

## Factors Affecting Adherence to Pediatrics Antiretroviral Therapy in Mekelle Hospital, Tigray Ethiopia

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### ABSTRACT

The most important factor in the success of HIV treatment is adherence to antiretroviral therapy (ART). The challenge to adherence to ART is particularly serious in Sub-Saharan Africa as the high rates of HIV/AIDS lead to greater numbers of affected individuals. Although long-term good ART adherence has been observed in certain settings of public sectors the magnitude of this challenge in Sub-Saharan Africa remains large and there is evidence for high rates of patient's poor adherence. Study aimed to assess the factors affecting adherence to pediatrics antiretroviral therapy (ART) among children in Mekelle hospital, Tigray, Ethiopia. A Hospital based cross-sectional study was conducted on 226 children on antiretroviral therapy from May 01 to 30/2014 at Mekelle hospital. Data was collected from care givers of children under 15 years old who are on ART. Of the 226 children under 15 years, 90.3 % reported complete adherence to antiretroviral therapy medications at the regular schedule over the past 7 days. Factors associated with adherence were having male care giver (AOR=2.10[1.01, 7.22]), age of the child (AOR=1.43[1.16, 3.98]) below 5 years and use of first line ART drugs (AOR=2.86[1.54, 3.67]). Over all the adherence of children on ART to their medication in this study is relatively higher as compared to others. However, complete adherence is expected in order to make the drugs effective. Different strategies have to be designed to improve the adherence level.

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## 1. INTRODUCTION

Globally, there were about 3.4 million HIV/AIDS infected below 15 years old children by the end of 2010. An estimated 250,000 children reported dead of AIDS related conditions. Majority (91%) of the HIV infected lived in Sub-Saharan Africa. However only about 21% had access to ART and HIV/AIDS remained one of the leading causes of under five children morbidity and mortality in sub-Saharan Africa [1].

An index case of HIV in Ethiopia was reported in 1984. Since then HIV/AIDS has become a major public health concern of the country. Children are profoundly affected. In 2009 an estimated 72,945 under 15 year old children were living with HIV. Out of which about 20,522 were in need of ART but only 43% of them got access to therapy [2],[3].

Antiretroviral therapy (ART) is a treatment for HIV that combines different types of antiretroviral medications, which should be taken throughout life in order to prevent resistance to medications and to

make them effective. The drugs are becoming increasingly available to children in resource-limited settings and have the potential to greatly improve the survival of HIV-positive children. The most important thing for the success of HIV treatment programs is adherence to antiretroviral treatment (ART). HIV treatment adherence levels that are greater than 95% result in optimal clinical outcomes and also ensure that individuals are able to stay on their first-line regimens for longer periods by limiting the emergence of resistance [4]. Poor adherences may be caused by failure of HAART early in therapy and will become a cause of drug resistance late after therapy. Thus evaluation of adherence is important to be able to measure the efficacy of antiretroviral therapy [5].

In 2010, below 15yrs old HIV infected children were 10% of all HIV infected persons, 14% of newly infected and 14% of all HIV related deaths worldwide [6]. Early initiation and adherence of ART in these children can save their lives. It has been demonstrated that 10% higher level of adherence results in 21% reduction in disease progression. With 95% adherence, viral suppression to below detectable levels occur in 80%, however a fall in adherence to 70% rapidly decreases viral suppression to 33% [7]. Even though there are limited studies on pediatrics ART adherence in African children a recent review reported that ART program in Africa retains only 60% of their patients after two years on ART [8],[9]. The same studies reported that 40% to 45% of children had no adherence to ART [10]. Another study suggests that one quarter (25%) of ART users do not achieve optimal adherence in Africa [11].

Despite of the importance of adherence to ART the level of adherence are affected by different factors. Several studies indicated that these factors that favors the adherence of ART include male sex of the child, duration of ART more than 28 months and the median CD4 count more than 440 cells/ $\mu$ l where as missing clinic appointment and increasing age of the child [12] facilitate non adherence. In another study the Predictors of poor adherence are mothers as the primary care giver, younger than 5 years, and presence of co morbidity. Having a medication reminder strategy, regular clinic visits and status disclosure predicted a better adherence [13].

In Ethiopia a study conducted in Harar and Dire-Dawa showed that 89.1% children who were on ART were adhered to their medication while 86.9% in Addis Ababa [14],[15]. However, little was known about pediatrics ART medication adherence in Tigray. This study assessed the factors which affects the adherence to pediatrics ART in Mekele hospital.

## 2. RESEARCH METHOD

**Study Area and Study Period:** This study was conducted in Mekelle hospital which is found in Tigray regional state, Ethiopia. The hospital have been giving services such as HIV counseling and testing, provision of ART, treatment of opportunistic infections; prevention of mother to child transmission, TB/HIV confection treatment, and care for HIV exposed infants. The numbers of children on ART at Mekelle hospitals were 438 and the data was collected from May 01 to 30, 2014. Study design: Institution based cross-sectional study was conducted. Source and Study Population: All primary caretakers of the HIV infected children were the source population. Caretakers of the children receiving care in the ART clinics of the study facilities were considered as the study population.

**Sample Size Determination:** The sample size for the study was calculated using the formula for simple random sampling at confidence interval of 95%, and degree of precision 5%. Considering 10 % non-response rate, the final sample size was 226 children on ARTs.

**Sampling and Data Collection Procedures:** According to the guideline of the hospital all HIV positive individuals who use ART service appointed every month. The total number of children on ART (438) divided by computed sample size (226) to determine the interval between the study subjects. The first client was selected randomly from the list of clients appointed for follow-up in the first day of data collection and 20 patients were appointed and every other patients caretaker were included until the required number of study participants were achieved. Structured interviewer administered questionnaire was used and the reliability of the instrument was checked using reliability coefficient which was 0.85. The coefficient showed good internal consistency of the instrument. Regularly appointment for ART follow up given after one month and there was no chance of being interviewed twice.

**Inclusion and Exclusion criteria:** Caretaker of children under the age of 15 years who were on ART for a minimum of one month was included in the study. Those children who were on ART for less than one month, those HIV infected children who didn't start ART were excluded.

**Data Processing and Analysis:** Data was entered into SPSS version 16 windows. The entered data was cleaned first and analyzed. Binary logistic regress was used to identify the significant determinants of dose adherence. Finally, multivariate analysis was used to identify the most important determinants.

**Ethical Considerations:** After thorough revision of the research ethical approval was obtained from the Institutional Research board of Mekelle University College of Health Sciences. Letter of cooperation was

written for Mekelle hospital. Oral consent was obtained from each care givers before the interview and the data was collected anonymously to maintain confidentiality of the clients.

### 3. RESULTS AND DISCUSSION

#### 3.1. Socio-demographic characteristics

The study was conducted on a total of 226 children on ART and the response rate was 100%. Nearly equal proportions of male (50.4%) and female (49.6%) subjects were involved in the study. Majority (88%) were above the age of five years. However, their age ranged from seven months to fourteen years plus two months and the median age was at 8.665 years. The reported length of time the children stayed on ART ranged from one to 93 months and the median was 47 months. Furthermore, majority (82.7%) of the children's care takers were males. Age of the care giver ranges from 19 to 84 years and those who were urban and rural dwellers accounted for 79.2% and 20.8% respectively. Those who were illiterates accounted for 39.4% (Table 1).

Table 1. General characteristics of the primary care givers and their children

Characteristics	Number (%)	
Age of care giver	<34 years >35 years	106(46.9) 120(53.1)
Sex of care giver	Male Female	39(17.3) 187(82.7)
Care givers education	Illiterate Primary Secondary and above	89(39.4) 93(41.2) 44(19.5)
Residence of care taker	Urban Rural	179 (79.2) 47(20.8)
Age of the child	< 5 years 5-9 years 10-14 years	27(11.9) 99(43.8) 100(44.2)
Sex of the child	Male Female	114(50.4) 112(49.6)
Duration of ART use	< 36 months 37-59 months >60 months	69(30.5) 89(39.4) 68(30.1)

#### 3.2. Adherence to Antiretroviral therapy

A total of 173 (76.5%) children on ART in the study area were taking their medication with the help of their care takers, but the rest 53 (23.5%) were taking their medication by themselves. All, (100%), were taking their medication twice per day and had fixed time to take ART. Informants of 205 (90.7%) children reported that there was no missed dose by the children seven days prior data collection. But missed dose was reported by 21 (9.3%) care givers within the last seven days and 16 (7.1%) within the last 3 days. All these children were taking less than 95% of their normal dose.

The numbers of missed doses range from 1-4 with a mean and SD of 2.33 and 0.9 doses respectively. The highest length of time the children missed their schedule range from 12 to 72 hours with a median of 12 hours.

#### 3.3. Reason for non adherence

Drug side effects, child illness, and care taker being busy were the most common reasons mentioned by 23.8%, 23.8%, and 14.3% of care givers of the children who were missed their doses respectively (Table 2).

Table 2. Reason for non adherence among pediatric ART patient

Reasons for non adherence	Number (%)
Child refusal	3(14.3)
Busy of caretaker	3(14.3)
Forgetfulness	2(9.5)
Taste of the drug	1(4.8)
Lack of trust on the efficacy of the drug	2(9.5)
Illness of the child	5(23.8)
Side effect of the drug	5(23.8)

### 3.4. Factors associated with antiretroviral therapy adherence

The percentage of male children (50.2%) who were not missed their dose schedule were almost similar to the female children (49.8%). Children with in age category of 10-14yrs, 47.6%, and 5-9yrs, 42.9%, were the majorities of the individuals who were missed their dose. Those children who have been on ART for 37-60 months (40%) were adherent to their medication. Around 53.4% were not missed their dose within seven days prior to data collection.

From the total 205 children who were not missed their medication, 95.1%, were disclosed their HIV status to people other than the care taker. Majority, 90.5%, of individuals who were adherent to their therapy were not get any support from any side. More than half, 66.6%, of the children who were adherent to their therapy had monthly follow up appointments.

Children with female care taker and children with care taker of 34yrs and below were 84.4% and 47.3% of the 205 children who were taking their treatment according the recommendation given by their health providers respectively. More than two third, 79%, of care takers of the well adhering children were living in urban area.

Various factors associated with pediatrics ART adherence are identified using bivariate analysis techniques. In the bivariate analysis; sex of care giver, education of care giver, age of the child, and types of ART drug were significantly associated with adherence of pediatric ART. Having male sex givers (OR=2.70, 95% CI (1.45, 9.63)) were more likely to adhere to ART than children with female care giver. Those children who had illiterate (OR=2.15, 95 CI (1.82, 15.45)) care giver were more likely to adhere to their treatment than their counter parts. Age of the children has significant association with adherence to their treatment. Those children below five years old (OR=1.23, 95% CI (1.14, 9.36)) were more likely to adhere to ART than above the age of five years. Participants who is on first line ART (OR=2.51, 95% CI (2.17, 6.52)) is more adherent than those on the second line ART drug.

All independent variables which showed a significant association with place of delivery care in the bivariate analysis were put in a multiple logistic regression model. The dependent variable which has been used in the bivariate analysis is also included in the multiple logistic regression analysis. This variable is classified as dichotomous response variable which is assigned the values 0 and 1.

In multivariate analysis only three independent variables showed significant association with ART adherence. These variables are; male sex care giver (AOR=2.10, 95% CI (1.01, 7.22)), age of the child below five years old (AOR=1.43, 95%CI (1.16, 3.98)) and use of first line ART drug (AOR=2.86, 95%CI (1.54, 3.67)). Education of the care giver which showed association in bivariate analysis didn't show association in the multivariate analysis after controlling for confounders (Table 3).

Table 3. Predictors of adherence of pediatrics ART in Mekelle hospital

Characteristics		Adherence		95% CI(COR)	95% CI (AOR)
		Adherent	Non adherent		
Sex of caregiver	Male	173 (84.4)	14 (66.7)	2.70(1.45,9.63)	2.10(1.01,7.22)*
	Female	32 (15.6)	7 (33.3)	1	1
Age of caregiver	< 34 years	97(47.3)	9(42.9)	1.19(0.85,11.74)	1.11 (0.33,2.06)
	>35 years	108(52.7)	12(57.1)	1	1
Education of caregiver	Illiterate	84(41)	5(23.8)	2.15(1.82,15.45)	2.32(0.12,5.69)
	Primary	82(40)	11(52.4)	0.95(0.38,8.53)	0.45(0.34,3.21)
	Secondary	39(19)	5(23.8)	1	1
Residence of caregiver	Urban	162(79)	17(81)	0.88(0.37,0.94)	0.43(0.36,0.99)
	Rural	43(21)	4(19)	1	1
Sex of the child	Male	103 (50.2)	11(52.4)	0.91(0.21,7.72)	0.51(0.44,2.67)
	Female	102 (49.8)	10(47.6)	1	1
Age of the child	<5 years	25(12.2)	2(9.5)	1.23(1.14,9.36)	1.43(1.16,3.98)*
	5 -9 years	89(43.4)	10(47.6)	0.88(0.21,8.43)	0.64(0.44,2.92)
	>10 years	91(44.4)	9(42.9)	1	1
Duration of ART use	<36 months	62(30.2)	7(33.3)	1.01(0.94,6.71)	1.91(0.32,2.97)
	37-59 months	82(40)	7(33.3)	1.34(1.21,7.43)	1.56(0.24,2.23)
	>60 months	61(29.8)	7(33.3)	1	1
Type of ART drug	First line	201(98)	20 (99.5)	2.51(2.17,6.52)	2.86(1.54,3.67)*
	Second line	4(2)	1(0.5)	1	1
Disclosure	Yes	195(95.1)	20(95.2)	0.97(0.73,15.23)	0.83(0.12,8.43)
	No	10(4.9)	1(4.8)	1	1
Presence of co morbidity	Yes	178(86.8)	20(95.2)	0.32(0.18,2.31)	0.12(0.04,0.57)
	No	27(13.2)	1(4.8)	1	1

\*significant at  $P < 0.05$ , CI= Confidence interval, COR= Crude odds ratio, AOR= Adjusted odss ratio

## DISCUSSION

It is widely accepted that adherence to therapy is crucial to successful outcomes of ART program. Adherence is essential for plasma viral suppression and immunological responses. ART has also been associated with an improved quality of life in people infected with HIV. Adherence to therapy, or the extent to which a patient's behaviors coincide with medical advice mutually negotiated between the health professional and the patient, is a universal challenge with all illnesses and in all age groups [16],[17]

In this study the level of complete adherence was 90.3 % in the 7 days prior data collection and 92.9% three days before. This finding is higher than the studies conducted in Addis Ababa which was 86.9%, and 89.1% in Diredawa and Harar [15],[18]. The possible explanations for such differences are the time of this study is relatively recent; it is expected that with time there will be progressive improvement of patient care and management systems, and difference in sample size which is a bit lower in this study. A study carried out among HIV-infected children attending hospitals in Nigeria indicates that out of a total of 212 children, 183 (86%) were adherent in the three days preceding the interview, while 29 (14%) were not adherent [19] which is a lower than in this study and the study in Dire-Dawa and Harar but consistent to the study in Addis-Ababa. Another qualitative systematic review of results from 13 studies that used caregiver reports indicated that 34% to 100% of caregivers reported 100% adherence, and 84% to 89% reported 95% adherence; reports of mean adherence according to caregivers ranged from 88.4% to 96%. Self-reports, which were used in 8 studies overall, indicated that 20% to 58% of patients reported 100% adherence, 44% reported 95% adherence, and 58% to 70% reported 90% adherence; self-reported mean adherence ranged from 93% to 97% [20].

Different caregivers related factors that affect pediatrics adherence to ARV medications were assessed. Male sex care givers favors adherence which is similar with the finding in the United States of America and Nigeria [16],[19]. In contrast to this study, in Zambia female patients were adherent than males [21].

Child related factor which showed significant association with adherence in this study were age of the child and types of ART drugs. Age of the child less than five years is significantly associated with adherence unlike to this finding a study conducted in Italy indicates that children over 10 years of age were more likely to adhere to their medications than below 10 yrs. The possible explanation for this variation might be due to the reason that children below the age of five years are unable to decide by themselves to take their drug and they need the support of their care givers. The care givers give more emphasis and remind the time and dose the ART drug to be taken by their child. First line ART drug users are adherent to their medication than second line drug users.

## 4. CONCLUSION

The study has tried to describe the socio demographic and clinical characteristics of the child, the level of adherence and common reasons for non adherence and the possible factors associated with adherence. The level of adherence was relatively good as compared to other studies. Variables which were significantly associated with adherence were male sex care giver, younger age group of the child less than five years and first line ART drug users. This study has some limitations such as recall bias and over estimation of the level of adherence as reported by care givers. Extensive health education for the care giver is necessary on techniques how to adhere to the drug and its importance for the well being of the child.

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