HIV VIRAL SUPPRESSION STATUS AND ASSOCIATED FACTORS AMONG CHILDREN AND ADOLESCENTS RECEIVING A DOLUTEGRAVIR-BASED ART REGIMEN

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ABSTRACT

BACKGROUND: Anti-Retroviral Treatment (ART) reduces morbidity and mortality, promotes normal growth and development, and improves the quality of life for children and adolescents living with HIV. Dultagravil (DTG) based treatment has highly potent antiviral activity, a high genetic barrier to resistance, and a high safety profile. But, the effect of DTG on viral suppression in children and adolescents is not understood in Ethiopian context.

OBJECTIVE: To assess the HIV viral load suppression status and associated factors among children and adolescents on DTG based Anti-Retroviral (AR) regimen, Addis Ababa, Ethiopia.

METHODS: We employed a health facility based cross-sectional study design on children and adolescents receiving dolutegravir based ART regimen for at least 12 months. Stratified sampling technique was employed to get 430 samples. Binary logistic regression model was carried out to identify predictors associated with viral load suppression. Model fitness was checked using Hosmer and Lemeshow test for goodness of fit. Odds ratio with a 95% confidence level was used to measure the strength of association. Variables with $p < 0.05$ were considered statistically significant.

RESULT: Out of 430 participants, 428 (97.2%) responded. The proportion of viral suppression was 89.1%. In multivariable analysis, good medication adherence (AOR = 3.83, 95% CI: 1.49–9.86), pre-DTG viral suppression (AOR = 3.05, 95% CI: 1.35–6.89), normal nutritional status (AOR = 3.65, 95% CI: 1.36–9.63), and having both parents alive (AOR = 3.31, 95% CI: 1.44–9.56) were independently associated with higher odds of virologic suppression. Conversely, being on a second-line regimen (AOR = 0.21, 95% CI: 0.07–0.67) and having a caregiver with only primary education (AOR = 0.21, 95% CI: 0.06–0.76) were associated with significantly lower odds of suppression.

CONCLUSION: Dalutagravir based regimen maintains high viral suppression rate (89.1%) and improves medication adherence significantly compared to previous regimen. Implementing effective mechanism to enhance tailored treatment strategies that specifically address the unique needs of children and adolescents are imperative.

KEYWORDS: Anti-retroviral, dolutegravir, viral load, children, adolescents , Ethiopia

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1. INTRODUCTION

Approximately 2.58 million children aged 0-19 were living with HIV globally (4% of the total population living with HIV)[1]. Even though there has been significant progress in preventing new HIV infections and reducing AIDS-related deaths and in expanding access to treatment, approximately 1.54 million (87%) of children (0–14 years) and 1.7 million (82%) of adolescents (10–19 years) living with HIV are found in sub-Saharan Africa (SSA)[2]. Eastern and Southern Africa carries a huge share of the global HIV burden in children and adolescents. According to the report done by United Nations Children's Fund (UNICEF) in 2023, in this region, Children (0-14 years) living with HIV 940,000 (63%), new infection 60,000 (46%) and AIDS related deaths 36,000 (43%). Whereas older adolescents (15-19 years) living with HIV 69,000 (69%), new infection 77,000 (55%) and AIDS related deaths 10,000 (67%) were found to be of the global total[2].

In Ethiopia, the prevalence of HIV/AIDS aged 15-59 years is estimated to be 0.9%[3]. The burden varies depending on factors such as gender, age, and residency. According to the Ethiopian Public Health Institute (EPHI), HIV related estimates and projections in Ethiopia for the year 2022-2023, the total number of People Living with HIV (PLWHIV) were decreased from 610,350 in 2022 to 603,537 in 2023, bringing national HIV prevalence of aged 15 years and above to 0.87% in 2023 which was slightly decreased from 0.9% by 2022 but children with HIV (aged 0-14) was estimated to be 33,026 which was about 5.5% of the total in 2023[4]. In Addis Ababa, peoples living with HIV total (all ages) was estimated to be 112,185 in 2022 but 110, 289 in 2023 which makes the prevalence to be 3.47 % in 2023. Whereas children with HIV (aged 0-14) were 3,206 in 2022 but 2,793 in 2023[3].

In Ethiopia, according to the President's Emergency Plan for AIDS Relief (PEPFAR-Ethiopia), in PEPFAR supported regions as of May 2021 final report, 79% of estimated PLHIV know their status, 97% of people living with HIV who know their status were on ART and 91 % of people who were on ART achieved viral suppression[4] . However, this report showed that only 64% of children under 15 years of age were know their status, 69% accessed ART and 75% virally suppressed[4]. This indicates that children are lags behind towards the UNAIDS 95 -95-95 target by 2025 as compared to adults 15 years and above.

Dolutegravir (DTG) is a second-generation integrase inhibitor with the advantage of once-daily dosing, a good short-term safety profile, low pharmacokinetic (PK) variability, few drug-to-drug interactions, rapid and robust virological response and better drug palatability as compared to protease inhibitors (PIs) and nucleoside reverse-transcriptase inhibitors (NRTIs)[5-8]. Minister of Health, Ethiopia adopted a guideline in 2018 which recommended two NRTIs combined with DTG for Adults and adolescents 10 years & above with body weight >30 kg following WHO update on ART guideline in 2018[9]. However, the remaining groups were unchanged.

DTG treatment has highly potent antiviral activity, a high genetic barrier to resistance, and a high safety profile. Even though dolutegravil has been approved in children and adolescents recently, the evidence of level of medication adherence and viral load suppression rate is not well justified. Moreover, the role of DTG in children and adolescents where the variations in pharmacogenetics, nutritional status, and other socio-demographic characteristics may significantly affect the effectiveness and safety of the regimen not well understood in Ethiopian context. Therefore, this study aimed to assess virological suppression and its associated factors of dolutegravir based regimen among children and adolescents receiving ART in Addis Ababa, Ethiopia.

2.0 Materials and Methods

2.1 Study area and period

There were 11 governments owned hospital providing ART service of which 5 were federal hospitals and 6 were regional hospitals governed by Addis Ababa City Health Bureau (AACHB). Eight hospitals were providing pediatric ART services

at time of the study. This were, St Paul Hospital Millennium Medical College, Yekatit 12 Hospital Medical College, Alert Specialized Hospital, St Peter Specialized Hospital, Zewditu Memorial Hospital, Minilik II Specialized Hospital and Tirunesh Beijing General Hospital. These hospitals were high load and high impact facilities with high number of adult and pediatric clients on ART. According to AACHB report as of September 2023, there were about 96607 total clients on ART, 95281 clients were 15 years and above but 1326 clients were below 15 years of age of which 753 (57 %) of children below 15 years were found in the above hospitals. Among children whose follow up were in hospitals, 752 (99%) receiving DTG based regimen. On the other hand, the numbers of older adolescents from 15-19 years who have follow up at hospitals were 1148 from which 1125(98%) adolescents were on DTG based regimen. The study was conducted from June 15/2024 to August 30/2024.

2.2 Study design

This was a facility-based cross-sectional study. To obtain historical exposure data, a concurrent retrospective review of participants' medical records was conducted covering the 12-month period prior to DTG initiation.

2.3 Population

2.3.1 Source population

The source populations were all HIV positive children and adolescents (0-19 years) in the selected government hospitals in Addis Ababa, Ethiopia.

2.3.2 Study population

All children and adolescents who were shifted to a DTG-based antiretroviral

2.4 Eligibility criteria

2.4.1 Inclusion criteria

All children (0-9) and adolescents aged (10-19) years who were on DTG based ART regimen for at least 12 months and with documented viral load result in the selected Hospitals.

2.4.2 Exclusion criteria

Adolescents who were on ART for less than 12 months' duration, pending or unknown Viral Load (VL), lost to follow up, transfer out to other treatment facility or deceased clients.

2.5 Sample size determination

The sample size was determined using a single population proportion formula with a 95% confidence interval, considering the proportion of viral suppression 50% as no previous study done in the study area with a relative precision 5% and 12% non-response rate in order to recruit the estimated sample size of 430.

2.6 Sampling technique/ procedure

About 1901 participants who were on DTG based ART regimen documented in the study hospitals. A multistage sampling method was employed and then proportional to sample size, allocation was computed to include participants from each selected hospital. Finally, each participant in each health facility was selected using a simple random sampling technique.

2.7 Data collection tools and techniques

Data was collected by using semi-structured and pre-tested questionnaire. It was contextualized based on the research objective from revised literature[4, 7, 10]. Face to face interview (for socio-demographic and behavioral variables) and EMR (ART smart care) extraction as well as medical record reviews using data extraction checklist. The questionnaire was translated into Amharic and back to English by language experts to ensure its consistency. The data was collected by data clerks and health officer was assigned for supervision following 2 days training.

2.8 Variables in the study

2.8.1 Dependent variable

- HIV viral load suppression: (categorized as Suppressed/Yes or Unsuppressed/No).

2.8.2 Independent variables

- **Socio demographic factors:** Age, sex, educational level , occupation, residence, marital status of caregivers, orphanage status, religion, PMTCT F/UP, relation, pregnancy status, care giver on ART.
- **Clinical and medication related factors:** Knowledge about ART, medication adherence level, previous regimen before shifted to DTG, current regimen with DTG, MMD, duration on ART (in months), base line CD4 level, current CD4, OI, BMI,WHO clinical staging, DTG based regimen, Base line viral load , Perinatal infection.
- **Behavioral factors:** Alcohol, chat, disclosure status and using reminder.
- **Psycho-social Factor:** Stigma, major depressive disorder (MDD) and anxiety disorder.

2.9 Operational definition

- **Viral load suppressed** –a viral copy of less than or equal to 50 copies /ml (11).
- **Children** -individuals with age less than 15 years old (12).
- **Adolescent** -defined by WHO as the second decade of life (10-19 years of age)(12).

2.10 Data quality management

Two-days training was given to data collectors on data collection, entry and how to approach to participants. The trained data collectors were assigned to a single supervisor. In order to assure the quality of data before starting the actual data collection, pre-test was done on 5% of children and adolescents on dolutegravir based regimen at Tikur Anbessa specialized hospital. Daily supervision was done during data collection period. The questionnaire was reviewed and checked for completeness, accuracy and consistency by supervisor and principal investigator. Double entry of 5 % data was carried out to ensure consistency and validity.

2.11 Methods of data analysis

Data entry was done using Epi-info version 7 and then exported to Statistical Package for Social Sciences (SPSS) version 26 for further analysis. Descriptive statistics were calculated for relevant variables. To compare pre- and post-intervention measurements, the Wilcoxon signed-rank test was used, given the non-normal distribution of the paired differences.

Binary logistic regression model was carried out to identify predictors that could independently associate with viral load suppression. Variables whose p-value less than 0.25 in the bivariate analysis was considered as a candidate variable for Multivariable model. Adjusted Odds ratio (AOR) along with a 95% confidence level were used to measure the strength of association. Variable were interpreted as having a statistically significant association if the p-value was < 0.05. Model fitness was checked using Hosmer and Lemeshow test for goodness of fit. Multicollinearity was also checked[13].

2.12 Ethical considerations

Ethical approval was obtained from the Research and Ethical Committee of the SPHMMC (IRB ref no: PM23/1233), and Addis Ababa Health Bureau Research directorate (IRB ref no: A/A/H/20669/227). A letter of cooperation was written from the School of public Health, SPHMMC to Addis Ababa Health Bureau and to hospitals where the research was conductedIn order to maintain privacy and confidentiality of study participants, data was recorded anonymously.

3. Results

3.1 Socio-demographic characteristics of the study participants

Most of respondents were in the age groups 15-19 years 175 (40.9%). Half 217 (50.7%) of participants were female and majority 316 (73.8%) were orthodox by religion. Nearly two third 290 (67.8%) of respondents were married. Almost similar proportion of respondent's 148 (34.6%) had primary and 146 (34.1%) seconders educational

level. Whereas, one-fourth of 107 (25 %) of study participants were private organization employee and majority366 (85%) of them were living in Addis Ababa (Table 1).

Table 1. Socio-demographic characteristics of the study participants in selected Governmental Hospitals, Addis Ababa, 2024 (N=428).

Variable	Sub-group	N(%)
Age in years	< 10	94 (22.0)
	10 -14	159 (37.1)
	15-19	175 (40.9)
Sex	Female	217 (50.7)
	Male	211 (49.3)
Marital status	Single	50 (11.7)
	Married	290 (67.8)
	Divorced	62 (14.5)
	Widowed	26 (6.0)
Religion	Muslim	52 (12.1)
	Orthodox	316 (73.8)
	Protestant	58 (13.6)
	Catholic	2 (0.5)
Education levela	No formal education	36 (8.4)
	Primary	148 (34.6)
	Secondary	146 (34.1)
	Tertiary	98 (22.9)
Place of residence	Addis Ababa	366 (85.5)
	Out of Addis Ababa	62 (14.5)
Occupation	House wife	87 (20.3)
	Daily laborer	97 (22.7)
	Government employee	73 (17.1)
	Private employee	107 (25)
	Merchant	50 (11.7)
	Retired	2 (0.5)
	Others	12 (2.8)

N.B: a=Primary education indicates 1–8th grades; secondary education indicates 9–12th grades; Tertiary education indicates college & above.

3.2 Psychosocial, behavioral and caregiver's knowledge

The majority of CALHIV (313; 73.1%) disclosed their HIV status. Almost equal proportions were diagnosed with anxiety (22; 5.1%) and major depressive disorder (23; 5.3%). Nearly all participants (407; 95.1%) reported no history of perceived or confirmed stigma. On the other hand, only 3 (0.7%) participants had a history of chewing Kchat, and 2 (0.5%) participants reported a history of alcohol consumption. Nearly half of the participants (211; 49.3%) had a low level of knowledge regarding medication adherence (result not shown).

3.3 Clinical and medication related characteristics

The majority of participants (397; 92.8%) were on a first-line regimen. A total of 238 (55.6%) participants were taking the TDF/3TC/DTG (TLD) regimen, while 173 (40.4%) participants were prescribed ABC/3TC/DTG following the shift to a DTG-based regimen. Half of the clients (214; 50%) had previously been prescribed a Nevirapine-based regimen before transitioning to DTG. In addition, 383 (89.5%) participants received TB prophylaxis, and 392 (91.6%) received Cotrimoxazole prophylaxis. However, only 77 (18.0%) participants received antiretroviral prophylaxis. Mild to moderate malnutrition was observed in 45 (10.5%) participants.

Among the study participants, only 10 (2.3%) developed side effects and 18 (4.2%) experienced opportunistic infections (OIs) following initiation of the DTG-based regimen. All participants had acquired HIV through mother-to-child transmission. The majority (336; 78.5%) reported using reminders to adhere to medication timing. Approximately two-thirds (290; 67.0%) were enrolled in the three-month multi-month dispensing (3MMD) model. Prior to transitioning to the DTG-based regimen, only 285(66.6%) participants were virally suppressed (Table 2).

Table 2.Clinical and medication related characteristics of the participants at selected government Hospitals, Addis Ababa, 2024(N=428)

Variable	Sub-group	N(%)
Line of regimen		
	First line	397 (92.8)
	Second line	31 (7.2)
Current regimen after shifted		
	ABC3TC DTG	173 (40.4)
	AZT 3TC DTG	17 (4.0)
	TDF 3TC DTG	238 (55.6)
Previous regimen		
	Nevrapine	214 (50.0)
	Lopinavir/r	127 (29.7)
	Efavirenze	77 (18.0)
	Atazanavir	10 (2.3)
TB prophylaxis		
	Yes	383(89.5)
	No	45 (10.5)
Cotrimoxazole/CPT prophylaxis		
	Yes	392(91.6)
	No	36(8.4)
ARV prophylaxis		
	Yes	77(18.0)
	No	351(82.0)
Nutritional status		
	Malnutrition	45(10.5)
	Normal	383(89.5)
OI		
	Yes	18(4.2)
	No	410(95.8)
Side effect		
	Yes	10(2.3)
	No	418(97.7)
Perinatal infection		
	Yes	428(100)
	No	0 (0.0)
Using Reminder		
	Yes	336(78.5)
	No	92(21.5)
MMD		
	<3 MMD	133(31.1)
	3-5 MMD	290(67.8
	6 MMD	5(1.2)
VS before		
	<=51	143(33.4)
	>51	285(66.6)

NB. ARV=Anti-retro Viral; OI= Opportunistic infection; MMD= Multi-month dispensing; VS= Viral suppression

3.4 Clinical characteristics of pre and post Dultagravir based regimen

The study showed that 48 (11.2%) participants developed tuberculosis prior to initiating the DTG-based regimen, whereas only 16 (3.7%) participants developed and were treated for TB after the transition. Similarly, 353 (82.5%) participants were classified as WHO Stage I before initiation, increasing to 420 (98.1%) after initiating the DTG-based regimen. Regarding medication adherence, 321 (75.0%) participants demonstrated good adherence prior to DTG initiation, compared to 370 (86.4%) following the switch to DTG (data not shown).

3.5 Virologic outcome of Dultagravir based anti-retro viral Regimen

Among the 428 study participants, 382 (89.3%) achieved viral suppression after one year of treatment with the dolutegravir (DTG)-based regimen. In contrast, only 285 (66.6%) had achieved viral suppression prior to transitioning to DTG. Nearly two-thirds of participants, 268 (70.0%), were virally suppressed both before and after initiation of the DTG-based regimen. Among the 143 previously unsuppressed individuals, 114 (79.7%) attained viral suppression following the switch to DTG (data not shown).

3.6 Factors associated with Virologic outcome of Dalutagravir based regimen

Bivariate and multivariate analysis was conducted to determine predictor of viral load suppression. In bivariate analysis Age, Educational level, Orphanage status, relation to child or adolescent, Line of regimen, Anxiety, MDD, Stigma, Base line WHO staging, Nutritional status, Reminder for medication timing, previous viral load suppression status and Post DTG medication adherence were significantly associated with viral load suppression. Factors independently associated with viral load suppression included Post DTG medication adherence, nutritional status, line of regimen, previous viral load suppression status, parents /care giver's educational level and Orphanage status.

Participants with good medication adherence had nearly four times higher odds of achieving Virologic suppression compared to those with poor adherence (AOR = 3.832; 95% CI: 1.489–9.860). The odds of Virologic suppression were three times higher among those who were virally suppressed prior to initiating DTG therapy (AOR = 3.051; 95% CI: 1.350–6.890). Similarly, participants with normal nutritional status had greater odds of Virologic suppression than those with mild to moderate malnutrition (AOR = 3.650; 95% CI: 1.356–9.634). Those whose parents were alive had higher odds of suppression compared to orphans (AOR = 3.308; 95% CI: 1.440–9.560). In contrast, participants on second-line regimens had significantly lower odds of Virologic suppression than those on first-line treatment (AOR = 0.211; 95% CI: 0.070–0.670). Moreover, participants whose caregivers had only primary education had reduced odds of suppression compared to those with tertiary education (AOR = 0.208; 95% CI: 0.057–0.762) (Table 3).

Table 3.Association between predictors and Virologic Suppression among CALWHIV on DTG-Based ART Regimen in Government Hospitals, Addis Ababa, 2024

Variable	Suppressed		COR with 95%CI	P-value	AOR with 95%CI	P-value
	Yes	No				
Medication adherence after DTG						
Poor /<85% (ref)	39	19	1		1	
Good /≥95% and above	343	27	6.18 (3.15-12.14)	0.000	3.832(1.489-9.86)	0.005**
Parents/care givers Education status						
Illiterate	34	2	0.723 (0.127-4.130)	0.716	0.21(0.14-37.76)	0.198
Primary	120	28	0.182 (0.062-0.538)	0.002	0.208 (0.057-0.762	0.018 *
Secondary	134	12	0.475 (0.149-1.519)	0.209	0.46 (0.124-1.77)	0.264
Tertiary (ref)	94	4	1		1	
Viral suppression pre DTG						
>=51 (ref)	114	29	1		1	
<51	268	17	4.01(2.12-7.87)	0.000	3.051(1.35-6.89)	0.007**
Nutritional status						
Malnutrition (ref)	30	15	1		1	
Normal	332	51	5.67(2.76-11.66)	0.000	3.65 (1.356-9-634)	0.010**
Orphan status						
Orphaned (ref)	57	12	1		1	
Parent alive	325	34	2.012(0.9844.117)	0.05	3.308 (1.44- 9.56)	0.027*
Line of regimen						
First line	364	33	1		1	
Second line	18	13	0.126 (0.057-0.279)	0.000	0.211(0.066-0.673)	0.009**

NB: Ref= reference; COR= Crude Odd Rations; AOR=Adjusted Odd Ratios.

4.0 DISCUSSION

In this study, the viral load suppression (VLS) rate among children and adolescents receiving ART was 89.3%. This finding aligns with studies conducted in Cameroon and Nigeria, which reported VLS rates of 88.2% and 88.4%, respectively[14-15]. Conversely, a comparative study in Kenya reported a slightly higher VLS rate of 93% among a similar population[16]. This difference may be attributed to the study's use of a lower threshold for suppression, defining VLS as a viral load below 400 copies/ml. Additionally, a study conducted in Tanga, Tanzania, found that 92.76% of children and adolescents achieved viral suppression, slightly exceeding the rate observed in the current study[17]. This difference might be due to variations in outcome measurement; the Tanzanian study defined VLS as a viral load of ≤1000 copies/m.

This study also demonstrated a higher viral suppression rate following the initiation of a Dolutegravir-based regimen compared to the pre-Dolutegravir regimen (89.3% vs. 66.6%, $Z = -10.741$, $p < 0.001$). This result aligns with findings from a study conducted in Nigeria among children and adolescents[18]. Furthermore, the study revealed that 70% of previously suppressed participants remained virologically suppressed, a finding consistent with similar research on this population in Nigeria[18]. However, the suppression rate observed in this study was lower than that reported in a pre-post study conducted in western Zimbabwe, which showed rates of 76% and 95%, respectively. This discrepancy may be attributed to differences in sample size and outcome measurement methods, as the Zimbabwean study defined viral suppression as a viral load of ≤1000 copies/mL[19].

Following the initiation of a Dolutegravir-based regimen, the proportion of clients demonstrating good adherence significantly increased from 75% to 86.4% (McNemar's test, $Z = -2.834$, $p = 0.005$). This finding supports the notion that Dolutegravir is associated with fewer side effects and improved palatability, contributing to better treatment compliance compared to previous regimens. In addition, the proportion of clients with a history of tuberculosis treatment declined from 11.2% to 3.7% ($\chi^2 = 26.694$, $p < 0.001$), suggesting that the Dolutegravir-based regimen may contribute to more rapid immune recovery and enhanced host immune function[8].

The present study demonstrates that the viral suppression rate was three times higher among participants with good adherence compared to those with poor adherence. This finding is supported by studies conducted in Hawassa, Southern Ethiopia, and Nigeria, which identified good adherence as a key determinant of viral suppression outcomes[18,20]. Similarly, the study identified that previously suppressed viral load and nutritional status were independently associated with favorable viral suppression outcomes. This finding aligns with studies conducted in Kisumu, Kenya, and Tanzania among children and adolescents receiving Dolutegravir-based regimens[17, 21]. In contrast, a primary education level was associated with poorer viral suppression outcomes compared to tertiary education. This result is consistent with findings from a study conducted in North Wollo, East Amhara region, Ethiopia[22]. Lastly, with regard to orphanage status, children and adolescents who had living parents were three times more likely to achieve favorable viral suppression compared to their counterparts. This finding is consistent with studies conducted in Addis Ababa, Ethiopia, and southern Tanzania among similar study populations[6, 10].

One of the strengths of this study is its inclusion of all government hospitals in Addis Ababa, Ethiopia providing pediatric HIV care and treatment services, which enhances the generalizability of the findings to the broader population. Both primary and secondary data sources were utilized to incorporate key variables and minimize potential confounders. To reduce documentation errors, data were cross-checked against ART Smart Care records and patient charts. A limitation of this study is the exclusion of ART-naive clients, which precludes assessment of viral suppression status among this subgroup,

despite evidence suggesting that Dolutegravir-based regimens offer superior viral suppression outcomes compared to earlier treatment protocols. Additionally, the cross-sectional design limits the ability to infer causal relationships. Some responses may be subject to recall bias and social desirability bias, particularly due to the use of interview-administered questionnaires.

Conclusion

The study found that 89.3% of children and adolescents achieved viral suppression, falling short of the ≥95% UNAIDS target set for 2025. Our findings also highlighted several factors influencing viral suppression, including good adherence, the educational status of parents or caregivers, previous viral suppression while under parental care, nutritional status, orphan status, and the type of antiretroviral regimen. Moreover, the study revealed that Dolutegravir-based regimens not only improve viral suppression outcomes but also promote better medication adherence emphasizing the need for tailored treatment strategies that specifically address the unique needs of children and adolescents.

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