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Association between differentiated HIV care delivery model and low-level viremia among people living with HIV in Rwanda

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Abstract

Background Low-level viremia (LLV) (HIV-RNA 51–999 copies/mL) is associated with increased risk of non viral load suppression (HIV-RNA ≥ 1000 copies/mL). We assessed the association between differentiated service delivery model (DSDM) and LLV among people living with HIV (PLHIV) in Rwanda.

Methods We conducted a retrospective cohort analysis using routinely collected data of adults living with HIV from 28-healthcare facilities in Rwanda before and after the introduction of DSDM. Under DSDM, PLHIV initiated treatment within seven days of HIV diagnosis and medication pick-up up to six months for those with sustained viral load suppression suppression. Proportions of LLV at 6,12 and 18 months were quantified. Multivariable log binomial regression models were used to assess the effect of DSDM on LLV. To handle missing data, multiple imputations was performed.

Results Of 976 people living with HIV, 645(66.0%) were female and 463(47.4%) initiated treatment during DSDM. The median age was 37 (interquartile range: 32–43) years. LLV was 7.4%, 6.6% and 5.4%, at 6,12 and 18 months, respectively. Compared to those who initiated treatment before DSDM, starting treatment during DSDM increased six-month LLV [adjusted risk ratio (aRR) = 2.8: 95%CI (1.15–6.91)] but not at 12 [aRR = 2.3: 95%CI (0.93–5.75)] and 18 months [aRR = 0.3: 95%CI (0.09–1.20)]. Using imputed datasets, the association between DSDM and LLV persisted.

Conclusions DSDM was associated with increased risk of LLV at 6-months. possibly due to the minimal amount of time PLHIV had in pondering and accepting the HIV diagnosis. Continued support is needed among people receiving early antiretroviral therapy initiation to prevent development of LLV.

Keywords Differentiated care delivery model, Low-level viremia, Viral load suppression, People living with HIV, Antiretroviral

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Introduction

Access to antiretroviral therapy (ART) for people living with HIV has reduced morbidity and mortality associated with HIV and opportunistic infections, globally [1]. ART has turned HIV into a manageable chronic illness with a significant improvement in quality of life for people living with HIV [2, 3]. The success of ART are notable in HIV programs with improved retention in care, ART adherence and viral load suppression [4, 5].

For monitoring clinical outcomes of people living with HIV receiving ART, the World Health Organization (WHO) recommends categorization of people living with HIV based on viral load. Those with a viral load of <1,000 copies/mL are regarded as virally suppressed and those with a viral load of ≥1,000 copies/mL as not suppressed [6]. People living with HIV with two or more consecutive viral loads of ≥1,000 copies/mL, often regarded as treatment failures, likely harbor resistance mutations and have higher risk of transmitting HIV to uninfected partners [7, 8]. Although people living with HIV with a viral load of <1,000 copies/mL have lower likelihood of transmitting infection compared to those with a viral load of ≥1,000 copies/mL, evidence has shown that, compared to those with a viral load of ≤50 copies/mL, those with low-level viremia (LLV; VL: 51–999 copies/mL) have a higher risk of becoming non-virally suppressed [9–11] and developing resistance mutations [12, 13]. This evidence prompted debates on whether the threshold of viral load suppression needs to be revised [14].

Since 2016, WHO has recommended a differentiated service delivery model (DSDM) with different components to tailor client needs [15]. By the beginning of 2017, all health care facilities were implementing DSDM in Rwanda. Under DSDM, people living with HIV were categorized as stable or unstable based on duration on and ART and virologic monitoring. Stable clients living with HIV (on ART for ≥18 months and two consecutive suppressed viral loads) have the option to have a longer prescription filled of up to six months and assigned to peer educators who provides moral and psychological support and promote adherence to treatment and retention within a specified catchment area. Unstable clients receive monthly prescriptions from the health facility, were not assigned to peer educators, but benefited from monthly adherence and counseling from healthcare providers on each drug pick-up appointment. A systematic review of 37 DSDM reported higher estimates of retention for HIV programs that did not report comparison groups; however, for those that did, retention was shown to be comparable between people living with HIV who were under DSDM and those who were not under DSDM [16]. Another component of DSDM is early initiation of ART following HIV diagnosis without an extended counselling period compared to initiation of ART based on CD4 count which was characterized with an extended period of counselling. Although early initiation of ART has been associated with reduced time to viral load suppression [17] and overall viral load suppression [18, 19], it has also been associated with loss to follow up (LTFU) [20]. It has been argued that absence of extended periods of counselling may partly explain LTFU among people living with HIV who initiate ART immediately following HIV diagnosis. Prior data has shown that some newly diagnosed people living with HIV are highly overwhelmed and traumatized by the HIV diagnosis making adherence to ART in the first few months of HIV diagnosis challenging [21].

A previous study in Rwanda found that frequent clinic appointments to pick up drugs is difficult because of transportation costs, long waiting times and stigma; therefore, adoption of DSDM was thought to minimize these structural barriers [22]. Since 2017, Rwanda has adopted DSDM with reportable success in the number of people living with HIV who initiate ART immediately following HIV diagnosis without affecting retention [23]. Despite this success, it is not known whether DSDM may have an impact on LLV, which is a known risk factor non-viral load suppression, development of drug resistance and treatment failure. In this analysis, we aimed to evaluate the incidence of LLV at 6, 12 and 18 months of follow-up among people living with HIV receiving treatment from twenty-eight healthcare facilities in Rwanda before and after the introduction of DSDM.

Methods

Study design and population

This was a retrospective cohort study that used routinely collected data of people living with HIV from twenty-eight healthcare facilities in Rwanda. Rwanda's healthcare delivery system is categorized as primary, secondary, and tertiary. Primary healthcare facilities are comprised of Health Post/Dispensaries, and Health Centers, secondary health facilities are District Hospitals while tertiary health facilties are comprised of National Referral and Univeristy Teaching Hospitals. Administratively, all twenty-eight healthcare facilities belong to the same primary health level of care. A validated chart abstraction tool (for adults) used by the AIDS Relief Project to evaluate patient-level outcomes [24] was adapted and used to collect patient demographics and clinical information, including viral load, CD4 count, compliance to appointments and adherence to ART. The data consisted of two cohorts of adult (≥18 years or older) people living with HIV who initiated ART from these facilities and were followed for 24 months. The first cohort (n=514) consisted of adults living with HIV who initiated treatment between January and April 2014 (prior to the rollout of DSDM) and the second cohort (n=463) involved people

living with HIV who initiated treatment between January and April 2017 (after the rollout of DSDM). Under DSDM PLHIV initiated ART regardless of their CD4 count within seven days of HIV diagnosis, without an extended counseling period. In addition, upon attaining sustained viral load suppression (two consecutive viral load suppressions), PLHIV had opportunity for up to six month drug refills.

Definition of variables

The main outcome of interest was LLV defined per WHO guidelines as people living with HIV with viral load of 51–999 copies/mL. People living with HIV who had viral load of ≤50 copies/mL were considered fully suppressed. The main predictor variable was DSDM categorized to people living with HIV who initiated ART before and after the rollout of DSDM. Other variables evaluated included age (18–24, 25–34, 35–44, 45–54, ≥55), sex (male, female), disclosure of HIV status (disclosed, did not disclose), baseline WHO staging (I, II, III and IV). HIV disclosure was defined as sharing one's HIV diagnosis to a partner, peer educator, friend or any family member). Self-reported adherence was measured based on the 30-day recall. Facilities assessed adherence in the past 30-days based on the prescription given during the past clinic vist. It was calculated as the proportion of pills taken out of the number prescribed within 30 days and categorized as optimal if adherence was ≥90% or suboptimal if adherence was <90%. Baseline CD4 cell count was measured during the first clinic visit following HIV diagnosis. Those with CD4 count<200 cells/mm^3 were considered to have advanced HIV disease and those with CD4 count≥200 cells/mm^3 were considered not to have advanced HIV disease. Six-, 12- and 18-month viral load data was categorized as ≤50, 51–999 and ≥1000 copies/mL. Participants with a viral load of <1,000copies/mL were considered virally suppressed.

Statistical analysis

Frequencies and proportions of categorical variables and median and interquartile range (IQR) for continuous variables were presented. We compared categorical participant characteristics by the status of DSDM using the Chi-square or Fisher's exact tests where appropriate. Independent t-tests were used to compare continuous variables. For the association between DSDM and LLV, all participants with viral load>1,000 copies/mL were excluded from the analysis. To assess the effect of DSDM on LLV, log binomial regression models were used to compute risk ratios (RRs) and 95% confidence intervals (CIs). First, bivariate log binomial regression models were fit. Then, all variables that were significantly associated with LLV on bivariate analysis along with factors that had a *p*-value of <0.20 were included in the final multivariable models. The study participants were clustered within healthcare facilities; the latter were considered as clusters and random effects models were used to account for clustering in both bivariate and multivariable analysis. Complete case analysis was conducted initially. To account for missing data in the covariates, we conducted five multiple imputations assuming a missing at random mechanism. DSDM, age, sex, education, disclosure of HIV status, adherence, and baseline CD4 count were included in the imputation model as predictors. Each imputed dataset was analyzed using log binomial regression models, and the final estimates were pooled according to Rubin's Rules [25]. Imputed data results were compared to those obtained under compete case analysis. All associations were presented as RR, adjusted odds ratio (aRR) and 95% CIs. Statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Ethical consideration

The Rwanda National Ethics Committee approved this study. IRB # 00001497 of IORG0001100.

Results

A total of 976 people living with HIV were included in this analysis of whom, 462 (47.3%) initiated treatment after the rollout of DSDM (Table 1). The median age was 37 (IQR, 32–43) years. Nearly two-thirds, 645 (67.0%), were female, 429 (44.0%) did not have formal education and 587 (60. 1%) disclosed their HIV status. Three quarters of the participants, 739 (75.7%), were classified to have WHO stage one at baseline, 160 (16.4%) presented with advanced HIV disease and 618 (63.3%) self-reported adherence of ≥90%. LLV at 6, 12 and 18 months were 52 (7.3%), 44 (6.5%) and 22 (5.4%), respectively. Viral load suppression at 6, 12 and 18 months was 91.9%, 92.7% and 95.8%, respectively. Stratified analysis of participant characteristics by the model of care showed that, there was heterogeneity in the distribution of age, level of education and six monthx viral load results between the two groups. All other characteristics were comparable.

Factors associated with LLV, complete case analysis and multiple imputation

Tables 2 and 3, respectively, present bivariate and multivariable factors associated with LLV under complete case analysis and after multiple imputation of missing covariate data. Overall, the effect sizes were similar in terms of magnitude and direction; however, the effect sizes under complete case analysis were characterized by wider 95% CIs due to missing data for certain covariates.

For the bivariate complete case analysis, compared to participants who initiated ART before the introduction of DSDM, those who initiated after the introduction of

Table 1 Participant characteristics

Characteristics	All	Received DSDM		*p*-value
		No	Yes	
	n = 976	*n* = 514	*n* = 462	
	n (%)	n (%)	n (%)	
Age, median (SD)	39.2 (10.2)	40.5 (10.5)	37.8 (9.7)	**< 0.001**
Age				
18–24	23 (2.4)	9 (1.7)	14 (3.0)	**0.004**
25–34	328 (33.6)	155 (30.2)	173 (37.4)	
35–44	411 (42.1)	216 (42.0)	195 (42.2)	
45–54	132 (13.5)	79 (15.4)	53 (11.5)	
≥55	82 (8.4)	55 (10.7)	27 (5.8)	
Sex				
Female	645 (67.0)	349 (68.0)	296 (64.2)	0.209
Male	329 (33.7)	164 (32.0)	165 (35.8)	
Missing	2 (0.3)	1	1	
Education				
No education	429 (44.0)	260 (51.5)	169 (38.1)	**< .0001***
Primary	416 (42.6)	191 (37.8)	225 (50.7)	
Secondary	97 (9.9)	52 (10.3)	45 (10.1)	
Tertiary	7 (0.7)	2 (0.4)	5 (1.1)	
Missing	27 (2.7)	9	18	
HIV status disclosed				
No	385 (39.4)	195 (38.2)	190 (41.2)	0.331
Yes	587 (60.1)	316 (61.8)	271 (58.8)	
Missing	4 (0.4)	3	1	
Initial WHO stage				
I	739 (75.7)	379 (84.0)	360 (85.9)	0.384
II	91 (9.3)	47 (10.4)	44 (10.5)	
III & IV	40 (4.1)	25 (5.5)	15 (3.6)	
Missing	106 (10.9)	63	43	
Adherence				
< 90%	248 (25.4)	144 (31.2)	104 (25.7)	0.078
≥ 90%	618 (63.3)	318 (68.8)	300 (74.3)	
Missing	110 (11.3)	52	58	
Advance HIV disease				
< 200	160 (16.4)	88 (19.5)	72 (19.8)	0.911
≥ 200	656 (67.2)	364 (80.5)	292 (80.2)	
Missing	160 (16.4)	62	98	
Viral load 6 months (*n* = 716)				
0–50	606 (84.6)	296 (86.3)	310 (83.1)	**0.029**
51–999	52 (7.3)	16 (4.7)	36 (9.7)	
≥1000	58 (8.1)	31 (9.0)	27 (7.2)	
Viral load 12 months (*n* = 663)				
0–50	572 (86.3)	286 (87.7)	286 (84.9)	0.410
51–999	44 (6.5)	17 (5.2)	27 (7.7)	
≥1000	48 (7.2)	23 (7.0)	25 (7.4)	
Viral load 18 months (*n* = 411)				
0–50	368 (89.8)	180 (88.2)	188 (91.3)	0.564
51–999	22 (5.4)	12 (5.9)	10 (4.8)	
≥1000	20 (4.9)	12 (5.9)	8 (3.9)	

DSDM indicates differentiated service delivery model. Missing data was not included in the assessment of heterogeneity between the two groups

DSDM had statistically significant higher risk of having LLV at 6 months [RR = 2.8; 95% CI(1.15–6.91)] but not at 12 [RR = 2.3; 95%CI (0.93–5.75)] or 18 months [RR = 0.3; 95%CI (0.09–1.20)] (Table 2). Men had higher risk of having LLV at 6 months [OR = 1.8; 95% CI (1.06–2.95)]. Similar results were noted in the multivariable analysis under complete case analysis.

In the bivariate analysis using imputed datasets, the risk of having LLV at 6 months among participants who initiated treatment under DSDM was twice that of participants who initiated ART before DSDM. In the multivariable analysis, compared to participants who initiated ART before the introduction of DSDM, those who initiated after the introduction of DSDM had statistically significant higher risk of having LLV at 6 months [aRR = 2.1; 95% CI(1.11–4.12)] but not at 12 [aRR = 1.5; 95% CI(0.77–3.03)] or 18 months [aRR = 0.4; 95% CI(0.14–1.06)] (Table 3). Participants who self-reported adherence of ≥90% at 6 months had 60% lower risk of having LLV compared to those who self-reported adherence of < 90%.

Discussion

In this cohort of PLHIV receiving ART in Rwanda, LLV was 7.3%, 6.5% and 5.4% at 6, 12 and 18 months, respectively. Prevalence of LLV from this study is similar to the ones reported from other neighboring east African countries, 8% in Uganda [26] and 9% in Tanzania [27]. Those who initiated ART during DSDM had higher risk of having LLV at 6 months compared to those who initiated prior to the introduction of DSDM. Initiation of ART during DSDM was not associated with risk of having LLV at 12 and 18 months of follow-up. The risk of having LLV was consistently higher among men than women at 6 and 18 months of follow-up.

It is a well-established fact that adherence to ART is key to achieving viral load suppression, and counselling on the importance of taking medication as prescribed is critical to achieving desirable benefits of HIV treatment. Historically, people living with HIV initiated ART based on CD4 count [28]. During these periods of serial CD4 count assessments, people received counselling about HIV for an extended period to prepare to initiate lifelong treatment. These moments benefited people living with HIV in understanding and accepting their illness, which in turn reduced internalized perceived stigma and improved medication adherence [21, 29]. Although early ART initiation as recommended under DSDM reduces time to viral load suppression, absence of extended periods of counselling may explain higher risk of having LLV among people living with HIV who initiated treatment during DSDM compared to the period prior to the introduction of DSDM. HIV programs should consider continuing with extended periods of counselling, particularly during the first 3–6 months of ART initiation, educating

Table 2 Factors associated with low-level viremia at 6, 12 and 18 months among people living with HIV in Rwanda: Bivariate analysis

Characteristics	Complete case analysis						Imputed datasets					
	6-months		12-months		18-months		6-months		12-months		18-months	
	RR (95% CI)	*p*-value	RR (95% CI)	*p*-value	RR (95% CI)	*p*-value	RR (95% CI)	*p*-value	RR (95% CI)	*p*-value	RR (95% CI)	*p*-value
Received DSMD												
No	1.0		1.0		1.0		1.0		1.0		1.0	
Yes	**2.0(1.06,3.83)**	**0.031**	1.5(0.80,2.73)	0.210	0.8(0.35,1.84)	0.612	**2.0(1.07,3.84)**	**0.031**	1.5(0.80,2.73)	0.210	0.8(0.35,1.84)	0.612
Age												
18–24	1.0		1.0				1.0		1.0		1.0	
25–34	0.7(0.21,2.69)	0.652	1.2(0.12,10.8)	0.897	–	–	0.7(0.20,2.69)	0.652	2.4(0.29,19.9)	0.416	1.9(0.39,9.81)	0.433
35–44	0.9(0.27,3.19)	0.902	1.3(0.14,11.8)	0.823	–	–	0.9(0.27,3.19)	0.902	2.6(0.32,21.6)	0.363	1.2(0.22,6.57)	0.840
45–54	0.6(0.12,2.66)	0.467	1.3(0.13,12.7)	0.833	–	–	0.6(0.11,2.66)	0.467	2.6(0.30,23.0)	0.381	0.8(0.08,8.16)	0.841
≥55	0.7(0.15,3.36)	0.670	0.6(0.03,10.8)	0.729	–	–	0.7(0.15,3.36)	0.670	–		–	–
Sex												
Female	1.0						1.0		1.0		1.0	
Male	**1.8(1.06,2.95)**	**0.030**	1.1(0.61,1.96)	0.769	1.5(0.68,3.40)	0.298	**1.7(1.03,2.84)**	**0.039**	1.1(0.61,1.96)	0.762	1.5(0.70,3.41)	0.293
Education												
No education	1.0				1.0		1.0		1.0		1.0	
Primary	1.0(0.61,1.75)	0.896	0.6(0.32,1.16)	0.135	0.7(0.30,1.65)	0.425	1.1(0.62,1.77)	0.848	0.5(0.29,1.05)	0.072	0.7(0.30,1.60)	0.391
Secondary	0.6(0.13,2.45)	0.446	0.4(0.05,2.55)	0.299	0.4(0.03,6.21)	0.509	0.6(0.13,2.48)	0.456	0.3(0.04,2.44)	0.269	0.4(0.02,6.20)	0.502
Tertiary							–	–	–	–	–	–
HIV status disclosed												
No	1.0		1.0		1.0		1.0		1.0		1.0	
Yes	0.9(0.55,1.54)	0.739	1.2(0.68,2.29)	0.476	1.0(0.44,2.33)	0.967	0.9(0.55,1.56)	0.781	1.3(0.68,2.32)	0.454	1.0(0.45,2.37)	0.933
Adherence												
< 90%	1.0		1.0		1.0		1.0		1.0		1.0	
≥ 90%	0.8(0.44,1.43)	0.444	0.7(0.39,1.35)	0.310	2.3(0.32,11.1)	0.407	0.7(0.40,1.11)	0.124	0.7(0.42,1.31)	0.303	1.5(0.50,4.36)	0.473
Advance HIV disease												
No	1.0		1.0		1.0		1.0		1.0		1.0	
Yes	0.7(0.39,1.28)	0.250	0.7(0.36,1.32)	0.267	0.7(0.27,1.59)	0.350	0.7(0.45,1.28)	0.303	0.8(0.45,1.46)	0.491	0.9(0.38,2.09)	0.790

Abbreviations: LLV indicates low level viremia; DSD indicates differentiated service delivery model; aOR indicated adjusted odds ratio; CI indicates confidence intervals

Table 3 Factors associated with low-level viremia at 6, 12 and 18 months among people living with HIV in Rwanda: multivariable analysis

Characteristics	Complete case analysis						Imputed datasets					
	6-months		12-months		18-months		6-months		12-months		18-months	
	aRR (95% CI)	*p*-value	aRR (95% CI)	*p*-value	aRR (95% CI)	*p*-value	aRR (95% CI)	*p*-value	aRR (95% CI)	*p*-value	aRR (95% CI)	*p*-value
Received DSDM												
No	1		1.0		1.0		1		1		1	
Yes	**2.8(1.15,6.91)**	**0.024**	2.3(0.93,5.75)	0.071	0.3(0.09,1.20)	0.093	**2.1(1.11,4.12)**	**0.023**	1.5(0.77,3.03)	0.229	0.4(0.14,1.06)	0.063
Age												
18–24	1		1.0		1.0		1		1		1	
25–34	3.4(0.39,30.3)	0.269	0.8(0.20,2.95)	0.700	0.9(0.15,5.83)	0.955	5.4(0.05,633)	0.485	1.1(0.38,3.17)	0.862	2.7(0.43,16.8)	0.291
35–44	3.1(0.34,28.1)	0.318	1.0(0.28,3.91)	0.937	0.8(0.30,2.28)	0.709	3.8(0.03,435)	0.584	1.4(0.62,3.07)	0.428	1.6(0.37,6.52)	0.540
45–54	–		1.2(0.36,5.53)	0.714	–		3.4(0.03,420)	0.611	0.6(0.14,2.70)	0.519	0.2(0.00,19.2)	0.516
≥55	2.0(0.13,31.5)	0.620	–		–		5.1(0.04,653)	0.510	–	–	–	–
Sex												
Female	1.0		1.0		1.0		1		1		1	
Male	1.4(0.77,2.46)	0.274	1.4(0.66,2.90)	0.393	2.5(0.76,8.02)	0.134	**2.7(1.59,4.54)**	**0.002**	0.8(0.42,1.54)	0.516	**2.6(1.12,5.90)**	**0.026**
Education												
No education	1.0		1.0		1.0		1		1		1	
Primary	0.8(0.36,1.92)	0.675	0.6(0.26,1.26)	0.163	0.6(0.21,1.85)	0.399	1.6(0.95,2.73)	0.073	0.6(0.33,1.08)	0.089	0.8(0.31,2.18)	0.692
Secondary	0.9(0.08,2.40)	0.350	0.6(0.15,2.64)	0.529	–		0.4(0.03,4.16)	0.425	0.3(0.04,2.23)	0.244	–	
Tertiary	–		–				–		–		–	
HIV status disclosed												
No	1.0		1.0		1.0		1		1		1	
Yes	0.9(0.49,1.62)	0.718	1.3(0.61,2.58)	0.530	2.6(0.35,18.7)	0.354	0.7(0.47,1.17)	0.200	1.5(0.78,2.99)	0.218	1.2(0.39,3.87)	0.730
Adherence												
< 90%	1.0		1.0		1.0		1		1		1	
≥ 90%	0.6(0.31,1.18)	0.140	0.8(0.40,1.83)	0.700	1.9(0.54,18.6)	0.304	**0.4(0.25,0.74)**	**0.002**	0.7(0.42,1.28)	0.121	1.0(0.21,4.98)	0.972
Advance HIV disease												
No	1.0		1.0		1.0		1		1		1	
Yes	0.5(0.40,5.85)	0.521	2.0(0.37,11.1)	0.413	0.5(0.18,1.33)	0.161	0.6(0.35,1.02)	0.063	0.8(0.39,1.54)	0.472	0.8(0.34,2.05)	0.692

Abbreviations: LLV indicates low level viremia; DSD indicates differentiated service delivery model; aRR indicated adjusted risk ratio; CI indicates confidence intervals

people living with HIV on the importance of treatment and adherence.

We found that men had higher risk of having LLV at 6 and 18 months of follow-up compared to women. This finding is inconsistent with others who did not show differences in the risk of having LLV and gender [30, 31]. Although men are more likely to be affected by HIV stigma and, hence, low levels of drug adherence compared to women [32, 33], the prevalence of optimal adherence in this study for men and women was comparable, with 71% and 72% of men and women, respectively, having optimal adherence. Further data triangulation revealed that 50% of men and 45% of women initiated treatment after the introduction of DSDM. As previously described, those who initiated ART after the introduction of DSDM had higher risk of developing LLV; therefore, the association between gender and LLV could partly be explained by time of ART initiation in addition to gender. Studies have found low baseline CD4 count to be associated with higher risk of LLV [30, 34, 35]; however, we did not find a statistically significant difference in this association. The lack of association could be due to missing values with 16% of our study participants missing baseline CD4 count.

Limitations of this analysis include missing data on some of the important covariates, such as baseline CD4 count. For example, among clients who initiated treatment before DSDM who had viral load results at 6-months, 95% and 59% had viral load results at 12 and 18 months compared to 90% and 55% for those who initiated treatment after DSDM. The missingness of data could be differential between the two groups. Despite the presence of missing data, our results from complete case analysis and imputed datasets consistently showed that initiation of ART during DSDM of care was associated with increased risk of developing LLV at 6 months. Understanding the deficiencies of self-reported adherence and we did not consistently show the association between optimal adherence and LLV.

Conclusion

Although viral load suppression was high in this cohort, DSDM was associated with increased risk of LLV at 6 month of follow up, possibly due to the minimal amount of time people living with HIV had in pondering and accepting the HIV diagnosis as well as the lack of knowledge on the importance of adherence, which was usually reiterated multiple times during extended periods of counselling. A patient-centered interventional approach is needed for newly diagnosed people living with HIV who have difficulties adhering to their treatment to achieve the 95-95-95 goals and reach the target of ending the HIV epidemic. In this era of immediate ART initiation following HIV diagnosis, continued support is paramount to prevent development of LLV which is known to negatively impact virologic suppression. We thefore further recommend counseling sessions that used to be provided prior to the introduction of DSDM to simultaneously be continued as clients initiate treatment. Furthermore, monthly intensive check in to understand any barriers of treatment adherence during the first 6 months of ART initiations will be critical. Barrier analysis has shown to improve retention in care among people living with HIV [36].

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Author contributions
J.S. formulated the research question, provided general oversight of this work, authored the first draft of the manuscript. H.O.R., conducted data analysis, interpreted results. M.S.M. and Z.A. M. oversaw data collection process, interpreted results, reviewed several versions of the manuscripts. T.L., P.M. and S.T., contributed to the interpretation of results, cross checked primary data analysis and reviewed several versions of the manuscripts. G.R. contributed to study design, assisted in the interpretation of results, and provided general oversight of this work. All authors reviewed this manuscript.

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Data availability
Access to study data is limited to study team members as per human research ethics committee approval.

Declarations

Competing interests
The authors declare no competing interests.

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