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Feasibility of smartphone-enabled asynchronous video directly observed therapy to improve viral suppression outcomes among HIV unsuppressed children and adolescents in Kenya

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Abstract

Background Video directly observed therapy (VDOT) has been used as an acceptable, cost-effective, client-centered intervention for tuberculosis management. VDOT targeting children (0–14 years) and adolescents (15–19 years) living with HIV (CALHIV) not achieving viral suppression (VS) [i.e., < 1000 copies/ml] was piloted in 73 facilities in Kenya. We conducted a feasibility study on the utilization and re-suppression rates of clients enrolled in VDOT.

Methods A review of data from 223 virally unsuppressed clients aged between 0–19 years on antiretroviral therapy (ART) who were enrolled to use the VDOT application daily for at least 12 weeks between February 2021 and October 2022 at 73 health facilities was conducted. Clients stopped using the application upon achieving VS. VS was assessed after at least 12 weeks of VDOT follow-up through self-care or healthcare worker (HCW)-led approaches. Using a multivariable Cox Proportional Hazards regression model, we assessed demographic and clinical determinants of VS presenting adjusted hazard ratios (aHR).

Results Most users, 163 (73.1%) were adolescents aged 10–19 years. Only 19 (8.5%) were on self-care VDOT. Median time on follow-up was 19 weeks, with 126 videos uploaded, and 75% VDOT adherence. Over three-fourths, 176 (78.9%) had achieved VS during follow-up. Results showed a higher likelihood of VS among children on once-daily compared to twice-daily ARV dosage, aHR = 2.51 (95% CI: 2.06 – 3.05), and those on second- or third-line regimens compared to those on first-line regimens, aHR = 3.05 (95% CI: 1.78 – 5.22). Similarly, those on a DTG-based regimen had a higher likelihood of VS compared to those on LPV/r-based, ATV/s-based, or EFV-based regimens, aHR = 1.95 (95% CI: 1.25 – 3.06). Children receiving care from guardians and siblings had a higher likelihood of VS compared to those receiving care from parent caregivers, 1.61 (95% CI: 1.27—2.03), and 2.00 (95% CI: 1.12 – 3.57), respectively.

Conclusion VDOT supported the achievement of VS among unsuppressed CALHIV on antiretroviral treatment and was significantly associated with dosage frequency, antiretroviral regimen, first- or second-line therapy,

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antiretroviral regimen classification, and type of caregiver. Findings suggest the utility of VDOT among unsuppressed CALHIV in resource-limited settings.

Keywords Children and adolescents living with HIV, Video directly observed therapy (VDOT), Viral suppression, Kenya, Antiretroviral treatment

Background

Globally, children living with HIV (CLHIV) constituted 4% of people living with HIV in 2022 [1]. However, CLHIV had inferior treatment coverage (52% v 76% among adults) and contributed to 13% of AIDS-related deaths globally [1, 2]. In the same year, population-level viral suppression for children at 46%, lagged behind the global targeted trajectory to achieve 75% and 86% suppression rates by 2023 and 2025 respectively [3]. In 2021, Kenya reported 4,098 AIDS-related deaths among children and adolescents. Deaths were attributed to late diagnosis, low antiretroviral treatment coverage, and lower viral suppression rates [4]. Children and adolescents living with HIV (CALHIV) face unique issues affecting adherence to medication because of dependence on caregivers for their treatment among children, while more independent adolescents experience physical and psychological developmental transitions that can affect their fidelity to long-term treatment and chronic care management [5–7].

Video directly observed treatment (VDOT) has been used as a tool to observe patients swallowing their medication remotely, which can then be reviewed by a health provider [8]. VDOT embraces technology such as use of a phone or tablet video recording to monitor medication intake and serves as an alternative to in-person directly observed therapy. Since early pilots of VDOT using videophones connected to telephone landlines, the ubiquity of mobile phones, including smartphones, has enabled innovation and scale [9, 10]. Near universal mobile phone penetration in Kenya, reported at 98% among adults in 2020, and smartphone use for access to the internet and social media enable mobile-phone-based health interventions to efficiently and rapidly achieve treatment outcomes [11].

The use of VDOT has been found to be feasible and acceptable in both high- and low-income settings [12]. This has been demonstrated in sub-Saharan Africa settings in a recent study in Uganda [13]. Studies have suggested the role of VDOT in addressing barriers to patient-centered care including distance [14, 15], autonomy [9, 12, 14, 16], increased efficiency through reduced travel costs [9, 15, 16], and maximizing health provider output [16–19]. The use of VDOT has also been associated with less stigma among tuberculosis (TB) patients compared to in-person directly observed treatment approaches [20].

VDOT could be synchronous or asynchronous. Synchronous VDOT is similar to video conferencing with live observation of medication ingestion compared to asynchronous, where videos are stored and forwarded with network availability for later review by a health provider [12]. While synchronous VDOT has limitations of business hours and network availability, asynchronous VDOT provides greater flexibility to patients to take their scheduled medications wherever and whenever it is convenient, promoting a patient-centered approach [9, 12, 21].

While VDOT has been adopted to support TB treatment, its use has been recommended for other health conditions requiring strict medication adherence and has been piloted among children with sickle cell disease and asthma [12, 22, 23]. HIV programs have embraced the use of mobile telephony, particularly text messaging to support health education, appointment-keeping, data collection, adherence, and provider-patient communication [10, 24–26].

Among adolescents and youth living with HIV, text message reminders [22, 27–29], web-based interventions [30, 31], phone calls [32, 33], digital gaming [34, 35], and mobile phone application interventions [36, 37] have been reported as acceptable, feasible, and associated with improved medication adherence, HIV knowledge, and viral suppression. Among poorly adherent and unsuppressed children and adolescents on HIV treatment, hospital, and community-based directly observed treatment (DOT) interventions have been piloted with some reported improvements in adherence and viral suppression outcomes [38, 39]. We assessed feasibility of the use of smartphone-based asynchronous VDOT among virally unsuppressed children and adolescents living with HIV in Kenya.

Methods

Intervention description

The name "NimeCONFIRM" was coined from Kenyan slang combining Kiswahili and English words meaning "I confirm" (in this case, that I have taken my medication). "NimeCONFIRM" is a video directly observed therapy (VDOT) application, designed to support enhanced adherence for children and adolescents who have an

unsuppressed viral load >1000c/ml. The application was designed to enable clients to take a short video confirming that they have swallowed their antiretroviral medication/dose for the day through an easy-to-use application interface. The NimeCONFIRM application was developed by the Centre for Health Solutions- Kenya (CHS), a local Kenyan non-profit, funded by the U.S. President's Emergency Plan for AIDS (PEPFAR) through the U.S. Centers for Disease Control and Prevention (CDC) – Kenya.

NimeCONFIRM application is only available in the Google Play Store for pre-authorized users who are either clients, caregivers, or case managers. Caregivers of viremic children are counseled at the facility and provide consent to be enrolled in NimeCONFIRM. Based on the health worker assessment, enrollment can be done in two ways—case manager or health care worker (HCW)- led, whereby the smartphone used is held by the case manager/HCW and they visit the client and take a video during medication intake daily. The second option is the self-care mode where the smartphone used is for a caregiver or someone who lives with the client and carries out the VDOT. These included parents, grandparents, guardians, relatives, and siblings.

The application features a secure log-in with a one-time password, a coded user identifier using random alphanumeric digits, a screenshot restriction feature while taking the videos, which restricted saving or storing video in the mobile phone. Data were encrypted at upload of videos and decrypted at a secure server. NimeCONFIRM videos were recorded on a client's or caregivers' or case managers' smartphone using the device's camera application and sent to a secure database. All the features in the NimeCONFIRM application comply with HIPAA, European Union—General Data Protection Regulation (GDPR), and the Kenya 2019 Data Protection Act.

NimeCONFIRM has several features that support medication adherence; a) A tailored pill calendar and alarm feature that sends a notification an hour and 30 min before the allocated time for taking medication, b) a closed group application, only accessible to authorized users among registered HIV positive children and adolescents, c) a time stamp for each video taken, d) a store and forward feature that allows videos taken off the internet to be pushed to the server, and, e) a visualization dashboard available to the clinical team to monitor adherence, with an interphase to the existing facility-based electronic medical records (EMR).

VDOT adherence was measured as a percentage of the number of videos uploaded against the expected uploads to the database. Those taking two doses were expected to have two video uploads daily while those on a single dose were expected to have a single video uploaded. Other outcomes of interest were successful completion (VS), loss to follow-up (LFTU), and discontinuation.

Study setting

Children and adolescents were enrolled from 73 health facilities in Machakos, Makueni, and Kitui counties of Kenya. The facilities provide HIV services to children and adolescents, through implementing partners funded by PEPFAR through CDC. Participants freely chose to use the VDOT app without any formal randomization. Additionally, the self-care or HCW-assisted options were personally selected by each user. The HIV services included providing HIV care and treatment for children and adolescents per national HIV treatment guidelines [40]. Viral suppression monitoring was evaluated through RNA polymerase chain reaction (PCR) viral load testing every 3 months until VS was achieved [41, 42].

Study design, population, and sample

The retrospective data from children and adolescents who enrolled in the feasibility pilot study and used the NimeCONFIRM VDOT application between February 2021 and October 2022 for any period were collected. However, we only analyzed data from those virally unsuppressed children (0–9 years) and adolescents (10–19 years) living with HIV on antiretroviral therapy (ART) who enrolled in and used the NimeCONFIRM VDOT application for at least 12 weeks. Those who had less than 12 weeks of follow-up, which was considered insufficient time to determine clinical changes, were excluded from the analysis. Furthermore, the timing was convenient given that routine viral loads were done every 3 months.

Data sources and collection

We collected data using the NimeCONFIRM VDOT application. There were two options for data collection at the respective dosage times: (1) VDOT users using the self-care approach where individual clients and (or) their caregivers used their own mobile devices; and (2) Healthcare worker (HCW)-assisted recording and upload of VDOT for those who did not have their own devices or opted for this approach. The enrolment and follow-up data were extracted from the VDOT database and prepared for analysis.

Variables

We analyzed various demographic and clinical factors in our study, including age at enrollment, sex, county of enrolment, caregiver (such as grandparents, guardian, parent, relative, or siblings), frequency of dosage (once daily or twice daily), regimen line (first, second, or third), core regimen (abacavir [ABC], zidovudine [AZT], and tenofovir [TDF-based]), regimen classification

(Lopinavir/Ritonavir [LPV/r] Based, Atazanavir/Ritonavir [ATV/r] Based, dolutegravir [DTG] based, Efavirenz [EFV Based], and Other), and type of care (self-care or healthcare worker-led). The core regimens were mutually exclusive. "Continuing on follow-up" clients were defined as children and adolescents who were enrolled in the VDOT application and currently unsuppressed but still being monitored through the VDOT application. We recorded the time it took for clients to achieve viral suppression in weeks, with a maximum follow-up period of 90 weeks. Viral suppression outcome was defined as < 1000 copies per milliliter.

Ethical Approval

The AMREF Ethics and Scientific Review Committee, Nairobi, Kenya, approved the protocol to conduct this analysis (protocol number: P412/2017) and waived the need for consent from study participants given the retrospective data use. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[§](§See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq). The study team only had access to de-identified data for analysis. The study procedures were done in accordance with the ethical principles outlined in the World Medical Association's Declaration of Helsinki, Kenya Government, Ministry of Health, CDC, and local IRB regulations.

Data analysis

Descriptive analysis of children and adolescent characteristics was done using counts and percentages as appropriate. Median and interquartile range (IQR) were presented for time to viral suppression outcome, and number of expected daily doses, the number of videos uploaded, and VDOTs adherence. Using Cox proportional hazards (CoxPH) models, survival regression analysis was done to assess the factors associated with viral suppression among children and adolescents who had used the VDOT application for at least 12 weeks and up to 90 weeks of follow-up [43]. The time to suppression was calculated as the number of weeks starting from 12 weeks after the date of VDOT enrolment until the point of VL suppression. Those who were still unsuppressed at 90 weeks of follow-up were censored. There was no missing data for all key variables. The estimated probability of viral suppression was based on the Kaplan–Meier estimates and presented as a plot. Using univariable and multivariable CoxPH models, we assessed demographic and clinical determinants of viral suppression presenting adjusted hazard ratios (aHR) and 95% confidence intervals (CI). The multivariable model included sex, age category, caregiver, dosage frequency, core regimen, regimen line, and type of care (healthcare worker-led or self-care user). Graphical and global tests were done to confirm that the assumption of proportional hazards was met. Overall global (Wald) hypothesis tests were done for categorical variables (age, and caregiver) with more than two categories to determine if the categories were jointly significantly associated with viral suppression. Survival plots by predictor categories were based on the multivariable CoxPH model estimates. All analyses were done using Stata, version 18.1 (StataCorp 2023. Stata Statistical Software, Release 18; College Station, TX).

Results

Description of client characteristics

The total number of children and adolescents enrolled was 470, representing an uptake of 60%. A total of 164 (34.9%) discontinuations were recorded before 12 weeks of follow-up. However, only about half, 223 (47.5%), of the 470 enrolled on the application who had used it for at least 12 weeks were analyzed. Of all those with at least 12 weeks of follow-up, 223 (100%), were retained at 21 weeks of follow-up. Most users, 163 (73.1%), were adolescents (10–19 years). Over half, 128 (57.4%), were males. There were 19 (8.5%) on the self-care VDOT option. The median time on follow-up was 19 weeks (interquartile range [IQR]: 17–23), with a median of one video uploaded (IQR: 0.7—1.5) per day, and a median of 126 (IQR: 96 –197) videos uploaded over a median follow-up of 19 weeks as shown in Table 1.

The overall median VDOT adherence was 76% (IQR: 60—85), and it did not significantly differ by age, sex, and regimen as shown in Table 2.

Viral suppression outcome

All 223 had viral load outcomes available by 90 weeks of follow-up. The probability of viral suppression at 16, 20, 24, and 28 weeks was 16.1%, 45.3%, 74.2%, and 87.5%, respectively. More than three-fourths, 176 (78.9%), had achieved viral suppression over the follow-up period, as shown in Table 1. Achievement of viral suppression did not differ significantly by age group among those on self-care (p-value = 0.545) or Healthcare worker-led (p-value = 0.393). The overall probability of viral suppression over follow-up is shown in Fig. 1.

Results of VDOTs by viral suppression status

The overall median number of weeks on follow-up for all clients was 19 weeks (IQR: 17—23). Clients who achieved VS had an almost similar median number of weeks using the application compared to those who were continuing follow-up since they had not suppressed, 20 weeks (IQR: 17—23) vs. 19 weeks (IQR: 16—22) respectively, p-value = 0.260. Results showed that those who suppressed had

Table 1 Suppression outcome among participants at the end of 90 weeks of follow-up, Kenya, Feb 2021—Oct 2022

Columns by: suppression outcome among those with least 12 weeks of follow up (*n* = 223)	Continuing follow-up	Suppressed	Total	*P* value
n (%)	47 (21.1)	176 (78.9)	223 (100.0)	
Sex, *n* (%)				0.745
Girls	21 (44.7)	74 (42.0)	95 (42.6)	
Boys	26 (55.3)	102 (58.0)	128 (57.4)	
Age at enrollment (years), median (IQR)	13.3 (8.8—15.9)	13.7 (9.7—16.4)	13.7 (9.6—16.2)	0.628
Age Category at enrollment (years), n (%)				0.241
0–4	8 (17.0)	15 (8.5)	23 (10.3)	
5–9	5 (10.6)	32 (18.2)	37 (16.6)	
10–14	19 (40.4)	65 (36.9)	84 (37.7)	
15–19	15 (31.9)	64 (36.4)	79 (35.4)	
Caregiver, *n* (%)				0.998
Grand parents	6 (12.8)	25 (14.2)	31 (13.9)	
Guardian	6 (12.8)	24 (13.6)	30 (13.5)	
Parent	32 (68.1)	117 (66.5)	149 (66.8)	
Relative	2 (4.3)	7 (4.0)	9 (4.0)	
Siblings	1 (2.1)	3 (1.7)	4 (1.8)	
Core ART regimen, *n* (%)				0.170
ABC Based	14 (29.8)	48 (27.3)	62 (27.8)	
AZT Based	27 (57.4)	83 (47.2)	110 (49.3)	
TDF Based	6 (12.8)	45 (25.6)	51 (22.9)	
Regimen Classification, *n* (%)				0.621
DTG Based	19 (40.4)	81 (46.0)	100 (44.8)	
LPV/r Based	22 (46.8)	69 (39.2)	91 (40.8)	
ATV/r Based	4 (8.5)	22 (12.5)	26 (11.7)	
EFV Based	2 (4.3)	3 (1.7)	5 (2.2)	
Other	0 (0.0)	1 (0.6)	1 (0.4)	
Regimen line, *n* (%)				0.716
First-line	18 (38.3)	76 (43.2)	94 (42.2)	
Second-line	29 (61.7)	99 (56.2)	128 (57.4)	
Third-line	0 (0.0)	1 (0.6)	1 (0.4)	
Type of care, *n* (%)				0.998
Healthcare worker led	43 (91.5)	161 (91.5)	204 (91.5)	
Self-care/User	4 (8.5)	15 (8.5)	19 (8.5)	
Dosage Frequency, *n* (%)				0.105
Once daily	17 (36.2)	87 (49.4)	104 (46.6)	
Twice daily	30 (63.8)	89 (50.6)	119 (53.4)	

IQR Interquartile range, *ABC* Abacavir, *AZT* Zidovudine, and *TDF* Tenofovir

LPV/r Lopinavir/Ritonavir, *ATV/r* Atazanavir/Ritonavir, *DTG* dolutegravir, *EFV* Efavirenz

a slightly lower median total number of daily doses compared to those who were continuing follow-up or discontinued, 186 doses (IQR: 128—288) vs. 210. doses (IQR: 164—262), respectively, p-value = 0.467. Results showed almost similar median adherence percentage among those who had viral suppression compared to those who were continuing follow-up or discontinued, 74% (IQR: 60%—84%) vs. 81% (IQR: 55%—86%), respectively, p-value = 0.241 as shown in Table 3.

Factors associated with viral suppression

The univariable analysis results indicated significant associations of time to viral suppression with ARV once or twice daily dosage, regimen line, and regimen classification as shown in Table 4. On multivariable analysis, there was an over two-fold significantly higher likelihood of viral suppression for those who were on once-daily compared to twice-daily ARV dosage, aHR = 2.51 (95% CI: 2.06–3.05), as shown in Table 4

Table 2 VDOT adherence percentage by age, sex, and regimen, Kenya, Feb 2021—Oct 2022

Variable	*n* (%)	DOTs adherence (Percent), median (IQR)	*P* value
Overall	223 (100)	76 (60—85)	-
Age Category at enrollment (years)			0.942
0–4	23 (10.3)	79 (41—85)	
5–9	37 (16.6)	79 (63—86)	
10–14	84 (37.7)	75 (56—88)	
15–19	79 (35.4)	75 (62—85)	
Sex			0.364
Girls	95 (42.6)	78 (61—87)	
Boys	128 (57.4)	74 (56—84)	
Regimen Classification			0.207
LPV/r Based	91 (40.8)	74 (46—86)	
ATV/r Based	26 (11.7)	74 (30—85)	
DTG Based	100 (44.8)	76 (65—86)	
EFV Based	5 (2.2)	72 (16—78)	
Other	1 (0.4)	31 (31—31)	
Regimen line			0.141
First-line	94 (42.2)	77 (66—86)	
Second-line	128 (57.4)	74 (48—85)	
Third-line	1 (0.4)	31 (31—31)	
Core ART regimen			0.102
ABC Based	62 (27.8)	71 (39—83)	
AZT Based	110 (49.3)	76 (53—85)	
TDF Based	51 (22.9)	78 (67—87)	

IQR Interquartile range, *ABC* Abacavir, *AZT* Zidovudine, and *TDF* Tenofovir, *LPV/r* Lopinavir/Ritonavir, *ATV/r* Atazanavir/Ritonavir, *DTG* Dolutegravir, *EFV* Efavirenz

and model estimated probabilities of VS over time in Fig. 2(a). Children and adolescents on second- or third-line regimens had a three-fold higher likelihood of viral suppression compared to those on first-line regimens, aHR = 3.05 (95% CI: 1.78–5.22), as shown in Table 4 and corresponding model estimated probabilities over time in Fig. 2(b). Similarly, children and adolescents on DTG-based regimens had close to two-fold higher likelihood of viral suppression compared to those on LPV/r-based, ATV/s-based, or EFV-based regimens, aHR = 1.95 (95% CI: 1.25–3.06), as shown in Table 4 and respective model estimated probabilities over time in Fig. 2(c). Overall, the caregiver variable was associated with viral suppression based on a global (Wald) hypothesis test (*P* value = 0.003). Specifically, those with guardians and siblings as caregivers had a higher likelihood of viral suppression compared to parents, 1.61 (95% CI: 1.27—2.03), and 2.00 (95% CI: 1.12–3.57), respectively.

Discussion

Implementation of VDOT supported the achievement of HIV viral load suppression for nearly 80 percent of enrolled children and adolescents in the follow-up period. This is particularly important since evidence suggests that children and adolescents lag behind adults in the achievement of HIV viral suppression after ART and are more vulnerable to developing drug resistance [44, 45]. To our knowledge, this study is the first to explore the feasibility of VDOT among virally unsuppressed children and adolescents living with HIV receiving antiretroviral treatment in a resource limited setting.

Our study included CALHIV aged between 0 and 19 years, a cohort that was comparable to the digital asthma study in West Baltimore that included children 2–18 years. Although the asthma study provided rewards for video upload, retention at 11–21 weeks was lower compared to our study's 21-week retention at 100% among those with at least 12 weeks of follow up [23]. The median follow-up time was just over 19 weeks, with at least 12 weeks of VDOT use for half the clients, and a median of 126 videos uploaded. This duration on the VDOT application contrasts with other studies. For example, a study in the United States and Mexico reported the mean duration of VDOT use at 22 weeks while another U.S. study reported a median time of 27 weeks [12, 46]. It is however notable that these studies involved TB patients on DOT follow-up for the duration of treatment. In our study, clients could exit the VDOT intervention upon achieving viral suppression, which could explain the shorter duration on the intervention.

The use of VDOT has been associated with high levels of adherence. A recent study in Uganda reported high adherence and satisfaction levels among adult clients on TB treatment using a VDOT application [13]. This finding has similarly been demonstrated in a study among adults in the United States and Mexico with adherence rates above 93% and 92% preference for VDOT over in-person TB DOT [12]. This contrasts with the lower VDOT adherence in our study at 76%. A synchronous VDOT study in Nassau County Department of Health, Mineola, New York reported similar adherence rates of 79% which compared with a Uganda study at 82.2% [13, 47]. While these studies provide comparisons of VDOT use for TB treatment, lower adherence rates have been reported among children using VDOT to observe inhaled corticosteroid use for asthma control, ranging from 50 to 64% [23].

Adherence levels measured from VDOT were likely affected by missed video uploads as has been observed in other studies [8]. A recent study in Uganda discussed common reasons for missed video uploads including malfunctions of phones and the VDOT application as

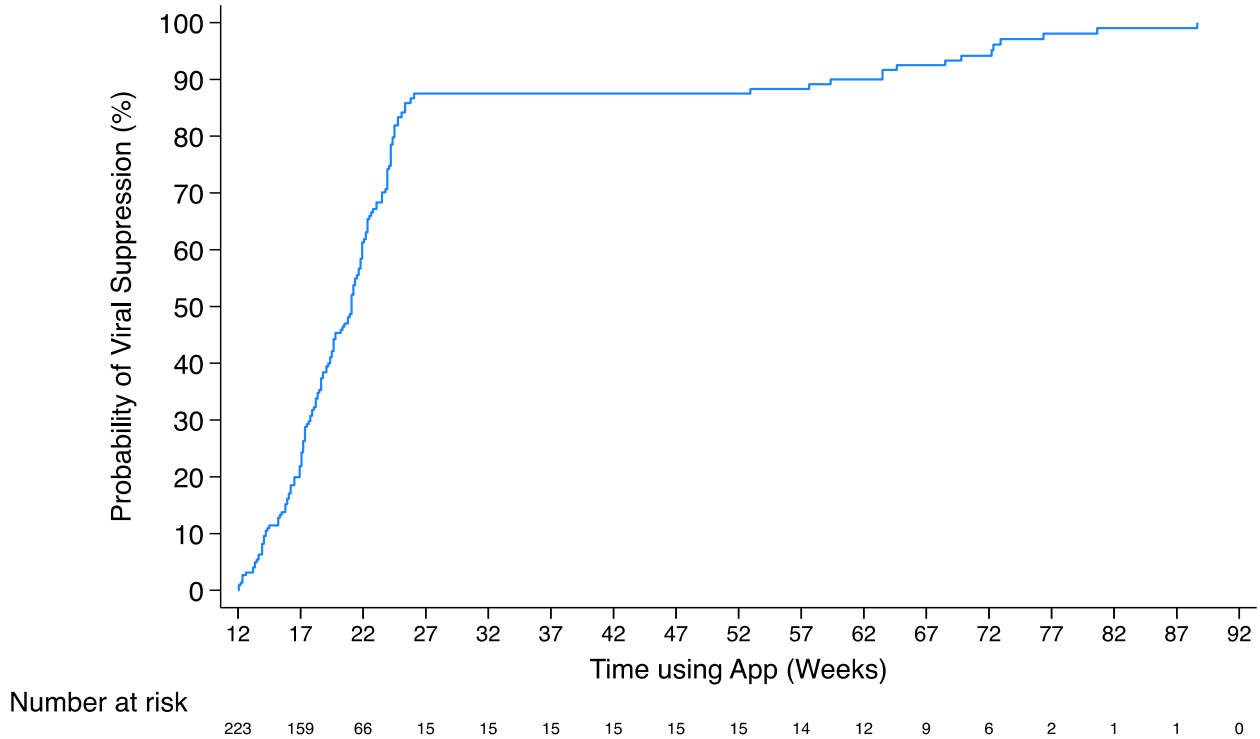

Fig. 1 Overall probability of viral suppression after at least 12 weeks of using the NimeCONFIRM application, Kenya, Feb 2021—Oct 2022

Table 3 VDOTS suppression outcome among children and adolescents living with HIV infection with at least 12 weeks of follow-up, Kenya, Feb 2021—Oct 2022

Suppression outcome ($n = 223$)	Continuing follow-up	Suppressed	Total	*P* value
n (%)	47 (21.1)	176 (78.9)	223 (100.0)	
vDOTS Information				
Time using Application (Weeks), median (IQR)	19 (16—21.93)	20 (17—23)	19 (17—23)	0.260
Total number of expected daily doses per user, median (IQR)	210 (164—262)	186 (128—288)	188 (134—280)	0.467
Total number of videos uploaded per user, median (IQR)	147 (91—201)	124 (96—194)	126 (96—197)	0.419
vDOTs adherence (Percent), median (IQR)	81 (55—86)	74 (60—84)	76 (60—85)	0.241

IQR Interquartile range

well as uncharged batteries [13]. Other barriers reported in the literature included desire for face-to-face interaction, lack of familiarity with the use of videos, illiteracy, privacy and confidentiality concerns, adverse effects, and demographic profile differences with the use of technology [18, 48, 49].

In this study, the likelihood of achieving viral suppression was higher among those on the self-care VDOT option compared to the HCW-led option. Further, a higher likelihood of viral suppression was also demonstrated among those with guardians and siblings as caregivers compared to parents. This is similar to studies that indicated that older adults are more likely to find the use of VDOT more challenging compared to younger and more educated adults, which could have affected uptake of the self-care VDOT option alongside access to smartphones [48, 49].

The study results showed over threefold higher likelihood of viral suppression among children and adolescents on second- and third-line regimens compared to those on first-line regimens. Poor adherence to treatment has been documented as a major reason for second-line failure, suggesting utility of the VDOT intervention in this population [50]. Our study also found over twofold higher odds of viral suppression among those on a once daily dosage regimens and close to twofold higher odds for clients on DTG based regimens. This is similar to other studies that have demonstrated higher rates of viral

Table 4 Cox proportional hazards model for viral suppression among children and adolescents living with HIV infection during the follow-up period while using the NIMECONFIRM application with at least 12 weeks of follow-up, Kenya, Feb 2021—Oct 2022

Outcome: viral suppression	Hazard ratio HR (95% CI)	*P* value	Adjusted hazard ratio aHR (95% CI)	*P* value
Sex				
Boys	Reference		Reference	
Girls	0.83 (0.57–1.20)	0.320	0.69 (0.45–1.06)	0.093
Age Category at enrollment (years)				
0–4	0.88 (0.48—1.62)	0.680	1.35 (0.72—2.55)	0.351
5–9	0.94 (0.86—1.03)	0.210	1.16 (0.90—1.48)	0.256
10–14	0.88 (0.80—0.97)	0.008	1.00 (0.86—1.16)	0.967
15–19	Reference		Reference	
Caregiver[a]				
Parent	Reference		Reference	
Grand parents	1.24 (0.94–1.65)	0.128	1.12 (0.91–1.38)	0.298
Guardian	1.38 (0.91–2.10)	0.126	1.61 (1.27–2.03)	< 0.001
Relative	0.99 (0.33–2.94)	0.983	0.89 (0.24–3.33)	0.864
Siblings	1.52 (1.24–1.87)	< 0.001	2.00 (1.12–3.57)	0.019
Dosage Frequency				
Twice Daily	Reference		Reference	
Once Daily	1.37 (1.26—1.49)	< 0.001	2.51 (2.06—3.05)	< 0.001
Regimen Line				
First line	Reference		Reference	
Second or Third line[b]	0.90 (0.82—0.98)	0.016	3.05 (1.78—5.22)	< 0.001
Regimen Classification				
LPV/r, ATV/s, or EFV based	Reference		Reference	
DTG based	1.27 (1.20—1.35)	< 0.001	1.95 (1.25—3.06)	0.003
Care Type				
Healthcare Worker Led	Reference		Reference	
Self-Care	1.39 (0.55—3.48)	0.483	1.37 (0.67—2.80)	0.387

ABC Abacavir, *AZT* Zidovudine, and *TDF* Tenofovir

LPV/r Lopinavir/Ritonavir, *ATV/r* Atazanavir/Ritonavir, *DTG* Dolutegravir, *EFV* Efavirenz

[a] Global (Wald) hypothesis test for caregiver (*P* value = 0.003)

[b] There was only 1 patient on the third line

suppression among children and adolescents receiving optimized DTG-based ART [51–53].

This study had some limitations. First VDOT adherence only measured whether the video captured the client taking the medication and not reported ART adherence. This may underestimate the actual ART adherence in cases where medication was taken but a video was not uploaded on the application. Given this resource-limited setting, it is likely that there were challenges in regular access to VDOT by healthcare workers and to mobile devices for most participants, or the internet for video uploads especially for those on self-care (using their own devices). We acknowledge that there were unobserved factors that may affect viral suppression outcomes. The second limitation was the relatively high proportion of clients who were discontinued due to various reasons and incomplete follow-up for some clients who were also not included in the study. Even though the study had a large sample, these reasons may over or underestimate the observed adherence and viral suppression outcomes. Finally, we acknowledge that this was a feasibility study without a control group to demonstrate improved efficacy of VDOT over standard of care.

Conclusion

The use of VDOT supported the achievement of VS among unsuppressed children and adolescents living with HIV on antiretroviral treatment. Achieving VS using VDOT was associated with the type of caregiver,

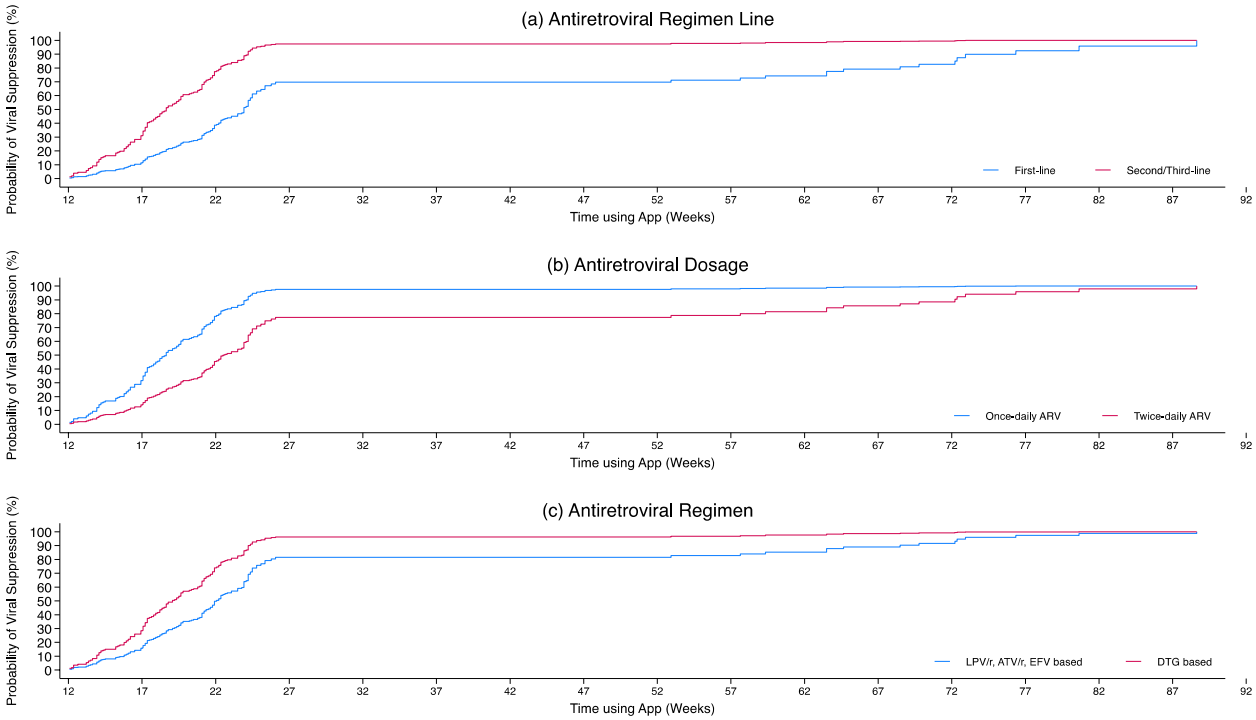

Fig. 2 Viral Suppression by antiretroviral regimen line, dosage, and regimen after at least 12 weeks of using the NimeCONFIRM application, Kenya, Feb 2021—Oct 2022. Legend: LPV/r – Lopinavir/Ritonavir, ATV/r – Atazanavir/Ritonavir, EFV – Efavirenz, and DTG – Dolutegravir

treatment regimen, dosing frequency, and self-care VDOT. Our findings highlight the beneficial impact of VDOT as an additional tool to ensure that HIV unsuppressed children and adolescents benefit from their access to life-saving care and treatment, especially in resource-limited settings.

Abbreviations

AIDS	Acquired immunodeficiency syndrome
aHR	Adjusted Hazard Ratio
AMREF	African Medical and Research Foundation
ABC	Abacavir
ART	Antiretroviral therapy
ATV/r	Atazanavir/Ritonavir
AZT	Zidovudine
DTG	Dolutegravir
GDPR	General Data Protection Regulation
DOT	Directly observed therapy
DGHT	Division of Global HIV&TB
EFV	Efavirenz
EMR	Electronic medical records
CALHIV	Children and adolescents living with HIV
CDC	Centers for Disease Control
CHS	Center for Health Solution - Kenya
CoAg	Co-agreement
CI	Confidence intervals
HCW	Health care worker
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
IQR	Interquartile range
LFTU	Loss to follow-up
LPV/r	Lopinavir/Ritonavir
PEPFAR	President's Emergency Plan for AIDS (PEPFAR)
RNA-PCR	Ribonucleic acid polymerase chain reaction
TDF	Tenofovir
TB	Tuberculosis
US	United States
VDOT	Video directly observed therapy
VS	Viral Suppression

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Authors' contributions
WP led the design, data collection, and interpretation, and wrote substantial portions and paper review. KO performed data analysis, interpretation, and results writeup, and paper review. IM guided the design, gave input on the analysis, and did paper reviews. MN, BM, MB, EN, KK, and AK assisted with the design, data collection, and paper review. All authors read and approved the final paper.

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Data availability
Data used for this analysis is a deidentified dataset of individual-level data and is not currently publicly available. However, the dataset can be obtained from the corresponding author based on a reasonable request.

Declarations

Ethics approval and consent to participate
The AMREF Ethics and Scientific Review Committee, Nairobi, Kenya, approved the protocol to conduct this analysis (protocol number: P412/2017). As this study used retrospective data, the AMREF Ethics and Scientific Review Committee, Nairobi, Kenya, waived the need for consent or assent from study participants. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[§] ([§]See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq). The investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes or analysis. The study procedures were done in accordance with the ethical principles outlined in the World Medical Association's Declaration of Helsinki, Kenya Government, Ministry of Health, CDC, and local IRB regulations.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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