

## ORIGINAL RESEARCH

# Adherence to Antiretroviral Therapy in HIV- Infected Children and Adolescents Attending Sekou Toure Care and Treatment Clinic in Mwanza, Tanzania

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## ABSTRACT

**Introduction:** Patients who are infected with human immunodeficiency virus (HIV) have to use a combination of drugs throughout their life time. The HIV mutates continuously and the mutants may be resistant to any of the prescribed drugs and hence the necessity for the combination therapy. Compliance to the prescribed antiretroviral drugs (ARVs) is a key factor in the success of antiretroviral therapy (ART). This study aimed at examining the extent at which children below 18 years complied to the prescribed drugs and the study also looked for some of the factors which could have been the cause of non adherence to the prescribed medicines.

**Material and Methods:** Children (aged between 8 and 18 years) who were selected to participate in the study were among those attending the Care and Treatment Center (CTC) at Sekou Toure Referral Hospital. After parents/guardians had given informed consent, 185 children were recruited into the study. A cross-sectional study design using questionnaires and pill counting was carried out to determine non-adherence to ART and the factors which could be associated with it.

**Results:** Based on self-report adherence method, about 70% of the children showed 100% adherence to ARV therapy. The pill counting method revealed that only 22.2% of the participants were more than 95% adherent. Friendly interaction between the drug dispensers and the children, employed parent/guardian and age of the child showed a positive association with adherence to ART. Forgetfulness on the part of parent/guardian and child was the main reason for non-compliance.

**Conclusions:** There was a big discrepancy between the self-reporting and pill counting results (70% versus 22% respectively). It is possible there were false positives in self-reporting and similarly dispensing errors could produce false negatives. Cordial relationship between the drug dispensers and parent/guardian/child, age of the child and unemployed parent/guardian had positive effects on adherence to therapy.

**Key words:** Children living with HIV, ART, ARV, Adherence, Mwanza, Tanzania.

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## INTRODUCTION

Authorities in Tanzania are trying very hard to provide antiretroviral drugs (ARVs) to patients who are infected with HIV. Attempts are made to provide the drugs to all eligible patients both adults and children but quite often these attempts are frustrated by poor compliance particularly in children.

Human immunodeficiency virus (HIV) infection is a pandemic disease. Over 35 million people worldwide are living with HIV,<sup>1</sup> and of these more than 3 million are children under 15 years. It is estimated that 2.4 million children infected with HIV live in Sub-Saharan Africa. Approximately 150,000 new cases of HIV infection were reported in 2011, with an incidence of about 400 new cases per day. Over 230,000 children in Tanzania were living with HIV in 2009.<sup>1</sup>

Mother to child transmission (MTCT) is the main source of HIV infection in children. Without treatment 15-30% of babies born to HIV positive women become infected with HIV during pregnancy and/or during delivery and about 5-20% become infected through breast milk.<sup>2</sup> Antiretroviral therapy (ART) has given hope to many people living with HIV including children. An-

tiretroviral therapy results in viral suppression and improvement in quality of life in adults and children.<sup>3</sup>

Through successful prevention of mother to child transmission (PMTCT) and ART many children are surviving into adolescence. However long-term antiretroviral therapy in adolescents may be associated with side effects, mental health issues and sexually transmitted diseases (STDs).<sup>4,5</sup>

Free antiretroviral therapy for adults and children in Tanzania was introduced in 2004 and benefits from this move partly depend on good adherence to the regimens.<sup>6</sup> Good adherence means not missing a dose of ARV at all.<sup>7</sup> A person missing more than three doses in a month is regarded as being less than 95% adherent; adherence implies abiding to a treatment plan agreed by both patient and health care provider.<sup>8</sup> Adherence of 95% or more is effective in decreasing viral load, morbidity and mortality in HIV infected children.<sup>9</sup> Least developed countries (LDC) face challenges in achieving and maintaining ART adherence during scale-up of pediatric ART programs.<sup>10</sup> A systematic review of pediatric ART adherence study in the middle and low income countries revealed that ART adherence level ranged from 49% to 100%.<sup>11</sup> Comparison of paediatric adherence to ART in LDCs and that seen in high income countries revealed that adherence to ART in high-income countries ranged even more widely from 20% to 100%.<sup>12</sup>

In Africa different adherence rates have been reported in various studies, the rates of adherence varied with study characteristics and method of assessing adherence i.e. individual reports, pharmacy records and pill counting.<sup>13</sup> Many developing countries have a high rate of treatment failure among HIV- infected children who are on ART, including those in Tanzania.<sup>14</sup> At Kilimanjaro Christian Centre, approximately 20% of children are on second line regimen following failure of the first line regimen.<sup>13</sup>

A systematic review and meta-analysis of studies in adults evaluating adherence to ART in Sub-Saharan Africa and North America revealed an estimated combined adherence rate of 66% for the two continents. The adherence rate for the North American studies was 55% while that for the African studies was 77%, indicating a higher level of ART adherence in Africa.<sup>15</sup>

Two studies were conducted by Medicines Sans Frontiers (MSF) to assess adherence in Chiradzulu and Thyolo districts in Malawi. The pill counting method in Chiradzulu revealed that 64% of the 367 patients studied had an adherence rate of 100%, while the self-reporting method showed an adherence of 96%.

In Thyolo district out of 151 patients, 99% were 95% adherent by pill counting method.<sup>15</sup> A study done in Blantyre, Malawi, at Queen Elizabeth Central Hospital ART clinic, revealed that 52% of 176 patients had an adherence rate of 100%.<sup>16</sup> In Kampala, Uganda, 72% of children aged between 2 and 18 years had an adherence rate  $\geq 95\%$  following home unannounced pill counting compared to 89% who had a similar rate which was observed after a 3 day self-reported adherence and 94% who had a similar of adherence which was seen in clinic-based pill counting.<sup>17</sup>

In Nigeria adherence to ART among HIV infected children in a tertiary hospital was 86% according to caregiver reports in the three days preceding the interview.<sup>18</sup> In Abidjan cote d' Ivoire assessment of adherence to the highly active antiretroviral therapy (HAART) in a cohort of African HIV infected children revealed that 33% had less than full adherence.<sup>19</sup>

There are a number of challenges which confront children on antiviral therapy; the challenges include availability of pediatric drug formulations, frequent changes of drug regimens and side effects caused by the drugs. Syrups facilitate proper dosing in young children; however, they can be difficult to use. They spill easily and a caregiver unfamiliar with liquid measurements may not understand how to measure the precise dose. Elderly caregivers in particular may have difficulty in manipulating a syringe and poor eye sight may result in wrong amounts being drawn into a syringe or fail to accurately pour liquids into a cup. Other challenges include palatability and need for refrigeration of syrups.<sup>20</sup> Most liquid formulations of ARVs are heat stable although stavudine and ritonavir need refrigeration. A complicated regimen is another important contributor to poor adherence.<sup>21</sup> A drug or a formulation may be out of stock and this may necessitate regimen alteration and hence confusion. The prescribed drug may be changed from syrup to a tablet or from a combination pill to the individual components. Similarly, as children grow, the dose of each drug increases, sometimes at every clinic visit.

Studies have revealed that ARVs are often discontinued when the patient cannot tolerate the side effects.<sup>21</sup> Adverse drug effects have influence on willingness of the patient to take the medication and have consistently been associated with poor adherence.<sup>21</sup> A study by Heyer conducted in 2006 revealed that patients experiencing adverse effects were 12.8 times less likely to be in the 95% to 100% adherence group compared to those who were not experiencing the side effects.<sup>22</sup>

Factors which lead to decreased ART adherence in-

clude stigma, absence of symptoms, and poor relationship with caregivers and health personnel.<sup>21</sup> Studies in US and Africa have shown that adherence to ART decreases as age increases among HIV infected children.<sup>23</sup> In addition, greater adherence is observed in patients who believe that HAART is effective, while negative beliefs reduce adherence.<sup>24</sup> Studies show that good relationship between caregiver and the patient increases adherence to ART.<sup>25</sup> Family instability has also been associated with non-adherence in children.<sup>26</sup>

Food is important for good adherence to particular drugs, and the caregivers may skip doses when food is scarce. Poor access to ART may lead to inconsistent use and thus poor adherence. Cultural norms may pressurize caregivers and children to reject ART and use alternative medicines instead. Alternative medicines may also be used in addition to ART and adverse drug interactions may therefore be a potential concern.<sup>27</sup>

This project therefore aimed at examining the extent at which children below 18 years complied to the prescribed drugs and it also aimed at looking at some of the factors which did contribute to non compliance to the prescribed drugs.

## MATERIAL AND METHODS

Subjective and objective methods were used in measuring adherence to ART. Subjective methods included provider assessment and child and caregiver self-reports. While objective methods consisted of pharmacy refill data and pill counts. Self-reports were not possible in some cases because the children were too young to be able to give the required information and hence caregivers had to report on behalf of the children.<sup>20</sup>

A cross-sectional study was carried out at the care and treatment center (CTC) at Sekou Toure Referral Hospital in Mwanza from May to July 2015 to determine adherence to ART in children. One hundred and eighty five HIV infected children aged between 8 and 18 years gave informed consent before recruitment into the study. The children were all attending the CTC at the Hospital. Sample estimation was done using the following formula:

$$n = (z/p)^2 \times \pi (1-\pi)$$

n=the required sample size

p =the desired maximum discrepancy (i.e.  $\pm 5\%$ )

$\pi$ = the population proportion

z = corresponds to the appropriate Z value from the normal distribution for the desired confidence interval, for 95% confidence interval=1.96

If the population proportion is about 86% and wish 95% confidence interval which will be no more than  $\pm$

5% of true population proportion,  
 $n = (1.96/0.05)^2 \times 0.86(1-0.86) = 185$

The minimum required sample size of HIV infected children aged 8 to 18 years attending the ART clinic at Sekou Toure Hospital for this study was 185 children. Children and their parents and/or relatives attending at the Care and Treatment Center (CTC) were asked by their doctors and nurses for permission to be enrolled in the study. Those who agreed were seen by the study nurses who explained to them the purpose of the study and those who were willing to participate, were then seen by the investigator to provide informed consent.

A Questionnaire was used to obtain the required data. The questionnaire was divided into two sections (A & B). Section A was on demographic data while Section B was about the medicines which had been prescribed to the child and about compliance to treatment. The child/parent or guardian would answer whether all doses were taken or whether there were some which were missed and would give reasons why those doses were missed some doses (Self-reporting method). The investigator would then ask the interviewee to make available the medicines container which has been used to keep the medicines obtained during the last visit. The investigator would then count the pills in the container and from the number of pills still in the container the investigator would determine whether the medicines were taken as prescribed or otherwise. (Pill - counting method).

## ETHICAL CONSIDERATION

The research proposal was reviewed by the Supervisor and the School of Pharmacy Research Committee and then it was approved by the Joint CUHAS/BMC Ethical Committee. Permission to conduct the study was obtained from the Mwanza Regional Administrative Secretary, the Nyamagana District Commissioner, the Regional Medical Officer, Mwanza, the Medical Officer-in-Charge at the Sekou Toure Referral Hospital and the CTC doctor in charge. Written informed consent was obtained from parents/guardians of the children before recruitment into the study. Participants were told that they were free to pull out of the study at any stage and this would not jeopardize their access to services at the CTC. Any child with an adherence rate of less 95% will be referred to the CTC for counseling and further attention. Confidentiality of all study participants was maintained by using codes instead of names of participants, and the result were stored under lock and key.

**STATISTICAL ANALYSIS**

Data generated from the questionnaires was entered into the computer and was analyzed using statistical package for social sciences (SPSS) version 16.0. Descriptive statistics were conducted first to summarize adherence rate measures and socio-demographic characteristics of the respondents. Multivariate analyses were run to find association between the exposure variables and adherence. All values with a p- value of <0.005 were considered as statistically significant.

**RESULTS**

The social-demographic characteristics of the study population, based on sex, age, education level and religious denomination are indicated in Table 1. A total of 185 children aged between 8 and 18 years were interviewed in the study. Ninety five per cent of the participants were in school and of these nearly 68% were in primary school. Fifty eight per cent of the participants were males and 42% were females.

More than half of the participants in this study were under the care of their biological parents (father and/or mother), almost two thirds of the caregivers were employed and about 90% of the caregivers had gone to school. The relationship with caregiver, caregiver occupation and level of education caregiver are shown in Table 2.

Based on self-report adherence methods Table 3, 69.7% (129/185) had 100% adherence (a child did not miss even a single dose since the last visit). About 92% (171/185) had an adherence rate of more than 95% (less than 3 doses were missed since last visit). Twenty five percent (14/56) were non-adherent (adherence less than 95%), they had missed more than 3 doses since last visit.

Using pill counting method, Table 3 only 22.2% (41/185) were >95% adherent. Many children had more pills in their bottles as compared to the amount of medications dispensed at the date of refill. Forgetfulness was the major reason for missing a dose as shown in table 4.

Caregivers reported that most children needed to be reminded to take the medications at appropriate times. Hence absence or forgetfulness of caregiver leads to poor adherence. Refusing to take medications, throwing away medications, stigma, side effects of medications, and disclosure to the children of their health status were other factors which contributed to poor adherence.

Children whose caregivers were employed showed poorer adherence to ART than those whose caregivers were not employed (P-value =0.002). Good relationship between caregivers and children showed good adherence to antiretroviral therapy (P-value = 0.003). Age of children were marginally associated with good

Parameter	Characteristics				
Sex	Male	Female			
Numbers	108	77			
Age (years)	8 – 10	11 - 15	16 - 18		
Numbers	39	102	44		
Education	Illiterate	Nursery	Primary	O Level	A Level
Numbers	4	17	121	41	2
Religious denominations	Christians	Moslems	Pagans		
Numbers	133	51	1		

**Table-1:** Demographic characteristics of the participants

Relationship						
Caregiver	Father/Mother	Grand Parent	Sister/Brother	Other		Total
Numbers	91	26	35	33		185
Caregiver occ.	Business	Employed	Unemployed	Unspecified	None	
Numbers	46	48	27	39	25	185
Caregiver educ.	Had education			Had no education		
Numbers	166			19		185

**Table-2:** Demographic characteristics of caregivers

adherence (P- value =0.064).

According to univariate analysis, all variables with P-value of < 0.20 were considered for multivariable logistics models using backward elimination. Children education level (P- value = 0.096), age P-value of 0.064, level of education of caregiver P-value of 0.179.

**DISCUSSION**

Almost seventy per cent of the children aged between 8 and 18 years were 100% adherent to ART offered at the CTC of Sekou Toure Hospital in Mwanza. About 92.7% (171/185) of the children had adherence more than 95% (they missed one to two doses of ARVs). About 25% (14/56) had an adherence rate of less than 95%, these children missed more than three doses of ARVs and were therefore ART failures and were at risk of developing resistance to the drugs,<sup>12,22</sup>

The level of adherence in this study was relatively high when compared to other studies like the Sub-Saharan African and the North American studies which revealed a combined adherence rate of 66%. The North American study reported that 55% of the children were 100% adherence, while the Sub-Saharan African study revealed that 77% of the children were 100% adherent to ART.<sup>15</sup> In Malawi a study conducted in Chiradzulu reported that 64% out of 367 children had 100% adherence while that in Blantyre at Queen Elizabeth Central Hospital revealed that 52% of the 176 participants were 100% adherent to ART. Our study has observed through self-reporting an adherence rate of about 70%. Our results and those reported above appear to overestimate the adherence rate. Self-reporting results are

useful when obtained from patients who admit to have poor adherence because such patients are truly not adherent.<sup>11</sup>

Pill counting method is a good method and can give reliable results if properly done but has pitfalls which can falsify the results. During our study at Sekou Toure Hospital issues which could have affected the results included missing records on the numbers of pills dispensed during the last visit, complicated second line regimens especially alternative first line and second line ARVs, inaccuracies in dispensing of pills by pharmacist and/or nurses during the last visit and finally pill counting could not show pill damage and/or pill dumping from children. These anomalies may explain the very poor adherence observed in our study from pill counting results when compared to the self-reporting results. These issues need to be addressed in future studies. Level of adherence on ART was observed to be high where caregiver, health care provider and child had good relationship in the whole process of ART. Adherence to antiretroviral agents in children requires teamwork.

A number of factors affected adherence to ART in this study, the factors included forgetfulness, poor caregiver support, and delay from play, caregiver not at home, rushing to school, and side effects of the drugs, throwing away pills, travelling and complicated regimens. Health care providers have to think in different dimensions on the causes of poor adherence and consider how to reduce these.

Out of 185 children in the study 27 children were on alternative first line drugs and 9 had been put on second line drugs. The reasons for changing treatment included side effects in 27 children, and 9 children had to be put on the second line regimen because of treatment failure and this was mainly due to poor adherence to ART.

There is an association between an employed caregiver and level of adherence in children, employed caregivers were busy and had little time for ART supervision and hence poor adherence while unemployed caregivers had more time to look after their children and therefore better adherence rates. Health care providers

Doses missed	Self-reporting (No. of responses)	Pill-counting (No. of responses)
Zero dose	129 (69.7%)	8 (4.3%)
One dose	23 (12.4%)	12 (6.5%)
Two doses	19 (10.3%)	21 (11.4%)
Three doses	4 (2.2%)	44 (23.8%)
Four doses +	10 (5.4%)	100 (54.1%)

**Table-3:** Adherence to prescribed doses

Reason	Rushing to school	Forgot	Side effects	Out to Play	Caregiver not at home	Others e.g. throwing away medicines, stigma
Nos.	26 (14.0%)	99 (53.6%)	7 (3.6%)	10 (5.36%)	23 (12.5%)	20 (10.7%)

**Table-4:** Reasons for missing doses

should make sure that employed caregivers take a positive attitude on maintenance of ART adherence through special training on adherence. They should emphasize that it is the right of the children to be given the medications.

Good relationship between caregiver and children taking ARVs was associated with good adherence to ART (P-value of 0.003). If caregivers are close to the children they become friends. Good relationship is very potential in improving adherence to ART in children as reported in different adherence to ART studies in children.<sup>19,24</sup>

## CONCLUSIONS

Self-reporting revealed that about 70% of the children were 100% adherent to the antiretroviral therapy while only 22% were 100% adherent as was shown by pill counting results. Respondents in questionnaires may give answers which they think will please the investigator while in pill counting the results may be confounded by pharmacists who did not dispense drugs as were prescribed. The relationship between the drug dispenser and parent/guardian/child, age of the child and unemployed parent/guardian had positive effects on adherence to the taking of the medications.

## Recommendations

Drug dispensers should interact with the children politely and that parents/guardians should remind the children when it is time to take the medicines and similarly the children should tell their parents/guardians to give them the medicines when it is time to do so.

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