# Same-day ART initiation as a predictor of loss to follow-up and viral suppression among people living with HIV in sub-Saharan Africa

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# 1 ABSTRACT

# 2 Background

3 Treat-All guidelines recommend initiation of antiretroviral therapy (ART) for all people living

4 with HIV (PLHIV) on the day of diagnosis when possible, yet uncertainty exists about the

5 impact of same-day ART initiation on subsequent care engagement. We examined the

6 association of same-day ART initiation with loss to follow-up and viral suppression among

7 patients in 11 sub-Saharan African countries.

### 8 Methods

9 We included ART-naïve adult PLHIV from sites participating in the International epidemiology

10 Databases to Evaluate AIDS consortium (IeDEA) who enrolled in care after Treat-All

11 implementation and prior to January 2019. We used multivariable Cox regression to estimate the

12 association between same-day ART initiation and loss to follow-up, and Poisson regression to

13 estimate the association between same-day ART initiation and 6-month viral suppression.

## 14 **Results**

Among 29,017 patients from 63 sites, 18,584 (64.0%) initiated ART on the day of enrollment.
Same-day ART initiation was less likely among those with advanced HIV disease versus earlystage disease. Loss to follow-up was significantly lower among those initiating ART ≥1 day of
enrollment, compared with same-day ART initiators (20.6% vs 27.7%; adjusted hazard ratio
0.66, 95% CI 0.57-0.76). No difference in viral suppression was observed by time to ART
initiation (adjusted rate ratio 1.00, 95% CI 0.98-1.02).

# 21 Conclusions

Patients initiating ART on the day of enrollment were more frequently lost to follow-up thanthose initiating later but were equally likely to be virally suppressed. Our findings support recent

WHO recommendations for providing tailored counseling and support to patients who accept an
 offer of same-day ART.
 Keywords: antiretroviral therapy, Treat-All, sub-Saharan Africa, loss to follow-up

## **1 INTRODUCTION**

Initiation of antiretroviral therapy (ART) soon after HIV diagnosis improves clinical outcomes
for people living with HIV (PLHIV) and reduces HIV transmission [1–3]. Accordingly, the
World Health Organization (WHO) 2015 "Treat-All" guidelines recommend rapid ART
initiation ART for all PLHIV as soon as possible after diagnosis, ideally within 7 days, and on
the same day when possible [4].

7

While nearly all countries have adopted Treat-All guidelines [5], uncertainty exists about the 8 impact of same-day ART (SDA) initiation on subsequent engagement in care including care 9 retention and viral suppression. Randomized controlled trials of SDA have demonstrated 10 outcomes that are as good as, or better than, later ART initiation among PLHIV [6–8], findings 11 replicated in a recent, large regression discontinuity analysis of routine clinical data in Zambia 12 [9]. However, several observational studies examining outcomes after Treat-All implementation 13 have found that SDA is associated with higher rates of loss to care [10–12]. Accordingly, 14 recently updated WHO guidelines now emphasize that an offer of SDA should include 15 approaches to improve uptake, treatment adherence and retention [13]. 16

17

Sub-Saharan Africa (SSA), where Treat-All implementation occurred later than other global regions, continues to be disproportionately impacted by HIV [14]. While virtually all countries in SSA have adopted Treat-All policies, investigations of SDA in this region have been limited to single-country studies, with most studying relatively small cohorts [10–12,15–18], and few reporting on viral suppression [8,17,18]. A more generalizable understanding of whether SDA has impacted clinical outcomes for patients in SSA is critical for reaching regional goals for epidemic control. We therefore examined the association between SDA and both loss to followup (LTFU) and viral suppression among patients enrolled in HIV care at clinics participating in
the global International epidemiologic Databases to Evaluate AIDS (IeDEA) consortium in 11
African countries.

5

# 6 METHODS

7

# 8 Data sources and management

9 We used data from HIV programs in SSA that participate in the global IeDEA consortium.

10 IeDEA pools clinical data on approximately 2.2 million PLWH enrolling in HIV care since 2004

in 44 countries globally, including 240 care and treatment sites in 23 countries in SSA [19,20].

12 Comprising public and private primary, secondary and tertiary-level health facilities, IeDEA is a

13 purely observational cohort reflecting real-world service delivery across diverse settings.

14

Prior to analysis, data from IeDEA regions were standardized in accordance with IeDEA data definitions and formatting standards [21]. Data were de-identified before extraction into regional databases and approved for use by local research ethics committees in each IeDEA region as well as the institutional review boards of regional data management centers.

19

# 20 Inclusion and exclusion criteria

All patients who enrolled in HIV care at an IeDEA site after the Treat-All adoption date in each country and before January 2019 were eligible for inclusion (N=241,723). We excluded patients who: 1) were in care at sites that did not provide pre-ART care (i.e., only served patients already

1	initiated on ART) or that did not consistently report data on pre-ART care (N=107,245); 2)
2	enrolled in care before national adoption of Treat-All (N=97,801); 3) were ART experienced at
3	enrollment (3,324); 4) had <12 months of potential follow-up time between enrollment and
4	database close (N=2,030); 5) were <15 years of age at enrollment (N=1,286); or 6) never
5	initiated ART (N=946) (Supplemental Figure 1). We excluded 74 patients with missing or
6	illogical data related to sex or dates of birth or death (e.g., recorded date of death that preceded
7	the date of HIV care enrollment).
8	

Countries where WHO's Treat-All recommendation was not officially reflected in national 9 guidelines by December 2018 were excluded. As noted above, HIV programs were excluded if 10 they did not provide any pre-ART care to patients or did not consistently report pre-ART data. 11 To identify such clinics, we examined the proportion of patients whose date of ART initiation 12 matched their date of enrollment in the two years prior to national Treat-All adoption, when 13 CD4-based or other clinical criteria were used to determine ART eligibility. Clinics in which 14 ≥75% of patients had matching enrollment and ART initiation dates in the pre-Treat-All period 15 were considered not to report data on patients' pre-ART care and therefore excluded. 16

17

18 Measures

The primary exposure was time from care enrollment to initiation of a combined ART regimen. Because the large majority (84%) of patients initiating ART within 1 week did so on the day of enrollment, we classified timing of ART initiation as *same-day ART* (i.e., initiation of ART on the same day as enrollment) versus  $\geq 1$  day after enrollment. The primary outcome of interest was *loss to follow-up*, defined as no contact with the health center for >180 days among patients not

1	known to have died or transferred to another facility [22]. We also examined viral suppression
2	at 6 months after ART initiation, defined as <1000 copies/mL, among patients with available
3	viral load (VL) test data from assays performed between 4 and 8 months after ART initiation.
4	
5	Additional enrollment characteristics included age, sex, body mass index (BMI; classified as
6	<18.5 kg/m2, ≥18.5, unknown/missing), WHO stage (I or II, III or IV, unknown/missing), AIDS
7	diagnosis at enrollment, and CD4 count in cells/mm <sup>3</sup> (<200, 200-349, 350-499, ≥500,
8	unknown/missing). Data were used if recorded within 90 days of enrollment; for patients with
9	more than one measure within 90 days, the observation closest to enrollment date was used. We
10	restricted CD4 measures to those within 30 days after ART initiation, given that CD4 counts
11	rebound rapidly after ART initiation [23]. Because of high levels of missingness in CD4 and
12	WHO staging data, we created a composite measure of advanced HIV disease at enrollment,
13	based on either CD4 cell counts <200 cells/ $\mu$ L or WHO stage 3 or 4.
14	
15	Site characteristics (e.g., urban vs. rural location, facility type) were extracted from IeDEA
16	databases. Information on HIV spending per prevalent case in 2017 was compiled from the
17	Institute for Health Metrics and Evaluation's Global Burden of Disease databases [24].
18	
19	Statistical analysis
20	All analyses were performed using SAS v9.4 (Cary, NC). We used descriptive statistics to
21	summarize patient characteristics; chi-squared tests were used to assess differences in categorical

variables, with Kruskal-Wallis tests used to assess differences in medians.

For time-to-event analyses, follow-up time was calculated in days from ART initiation to the last
clinic contact (among those who were known to have died or transferred or were lost to clinic),
or was censored at 365 days after ART initiation if none of those outcomes occurred. For all
patients, one day of follow-up time was added to avoid the occurrence of zero follow-up time
among patients who did not return to the clinic after the date of enrolling in care.

6

We used bivariate and multivariable Poisson regression models to estimate crude and adjusted 7 relative risks of SDA and viral suppression. We used bivariate and multivariable Cox 8 proportional hazards regression models with sandwich variance estimators to estimate hazards of 9 LTFU within 12 months of enrollment. Because over half of the sample was missing VL data, 10 we also used Poisson regression models to examine unadjusted and adjusted associations 11 between predictor variables and VL missingness. Multivariable models adjusted for sex, age 12 group, BMI, disease stage, facility location, health facility level, HIV spending per prevalent 13 case in 2017; we did not include pregnancy status in models because of concern that pregnancy 14 was substantially underreported. All models accounted for site-level clustering using generalized 15 estimating equations (GEE). 16

17

# 18 Sensitivity analyses

We conducted several sensitivity analyses to test the robustness of our findings on the
association of SDA with LTFU and viral suppression. First, to assess heterogeneity among those
initiating ART after the day of enrollment, we used a four-level variable for the timing of ART
initiation: same-day, 1-7, 8-30 and >30 days. Second, to better understand the impact of missing
clinical data (disease stage, BMI) at enrollment, we restricted models to patients with complete

1 data for these variables. Third, a substantial number of patients had no follow-up data after the enrollment visit (i.e. single contact with the site), with no way to determine whether this was 2 secondary to true LTFU, data error (e.g. undocumented transfer), or sites that operate on a hub-3 and-spoke model, transferring patients to peripheral clinics after ART initiation [25]. Therefore, 4 we calculated the proportion of patients with a single contact at each site and excluded sites 5 where >10% of patients never returned after the enrollment visit. Fourth, to address potential 6 selection bias created by excluding patients who never initiated ART, we examined LTFU using 7 models that included this group. For this sensitivity analysis, we categorized non-initiators 8 together with those initiating ART  $\geq 1$  day after enrollment, with follow-up time starting at 9 enrollment rather than ART initiation for patients never initiating treatment. Finally, given 10 updated WHO guidelines defining viral suppression as <50 copies/mL [13], we repeated 11 analyses for this outcome using this lower threshold 12 13

14 **RESULTS** 

In total 29,017 patients were included (Supplemental Figure 1); among them, 17,610 (60.7%) 15 were female and median age was 35 years (interquartile range 28-43) (Table 1). Most patients 16 (90%) were from IeDEA cohorts in East Africa (Kenya, Tanzania, Uganda) and Central Africa 17 (Burundi, Cameroon, Democratic Republic of Congo, Republic of Congo, Rwanda); the 18 remainder were from West Africa (Cote d'Ivoire, Senegal) and South Africa. At enrollment, 19 20 21,458 (74.0%) were missing CD4 count and 11,742 (40.5%) were missing WHO stage. Among 18,836 (64.9%) with available data on either CD4 count or WHO stage, 6,195 (32.9%) were 21 22 classified as having advanced disease at enrollment. The majority received care from district

hospitals (7,983, 27.5%) or regional, provincial or university hospitals (12,355, 42.6%), located
 in urban or mostly urban areas (21,586, 74.4%).

3

# 4 *Time to ART initiation*

- 5 Among all ART patients, median time to ART initiation was 0 days (95% CI 0,0). Overall,
- 6 18,584 (64.0%) initiated ART on the same day, 3,432 (11.8%) between 1-7 days, 4,409 (15.2%)
- 7 between 8 and 30 days, and 2,592 (8.9%) >30 days after enrollment. SDA was less likely among
- 8 those with advanced versus early-stage disease (adjusted risk ratio [aRR] 0.83, 95% CI 0.72-

9 0.95) (Table 2). SDA was more likely at rural/mostly rural sites (vs. urban/mostly urban: aRR

10 1.40, 95% CI 1.11-1.75).

11

# 12 Loss to follow-up

During the 12 months after enrollment, 1,941 patients (6.7%) had documented transfers and 13 1,111 (3.8%) died. A total of 7,293 (25.1%) were LTFU, with a median time to LTFU of 29 14 days (95% CI 28, 31). Among SDA initiators, 27.7% were lost to clinic (including 11.5% who 15 never returned after the enrollment visit) compared with 20.6% of those initiating  $\geq 1$  day after 16 enrollment. In the adjusted model, hazard of LTFU within 12 months was 34% lower among 17 those initiating ART  $\geq 1$  day of enrollment, compared with SDA initiators (aRR 0.66, 95% CI 18 0.57-0.76) (Table 3, Supplemental Figure 2). Hazard of LTFU was higher among men versus 19 20 women, younger (15-19, 20-24 and 25-34 years) versus older (>34 years) patients, patients at district hospitals versus health centers, and in countries in the 1st (vs 2nd and 3rd) tertile of per-21 22 capita HIV spending.

In a sensitivity analysis using a four-level variable for time to ART initiation, compared with
SDA initiators, hazard of LTFU decreased monotonically with increased time to initiation, from
0.77 (95% CI: 0.65-0.92) among those initiating ART at 1 to 7 days after enrollment to 0.59
(95% CI: 0.49-0.70) among those initiating ART >30 days after enrollment (Supplemental
Table 2, Supplemental Figure 2). We observed results similar to our main analysis in
additional sensitivity analyses examining LTFU (Supplemental Table 1).

7

# 8 Viral suppression

Among 28,894 patients with  $\geq$ 8 months (244 days) of potential follow-up time after ART 9 initiation or any VL testing between 4-8 months after ART initiation, 11,898 (41.2%) had a VL 10 measured between 4-8 months after ART initiation. VL was more likely to be missing among 11 SDA initiators, men, younger patients, and those with advanced disease at enrollment 12 (Supplemental Table 3). Among those with VL data, 10,487 (88.1%) were virally suppressed. 13 Among patients with a measured VL, no difference in rate of suppression was observed among 14 SDA initiators versus those initiating  $\geq 1$  day after enrollment (aRR 1.00, 95% CI 0.98-1.02) 15 (Table 4). Suppression was less likely among patients with BMI <18.5 (vs  $\ge$ 18.5) kg/m<sup>2</sup> and 16 those with advanced disease at enrollment compared with patients without advanced disease. 17 Results from sensitivity analyses were similar (Supplemental Tables 2 and 4). 18

19

# 20 DISCUSSION

In this analysis of routine clinical data from diverse HIV service delivery settings in 11 African
countries, most patients initiated ART quickly after enrollment, with nearly two-thirds initiating
on the same day. A substantially higher proportion of these patients were lost to follow-up

1 compared with those who initiated ART later-results that were similar in sensitivity analyses. Notably, LTFU was not associated with advanced disease at care enrollment (including in 2 analyses stratified by time to ART initiation, not shown), suggesting that this factor is not a 3 primary driver of care engagement. Our results are consistent with findings from observational 4 5 studies in eSwatini, Ethiopia, and South Africa [10–12,17] reporting that SDA initiators were more likely to be lost to follow-up. While SDA may reduce logistical and structural challenges to 6 delivering care, prior research under Treat-All has identified patient-level barriers to rapid ART 7 initiation, including feeling overwhelmed by the diagnosis, fear of lifelong medication, and 8 feeling insufficiently engaged in care [26–28]. In this context, our findings support recent WHO 9 recommendations for providing tailored counseling and support to patients who accept an offer 10 11 of SDA [13].

12

It is possible that the higher LTFU among SDA initiators reflects undocumented transfers or 13 deaths immediately after initiation, as has been documented in prior tracing studies in SSA [29-14 31]. However, in sensitivity analyses excluding sites where high proportions of patients had only 15 one contact with the health center, the association between SDA and LTFU was not 16 substantively attenuated. Furthermore, it is unlikely that many SDA initiators died prior to 17 follow-up, given that this group was less likely to have advanced HIV at enrollment than patients 18 who initiated ART later. Our findings suggest a need for supplementary investigations such as 19 20 tracing studies and sampling-based approaches that augment routinely collected data to better ascertain outcomes and to understand reasons for disengaging from care. 21

1 We observed high rates of viral suppression among patients with available VL, with no differences by timing of ART initiation-results consistent with the very limited literature 2 3 published to date [8,17]. These results provide some reassurance that the timing of ART initiation (same-day versus later) likely does not negatively impact subsequent viral suppression 4 among those with a VL test. Our findings suggest that later initiation of ART is a reasonable 5 approach when patient or provider concerns arise, consistent with guidance from WHO [13]. 6 Notably, only 41% of patients had available VL data between 4 to 8 months after ART initiation, 7 despite longstanding WHO guidance recommending monitoring at 6 months [13, 32], suggesting 8 that gaps remain in reaching VL monitoring goals. Furthermore, observed differences in VL 9 availability by time to ART, age and disease stage, suggest that patterns of viral suppression may 10 differ among the entire cohort compared with those with available VL, and that patients less 11 likely to be engaged in care (e.g. SDA initiators) are potentially less likely to be virally 12 suppressed. 13

14

Several additional findings from this analysis are worth noting. The rapid time to LTFU (median 15 29 days) highlights the need for adequate support systems immediately after enrollment, a 16 particularly vulnerable time for newly-diagnosed PLHIV. Younger patients were as likely as 17 patients >24 years to initiate ART on the day of enrollment, but more likely to be lost to clinic. 18 HIV incidence is higher among adolescents and young adults than every other age group in SSA 19 20 [33]: they remain at high risk of poor outcomes, including potential for onward transmission of HIV given relatively higher rates of sexual activity [34, 35]. Our findings suggest that particular 21 22 care should be taken to ensure support systems are in place prior to offering SDA to younger

PLHIV. We also observed that patients with more advanced HIV were less likely to initiate ART
 immediately and less likely to be virally suppressed but did not experience higher rates of LTFU.

3

A key strength of this observational study is the use of data from a large number of patients 4 enrolled in HIV care across a diverse group of 63 sites in 11 African countries. Results from this 5 large, diverse sample are reflective of real-world implementation of WHO's recommendations 6 for ART initiation [4]. This study also has several limitations. Despite the size and diversity of 7 the sample, certain groups (e.g., pregnant women and patients at sites with limited data on pre-8 ART care) were likely underrepresented in the study, and our findings may not be fully 9 generalizable to these subgroups. Because of incomplete data on the date of HIV diagnoses, we 10 were not able to directly measure the impact of ART initiation on the day of diagnosis and could 11 only assess the timing of ART initiation relative to care enrollment. Additional studies are 12 needed to understand trajectories of linkage to care and very early care engagement in the Treat-13 All era, including prevalence and predictors of early transfers. We were not able to ascertain 14 definitively what proportion of those LTFU were truly lost from care. We were also unable to 15 measure other important factors that may influence decision-making on when to initiate ART 16 (e.g., type of ART counseling received, presence of medical conditions that may impact ART 17 timing, or patient or clinician assessments of readiness for ART. Finally, the substantial amount 18 of missing VL data may have introduced bias into the analysis of viral suppression. 19

20

In sum, we observed high levels of same-day ART initiation among patients across diverse HIV
care programs in various countries in SSA, suggesting that WHO's recommendations for rapid
ART initiation for patients newly enrolling in HIV care have been widely adopted and scaled up.

Nonetheless, patients initiating ART on the day of enrollment were more likely to be LTFU than
those initiating later. Our findings suggest that careful consideration of patient and programmatic
factors is necessary to optimize timing of ART as programs increasingly move towards rapid
initiation of treatment for all PLHIV.

6 7 8 **NOTES** 

9

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# 1 TABLE 1. Baseline characteristics and clinical outcomes among ART-naïve patients who enrolled in care

2 and initiated ART at an IeDEA site in sub-Saharan Africa after Treat-All implementation.

			Time to AF	RT initiation	
		Median time to	Same day	Not same day	
Variables	Ν	in days (IOR)	n (%)	n (%)	P value
Total	29017	0 (0-7)	18584 (64.0)	10433 (36)	
CHARACTERISTICS		~ /			
<u>Patient-level</u>					
Sex					< 0.0001
Female	17610 (60.7)	0 (0-7)	11492 (61.8)	6118 (58.6)	
Male	11407 (39.3)	0 (0-8)	7092 (38.2)	4315 (41.4)	
Age					
Median age in years (IQR)	35 (28, 43)	-	35 (28, 43)	36 (29, 44)	< 0.0001
15-19	723 (2.5)	0 (0-12)	451 (2.4)	272 (2.6)	< 0.0001
20-24	3331 (11.5)	0 (0-6)	2253 (12.1)	1078 (10.3)	
25-34	9442 (32.5)	0 (0-7)	6178 (33.2)	3264 (31.3)	
>34	15521 (53.5)	0 (0-7)	9702 (52.2)	5819 (55.8)	0.0001
Pregnant at enrollment (among females)	7922 (44.4)		5652 (40.0)	0170 (05 5)	<0.0001
Not pregnant	7823 (44.4)	0 (0-2)	5653 (49.2)	2170 (35.5)	
Pregnant	942 (5.4)	0 (0-15)	619 (5.4)	323 (5.3)	
Unknown status	8845 (50.2)	0 (0-9)	5220 (45.4)	3625 (59.3)	-0.0001
BMI at enrollment (kg/m <sup>-</sup> )	17(0)(1(1))	0 (0,7)	207((100))	1(02(102))	<0.0001
<18.5	4/69 (16.4)	0(0-7)	30/6 (16.6)	1693 (16.2)	
≥18.5	18804 (64.8)	0(0-5)	12633 (68.0)	6171 (59.1)	
	5444 (18.8)	0 (0-21)	28/5 (15.5)	2569 (24.6)	-0.0001
who Stage at enrollment	9591 (20 ()		5712 (20.7)	20(0,07,5)	<0.0001
l u	8581 (29.6)	0(0-4)	5/13(30.7)	2868 (27.5)	
	4513 (15.6)	0(0-1)	3307 (17.8)	1206 (11.6)	
	3144 (10.8)	0(0-8)	1838 (9.9)	1306 (12.5)	
IV Missing	1037 (3.0)	2(0-14)	4/1(2.5)	300(3.4)	
CD4  sound at annullment (colle/mm3)	11742 (40.3)	0 (0-13)	1255 (59.0)	4467 (43)	<0.0001
<pre>CD4 count at enronment (cens/min ) &lt;200</pre>	2401 (8.6)	0(0,0)	1280 (6.0)	1202 (11.5)	<0.0001
200-349	1632(5.6)	0(0-3) 0(0-7)	906(4.9)	726(7.0)	
350-499	1372(4.7)	0(0-7)	796 (4.3)	576 (5.5)	
>500	2064(7.1)	0(0-7)	1225 (6.6)	970 (9.9) 830 (8.0)	
2500 Missing	2004(7.1)	0(0-7)	1223(0.0) 14368(77.3)	7000 (68)	
AIDS diagnosis at enrollment	21438 (74.0)	0 (0-7)	14308 (77.3)	7090 (08)	<0.0001
No AIDS diagnosis	13249 (45 7)	0(0-3)	9058 (48.7)	4191 (40.2)	<0.0001
AIDS diagnosis	4695 (16 2)	0(0-14)	2543 (13.7)	2152 (20.6)	
Missing/unknown	11073 (38.2)	0(0-12)	6983 (37 6)	4090 (39.2)	
Disease stage at enrollment*	110/0 (00.2)	0 (0 12)	0,00 (0,110)		< 0.0001
Non-advanced disease	12641 (43.6)	0(0-4)	8668 (46.6)	3973 (38.1)	
Advanced disease	6195 (21.4)	0 (0-12)	3330 (17.9)	2865 (27.5)	
Missing/unknown	10181 (35.1)	0 (0-11)	6586 (35.4)	3595 (34.5)	
Clinic- and country-level					
Urban/rural					< 0.0001
Urban/Mostly urban	21586 (74.4)	0 (0-10)	12643 (68.0)	8943 (85.7)	
Rural/Mostly rural	7431 (25.6)	0 (0-0)	5941 (32.0)	1490 (14.3)	
Level of facility	- ()	- ( /	()	- (- ····)	< 0.0001
Health center	8679 (29.9)	0 (0-6)	5467 (29.4)	3212 (30.8)	
District hospital	7983 (27.5)	0 (0-1)	5932 (31.9)	2051 (19.7)	
Regional, provincial or university hospital	12355 (42.6)	0 (0-9)	7185 (38.7)	5170 (49.6)	
HIV spending per prevalent case in 2017			()	× /	< 0.0001
1st tertile (\$218 - \$284)	3550 (12.2)	0 (0-3)	2146 (11.5)	1404 (13.5)	

			Time to ART initiation		
		Median time to ART initiation	Same day	Not same day	
Variables	Ν	in days (IQR)	n (%)	n (%)	P value
2nd tertile (\$285 - \$362) 3rd tertile (\$363 - \$611)	6875 (23.7) 18592 (64.1)	0 (0-14) 0 (0-5)	3603 (19.4) 12835 (69.1)	3272 (31.4) 5757 (55.2)	
				RIP	
			2~		

			Time to AR	T initiation	
Variables	N	Median time to ART initiation in days (IOR)	Same day n (%)	Not same day n (%)	P value
OUTCOMES AFTER ART	14	in uuys (IQK)			1 value
INITIATION					
Transfer within 12 months of					0.0003
Did not transfer	27076 (93.3)	0 (0-7)	17414 (93.7)	9662 (92.6)	
Transferred out	1941 (6.7)	0 (0-8)	1170 (6.3)	771 (7.4)	6
Death within 12 months					0.505
Did not die	27906 (96.2)	0 (0-7)	17862 (96.1)	10044 (96.3)	
Died	1111 (3.8)	0 (0-8)	722 (3.9)	389 (3.7)	/
Lost to follow-up within 12 months					< 0.0001
Not lost	21724 (74.9)	0 (0-8)	13437 (72.3)	8287 (79.4)	
Lost	7293 (25.1)	0 (0-2)	5147 (27.7)	2146 (20.6)	
Viral suppression at 6 months					< 0.0001
Not suppressed (≥1000 copies)	1802 (6.2)	0 (0-8)	1094 (5.9)	708 (6.8)	
Suppressed (<1000 copies)	12575 (43.3)	0 (0-8)	7768 (41.8)	4807 (46.1)	
No measured VL	14640 (50.5)	0 (0-7)	9722 (52.3)	4918 (47.1)	

ART: antiretroviral therapy; IQR: interquartile range; BMI: body mass index \*Advanced disease at care entry: WHO stage 3 or 4 or CD4 at enrollment < 200, or AIDS diagnosis at enrollment

1	TABLE 2. Factors	associated with	same-day ART	'initiation among	all included	patients.
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Variables		Ν	n (%)	RR (95% CI)*	aRR (95% CI)*^
T	otal	29017	18584 (64.0)		
<u>Patient-level</u>					
Sex					
М		11407	7092 (62.2)	0.95 (0.91-1.00)	0.97 (0.92-1.02)
F (ref)		17610	11492 (65.3)	1	1
Age					
15-19 (ref)		723	451 (62.4)	1.00 (0.91 - 1.09)	1.00 (0.90 - 1.10)
20-24		3331	2253 (67.6)	1.08 (1.00 - 1.17)	1.05 (0.98 - 1.13)
25-34		9442	6178 (65.4)	1.05 (0.99 - 1.11)	1.03 (0.98 - 1.08)
>34		15521	9702 (62.5)	1	1
BMI at enrollment					
<18.5 (ref)		4769	3076 (64.5)	1	1
≥18.5		18804	12633 (67.2)	1.04 (0.97-1.12)	1.05 (1.02-1.09)
Unknown/missing		5444	2875 (52.8)	0.82 (0.73-0.91)	0.88 (0.79-0.99)
Disease at enrollment					
Non-advanced disease (ref)		12641	8668 (68.6)	1	1
Advanced disease		6195	3330 (53.8)	0.78 (0.68-0.90)	0.83 (0.72-0.95)
Unknown/missing		10181	6586 (64.7)	0.94 (0.75-1.18)	0.95 (0.79-1.13)
Clinic and country layer					
<u>Clinic- and country-level</u> Urban/rural					
Urban/mostly urban (ref)		21586	12643 (58.6)	1	1
Rural/Mostly rural		7431	5941 (79.9)	1 37 (1 14.1 64)	1 40 (1 11.1 75)
Level of facility		/ 131	5511 (15.5)	1.57 (1.14-1.04)	1.40 (1.11-1.75)
Health center (ref)		8679	5467 (63.0)	1	1
District hospital		7983	5932 (74.3)	1.18 (0.96-1.45)	1.12 (0.92-1.36)
Regional, provincial or university hospital	/	12355	7185 (58.2)	0.92 (0.66-1.29)	1.09 (0.82-1.45)
HIV spending per prevalent case in 2017				(,	(,
1st tertile (\$218 - \$284) (ref)		3550	2146 (60.5)	1	1
2nd tertile (\$285 - \$362)		6875	3603 (52.4)	0.87 (0.50-1.51)	0.76 (0.46-1.28)
3rd tertile (\$363 - \$611)	$\checkmark$	18592	12835 (69.0)	1.14 (0.94-1.38)	1.03 (0.77-1.37)

3 ART: antiretroviral therapy; IQR: interquartile range; BMI: body mass index; RR: rate ratio; CI: confidence interval 4

\* Rate ratios estimated via Poisson regression, accounting for clustering within health center. Models include patients with missing data related to BMI and HIV disease stage at time of enrollment in HIV care.

^ Adjusted for sex, age group, BMI at enrollment, disease stage at enrollment, urban vs. rural facility location, health facility level, HIV spending per prevalent case in 2017.

# 1 TABLE 3. Factors associated with loss to follow-up (LTFU) within 12 months after ART initiation.

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	NT	LTFU within	Median time to		
Variables	N	12  months	LIFU Days	HR (95% CI)*	анк (95% CI)**
variables Total	20017	$\frac{11(\%)}{7203(25.1)}$	$\frac{(IQK)}{20(1.153)}$		
Patient lavel	29017	7293 (23.1)	29 (1-133)		
Same-day ABT initiation					
Initiated $\geq 1$ day after enrollment	10/33	2146 (20.6)	56 (1-183)	0 71 (0 50-0 84)	0.66 (0.57-0.76)
Initiated on same day as enrollment (ref)	1858/	5147(27.7)	19 (1-136)	1	1
Sov	1050-	5147 (27.7)	17 (1-150)	1	
M	11407	2830 (24.8)	29(1-148)	0.98 (0.91-1.07)	1 09 (1 03-1 15)
F (ref)	17610	4463 (25.3)	30(1-155)	1	1.05 (1.05-1.15)
Ασε	17010	1103 (23.3)	50 (1 155)	·	
15-19	723	244 (337)	16 (1-122)	1.67 (1.37-2.04)	1.80 (1.49-2.17)
20-24	3331	1098 (33.0)	43 (1-161)	1.58 (1.40-1.79)	1.73 (1.58-1.89)
25-34	9442	2546 (27.0)	30 (1-155)	1.26 (1.16-1.36)	1.32 (1.23-1.42)
>34 (ref)	15521	3405 (21.9)	26 (1-151)	1	1
BMI at enrollment					
<18.5 (ref)	4769	1092 (22.9)	40 (1-149)	1	1
≥18.5	18804	4326 (23.0)	34 (1-165)	0.97 (0.87-1.09)	0.93 (0.84-1.03)
Unknown/missing	5444	1875 (34.4)	9 (1-125)	1.61 (1.21-2.14)	1.68 (1.31-2.17)
Disease at enrollment		× ,		. , ,	
Non-advanced disease (ref)	12641	3027 (23.9)	33 (1-159)	1	1
Advanced disease	6195	1529 (24.7)	22 (1-139)	1.06 (0.90-1.26)	1.10 (0.94-1.27)
Unknown/missing	10181	2737 (26.9)	29 (1-149)	1.16 (0.90-1.50)	1.09 (0.90-1.31)
			7		
Clinic- and country-level					
Urban/rural					
Urban/mostly urban (ref)	21586	5612 (26.0)	24 (1-147.5)	1	1
Rural/Mostly rural	7431	1681 (22.6)	44 (1-165)	0.86 (0.63-1.16)	0.86 (0.67-1.12)
Level of facility		*			
Health center (ref)	8679	1925 (22.2)	73 (1-186)	1	1
District hospital	7983	2258 (28.3)	37 (1-144)	1.32 (0.93-1.88)	1.45 (1.11-1.91)
Regional, provincial or university hospital	12355	3110 (25.2)	3 (1-120)	1.17 (0.78-1.77)	1.01 (0.59-1.72)
HIV spending per prevalent case in 2017					
1st tertile (\$218 - \$284) (ref)	3550	1312 (37.0)	1 (1-57)	1	1
2nd tertile (\$285 - \$362)	6875	1468 (21.4)	58 (1-166)	0.55 (0.35-0.85)	0.53 (0.38-0.73)
3rd tertile (\$363 - \$611)	18592	4513 (24.3)	40 (1-162)	0.62 (0.51-0.75)	0.50 (0.30-0.84)

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ART: antiretroviral therapy; IQR: interquartile range; BMI: body mass index; HR: hazard ratio; CI: confidence interval

\* Hazard ratios estimated via Cox proportional hazards regression, accounting for clustering within site/center. Models include patients unknown BMI and HIV disease stage at time of enrollment in HIV care.

<sup>^</sup> Adjusted for sex, age group, BMI at enrollment, disease stage at enrollment, urban vs. rural facility location, health facility level, HIV spending per prevalent case in 2017.

#### TABLE 4. Viral load monitoring among patients initiating ART, and factors associated with viral 1

suppression among patients with a viral load measured between 4 to 8 months after ART initiation.<sup>#</sup>

2 3

Variables	N	Viral load measured n (%)	Viral load suppressed (among those measured) n (%)	RR (95% CI)*	aRR (95% CI)*^
Total	28894	11898 (41.2)	10487 (88.1)		
Patient-level					
Same-day ART initiation					
Initiated $\geq 1$ day after enrollment	10310	4322 (41.9)	3809 (88.1)	1.00 (0.97-1.03)	1.00 (0.98-1.02)
Initiated on same day as enrollment	18584	7576 (40.8)	6678 (88.1)		1
Sex					
Μ	11363	4563 (40.2)	3993 (87.5)	0.99 (0.97-1.01)	0.99 (0.98-1.01)
F (ref)	17531	7335 (41.8)	6494 (88.5)		1
Age					
15-19 (ref)	718	227 (31.6)	194 (85.5)	0.98 (0.94 - 1.02)	0.96 (0.92 - 1.01)
20-24	3321	1199 (36.1)	1079 (90.0)	1.03 (1.01 - 1.05)	1.01 (0.99 - 1.03)
25-34	9401	3792 (40.3)	3377 (89.1)	1.02 (1.00 - 1.04)	1.01 (0.99 - 1.03)
>34	15454	6680 (43.2)	5837 (87.4)		1
BMI at enrollment		~ /			
<18.5 (ref)	4761	2000 (42.0)	1679 (84)	1	1
≥18.5	18773	8484 (45.2)	7570 (89.2)	1.06 (1.04-1.08)	1.05 (1.03-1.07)
Unknown/missing	5360	1414 (26.4)	1238 (87.6)	1.04 (1.00-1.08)	1.03 (0.99-1.07)
Disease at enrollment				· · · · ·	· · · · · ·
Non-advanced disease (ref)	12613	5503 (43.6)	5023 (91.3)	1	1
Advanced disease	6179	2225 (36)	1941 (87.2)	0.96 (0.94-0.98)	0.96 (0.94-0.97)
Unknown/missing	10102	4170 (41.3)	3523 (84.5)	0.93 (0.90-0.95)	0.94 (0.91-0.96)
<i>Clinic- and country-level</i>					
Urban/rural					
Urban/mostly urban (ref)	21479	8532 (39.7)	7482 (87.7)	1	1
Rural/Mostly rural	7415	3366 (45.4)	3005 (89.3)	1.02 (0.97-1.07)	1.02 (1.00-1.04)
Level of facility			· · ·		
Health center (ref)	8632	3673 (42.6)	3258 (88.7)	1	1
District hospital	7958	3678 (46.2)	3115 (84.7)	0.95 (0.92-0.99)	0.97 (0.94-1.00)
Regional, provincial or university	10204	4547 (27 0)	4114 (00 5)	1.02(0.09, 1.06)	1.00(0.001.05)
hospital	12304	4547 (37.0)	4114 (90.5)	1.02 (0.98-1.06)	1.00 (0.96-1.05)
HIV spending per prevalent case in					
2017					
1st tertile (\$218 - \$284) (ref)	3536	827 (23.4)	756 (91.4)	1	1
2nd tertile (\$285 - \$362)	6817	2881 (42.3)	2635 (91.5)	1.00 (0.95-1.05)	1.00 (0.96-1.03)
2nd toutile (\$262 \$611)	185/11	8190 (11 2)	7096 (86 6)	0.95(0.92-0.97)	$0.96(0.92 \cdot 1.01)$

ART: antiretroviral therapy; BMI: body mass index; RR: rate ratio; CI: confidence interval

# Analyses restricted to patients with at least 244 days' potential follow-up time between ART initiation and database close or <244 days potential follow-up time and a viral load test between 120 and 244 days after ART initiation)

\*Rate ratios estimated via Poisson regression, accounting for clustering within site/center.

8 9 ^ Adjusted for sex, age group, BMI at enrollment, disease stage at enrollment, urban vs. rural facility location, health facility level,

HIV spending per prevalent case in 2017. 10

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