in Ethiopia where starting ART the same day of diagnosis was significantly associated with good adherence to option B plus ART [16]. On the contrary, respondents who started ARV drugs after one month of HIV diagnosis were more likely to adhere than those who started on the same day of HIV diagnosis [17]. Mothers who began ARV drugs on the same day may have gotten little support for future care thus, tend not to adhere as time goes by. Other socio demographic factors affecting adherence level included: young mothers of 25 years age or less, with no formal education, who experienced drug side effects were

less adherent compared to those who had good knowledge of PMTCT, and get support from partner/family <sup>[18]</sup>. In Sub-Saharan Africa, numerous factors as stigma, cost of transportation, food deprivation and a woman's disclosure or non-disclosure of her HIV status to a partner may have limited or extent the adherence to the ARV drugs during pregnancy <sup>[18]</sup>. In Nigeria, the level of adherence was good (83.3%) and association with non-adherence to ART included: forgetfulness, lack of food, disclosure of HIV status, being too busy <sup>[20]</sup>. On the contrary in Southeastern Nigeria, the adherence was only 56.2%. Lack of transport fare, long-distance to clinic located in of a tertiary institution, negative attitude of the health care workers, and lack of partners and parents support demotivated adherence <sup>[21]</sup>. In the present study, the most represented mothers were married or cohabitating with a partner 87(79.1%). This was similar in 2018 in Southern Ethiopia and in 2017 in Malawi <sup>[22, 23]</sup>. In the couple setting, mothers are prone to receive moral encouragement and social support compared to those who lived alone or are being single. Additionally, the majority of the mothers resided in urban areas and were more likely to adhere 106 (99.1%). In Tanzania on the contrary, the rural residents were 4.86 times more likely to adhere compared to their counterparts in an urban area with adherence rate to option B+ PMTCT drugs of 61.1% vs 26.3% in the urban setting <sup>[24]</sup>. This was not the same picture in the northeast Ethiopia where mothers who lived in rural areas had a lower adherence to option B+ PMTCT drugs than those from the urban areas <sup>[5, 24]</sup>. In this context, traveling long distances could represent a real constraint and explain the miss appointments. The greater the number of ANC expose more to the education and relevant information about the prevention of HIV thus, the higher the level of adherence <sup>[17]</sup>.

There is evidence that, maternal PMTCT interventions decrease the HIV positivity in infants(5). The prevalence of HIV among infants born from HIV positive mothers is reduced to the meaningful number (<5%) because of the appropriate measure such as sensitization given to these mothers thereby reducing the transmission of HIV from mothers to infants <sup>[5]</sup>.

In the present study, 4 infants over 110 (3.64%) were positive for HIV-DNA PCR. This was greater than the rate of HIV infection in the study conducted in Lesotho whereby 1 infant was found positive at 6 weeks out of the 107 exposed infants <sup>[25]</sup>. The suppression of HIV viral load prevent mother –to –child transmission, this relies on the duration of therapy and adherence <sup>[26]</sup>. We observed an association between the level of adherence and the infants' status.

## Conclusion

Cameroon has committed to eliminate mother-to-child transmission of HIV. Adherence to ARVs is crucial for mothers during pregnancy and in the post-partum period. It is important to ensure the availability of stocks of anti-retroviral drugs to reach the goal.

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## Conflicts of Interest

None.

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