

# The Electronic Alarm Reminder System: Should We Integrate it into Routine Practice to Improve Adherence to Antiretroviral Therapy and Viral Load Outcomes among Pediatrics and Adolescents Living with Human Immunodeficiency Virus disease?

Chukwudi Kennedy Okwor, Benedicta Ozonweke, Greg Abiaziem, Fabian Bassey, Olayiwola Olarewaju, Amana Effiong, John Oko Okpanachi, Uchechukwu Obodochina.

\*HIV Care and Treatment Intervention Program,  
Caritas Nigeria,  
Abuja, Nigeria.

**Abstract:- Background:** Adherence to antiretroviral medication is critical in sustaining viral suppression among people living with HIV. This is problematic in pediatrics and adolescents who rely on caregivers for optimal treatment outcomes. This paper highlights the role of the use of an electronic alarm reminder system on ART adherence and viral load suppression with a view to adopting it in the routine management of pediatrics and adolescents with HIV.

**Methods:** A cohort of children and adolescents with unsuppressed viral load results were listed and divided into two groups based on their caregivers' ownership of an electronic alarm device. Group A were 52 in number and had phone alarm device while Group B were eight in number and had no alarm device. An electronic reminder alarm for medication timing was activated for clients with phone alarm devices. They were followed up for three months of Enhanced Adherence Counselling. Their levels of adherence were determined and the viral load values pre- and post-alarm activation were compared using Paired t-Test.

**Results:** The mean value of pediatrics and adolescents' viral load suppression decreased from the pre-alarm to the post-alarm period (pre-alarm reminder period,  $M = 2.0$ ,  $SD = \pm 0.00$  to post-alarm period,  $M = 1.1$ ,  $SD = \pm 0.32$ ;  $t = 21.1$ ,  $p < .001$ ,  $d = 59$ ). Caregivers' use of an alarm device was significantly associated with ART adherence (99% CI;  $p = 0.000$ ) and viral load suppression (99% CI;  $p = 0.000$ ) in pediatrics and adolescents. There was no association between the socioeconomic status of the caregivers and adherence to ART (99% CI;  $p = 0.79$ ).

**Conclusion:** The improvement in adherence and viral load outcomes among HIV-positive pediatrics and adolescents on antiretroviral medications after the activation of the electronic alarm reminder system is a pointer that the electronic alarm reminder system could justifiably be introduced in routine pediatric and adolescent ART services.

**Keywords:-** Adherence; Problematic; Adopting; Electronic Alarm Reminder; Viral Load Value; Introduced.

## I. INTRODUCTION

Routine antiretroviral therapy (ART) is critical in the epidemic control of HIV. It has been validated that antiretroviral drugs have the therapeutic potential to arrest the spread of HIV infection among the population<sup>1</sup>. Adherence is defined as taking medications or interventions correctly according to prescription. Adherence to antiretroviral therapy plays a key role in viral suppression and the improvement of quality of life among people living with HIV. Although some literature posited that a lower adherence rate could guarantee viral suppression, an adherence benchmark of 95% to antiretroviral therapy is critical for maximal and durable viral load suppression<sup>2-3</sup>. At least 95% viral suppression is required to bend the curve of HIV transmission in poorly developed nations. Suboptimal adherence predisposes HIV patients to the acquisition of drug-resistant HIV strains which are more rigorous and cost-ineffective to treat<sup>4</sup>. Globally, about 10% of pediatrics and adolescent on antiretroviral therapy have HIV strains that are resistant to the Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) and signals the urgent need for transition to dolutegravir-based regimen<sup>5-6</sup>. If viral suppression is achieved and sustained over a long period, drug-resistant HIV strains are less likely to develop. In its 2022 annual report, the UNAIDS highlighted a worrisome treatment outcome among pediatrics and adolescents<sup>7</sup>.

Achieving optimal viral suppression is more challenging in pediatrics than in adults, as adults are more in charge of and responsible for their health decisions. Furthermore, younger children lack the well-developed immune systems needed for complex immunological infection-control decision-making processes to curtail the progression of HIV disease. They have high rates of viral replication, high rates of CD4+ cell turnover, higher incidences of virologic mutations, faster rates of disease progression, and their immune system responds faster to antiretroviral therapy<sup>8</sup>. Treatment failure results from the loss of antiretroviral therapy efficacy leading to faster replication of mutated viral strains which signals the switch to a second-line regimen<sup>9</sup>. Antiretroviral therapy aims to lower the HIV viral copies beyond the detectable and

untransmittable level and ensure HIV epidemic control. Viral replication and mutation are complex phenomena involving antigen recognition, innate and humoral immune responses, disease control, and memory formation regarding recent infectious antigenic materials. Failure of any of these processes may lead to faster viral replication and an increase in the viral mutative potential.

Factors affecting adherence to ART among pediatrics and adolescents tend to be associated with caregivers' behavior. It is often the case that caregivers' financial challenges and forgetfulness impact ART adherence in pediatrics and adolescents with forgetfulness contributing the highest quota<sup>8</sup>. Financial challenges prohibit HIV clients from accessing timely care from healthcare facilities which affect their quality of life, especially in sub-Saharan Africa where health insurance policies are poorly developed. Many pieces of literature have reported that children living far from ART centers had poor adherence to antiretroviral therapy<sup>10</sup>. Other factors that militate against ART adherence in children and adolescents include but are not limited to pill size, and medication side effects that lead to drug fatigue. With the PEPFAR-funded ART program, antiretroviral medications are free and allow for once-daily dosing and the tolerability of antiretroviral medication has improved over time due to the introduction of new molecules that have relatively better formulations and fewer side effects. The most common reason for missed doses of antiretroviral medication was due to the caregiver's forgetfulness<sup>11</sup>. The factors that caused forgetfulness were emotional problems, the thought of financial challenges, and drug and alcohol abuse among the caregivers<sup>12</sup>.

The success of pediatric ART programs is pivoted on the strength of caregiver support, pediatric-friendly therapeutic formulations, and age-appropriate adherence support in the offing<sup>13</sup>. The treatment of HIV in children requires a distinct pediatric-friendly adherence approach that guarantees optimal viral load suppression, and a longer, healthy life<sup>9</sup>. Differentiated service delivery (DSD) models that promote the participation of children and adolescents should be encouraged especially in sub-Saharan Africa where the burden of HIV disease is high among pediatric and adolescent population<sup>14</sup>. Many social support programs such as Operation Tripple Zero (OTZ), Kids Club, and caregivers' support groups have been introduced to support pediatric ART adherence and improve treatment outcomes. These social programs have been crucial in building social bonding among children and adolescents living with HIV and improving the knowledge of and adaptation to HIV disease. The Orphan and Vulnerable Children (OVC) services is a PEPFAR-funded program aimed at mitigating the burden of HIV disease on children and their caregivers. The OVC program supports indigent children and families to access ART services through the provision of transport support for drug pick-ups, viral load, and adherence services.

Various HIV programs have utilized one form of electronic health (eHealth) services or another. The electronic health system is user-friendly, cost-effective, and efficient in reaching out to the underserved population<sup>15</sup>. The impact of

electronic alarm reminder systems (EARS) on ART adherence in adults has been reported by many literatures<sup>15,21-22</sup>. However, there is a paucity of literature on the impact of EARS on ART adherence and viral load outcome in pediatrics and adolescents with HIV.

Even with PEPFAR's free ART program in sub-Saharan Africa, ART adherence bottlenecks abound due to diverse caregivers' challenges that disrupt the dosing of ART medications in pediatrics and adolescents living with HIV. Healthcare providers have piloted several approaches that could improve ART adherence and upturn viral suppression among pediatrics and adolescents with HIV<sup>16</sup>. This study investigated the effect of electronic alarm reminders on adherence and viral load outcomes and pediatrics and adolescents living with HIV disease.

## II. METHODS

This is a closed prospective cohort study on HIV-positive pediatric and adolescent patients who had unsuppressed viral load results after six-month ART initiation. The list of 60 pediatrics and adolescents aged between 18 months and 19 years with unsuppressed viral loads was generated from the electronic medical records (EMR) and validated with the facility viral load outcome registers. The review cohort was pediatrics and adolescents who had unsuppressed viral load at the end of March 2022 and were subsequently enrolled in 3-month Enhanced Adherence Counselling (EAC). Prior to the viral load outcome, the children were enrolled in the OVC program which provided support such as transport stipends for clinic visits, and household financial assistance to improve their quality of life. There were 57 caregivers, with three having two children each. The caregivers received the same caregivers' treatment preparation counseling during ART enrolment. During the viremia counseling sessions, the caregivers volunteered that forgetfulness was their major challenge to ART adherence among the children. The living status (both parents; the father only; mother only; significant other) of the children's caregivers was determined using oral interviews. The socioeconomic status (SES) of the caregivers was determined using the revised Scoring Scheme for the Classification of Socioeconomic Status in Nigeria<sup>17</sup>. The tool classified socioeconomic status into high, medium, and low based on the average score on the level of education, occupation, and income of the participants. It is graded on a score of 1 to 5; 1 being the highest and 5 being the lowest. The average score of the three variables is calculated. A person with a score of 1 to 2 belongs to the high socioeconomic class, 2.1 to 3, and 3.1 to 5 belongs to the middle and low socioeconomic classes, respectively. The caregivers were divided into two groups based on their ownership of electronic alarm devices: the electronic alarm reminder system group (EARS group) consisted of 52 caregivers who owned an alarm device and the non-electronic alarm reminder system group (Non-EARS group) consisted of eight caregivers who did not own an alarm device. For the EARS group, the OVC case managers set up an alarm reminder for antiretroviral medication dosing on their phones. Both groups were retained on first-line regimens during the period and they received routine adherence support

services. The cohort was monitored for three months while on EAC. No death was reported among both groups and there was no transfer in or out from the groups during the period of cohort monitoring. At the end of three months, their blood samples were collected for viral load analysis and the results were retrieved from the reference laboratory after two weeks. The rate of ART adherence was calculated by:  $\text{Number of pills doses taken} \div \text{number of pills doses prescribed} \times 100$  (where the number of pills taken = the number of pills prescribed – number of pills missed). The data were collected and coded, inputted, and analyzed using SPSS version 20. The observations were presented as mean, median, standard deviations, and proportions. Correlation tests were applied where applicable to determine if the relationship between variables were significant. Tables and, charts were used for data presentation.

### III. RESULTS

#### ➤ Patient Demographics.

A cohort of 60 unsuppressed children was followed up for three months to determine the effect of an electronic alarm reminder on their ART adherence and viral load outcome (Table 1). Their caregivers volunteered that forgetfulness was the most crucial factor culminating in poor adherence and poor viral load outcome in the cohort. There were 52 (87%) caregivers with electronic alarm reminder devices while 8 (13%) were without the device. The socioeconomic status of the caregivers was 50 (83%), 9(15%), and 1(2%) for low, middle, and upper socioeconomic classes respectively (Fig 1). The mean age of the children was 9.9 years (SD ±4.6) with 34 (57%) being females. Twenty-three (38%) of the unsuppressed peditrics and adolescents lived with both parents while 7 (12%) lived with a significant other (Table 2).

Table 1: Patients Adherence status of the peditric and adolescent HIV patients during the study period.

		Frequency	%
Valid	Good adherence	54	90.0
	Poor Adherence	6	10.0
	Total	60	100.0

Table 2: Living status of HIV-positive peditrics and adolescents with parents or caregivers.

		Frequency	%
Valid	Living both parents	23	38.3
	Live with father alone	19	31.7
	Living with mother alone	11	18.3
	Living with significant other	7	11.7
	Total	60	100.0

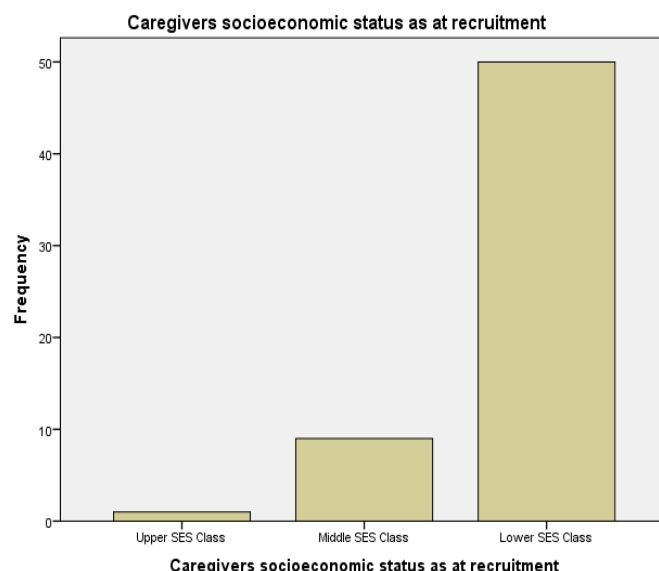


Fig 1: The caregivers' socioeconomic status.

#### ➤ Factors associated with ART adherence and viral load.

A total of 54(90%) peditrics and adolescents had a 95% ART adherence during the 3-month follow-up while 53(88%) of the peditrics and adolescents whose caregivers had an alarm reminder device had suppressed viral load after three months of the intervention (Fig 2). A significant association existed between the use of an electronic alarm reminder and ART adherence in the sample population (99% CI; p = 0.000).

Also, there was a significant association between ART adherence, and the repeat viral load suppression rate (99% CI; p = 0.000). The use of an electronic alarm device correlated significantly with viral load suppression in peditrics and adolescents (99% CI; p = 0.268) (Table 3). The SES of the caregivers was not significantly associated with ART adherence (99% CI; p = 0.79). Paired sample t-test investigated the differences in the mean values of the viral load results observed pre- and post-electronic alarm reminder and it showed a significant difference in the mean values of the first and the repeat viral loads results (pre-alarm reminder period, M = 2.0, SD = 0.00; post- alarm period, M = 1.1, SD = 0.32; t = 21.1, p < .001, d = 59) (Table 5,6).



Fig 2: The repeat viral load results of pediatrics and adolescents after three months.

Table 3: Correlations between use of alarm device, adherence status, and patient viral load status

		Caregivers' ownership of an alarm device	Patients Adherence status	Patient VL status at repeat VL result
Caregivers' ownership of an alarm device	Pearson Correlation	1	.686**	.468**
	Sig. (2-tailed)		.000	.000
	N	60	60	60
Patients Adherence status	Pearson Correlation	.686**	1	.744**
	Sig. (2-tailed)	.000		.000
	N	60	60	60
Patient VL status at repeat VL result	Pearson Correlation	.468**	.744**	1
	Sig. (2-tailed)	.000	.000	
	N	60	60	60

\*\* . Correlation is significant at the 0.01 level (2-tailed).

Table 4: Paired Samples Statistics of the first and repeat viral load values.

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Patients first VL result	438691.9500	60	2452468.75838	316612.35
	Patients repeat VL result	7091.6667	60	27217.92756	3513.81
Pair 2	Patient VL status at first VL result	2.0000	60	.00000	.000
	Patient VL status at repeat VL result	1.1167	60	.32373	.041

Table 5: Paired statistical correlation between the mean values of the first and repeat viral load results and suppression.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Patients first VL result - Patients repeat VL result	431600.28	2452572.66	316625.76	-201966.41	1065166.98	1.363	59	.178
Pair 2	Patient VL status at first VL result - Patient VL status at repeat VL result	.88333	.32373	.0419	.79970	.96696	21.13	59	.000

#### IV. DISCUSSION

In this study, the caregivers reported an ART adherence rate greater or equal to 95% following the use of electronic alarm reminder devices during EAC in 90% of the pediatrics and adolescents with HIV disease (table 1). A similar ART adherence rate was reported in a study on ART among pediatrics and adolescents with HIV in India<sup>18</sup>. A systematic review of studies on ART adherence found that ART adherence rates ranged from 16% to 99%<sup>19</sup>. In both studies listed above, ART adherence among this population of patients was strengthened by one form of adherence support or another. Our study illustrated that ART adherence services for pediatrics and adolescents with HIV were improved when device-assisted caregiver support was introduced. Oftentimes, caregivers were faced with life pressure that impacts the health of their children.

The study demonstrated that most caregivers of ART patients (83%) were in the low socioeconomic class. This is in sharp contrast to a similar study in India which found high socioeconomic status of 74% among the caregivers<sup>8</sup>(Fig 1). The high proportion of the low socioeconomic status caregivers in our study suggests that caregivers were involved with several life pursuits that led to forgetfulness in taking antiretroviral medication. This signals an HIV program design that assists caregivers in caring for HIV-positive pediatrics and adolescents. Similarly, this study did not find any association between SES and ART adherence as reported in a similar study in low- and middle-income countries<sup>20</sup>. However, a study that compared the disaggregated socioeconomic factors like literacy level, found that literacy level was significantly associated with ART adherence<sup>21</sup>.

The use of EARS was found to have a strong association with ART adherence in pediatrics and adolescents on antiretroviral medications. The use of technology in healthcare has been widely researched with a number of studies reporting that lack of sufficient data made it difficult to conclude its usefulness in improving ART adherence<sup>22</sup>. A randomized controlled study on the effect of alarm reminders on ART adherence found that ART adherence improved three weeks after the introduction of an alarm reminder system<sup>23</sup>. This study demonstrated that the use of EARS improved ART adherence among erstwhile virally unsuppressed pediatrics and adolescents. The EARS served

as a reminder for the timing of antiretroviral medications, especially among patients and caregivers, whose poor ART adherence is due to forgetfulness. Furthermore, the use of an electronic alarm device correlated statistically significantly with viral load suppression in pediatrics and adolescents. This could be due to the ability of alarm devices to remind patients and caregivers of the antiretroviral medication timing which in turn, improves ART adherence and viral suppression (table 3).

Most importantly, this study further examined the effect of EARS on the mean values of the viral load results recorded three months before and after the introduction of the EARS. We observed that the mean values of pediatrics and adolescents' viral load suppression rates increased from the pre-alarm reminder period to the post-alarm period (Table 4,5). This reveals that the EARS is a critical adherence package to consider when poor pediatric and adolescent viral suppression is due to sub-optimal adherence to ART.

This study did not consider either the psychological effect of routine alarms on the subjects or cases of stigma arising from having to take medication each time an alarm beeps. In our subsequent study, we will examine the psychosocial effect of the EARS on this fragile population with HIV disease.

#### DECLARATION OF INTEREST.

There is no interest to declare from the authors.

#### AUTHOR RESPONSIBILITIES.

CKO drafted the manuscript with contributions from GA, FB, OO, AE, JOO, and UO. CKO oversaw data analysis while BO managed viral load sample data of the study group. The authors studied and adopted the final manuscript.

#### ACKNOWLEDGEMENT

We thank the HIV-positive pediatric and adolescent patients and their caregivers for participating in the study. We also acknowledge Emmanuel Iheomamere for assisting with the patient list for this study.



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