

Long-term treatment outcomes from a large-scale programmatic implementation of dolutegravir-based antiretroviral therapy among people with HIV: an observational cohort study from India

Reshu Agarwal^{1,*}, Melissa Nyendak¹, Nalini Chava², Ramesh R. Allam¹, Prabhu Turaka², Ramesam Ganti², Ajit R. Polsani², Praveen K. Ragi², JayaKrishna Kurada², Vijay V. Yeldandi², Rajendra P. Prasad², Sreeramu S. Chakravarthy³, Manjula Thogarucheti³, K Neelakanta Reddy³

¹Division of Global HIV and TB, U.S. Centers for Disease Control and Prevention (CDC), New Delhi, 110021, India

²Society for Health Allied Research & Education India, Hyderabad, 501401, India

³Andhra Pradesh State AIDS Control Society, Vijayawada, 520001, India

*Corresponding author: Division of Global HIV and TB (India Office), U.S. Centers for Disease Control and Prevention, American Embassy, Shantipath, Chanakyapuri, New Delhi, 110021, India. Email: dr.reshu.agarwal@gmail.com.

Editor: Dan-Sebastian Dirzu

Abstract

Background and aims Dolutegravir (DTG)-based regimens are the most commonly used antiretroviral therapy (ART) for people with HIV (PWH). However, there are limited real-world data on long-term outcomes.

Methods We followed a cohort of 115 520 treatment-naïve and treatment-experienced PWH initiated or transitioned to DTG-based ART in Andhra Pradesh, India, and assessed retention and viral suppression. We performed Cox proportional hazards regression and multivariable logistic regression to determine factors associated with deaths and viral non-suppression.

Results At 48 months, 91.9% PWH were retained in care (92.9% among treatment-experienced and 75.7% among treatment-naïve), 1.8% were lost to follow-up, and 6.3% died. Of the 110 287 PWH with a documented viral load (VL) test, 97.1% were virally suppressed, including 10 698 of 11 956 (89.5%) PWH who achieved viral suppression with enhanced adherence counseling after initial viral non-suppression on DTG. For treatment-experienced PWH, viral suppression was 87.8% among those with viral non-suppression at transition, and 93.2% among those without a VL test at transition, and highest when tenofovir/lamivudine was recycled with DTG.

Factors associated with increased risk of death and viral non-suppression included being male, treatment-naïve, CD4 count < 200 cells/mm³ at transition, and current or past tuberculosis (TB). Additionally, age ≥ 50, receiving an abacavir/protease-inhibitor containing regimen, and viral non-suppression were associated with a higher risk of death. Similarly, key populations, adolescents, young adults (20–29 years), receiving a zidovudine-containing regimen, not receiving multi-month dispensation, and being lost to follow-up (specifically > 3 times during the last 12 months) were significantly associated with higher odds of viral non-suppression.

Conclusion DTG was associated with high treatment retention and viral suppression, including treatment-experienced PWH with recycled tenofovir/lamivudine. Tailored differentiated services could further optimize DTG impact on viral suppression and mortality, particularly among PWH with advanced HIV disease, TB-coinfection, age > 50 years, or adolescents.

Keywords dolutegravir, mortality, viral load suppression, HIV, antiretroviral treatment

Received: January 13, 2026. Revised: May 8, 2026. Accepted: May 25, 2026

© The Author(s) 2026. Published by Oxford University Press.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact reprints@oup.com for reprints and translation rights for reprints. All other permissions can be obtained through our RightsLink service via the Permissions link on the article page on our site—for further information please contact permissions@oup.com.

What this study adds

Dolutegravir (DTG)-based regimens are a cornerstone of HIV treatment, recognized for their high resistance barrier, excellent tolerability, and durable viral suppression. Although DTG has been widely adopted, a critical gap remains in the evidence on long-term treatment outcomes from real-world programmatic settings. Addressing this crucial gap, our study provides large-scale, real-world programmatic evidence on the long-term effectiveness of dolutegravir (DTG)-based antiretroviral therapy (ART), particularly in a high-burden context like India. Following a large cohort of 115 520 people with HIV (PWH), this study provides robust, long-term data on “retention and virological outcomes” for both treatment-experienced and treatment-naïve PWH. In our programmatic cohort, implementation of DTG, alongside the programmatic interventions, was associated with improved treatment outcomes, yielding a 91.9% retention rate and a 97.1% viral suppression rate at 48 months. Leveraging a “four-year follow-up period,” these findings add critical information on the durability of DTG-based regimens, specifically showing that viral suppression remains robust even when tenofovir/lamivudine is recycled in treatment-experienced individuals in combination with DTG. Furthermore, this study highlights the “factors associated with mortality and viral non-suppression,” offering a nuanced understanding of risks for negative outcomes, even in the context of highly robust and tolerable DTG-based ART. Crucially, this study highlights actionable factors that require urgent intervention, including person-centered strategies targeting adolescents, treatment-naïve individuals, and those with TB coinfection or advanced HIV disease. Finally, the study underscores the clinical value of “enhanced adherence counseling” (EAC). In this regard, we report that 89.5% of PWH with initial viral non-suppression achieved viral re-suppression after completing EAC, thereby preventing premature and costly regimen switches.

Background

Effective antiretroviral therapy (ART) with expanded access reduces morbidity and mortality among PWH and prevents transmission through suppression of viral load (VL) [1–3]. In this regard, dolutegravir (DTG) has a high resistance barrier, is well tolerated, and is associated with nearly universal improvement in viral suppression at the population level [4–6]. India’s National AIDS Control Programme (NACP), with an estimated 2.56 million PWH and 1.75 million PWH receiving ART [7], adopted DTG-based regimens as the preferred ART regimens in 2020, to accelerate progress toward the Sustainable Development Goal of “Ending the AIDS epidemic.”

DTG-based regimens are the most commonly used ART for >85% of PWH in more than 110 low- and middle-income countries [8]. Recent programmatic evidence from large-scale analyses in low- and middle-income countries demonstrates consistently high levels of viral suppression with DTG-based ART, exceeding 95% at 12 months and approaching 98% at 24 months [9, 10]. Cohort studies from diverse settings, including Haiti, Uganda, and Tanzania, further confirm these findings, while also highlighting relatively lower suppression among individuals with pre-existing virological failure and emphasizing the central role of adherence and treatment history in determining outcomes [11, 12]. Additionally, the large-scale implementation of DTG has involved transitions from non-nucleoside reverse transcriptase inhibitor-based regimens, raising important considerations around prior resistance and future regimen durability. Together, these concerns highlight the importance of evolving differentiated service delivery models and adherence support strategies, such as multi-month dispensing that accelerated during the COVID-19 pandemic [13]. Despite the rapid and widespread implementation of DTG-based ART, evidence on long-term treatment outcomes in large-scale programmatic settings remains limited, particularly in high-burden settings like India. This highlights the need to assess and track outcomes among treatment-naïve and treatment-experienced PWH initiated or transitioned to DTG-based ART over time, in the real-world setting. The manuscript describes retention and virological suppression as major treatment outcomes, along with the factors associated with deaths and viral

non-suppression among PWH on DTG-based ART over a 48-month longitudinal follow-up period.

Methods

Study design, setting, and population

We undertook a prospective observational cohort study among all PWH newly initiated on (treatment-naïve) or those transitioned to (treatment-experienced) DTG-based ART during November 2020 to March 2021 (first phase of programmatic implementation of DTG under NACP) at 45 ART centers in Andhra Pradesh—the state having the second-highest HIV burden in India, with an estimated adult HIV prevalence of 0.64% and 227 721 PWH receiving ART [14]. In line with WHO guidelines, NACP adopted DTG-based regimens as the preferred ART regimens (first line, second line, and third line) for ART naïve as well as treatment-experienced PWH, including adults, adolescents, and children (weighing more than 20 kg and age ≥6 years) and started phased implementation in 2020. Viral load testing is recommended at 6 months, 12 months post-ART initiation, and then annually for all PWH on ART within the NACP.

Data sources and variables

Routine program data were extracted from the NACP electronic database, which captures demographic, clinical, and laboratory information for treatment monitoring. We used key variables such as age, sex, CD4 counts, VL, TB status, ART regimen, and dates (ART initiation, last pill pick-up, and/or death). The NACP electronic database employs built-in validation checks to ensure data range, format, completeness, and consistency. For this study, data cleaning included rigorous assessment for completeness, range, duplicate records and chronological consistency of dates. Logical consistency checks were performed across related variables (eg, treatment status, follow-up status, and outcomes) to ensure internal validity. Incomplete or inconsistent data entries were resolved through standard data verification procedures before analysis. Additionally, as part

of the NACP's routine quality assurance, random cross-verification of electronic data against source records was performed during the periodic supervisory visits. We analyzed de-identified data using Microsoft Excel—MSO16.0.14326.20936, and IBM SPSS 29.0.

Outcomes

We followed all PWH for 48 months to assess treatment outcomes, such as retention and viral suppression. The primary endpoints were “being alive on ART,” “death during follow-up,” or lost to follow-up (LTFU). Follow-up time was defined from the date of ART initiation or transition to DTG-based therapy until death or the last recorded visit for loss to follow-up, or administrative censoring at 48 months. We defined retention as “being alive and on ART” at 12, 24, 36, and 48 months. Lost to follow-up (missed pill pick-up for >28 days), and those who died during the follow-up were not considered as “retained” in care. We defined viral suppression as VL<1000 copies/ml and viral non-suppression as VL≥1000 copies/ml. For those retained on ART, we considered the HIV-1 RNA test done at the end of follow-up (±12 months), and for those who died or LTFU, the last documented VL test before the reported outcome was included. PWH with VL≥1000 copies/ml were offered enhanced adherence counseling (EAC) for at least 3 months, followed by a repeat VL test. We considered the repeat VL test result for such PWH, where available.

Data analysis

We calculated frequencies and percentages to describe baseline characteristics, retention, and viral suppression. We used Kaplan-Meier survival curves to graph overall survival time and to estimate the cumulative probability of survival. We applied log-rank tests to compare survival across the selected sub-groups—stratified by treatment history (treatment-experienced and treatment-naïve) and virological status (virally suppressed and virally non-suppressed during follow-up). We performed a Cox proportional hazards regression to assess factors associated with deaths and reported adjusted hazard ratios (aHR). Sensitivity analyses were conducted by treating individuals LTFU as deaths to assess the robustness of the findings. We performed multivariable analysis using binary logistic regression to assess factors associated with viral non-suppression and reported adjusted odds ratios (aOR). Variables for models were selected a priori based on clinical relevance and prior literature, and all key demographic and clinical variables were included in the final multivariable models. To account for the multi-site design, cluster-robust standard errors were used at the ART center level. For treatment-experienced PWH, we also calculated the risk difference (RD) in percentage points for viral suppression by regimen. All statistical tests were two-sided, and a *P*-value < .05 was considered statistically significant. All analyses reported 95% confidence intervals (CI).

Handling missing data

For missing baseline and follow-up CD4 counts and VL results, we included explicit “CD4 not done” and “VL not done” categories in the multivariable models. This approach allowed for the inclusion of the full cohort in the analysis and minimized potential bias associated with complete-case exclusion. There were no missing data for other key variables included in the analysis.

This analysis conforms to the STROBE guidelines for reporting observational cohort studies. The NACP considered this work a routine programmatic activity, in accordance with the national guidelines, and involving only a secondary analysis of existing program data. This analysis was reviewed and approved by the Science Integrity Branch of the Centers for Disease Control (CDC) and Prevention and was conducted in a manner consistent with the human subjects' research protections applicable under US federal law and CDC policy.

Results

Baseline characteristics

Of the total 115 520 PWH, 57.1% were females, 0.9% belonged to key population groups, 94.4% were treatment-experienced, and 95% were receiving first-line ART. The median age was 44 years (IQR: 37–51), with 1% adolescents (ages 10–19 years). Almost an equal proportion of PWH were accessing ART from a tertiary (51.7%) versus a secondary/primary (48.3%) care facility. Among treatment-naïve PWH (*n*=6455), 13% had a CD4 count <200 cells/mm³ and 12.3% had tuberculosis (TB) disease. Among treatment-experienced PWH (*n*=109 065), 82% had viral suppression at DTG transition. Overall, 97.7% received fixed-dose tenofovir+lamivudine+dolutegravir (TLD) on transition (Table 1).

Treatment outcomes

Retention

Of the total 115 520 PWH, 91.9% were retained in care, 6.3% had died, and 1.8% were LTFU at the end of the 48 months (Fig. 1).

Annual trends

Retention was 96.4% at 12 months, 94.7% at 24 months, 93.2% at 36 months, and 91.9% at 48 months. Among treatment-experienced PWH, retention gradually decreased from 97.3% at 12 months to 92.9% at 48 months. Similarly, among treatment-naïve PWH, retention reduced from 82.6% at 12 months to 75.7% at 48 months (Fig. 2). The overall LTFU remained largely unchanged over the years—0.8% at 12 months and 1.8% at 48 months.

Retention in care declined over 48 months, with the largest drop seen during the initial 12 months. The annual death rate was also the highest (2.8%) during the first year and stabilized to 0.9% by year 4 (Fig. 3). Among treatment-naïve PWH, nearly three-quarters of deaths (71% of 1183) and LTFU (75% of 388) were reported within the first 12 months.

Survival probability

The 115 520 PLHIV contributed 430 788 person-years (PY) of follow-up with an all-cause mortality of 1.68 per 100 PY (95% CI 1.65–1.72). The mean survival time was 46.1 months (95% CI 46.1–46.2), and cumulative survival probability at 6, 12, 24, 36, and 48 months was 98.2%, 97.4%, 96.0%, 94.7%, and 93.6%, respectively (Fig. 4). Treatment-naïve PWH had a low survival probability of 88.9% at 6 months and 81.1% at 48 months, whereas treatment-experienced PWH had a survival probability of 98.6% at 6 months and 94.3% at 48 months (Fig. 5). Mean survival also differed significantly by VL status during

Table 1 Clinical and demographic characteristics of people with HIV (PWH) initiated on/transitioned to DTG-based ART from November 2020 to March 2021 in Andhra Pradesh, India.

Characteristics		Treatment experienced <i>n</i> = 109 065	%	Treatment naïve <i>n</i> = 6455	%	Total <i>N</i> = 115 520	%
Age (years)	6–10	15	0.0	3	0.1	18	0.0
	11–19	1102	1.0	99	1.5	1201	1.0
	20–29	7315	6.7	1042	16.1	8357	7.2
	30–39	26 903	24.7	1838	28.5	28 741	24.9
	40–49	41 508	38.1	2143	33.2	43 651	37.9
	≥50	32 222	29.5	1330	20.6	33 552	29.0
Sex	Female	62 811	57.6	3100	48.0	65 911	57.1
	Male	46 254	42.4	3355	52.0	49 609	42.9
Population type	General population	108 118	99.1	6408	99.3	114 526	99.1
	Key populations	947	0.9	47	0.7	994	0.9
Type of facility	Tertiary care	56 383	51.7	3343	51.8	59 726	51.7
	Primary and secondary care	52 682	48.3	3112	48.2	55 794	48.3
Line of treatment at initiation/transition	First line	103 357	94.8	6455	100	109 812	95.1
	Second and third line	5708	5.2	0	0.0	5708	4.9
DTG-based regimen initiated/transitioned to	TLD	106 398	97.6	6410	99.3	112 808	97.7
	ZLD	923	0.8	6	0.1	929	0.8
	ALD	146	0.1	29	0.4	175	0.2
	DTG+PI	1598	1.5	10	0.2	1608	1.4
CD4 (cells/cumm) at DTG transition or initiation	<100	815	0.7	312	4.8	1127	1.0
	100–200	2676	2.5	529	8.2	3205	2.8
	200–350	8858	8.1	1127	17.5	9985	8.6
	≥350	65 651	60.2	2771	42.9	68 422	59.2
	not done	31 065	28.5	1716	26.6	32 781	28.4
Viral load (copies/ml) at DTG transition	<1000	89 478	82.0	Not applicable	—	89 478	77.5
	≥1000	9197	8.4	Not applicable	—	9197	8.0
	Not eligible	Not applicable	—	6455	100.0	6455	5.6
	VL not done	10 390	9.5	Not applicable	—	10 390	9.0
TB status at DTG transition/initiation	No history of TB (past or current)	102 467	94.0	5459	84.6	107 926	93.4
	Current TB	1199	1.1	796	12.3	1995	1.7
	TB in past	5399	5.0	200	3.1	5599	4.8

TLD: tenofovir+lamivudine+dolutegravir; ZLD: zidovudine+lamivudine+dolutegravir; ALD: abacavir+lamivudine+dolutegravir; PI: lopinavir/ritonavir; atazanavir/ritonavir; darunavir/ritonavir.

follow-up—47.3 months among those with viral suppression (95% CI 47.27–47.32); 44.5 months among those with VL ≥ 1000 copies/ml (95% CI 44.2–44.9); and 19.5 months among those without a documented VL test (95% CI 18.9–20.0). At 48 months, survival probability was 96.7% (95% CI 96.6–96.8) among those with viral suppression; 85.4% (95% CI 84.2–86.7) among those with viral non-suppression; and 22.3% (95% CI 20.8–23.8) among those without a VL test (Fig. 6).

Factors associated with death during 48-month follow-up

On multivariable Cox proportional hazards analysis, being treatment-naïve (aHR: 1.45; CI 1.32–1.60), age ≥ 50 years (aHR: 1.66; CI 1.56–1.77), and male sex (aHR: 1.35; CI 1.28–1.41) were significantly associated with an increased hazard of death. Lower CD4 counts, specifically CD4 count < 100 cells/mm³ (aHR: 2.76; CI 2.30–3.31); CD4 count 100–200 cells/mm³ (aHR: 1.83; CI 1.63–2.05); CD4 count 201–350 cells/mm³ (aHR: 1.40; CI 1.29–1.52) were significantly associated with higher risk of death compared to CD4 count ≥ 350 cells/mm³. People with HIV with current TB (aHR-1.53,

CI 1.37–1.72) and TB in the past (aHR-1.32, CI 1.10–1.58) had an increased risk of death compared to PWH without a history of TB. PWH on abacavir+lamivudine+dolutegravir (ALD) (aHR: 2.57; CI 1.97–3.34) had a significantly higher risk of death compared to TLD. PWH without a VL test (aHR: 49.73; CI 41.78–59.18) and those virally non-suppressed (aHR: 4.45; CI 3.85–5.15) during follow-up had a higher risk of death compared to those who were virally suppressed (Table 2). Sensitivity analyses, conducted by classifying individuals LTFU as deaths, showed consistency with the primary analysis, indicating robustness of the findings (Supplementary Table 1, see online supplementary material for a color version of this table).

Viral suppression

Of the total, 110 287 PWH had a documented VL test, 97.1% (95.1% among the treatment-naïve group [*n* = 5134] and 97.2% among the treatment-experienced group [*n* = 105 153]) were virally suppressed at 48 months. In sub-group analysis, we observed that VL suppression varied among PWH who were

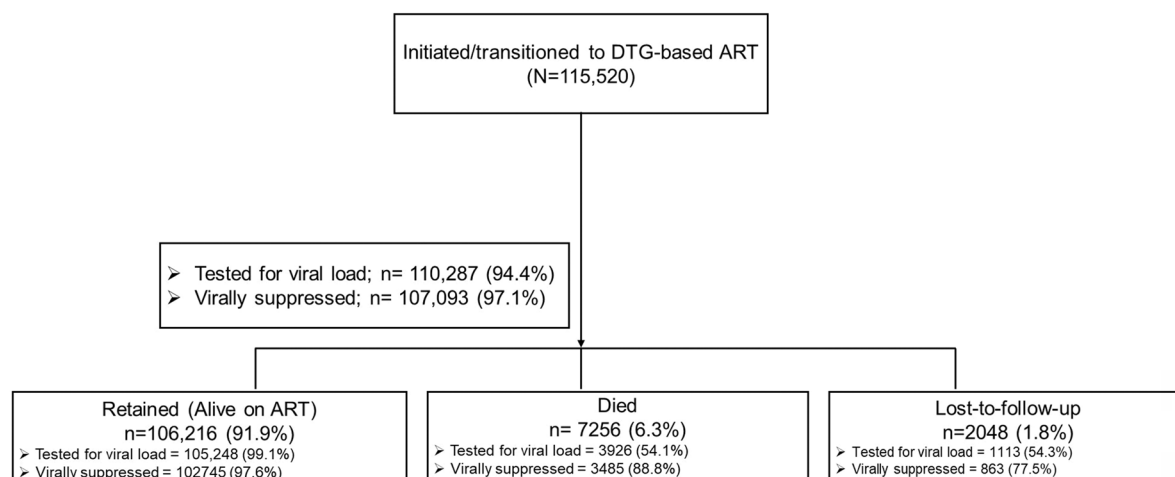


Figure 1 Treatment outcomes of people with HIV (PWH) initiated/transitioned to DTG-based ART from November 2020 to March 2021 during a 48-month follow-up.

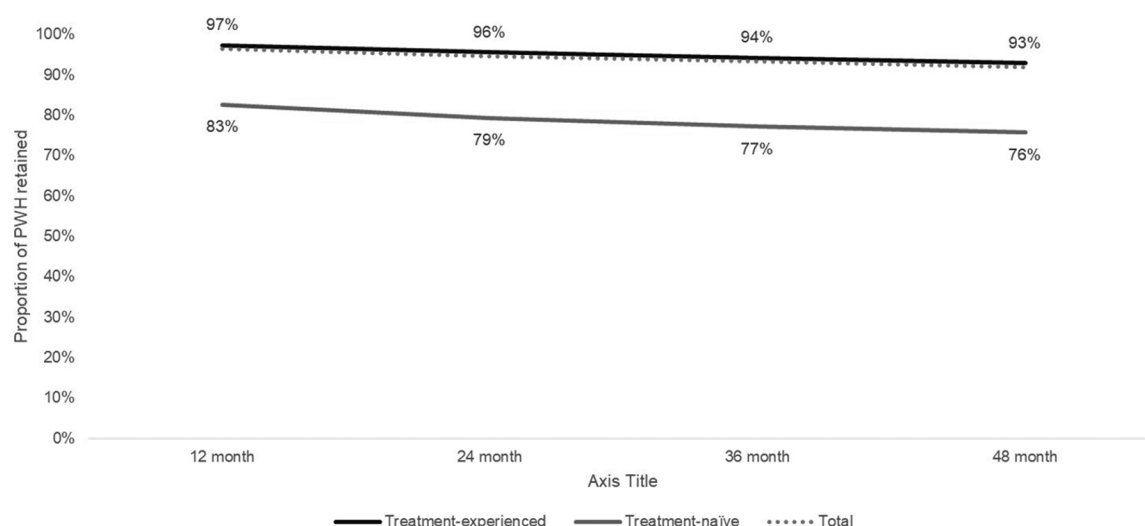


Figure 2 Retention among people with HIV (PWH) initiated on/transitioned to DTG-based ART from November 2020 to March 2021 at 12, 24, 36, and 48 months.

retained/alive and on ART (97.6%), died (88.8%) and LTFU (77.5%) (Fig. 1).

Viral suppression by regimen among treatment-experienced PWH during 48-month follow-up

Among the treatment-experienced PWH who were virally suppressed at transition, 98.4% remained suppressed at 48 months. Among PWH who were virally non-suppressed at transition, 87.8% achieved viral suppression during 48 months follow-up—the highest proportions of viral suppression were with TLD (89.2%), followed by DTG+PI (87.0%; RD -2.2%, CI -4.1 to -0.2) and ZLD (75.2%; RD -14.0%, 95% CI -17.4 to -10.5). Similarly, among PWH who underwent transition to a DTG-based regimen without a VL test, 93.2% were virally suppressed at 48 months; the highest proportions of viral suppression were with TLD (93.3%), followed by ALD (92.9%; RD -0.4%, 95% CI -13.9 to 13.1), DTG+PI (90.9%; RD -2.3%, 95% CI -12.2 to -7.5) and ZLD (70.8%; RD -22.4%, 95% CI -40.6 to -4.2; Fig. 7).

Enhanced adherence counseling

Of the 13 892 PWH with viral non-suppression after DTG initiation or transition, 86.1% underwent repeat VL testing after EAC completion, and 89.5% had subsequent VL re-suppression (Fig. 8).

Factors associated with viral non-suppression during 48-month follow-up

On multivariable analysis, male (aOR: 1.12; CI 1.04–1.21) and treatment-naïve (aOR: 1.83; CI 1.58–2.12) PWH and those belonging to key populations (aOR: 1.78; CI 1.29–2.47) had higher odds of viral non-suppression compared to female, treatment-experienced and general population PWH, respectively. Adolescents (aOR: 1.92; CI 1.45–2.53), young PWH aged 20–29 (aOR: 1.59; CI 1.40–1.80) had higher odds of viral non-suppression compared to older PWH. Lower CD4 counts at the time of DTG transition or initiation, specifically CD4 count <100 cells/mm³ (aOR: 1.66; CI 1.27–2.16); CD4 count 100–200 cells/mm³ (aOR: 1.84; CI 1.56–2.16); and CD4 count 201–350 cells/mm³ (aOR: 1.40; CI 1.25–1.55) were associated with

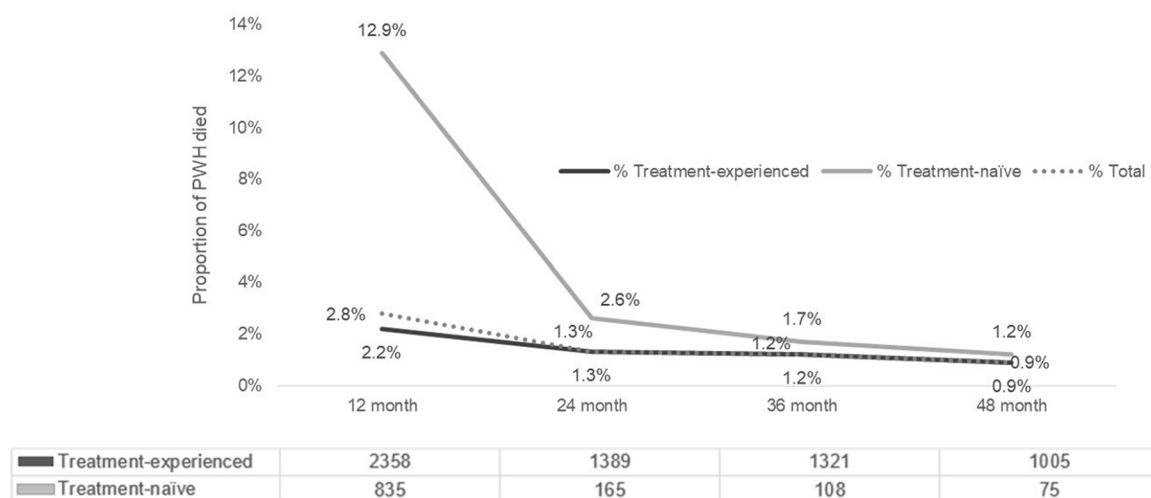


Figure 3 Annual death trends among people with HIV (PWH) initiated on/transitioned to DTG-based ART from November 2020 to March 2021 at 12, 24, 36, and 48 months.

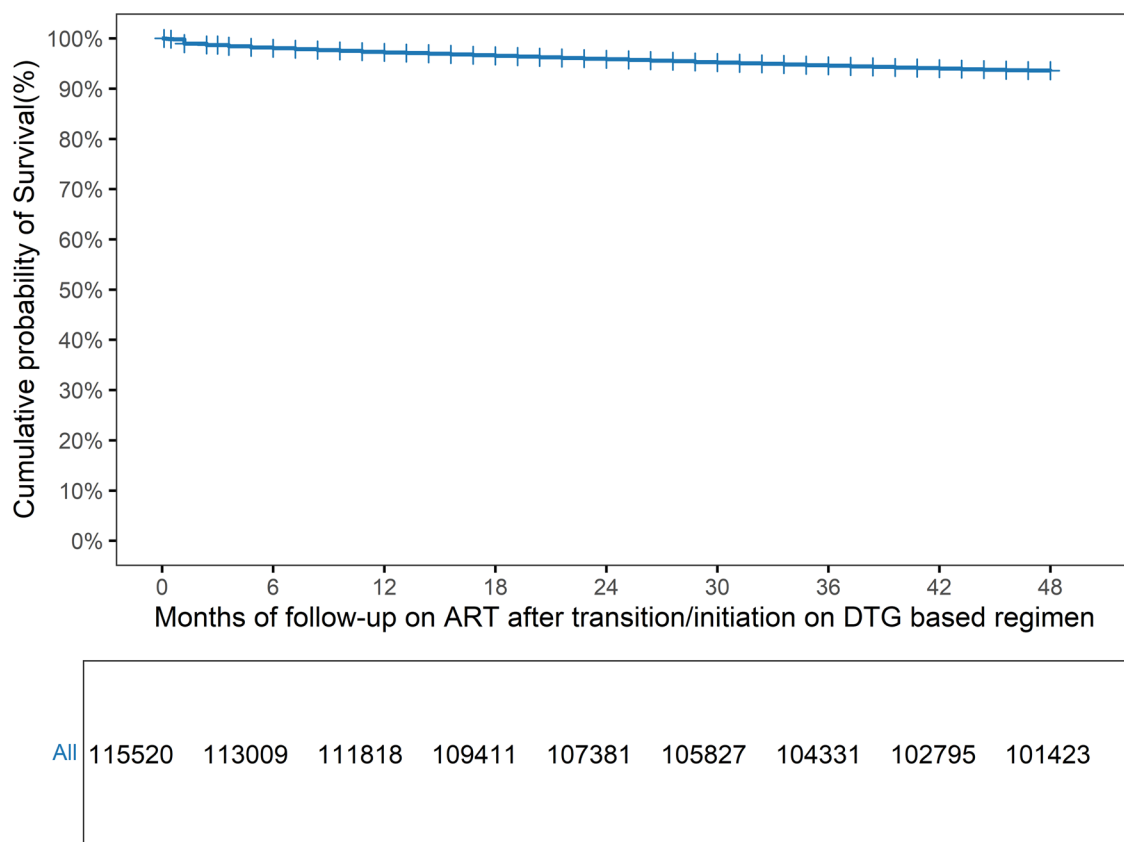


Figure 4 Cumulative probability of survival among people with HIV (PWH) in Andhra Pradesh, India, initiated or transitioned to DTG-based ART during November 2020 to March 2021, across a 48-month follow-up.

higher odds of viral non-suppression compared to CD4 count >350 cells/mm³. People with HIV with current TB (aOR: 1.70; CI 1.46–1.99) and TB in the past (aOR: 1.26; CI 1.09–1.47) had increased odds of death compared to PWH without a history of TB. Viral non-suppression at transition (aOR: 5.40; CI 4.88–5.98) or VL not done at transition (aOR: 2.97; CI 2.68–3.29) were associated with higher odds of viral non-suppression compared to viral suppression at transition.

People with HIV receiving ZLD (aOR: 1.71; 95% CI 1.38–2.11) had higher odds of viral non-suppression compared to those receiving TLD. Being LTFU during the last 12 months (LTFU >3 times, aOR: 36.88, CI 20.34–66.86; and LTFU ≤ 3 times, aOR: 8.58, CI 4.71–15.61) were associated with a significant risk of non-suppression. PWH not on multi-month dispensation (MMD) (aOR: 1.96; CI 1.81–2.13) had higher odds of viral non-suppression compared to those on MMD. Similarly, PWH receiving ART at a primary or secondary care

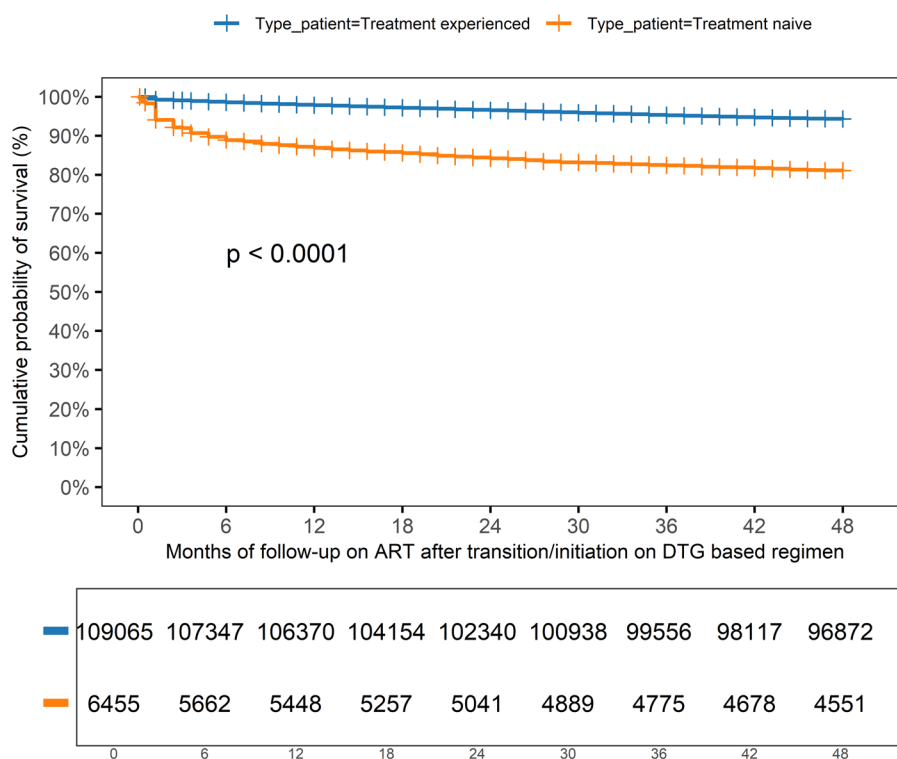


Figure 5 Cumulative probability of survival among people with HIV (PWH) in Andhra Pradesh, India, initiated or transitioned to DTG-based ART during November 2020 to March 2021, across a 48-month follow-up—stratified by treatment-naïve and treatment-experienced status.

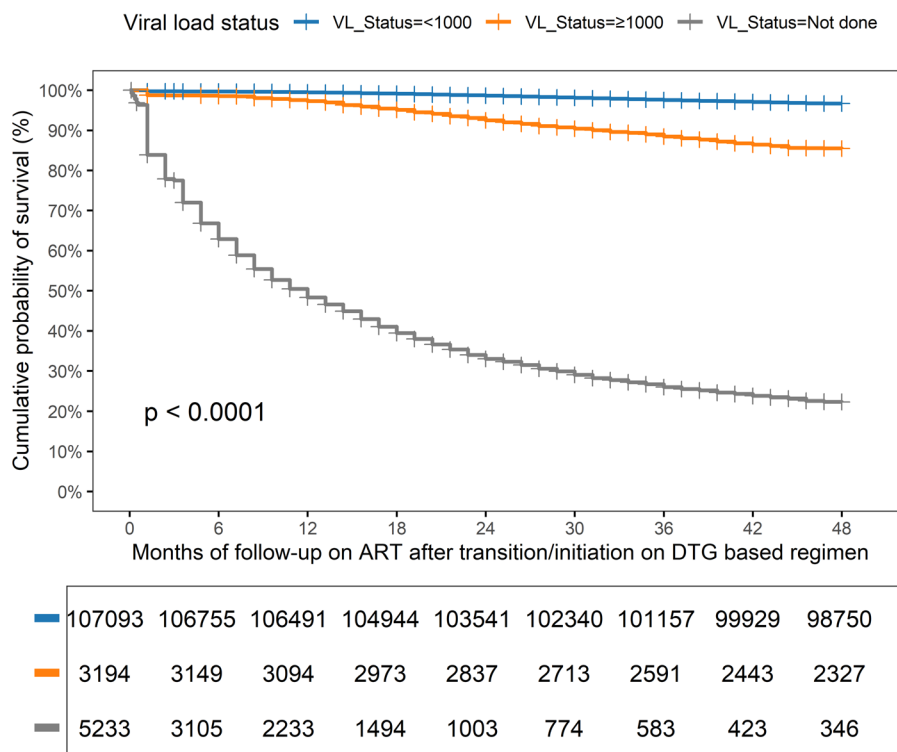


Figure 6 Cumulative probability of survival among treatment-experienced people with HIV (PWH) in Andhra Pradesh, India, transitioned to DTG-based ART during November 2020 to March 2021, across a 48-month follow-up—stratified by viral load status during follow-up.

Table 2 Factors associated with deaths during 48-month follow-up among people with HIV (PWH) initiated on/transitioned to DTG-based ART from November 2020 to March 2021 in Andhra Pradesh, India.

Characteristics	Total		Died		P-value	HR	LL	UL	P-value	aHR	LL	UL
	N	%	N	%								
Age in years	6–10	18	0	1	5.6	1.03	0.14	7.83	.40	0.37	0.04	3.62
	11–19	1201	1	55	4.6	0.85	0.62	1.16	.06	0.75	0.55	1.02
	20–29	8357	7.2	315	3.8	.00	0.63	0.77	.00	0.46	0.40	0.53
	30–39	28 741	24.9	1245	4.3	.00	0.73	0.85	.00	0.70	0.65	0.75
	40–49	43 651	37.8	2393	5.5	Referent	...	...	...	...	...	...
	≥50	33 552	29	3247	9.7	.00	1.68	1.93	.00	1.66	1.56	1.77
Sex	Female	65 911	57.1	2933	4.4	Referent	...	...	...	...	...	...
	Male	49 609	42.9	4323	8.7	.00	1.93	2.10	.00	1.35	1.28	1.41
ART status	Experienced	109 065	94.4	6073	5.6	...	...	...	...	...	...	...
	Naïve	6455	5.6	1183	18.3	.00	3.52	4.09	.00	1.45	1.32	1.60
Viral load(copies/ml) during follow-up	<1000	107 093	92.7	3485	3.3	Referent	...	...	...	...	...	...
	≥1000	3194	2.8	441	13.8	.00	3.95	5.48	.00	4.45	3.85	5.15
	VL not done	5233	4.5	3330	63.6	.00	61.71	73.81	.00	49.73	41.78	59.18
	<100	1127	1	352	31.2	.00	9.90	12.66	.00	2.76	2.30	3.31
CD4 (cells/cumm) at DTG transition or initiation	100–200	3205	2.8	522	16.3	.00	3.66	5.40	.00	1.83	1.63	2.05
	200–350	9985	8.6	861	8.6	.00	1.95	2.50	.00	1.40	1.29	1.52
	≥350	68 422	59.2	2755	4	Referent	...	...	...	...	...	...
	CD4 not done	32 781	28.4	2766	8.4	.00	1.80	2.65	.00	1.29	1.17	1.43
Population type	General	114 526	99.1	7221	6.3	Referent	...	...	...	...	...	...
	KP	994	0.9	35	3.5	.00	0.43	0.68	.30	0.87	0.68	1.13
DTG-based regimen transitioned to	TLD	112 808	97.7	6806	6	Referent	...	...	...	...	...	...
	ZLD	929	0.8	194	20.9	.00	3.28	4.80	.35	1.10	0.90	1.33
	ALD	175	0.2	56	32	.00	4.38	10.06	.00	2.57	1.97	3.34
	DTG+PI	1608	1.4	200	12.4	.00	1.97	2.35	.07	1.18	0.99	1.40
Type of facility	Tertiary care	59 726	51.7	3746	6.3	Referent	...	...	...	...	...	...
	Primary and secondary care	55 794	48.3	3510	6.3	.92	0.92	1.10	.79	1.01	0.91	1.13
TB status	No history of TB	106 669	92.3	6012	5.6	Referent	...	...	...	...	...	...
	Current TB	3191	2.8	634	19.9	.00	3.42	4.35	.00	1.53	1.37	1.72
	History of TB	5660	4.9	610	10.8	.00	1.62	2.39	.00	1.32	1.10	1.58

Models were adjusted for clustering at the ART-centre level using cluster-robust standard errors. TLD: tenofovir+laminivudine+dolutegravir; ZLD: zidovudine+laminivudine+dolutegravir; ALD: abacavir+laminivudine+dolutegravir; PI: lopinavir/ritonavir; atazanavir/ritonavir; darunavir/ritonavir. HR: hazards ratio, aHR: adjusted hazards ratio. Values in bold depict variables with significant aHR.

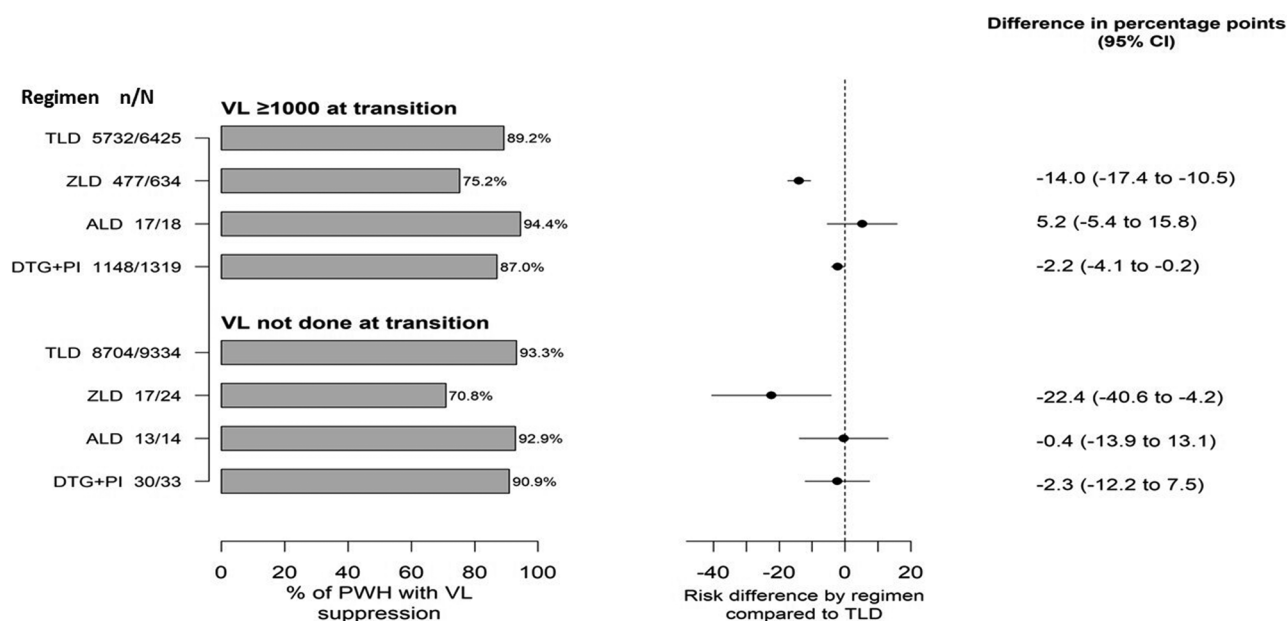


Figure 7 Analyses of viral suppression among treatment-experienced people with HIV (PWH) by regimen at 48 months.

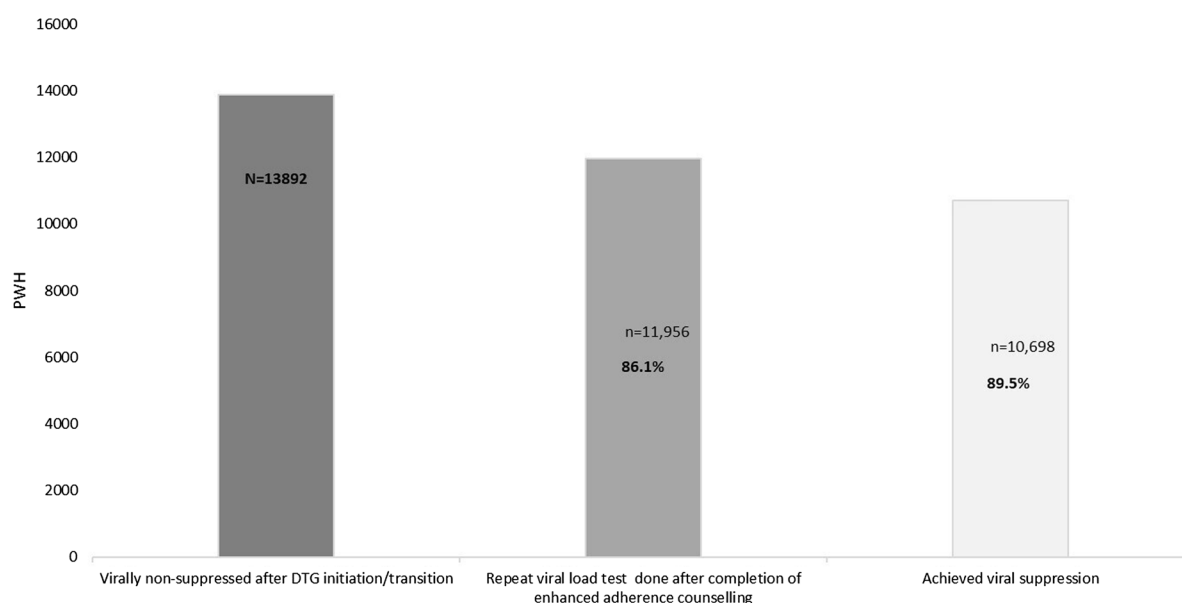


Figure 8 Cascade of people with HIV (PWH) with viral non-suppression after DTG initiation or transition.

facility (aOR: 1.13; CI 1.05 –1.22) were less likely to be virally suppressed compared to PWH receiving ART at a tertiary level facility (Table 3).

Discussion

Addressing the critical gap in evidence on long-term outcomes of DTG-based ART, our study describes 48-month treatment outcomes of DTG-based regimens among one of the largest programmatic cohorts of PWH ($n=115\,520$), within a real-world setting. Leveraging a surveillance period of 4 years, we provide long-term data on retention and virological outcomes, encompassing both treatment-experienced and treatment-naïve PWH.

Additionally, we highlight factors associated with deaths and viral non-suppression, offering a more nuanced understanding of risks for negative outcomes (mortality and viral non-suppression) in the context of DTG-based robust ART.

We report a high retention in care of 92% at 48 months, substantially higher than an earlier study in India, in the pre-DTG era [15]. The increase in overall retention may be partly attributed to the phasing-in of DTG into the national program. We observed a higher treatment retention among treatment-experienced PWH than treatment-naïve PWH. Although retention remained low among treatment-naïve PWH, 12-month retention was 9% higher compared to the pre-DTG era [16].

In our study, the death rate was highest during the initial 12 months, particularly among treatment-naïve PWH. Furthermore,

Table 3 Factors associated with viral load non-suppression during 48-month follow-up among people with HIV (PWH) initiated on/transitioned to DTG-based ART from November 2020 to March 2021 in Andhra Pradesh, India.

Characteristics	Total		Viral load (copies/ml)		P-value	OR	LL	UL	P-value	AOR	LL	UL			
	N=110 287	%	Viral load (copies/ml)												
			<1000 n=107 093	≥1000 n=3194											
Age in years	6–10	16	0.0	15	93.8	1	6.3	36	2.58	0.34	19.55	.57	1.84	0.22	15.06
	11–19	1151	1.0	1084	94.2	67	5.8	.00	2.39	1.86	3.08	.00	1.92	1.45	2.53
	20–29	7866	7.1	7471	95.0	395	5.0	.00	2.05	1.82	2.30	.00	1.59	1.40	1.80
	30–39	27 501	24.9	26 453	96.2	1048	3.8	.00	1.53	1.41	1.67	.00	1.40	1.28	1.53
	40–49	41 931	38.0	40 875	97.5	1056	2.5	...	Referent	...	...	...	...	...	...
Sex	≥50	31 822	28.9	31 195	98.0	627	2.0	.00	0.78	.70	.86	.00	.78	.70	.87
	Female	63 678	57.7	62 063	97.5	1615	2.5	...	Referent	...	...	...	...	...	...
ART status	Male	46 609	42.3	45 030	96.6	1579	3.4	.00	1.35	1.26	1.45	.00	1.12	1.04	1.21
	Experienced	105 153	95.3	102 209	97.2	2944	2.8	...	Referent	...	...	...	...	...	...
	Naïve	5134	4.7	4884	95.1	250	4.9	.00	1.78	1.56	2.03	.00	1.83	1.58	2.12
Population type	General	109 314	99.1	106 164	97.1	3150	2.9	...	Referent	...	...	...	...	...	...
	KP	973	0.9	929	95.5	44	4.5	.00	1.60	1.18	2.16	.00	1.78	1.29	2.47
Type of facility	Tertiary care	57 006	51.7	55 544	97.4	1462	2.6	...	Referent	...	...	...	...	...	...
	Primary and secondary care	53 281	48.3	51 549	96.7	1732	3.3	.00	1.28	1.19	1.37	.00	1.13	1.05	1.22
	<100	830	0.8	753	90.7	77	9.3	.00	4.68	3.68	5.96	.00	1.66	1.27	2.16
CD4 (cells/cumm) at DTG transition/initiation	100–200	2825	2.6	2598	92.0	227	8.0	.00	4.00	3.46	4.63	.00	1.84	1.56	2.16
	200–350	9447	8.6	8990	95.2	457	4.8	.00	2.33	2.09	2.59	.00	1.40	1.25	1.58
	≥350	66 977	60.7	65 546	97.9	1431	2.1	...	Referent	...	...	...	...	...	...
	CD4 not done	30 208	27.4	29 206	96.7	1002	3.3	.00	1.57	1.45	1.71	.00	1.23	1.12	1.34
	<1000	87 352	79.2	86 071	98.5	1281	1.5	...	Referent	...	...	...	...	...	...
Viral load (copies/ml) at transition/initiation	≥1000	8396	7.6	7374	87.8	1022	12.2	.00	9.31	8.55	10.14	.00	5.40	4.88	5.98
	VL not done	9405	8.5	8764	93.2	641	6.8	.00	4.91	4.46	5.42	.00	2.97	2.68	3.29
	VL not eligible	5134	4.7	4884	95.1	250	4.9	...	...	...	...	...	...	...	...
	TLD	107 996	97.9	105 157	97.4	2839	2.6	...	Referent	...	...	...	...	...	...
	ZLD	709	0.6	542	76.4	167	23.6	.00	11.41	9.56	13.63	.00	1.71	1.38	2.11
DTG-based regimen initiated on/transitioned to	ALD	132	0.1	124	93.9	8	6.1	.02	2.39	1.17	4.89	.86	1.07	.49	2.33
	DTG+PI	1450	1.3	1270	87.6	180	12.4	.00	5.25	4.47	6.16	.31	.91	.75	1.09
	1st line	105 110	95.3	102 657	97.7	2453	2.3	...	Referent	...	...	...	...	...	...
Line of treatment initiated on/transitioned to	2nd and 3rd line	5177	4.7	4436	85.7	741	14.3	.00	6.99	6.41	7.63	.00	...	...	...
	No history of TB (past or current)	102 320	92.8	99 601	97.3	2719	2.7	...	Referent	...	...	...	...	...	...
	TB status during follow-up period														
Multi-month dispensation	Current TB	2737	2.5	2500	91.3	237	8.7	.00	3.47	3.02	3.99	.00	1.70	1.46	1.99
	History of TB	5230	4.7	4992	95.4	238	4.6	.00	1.75	1.53	2.00	.00	1.26	1.09	1.47
	No	22 720	20.6	21 170	93.2	1550	6.8	.00	3.83	3.56	4.11	.00	1.96	1.81	2.13
	Yes	87 567	79.4	85 923	98.1	1644	1.9	...	Referent	...	...	...	...	...	...

(Continued)

Table 3 Continued.

Characteristics	Total	Viral load (copies/ml)					P-value	OR	LL	UL	P-value	AOR	LL	UL	
					% (2.9%)										
		N = 110 287	%	<1000 n = 107 093		≥1000 n = 3194									
Episodes of treatment interruptions or LTFU in the last 12 months	No interruption	4807	4.4	4796	99.8	11	0.2	...	Referent	...	...	...	...	...	
	Treatment interrupted but never became LTFU	56 167	50.9	55 419	98.7	748	1.3	...	5.88	3.24	10.68	6.62	3.64	12.04	
	Became LTFU	29 997	27.2	29 424	98.1	573	1.9	.00	8.49	4.67	15.43	.00	8.58	4.71	15.61
	Became LTFU <3 times	19 316	17.5	17 454	90.4	1862	9.6	.00	46.51	25.69	84.21	.00	36.88	20.34	66.86
	Became LTFU ≥3 times	4807	4.4	4796	99.8	11	0.2	...	Referent	...	...	...	...	...	
Number of total days with treatment interruption	No interruptions	44 718	40.5	44 153	98.7	565	1.3	.00	5.58	3.07	10.14	.00	5.58	3.07	10.14
	≤28 days	40 329	36.6	39 143	97.1	1186	2.9	.00	13.21	7.29	23.94	.00	13.21	7.29	23.94
	>28 to 90 days	20 433	18.5	19 001	93.0	1432	7.0	.00	32.86	18.14	59.52	.00	32.86	18.14	59.52
	>90 days														

we observed an increased risk of deaths among PWH who were treatment-naïve, had CD4 counts <200 cells/mm³, or had TB, consistent with prior studies [17–19]. This underscores the need for intensified follow-up during the initial 12 months of ART initiation and full implementation of the advanced disease management package to reduce mortality, in addition to the standard package of care [20–22]. Our 48-month survival analysis reveals a profound survival advantage associated with virological success, with survival reaching 96.7% when viral suppression is achieved. Conversely, the markedly lower survival probability of 22.3% and significantly high aHR for death among those without a documented VL test likely reflect a late presentation, where disengagement from care due to clinical instability or early mortality may have precluded routine monitoring. This finding reaffirms the importance of early diagnosis, management of advanced HIV disease and robust tracking mechanisms.

While age > 50 was associated with viral suppression, we report two times higher odds of deaths among PWH aged ≥50 years. This necessitates a closer look at preventable causes of death in an ageing cohort, including the integrated management of non-communicable diseases [23]. We also observed that abacavir-containing regimens were associated with a higher risk for death. While this could be a proxy for people with underlying renal comorbidities, this finding needs further study, as abacavir-containing ART is reported to be associated with an increase in major adverse cardiovascular events, including deaths [24]. Furthermore, simplified regimens, such as two-drug combination of dolutegravir+lamivudine for PWH with undetectable VL, could be beneficial [25, 26].

Consistent with DTG-based ART as a robust and tolerable regimen, we observed an overall high viral suppression of 97.1% (95.1% among treatment-naïve and 97.2% among treatment-experienced) at 48 months on DTG, reflecting a substantial increase of 17% (compared to 80% in 2020) [11] after the implementation of DTG. Additionally, our results are consistent with high viral suppression rates reported in the routine programmatic settings in Ukraine (90%) [27], Ethiopia (92%) [28], Uganda (94%) [29], and Malawi (97.9%) [30] and prior studies in research settings [31, 32] at 12 months and substantially higher than the 4-year cumulative probability reported from the ICONA cohort [33] and ADVANCE trial [34]. Consistent with the global PHIA survey, we also observed that older people and women had higher viral suppression [35]. We also found that person-centered treatment strategies, such as MMD, were associated with higher viral suppression (98.1%), consistent with a study from Lesotho [36].

Children and adolescents continue to lag globally in terms of viral suppression [37]. Notably, we observed a robust viral suppression among children and adolescents (94%) on DTG during 48-month follow-up, substantially higher than reported in other studies (Tanzania under programmatic settings—70.2% at 24 weeks) [38] and in the Odyssey trial (87% at 48 weeks) [39].

Even with good tolerability of DTG, we showed that people who were treatment-naïve compared to treatment-experienced PWH had a higher risk of viral non-suppression, possibly linked with the increased mortality in this group. This highlights the importance of treatment literacy, adherence counseling and close follow-up of PWH, newly initiated on ART. Further, we observed that the risk of viral non-suppression was higher among PWH with lower CD4 counts, underscoring the need for early detection and ART initiation.

Tuberculosis co-infection remains a significant opportunistic infection in India among PWH. In our study, TB coinfection was associated with higher odds of death and viral non-suppression. However, we observed a comparatively higher (91.3%) viral suppression rate among TB-coinfected PWH on DTG, in contrast to a cohort study from 11 Sub-Saharan countries (viral suppression at 58.9%) [40]. This may be partly due to the strong convergence between the national TB and HIV programs and integrated HIV-TB services for the timely and seamless diagnosis and management of TB among PWH.

Among PWH who were virally non-suppressed before DTG transition, 90.5% achieved viral suppression, notably higher than an earlier study in India (78.2%) [41] and Ethiopia (82.39%) [42] among PWH on second-line ART before DTG, but comparable to outcomes reported in Sub-Saharan Africa [43] following the implementation of DTG. Consistent with findings from global clinical trials [44], we observed that virological suppression was significantly higher among treatment-experienced PWH when tenofovir/lamivudine was recycled (as part of a DTG-based regimen), compared to zidovudine. Our finding provides critical real-world programmatic evidence on the long-term durability—extending to 48 months—of virological suppression when recycling tenofovir. These results strongly support the World Health Organization's (WHO) recommendation for tenofovir plus lamivudine as the preferred NRTI backbone for subsequent ART for adults and children weighing more than 30 kg, including those previously treated with or exposed to tenofovir or zidovudine [45].

Underscoring the importance of EAC, we observed that 89% of PWH achieved viral suppression after at least three EAC sessions. This is higher than VL re-suppression rates reported from India (28%) [46], Kenya (51%) [47], Ethiopia (51.7%) [48], Malawi (79%) [49], Uganda (48.2%) [50], Nigeria (74%) [51] before DTG, but comparable to the ADVANCE study (85%) [52], where DTG was used. Our findings strongly support the WHO recommendation of EAC before regimen switch. This also underscores the need to examine the role and timing of HIV drug resistance testing for sequencing in the setting of EAC interventions.

Limitations

This study was done in a routine program setting with variability in the quality of care and EAC across sites. Further, there could have been under-reporting of viral suppression as some PWH were still due for repeat VL after EAC. Viral load measurements were based on routine programmatic testing and may not have been performed at uniform time intervals. Observed RDs in viral suppression and mortality across regimens may have been influenced by residual confounding, including underlying clinical characteristics and treatment history.

Conclusion

The rapid and wide-scale implementation of DTG, along with other programmatic interventions, contributed to improved treatment retention and viral suppression in India, supporting progress toward the NACP targets and the UNAIDS 95-95-95 targets. In our programmatic cohort, DTG-based ART demonstrated

high efficacy and durability among treatment-naïve and treatment-experienced PWH, including those with recycled tenofovir/lamivudine, in combination with DTG. The increase in VL re-suppression rates emphasizes the role of EAC in preventing premature regimen switch. While we saw gains across all PWH, scale-up of person-centered and quality-driven differentiated service delivery strategies could further optimize the impact of DTG on viral suppression, morbidity, and mortality, particularly among PWH who are treatment-naïve, with advanced HIV disease, TB-coinfection, people over 50 years, adolescents or belonging to key populations.

Acknowledgments

The authors thank and acknowledge the invaluable contributions of the ART center staff and the participation of the patients and the PWH community without whom this activity would not have been possible. We also thank and acknowledge the support and guidance from Care, Support & Treatment Division, National AIDS Control Organization (NACO); and Andhra Pradesh State AIDS Control Society (APSACS).

Author contributions

Reshu Agarwal (Conceptualization [lead], Data curation [lead], Formal analysis [lead], Investigation [lead], Methodology [lead], Project administration [equal], Writing—original draft [lead], Writing—review & editing [lead]), Melissa Nyendak (Conceptualization [equal], Formal analysis [equal], Methodology [equal], Resources [supporting], Visualization [equal], Writing—original draft [equal], Writing—review & editing [equal]), Nalini Chava (Data curation [equal], Formal analysis [equal], Software [lead], Validation [equal], Visualization [equal], Writing—review & editing [equal]), Ramesh R. Allam (Data curation [equal], Formal analysis [equal], Methodology [equal], Project administration [equal], Writing—review & editing [equal]), Prabhu Turaka (Methodology [equal], Project administration [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Ramesam Ganti (Data curation [supporting], Formal analysis [supporting], Project administration [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Ajit R. Polsani (Project administration [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Praveen K. Ragi (Project administration [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), JayaKrishna Kurada (Project administration [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Vijay V. Yeldandi (Funding acquisition [equal], Project administration [equal], Resources [equal], Writing—original draft [supporting], Writing—review & editing [equal]), Rajendra P. Prasad (Project administration [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Chakravarthy S. Sriram (Methodology [equal], Project administration [equal], Resources [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), Manjula Thogarucheeti (Methodology [equal], Project administration [equal], Resources [equal], Supervision [equal], Validation [equal], Writing—review & editing [equal]), and K. Neelakanta Reddy (Funding acquisition [equal], Resources [equal], Writing—review & editing [equal]).

Supplementary material

Supplementary material is available at *Research Connections* online.

Conflicts of interest

None declared.

Funding

The implementation of DTG among PWH and data collection were supported by the existing staff and infrastructure of the National AIDS Control Program as a routine programmatic work. Additionally, this project has been partially supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of Cooperative Agreement # GH002312 for data monitoring and analysis.

Data availability

Deidentified individual participant data and the corresponding data dictionary will be made available upon reasonable request, conditional upon written approval from the Government of India's National AIDS Control Organization. Requests can be initiated by contacting the corresponding author, who will facilitate necessary approvals.

Ethics

The NACP considered this activity to be a routine programmatic activity, in accordance with the national guidelines, and involved only a secondary review of existing program data. This study was reviewed and approved by Science Integrity Branch of the Centers for Disease Control and Prevention (CDC) and was conducted consistent with human subjects' research protections applicable U.S. federal law and CDC policy.

CDC disclaimer

The findings and conclusions in this publication are those of the authors and do not necessarily represent the official position of the funding agencies.

References

1. Braitstein P, Brinkhof MW, Dabis F, *et al.* Mortality of HIV-1 infected patients in the first year of antiretroviral therapy: comparison between low-income and high-income countries. *Lancet* 2006;**367**:817-24. [https://doi.org/10.1016/S0140-6736\(06\)68337-2](https://doi.org/10.1016/S0140-6736(06)68337-2)
2. Cohen MS, Chen YQ, McCauley M, *et al.* Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med* 2016;**375**:830-9. <https://doi.org/10.1056/NEJMoa1600693>
3. Chun HM, Dirlikov E, Cox MH, *et al.* Vital signs: progress toward eliminating HIV as a global public health threat through scale-up of antiretroviral therapy and health system strengthening supported by the U.S. President's emergency plan for AIDS relief-worldwide, 2004-2022. *MMWR Morb Mortal Wkly Rep* 2023;**72**:317-24. <https://doi.org/10.15585/mmwr.mm7212e1>
4. Walmsley S, Baumgarten A, Berenguer J, *et al.* Brief report: dolutegravir plus abacavir/lamivudine for the treatment of HIV-1 infection in antiretroviral therapy-naïve patients: week 96 and week 144 results from the SINGLE randomized clinical trial. *J Acquir Immune Defic Syndr* 2015;**70**:515-9. <https://doi.org/10.1097/QAI.0000000000000790>
5. Llibre JM, Pulido F, García F, *et al.* Genetic barrier to resistance for dolutegravir. *AIDS Rev* 2015;**17**:56-64.
6. Cottrell ML, Hadzic T, Kashuba AD. Clinical pharmacokinetic, pharmacodynamic and drug-interaction profile of the integrase inhibitor dolutegravir. *Clin Pharmacokinet* 2013;**52**:981-94. <https://doi.org/10.1007/s40262-013-0093-2>
7. National AIDS Control Organisation. *Sankalak: Status of National AIDS & STD Response* (7th edn). New Delhi: National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, 2025.
8. World Health Organization. *Update on the Transition to Dolutegravir-Based Antiretroviral Therapy: Report of a WHO Meeting, 29-30 March 2022*. Geneva: World Health Organization, 2022.
9. Majula RT, Mwera CN. Brief communication: long-term treatment outcomes of transitioning to dolutegravir-based ART from efavirenz in HIV study participants in Mbeya, Tanzania. *AIDS Res Ther* 2024;**21**:98. <https://doi.org/10.1186/s12981-024-00684-x>
10. Girón-Callejas A, Lorenzana R, Pickles M, *et al.* High HIV viral suppression among adults receiving WHO-recommended first-line dolutegravir-based antiretroviral therapy in low- and middle-income countries: a systematic review and meta-analysis of programmatic evidence. *AIDS Res Ther* 2025;**22**:91. <https://doi.org/10.1186/s12981-025-00712-4>
11. Liautaud B, Chico AS, Macius Y, *et al.* Three-year outcomes after programmatic transitioning to dolutegravir in the context of severe civil unrest in Haiti. *Open Forum Infect Dis* 2025;**12**:ofaf526. <https://doi.org/10.1093/ofid/ofae482>
12. Namayanja GA, Da Silva JF, Elur B, *et al.* High viral suppression rates among PLHIV on dolutegravir who had an initial episode of viral non-suppression in Uganda September 2020-July 2021. *PLoS One* 2024;**19**:e0305129. <https://doi.org/10.1371/journal.pone.0305129>
13. Kalua T, Egger M, Jahn A, *et al.* HIV suppression was maintained during the COVID-19 pandemic in Malawi: a program-level cohort study. *J Clin Epidemiol* 2022;**150**:116-25. <https://doi.org/10.1016/j.jclinepi.2022.06.014>
14. National AIDS Control Organisation *Sankalak: status of National AIDS & STD Response* (6th edn). New Delhi: National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, 2024.
15. Chidrawar S, Sane S, Mamulwar M, *et al.* Effect of antiretroviral therapy on retention of people living with HIV in India (2012-2017): a retrospective, cohort study. *Lancet Reg Health*

- Southeast Asia* 2025;**34**:100552. <https://doi.org/10.1016/j.lansea.2025.100552>
16. National AIDS Control Organisation Government of India. *Status of National AIDS response* (2nd edn). Sankalak: New Delhi: National AIDS Control Organisation, Ministry of Health and Family Welfare, 2020.
 17. Portilla-Tamarit J, Reus S, Portilla I, *et al.* Impact of advanced HIV disease on quality of life and mortality in the era of combined antiretroviral treatment. *J Clin Med* 2021;**10**:716. <https://doi.org/10.3390/jcm10040716>
 18. Mocroft A, Lundgren JD, Sabin ML, *et al.* Risk factors and outcomes for late presentation for HIV-positive persons in Europe: results from the Collaboration of Observational HIV Epidemiological Research Europe Study (COHERE). *PLoS Med* 2013;**10**:e1001510. <https://doi.org/10.1371/journal.pmed.1001510>
 19. Walker AS, Prendergast AJ, Mugenyi P, *et al.* Mortality in the year following antiretroviral therapy initiation in HIV-infected adults and children in Uganda and Zimbabwe. *Clin Infect Dis* 2012;**55**:1707-18. <https://doi.org/10.1093/cid/cis797>
 20. Mfinanga S, Chanda D, Kivuyo SL, *et al.* Cryptococcal meningitis screening and community-based early adherence support in people with advanced HIV infection starting antiretroviral therapy in Tanzania and Zambia: an open-label, randomised controlled trial. *Lancet* 2015;**385**:2173-82. [https://doi.org/10.1016/S0140-6736\(15\)60164-7](https://doi.org/10.1016/S0140-6736(15)60164-7)
 21. Hakim J, Musiime V, Szubert AJ, *et al.* Enhanced prophylaxis plus antiretroviral therapy for advanced HIV infection in Africa. *N Engl J Med* 2017;**377**:233-45. <https://doi.org/10.1056/NEJMoa1615822>
 22. Agarwal R, Nyendak M, Chava N, *et al.* Long-term protection from tuberculosis preventive treatment among people with HIV in a high-burden tuberculosis setting: an observational cohort study from India. *Clin Infect Dis* 2025;**81**:970-9. <https://doi.org/10.1093/cid/ciaf322>
 23. Smit M, Brinkman K, Geerlings S, *et al.* ATHENA observational cohort Future challenges for clinical care of an ageing population infected with HIV: a modelling study. *Lancet Infect Dis* 2015;**15**:810-8. [https://doi.org/10.1016/S1473-3099\(15\)00056-0](https://doi.org/10.1016/S1473-3099(15)00056-0)
 24. DaviesSmith E, Malvestutto C, Ribaudo HJ, *et al.* Cardiovascular hazards of abacavir- versus tenofovir-containing antiretroviral therapies: insights from an analysis of the REPRIEVE trial cohort. *Open Forum Infect Dis* 2025;**12**:ofaf177. <https://doi.org/10.1093/ofid/ofaf177>
 25. World Health Organization. *Overview of WHO Recommendations on HIV and Sexually Transmitted Infection Testing, Prevention, Treatment, Care and Service Delivery*. Geneva: WHO, 2025.
 26. Kulkarni V, Parchure R, Gundu S, *et al.* Long-term efficacy and safety of fixed-dose dolutegravir-lamivudine in people with HIV: a retrospective study from India. *Int J STD AIDS* 2025;**36**:930-8. <https://doi.org/10.1177/09564624251234567>
 27. Dumchev K, Kiriazova T, Riabokon S, *et al.* Comparative clinical outcomes with scale-up of dolutegravir as first-line antiretroviral therapy in Ukraine. *J Acquir Immune Defic Syndr* 2022;**91**:197-209. <https://doi.org/10.1097/QAI.0000000000003038>
 28. Mehari EA, Muche EA, Gonete KA. Virological suppression and its associated factors of dolutegravir based regimen in a resource-limited setting: an observational retrospective study in Ethiopia. *HIV AIDS (Auckl)* 2021;**13**:709-17. <https://doi.org/10.2147/HIV.S316776>
 29. Nabitaka VM, Nawaggi P, Campbell J, *et al.* High acceptability and viral suppression of patients on dolutegravir-based first-line regimens in pilot sites in Uganda: a mixed-methods prospective cohort study. *PLoS One* 2020;**15**:e0232419. <https://doi.org/10.1371/journal.pone.0232419>
 30. Schramm B, Temfack E, Descamps D, *et al.* Viral suppression and HIV-1 drug resistance 1 year after pragmatic transitioning to dolutegravir first-line therapy in Malawi: a prospective cohort study. *Lancet HIV* 2022;**9**:e544-53-e553. [https://doi.org/10.1016/S2352-3018\(22\)00136-9](https://doi.org/10.1016/S2352-3018(22)00136-9)
 31. Walmsley SL, Antela A, Clumeck N, *et al.* SINGLE Investigators Dolutegravir plus abacavir-lamivudine for the treatment of HIV-1 infection. *N Engl J Med* 2013;**369**:1807-18. <https://doi.org/10.1056/NEJMoa1215541>
 32. Allahna E, Nicole D, Neha S, *et al.* Brief report: virologic impact of the dolutegravir transition: prospective results from the Multinational African Cohort Study. *J Acquir Immune Defic Syndr* 2022;**91**:285-9. <https://doi.org/10.1097/QAI.0000000000003065>
 33. D'arminio Monforte A, Tavelli A, Sala M, *et al.* Long-term outcome of dolutegravir-containing regimens according to sex: data from the ICONA study. *J Antimicrob Chemother* 2023;**78**:933-45. <https://doi.org/10.1093/jac/dkad026>
 34. Sokhela S, Venter WDF, Moorhouse M, *et al.* Final 192-week efficacy and safety results of the ADVANCE trial, comparing 3 first-line antiretroviral regimens. *Open Forum Infect Dis* 2024;**11**:ofae007. <https://doi.org/10.1093/ofid/ofae118>
 35. Chun HM, Dirlikov E, Cox MH, *et al.* Vital signs: progress toward eliminating HIV as a global public health threat through scale-up of antiretroviral therapy and health system strengthening supported by the U.S. President's Emergency Plan for AIDS Relief-Worldwide, 2004-2022. *MMWR Morb Mortal Wkly Rep* 2023;**72**:317-24. <https://doi.org/10.15585/mmwr.mm7211e1>
 36. Tukei BB, Fatti G, Tiam A, *et al.* Twelve-month outcomes of community-based differentiated models of multimonth dispensing of ART among stable HIV-infected adults in Lesotho: a cluster-randomized noninferiority trial. *J Acquir Immune Defic Syndr* 2020;**85**:280-91. <https://doi.org/10.1097/QAI.0000000000002439>
 37. Joint United Nations Programme on HIV/AIDS. *Dangerous inequalities: World AIDS Day report 2022*. UNAIDS, Geneva, 2022.
 38. Mutagonda RF, Mlyuka HJ, Maganda BA, *et al.* Adherence, effectiveness and safety of dolutegravir based antiretroviral regimens among HIV infected children and adolescents in Tanzania. *J Int Assoc Provid AIDS Care* 2022;**21**:23259582221109613. <https://doi.org/10.1177/23259582221109613>
 39. Turkova A. (March 6-10, 2021) Dolutegravir-based ART is superior to NNRTI/PI-based ART in children and adolescents. In: *Paper presented at: 28th Conference on Retroviruses and Opportunistic Infections (CROI)*; Abstract 174, Virtual.
 40. Romo ML, Brazier E, Mahambou-Nsonde S, *et al.* Real-world use and outcomes of dolutegravir-containing antiretroviral therapy in HIV and tuberculosis co-infection: a site survey and cohort study in Sub-Saharan Africa. *J Int AIDS Soc* 2022;**25**:e25961. <https://doi.org/10.1002/jia2.25961>
 41. Chakravarty J, Sundar S, Chourasia A, *et al.* Outcome of patients on second line antiretroviral therapy under programmatic condition in India. *BMC Infect Dis* 2015;**15**:517. <https://doi.org/10.1186/s12879-015-1270-8>

42. Wedajo S, Degu G, Deribew A, *et al.* Rate of viral re-suppression and retention to care among PLHIV on second-line antiretroviral therapy at dessie comprehensive specialized hospital, northeast Ethiopia: a retrospective cohort study. *HIV AIDS (Auckl)* 2021;**13**:877-87. <https://doi.org/10.2147/HIV.S323445>
43. Romo ML, Edwards JK, Semeere A, *et al.* Viral load status before switching to dolutegravir-containing antiretroviral therapy and associations with human immunodeficiency virus treatment outcomes in Sub-Saharan Africa. *Clin Infect Dis* 2022;**75**:630-7. <https://doi.org/10.1093/cid/ciab1006>
44. Paton NI, Musaazi J, Kityo C, *et al.* Efficacy and safety of dolutegravir or darunavir in combination with lamivudine plus either zidovudine or tenofovir for second-line treatment of HIV infection (NADIA): week 96 results from a prospective, multicentre, open-label, factorial, randomised, non-inferiority trial. *Lancet HIV* 2022;**9**:e381-93-e393. [https://doi.org/10.1016/S2352-3018\(22\)00092-3](https://doi.org/10.1016/S2352-3018(22)00092-3)
45. World Health Organization. *WHO updated recommendations on HIV clinical management: recommendations for a public health approach*. Geneva: WHO, 2025.
46. Laxmeshwar C, Acharya S, Das M, *et al.* Routine viral load monitoring and enhanced adherence counselling at a public ART Centre in Mumbai, India. *PLoS One* 2020;**15**:e0233241. <https://doi.org/10.1371/journal.pone.0233241>
47. Awolude OA, Olaniyi O, Moradeyo M, *et al.* Virologic outcomes following enhanced adherence counselling among treatment experienced HIV positive patients at University College Hospital, Ibadan, Nigeria. *Int STD Res Rev* 2021;**10**:53-65. <https://doi.org/10.9734/ISRR/2021/v10i130124>
48. Atnafu GT, Moges NA, Wubie M, *et al.* Incidence and predictors of viral load suppression after enhanced adherence counseling among HIV-positive adults in West Gojjam zone, Amhara region, Ethiopia. *Infect Drug Resist* 2022;**15**:261-74. <https://doi.org/10.2147/IDR.S343603>
49. Nicholas S, Poulet E, Wolters L, *et al.* Point-of-care viral load monitoring: outcomes from a decentralized HIV programme in Malawi. *J Int AIDS Soc* 2019;**22**:e25387. <https://doi.org/10.1002/jia2.25387>
50. Kikaire B, Ssemamanda M, Asiimwe A, *et al.* HIV viral load suppression following intensive adherence counseling among people living with HIV on treatment at military-managed health facilities in Uganda. *Int J Infect Dis* 2021;**112**:45-51. <https://doi.org/10.1016/j.ijid.2021.09.006>
51. Akpan U, Nwanja E, Ukpong KA, *et al.* Reaching viral suppression among people with HIV with suspected treatment failure who received enhanced adherence counseling in Southern Nigeria: a retrospective analysis. *Open Forum Infect Dis* 2022;**9**:ofac651. <https://doi.org/10.1093/ofid/ofac651>
52. Bosch B, Chandiwana N, Akpomiemie G, *et al.* High rates of long-term HIV RNA re-suppression after virological failure on dolutegravir in the ADVANCE trial. *J Int AIDS Soc* 2023;**26**:e26134. <https://doi.org/10.1002/jia2.26134>