

# Human Immunodeficiency Virus Viral Load Monitoring and Rate of Virologic Suppression Among Patients Receiving Antiretroviral Therapy in Democratic Republic of the Congo, 2013–2020

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**Background.** Antiretroviral therapy (ART) expansion and viral load as a treatment monitoring approach have increased the demand for viral load testing. Many hurdles affect the coverage, quality, and use of viral load results. Estimates of viral load monitoring and viral suppression rates are needed to assess the performance of ART programs and improve human immunodeficiency virus (HIV) management outcomes.

**Methods.** People with HIV (PWH) viral load monitoring data were routinely collected in 84 health facilities in Kinshasa, Democratic Republic of the Congo (DRC), between 2013 and 2020. The number of PWH under ART, the number of participants with at least 1 viral load test result, the rate of viral suppression (defined as  $\leq 1000$  HIV ribonucleic acid copies per mL), and the mean turnaround time from sample collection to release of viral load test results were collected together with clinical data.

**Results.** A total of 14 057 PWH were included in the analysis. People with HIV were mainly enrolled after the “test and treat” implementation. The patients were followed for a median period of 27 months. The proportion of PWH with at least 1 available viral load largely increased in recent years. The delay from sample collection to release of viral load test results decreased overtime, from 35 days in 2018 to 16 days in 2020. Pregnancy and advanced HIV disease were associated with a lower chance of viral suppression.

**Conclusions.** There has been considerable success in increasing viral load access for all PWH under therapy in DRC. Nevertheless, viral load testing should be intensified with a particular effort to be made in groups at higher risk of viral failure.

**Keywords.** ART; monitoring; testing; viral load; virologic suppression.

The availability of antiretroviral therapy (ART) has dramatically improved the prognosis of human immunodeficiency virus (HIV) infection. It has also improved the quality and life expectancy of people with HIV (PWH) [1]. Antiretroviral therapy uptake is rapidly expanding in low- and middle-income countries (LMICS), notably in sub-Saharan Africa (SSA). Numerous studies suggested an improvement in health, economic productivity, and a change in the epidemic trajectory

after the scaling up of ART coverage as well as a positive impact on HIV incidence in the population with earlier initiation of ART [2, 3].

To improve access to ART and follow the World Health Organization (WHO) recommendations, the Democratic Republic of Congo (DRC) has adopted the “test and treat” (T&T) strategy since November 2016 [4, 5]. In addition, to improve treatment monitoring in LMICS, the WHO has recommended viral load (VL) testing as the preferred strategy for monitoring the effectiveness of ART, leading to progressive phasing out of baseline CD4 T-cell count testing [6, 7]. Indeed, VL monitoring allows early detection of treatment failure, before immunologic decline. One target of UNAIDS to end the HIV/acquired immune deficiency syndrome (AIDS) epidemic by 2030 is to achieve undetectable VL in 95% of all persons receiving ART. Viral suppression (VS) is not only associated with a decrease in HIV disease progression but also with the prevention of HIV transmission. Viral load measurement thus became a critical instrument to assess the impact

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of HIV treatment efforts, and it is now the primary methodology for monitoring response to ART [7, 8]. Most country guidelines called for VL testing at 6 and 12 months after ART initiation and then annually.

Both ART expansion and VL testing as a treatment monitoring approach have increased demand for VL testing. However, many hurdles have been identified affecting the coverage, quality, and use of results. These comprise correct sampling procedures, transporting samples to laboratories, guaranteeing tests are timely performed, and allowing rapid access to test results.

Estimates of VL monitoring and VS rates are needed to assess the performance of ART programs and improve HIV management outcomes. We performed the first multicentric longitudinal study assessing the impact of the “test and treat” strategy on VL monitoring and viral suppression rate in a very large population of PWH in Kinshasa, DRC.

## METHODS

### Study Design, Framework, and Periods

This is a historical cohort analysis using PWH monitoring data routinely collected in 84 health facilities in Kinshasa, mainly health centers that constitute the peripheral and operational level of the health system in the DRC, between January 1, 2013 and December 31, 2020. The duration of the study was divided into 2 periods—from 1 January 1, 2013 to October 31, 2016 and after November 1, 2016 to December 31, 2020—corresponding to the periods before and after the implementation of the T&T strategy.

### Participants and Viral Load Testing

All PWH over the age of 15 years who initiated first-line ART during the study period were included. Antiretroviral therapy should have been initiated between January 1, 2013 and December 31, 2019. Data were collected until December 31, 2020. Participants with a follow up shorter than 5 months were excluded. The Congolese national HIV program offers free ART using WHO-preferred antiretroviral regimens as well as VL monitoring [6]. Virologic monitoring should consist of VL measurements at 6 and 12 months after ART initiation and annual measurements thereafter. Virologic failure is defined as viral load above 1000 copies/mL based on 2 consecutive viral load measurements in a 3-month interval, with adherence support after the first viral load test, after at least 6 months of starting a new ART regimen [6].

### Data Sources and Data Collection

The study population’s demographic, clinical, and laboratory data were extracted from the Tier.Net electronic database. Tier.Net is an electronic system with modules to capture patient-level data on HIV counseling, testing, pre-ART, and ART services. The use of this tool is recommended in the

DRC and is already widely used in Kinshasa [9]. The implementation of Tier.Net is ongoing in other provinces of DRC. All patients on ART included in the study are systematically recorded at each clinical visit in a standardized clinical file and then in electronic registers. Tier.net data are regularly validated against patient records. Viral load results were retrieved from the electronic VL database.

Variables recorded at ART initiation included age, gender, weight, height, body mass index, WHO stage, CD4 T cells, the size of the health facility (categorized as small, medium, and large and, respectively, for <100, 100–500, and >500 PWH under follow up), ART regimen, delay to ART initiation (time between HIV diagnosis and ART initiation, categorized as <7 and  $\geq 7$  days), the notion of advanced HIV disease (AHD) (defined as CD4 T cells <200 cells/mm<sup>3</sup> and/or WHO clinical stage 3 or 4), prophylaxis with cotrimoxazole and isoniazid, and type of care providers.

Viral load suppression was defined as all viral load results  $\geq 5$  months from ARV initiation indicating viral suppression (<1000 copies/mL). First-year viral load suppression was defined as all viral load results between 5 and 13 months from ARV initiation indicating viral suppression (<1000 copies/mL).

### Statistical Analyses

Continuous variables are presented using mean and standard deviation (SD) or median with interquartile ranges (IQRs) as appropriate. Qualitative variables are described using frequency tables (numbers and percentages). Comparison of patients for the 2 studied periods, before and after T&T implementation, used  $\chi^2$ , analysis of variance, or Kruskal-Wallis tests, as appropriate.

Logistic regression models were used to evaluate the impact of each prognostic factor on VS. Variables with a *P* value lower than .1 in the single logistic models were included in the multiple model.

The results were considered significant at the 5% level (*P* < .05). Missing data have not been replaced and calculations have always been made on the maximum number of data available. Data analysis was performed using SAS (version 9.4 for Windows). R packages (version 3.6.1) were used for the figures.

### Ethics Approval and Patient Consent Statement

The design of the work has been approved by local ethical committees and it conforms to standards currently applied in DRC. Approval was granted by the Scientific Committee and the Research Ethics Committee of the School of Public Health of the Faculty of Medicine of the University of Kinshasa in the DRC (ESP/CE/005/2019). Patient data were extracted anonymously, and confidentiality was respected. All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was not required, according to the Ethics Committee recommendations, because this study does not include factors necessitating patient consent.

## RESULTS

### Participants' Characteristics

Data from 14 057 patients infected with HIV out of the 17 023 PWH who started ART between 2013 and end of 2019 registered in the databases met the inclusion criteria (Figure 1).

Table 1 describes the general characteristics of PWH at ART initiation. The patients were mostly women (67.2%). The mean age was  $40.0 \pm 11.4$  years. The median CD4 T-cell count was 254 (IQR, 141–400) cells/mm<sup>3</sup> with 68.3% of participants with CD4 T-cell count below 350 cells/mm<sup>3</sup> and 31.4% with WHO clinical stage at 3 or 4. At ART initiation, 68.3% of regimens contained efavirenz (EFV) and 17.2% contained dolutegravir (DTG). Eighty-four percent of PWH started ART within 1 week after diagnosis of HIV infection. Eighty-seven percent of participants had cotrimoxazole prophylaxis (CPT).

People with HIV were mainly enrolled during the T&T period (72.9%). Compared to the period before this strategy, there were significantly ( $P < .0001$ ) fewer adolescents (2% vs 2.6%), fewer women, pregnant or not (65.7% vs 71.4%), and less AHD (25.1% vs 53.9%). Patients were more likely to start ART within 7 days (94.6% vs 51.3%) and to receive ART containing DTG (23.5%) as well as CPT (90.8% vs 76.7%) (Table 1).

### Viral Load Testing

The patients were followed for a median period of 27 months (IQR, 17–44). Only 65.8% of PWH had at least 1 available VL test. The percentage of participants having a VL test within 1 year after ART initiation increased overtime (Supplementary Table S1). When comparing the periods before and after the

T&T implementation, the proportion of patients with at least 1 available VL (68.6% vs 58.3%,  $P < .0001$ ) (Supplementary Table S1) and with a VL within the year of ART initiation (55.6% vs 4.4%,  $P < .0001$ ) (Figure 2) was higher in recent years.

Despite a drastic increase in the number of VL tests performed during recent years, the delay from sample collection to return of viral load test results decreased overtime, from 35 days in 2018 to 16 days in 2020 (Figure 3 and Supplementary Table 2).

### Rate of Viral Suppression

The overall rate of VS was 82.3% at the threshold of VL less than 1000 copies/mL (Supplementary Table S3). Considering the first available VL only, 87.2% of the participants were virally suppressed at the threshold <1000 copies/mL. Considering both the total available VL tests and the VL tests performed within 1 year after ART initiation, viral suppression did not significantly differ before or after T&T implementation (Figure 4) and remained above 80%.

When the VL was greater than 1000 copies/mL, 72.5% of PWH had control of the VL after a median delay of 116 days (IQR, 26–193) and 23.1% maintained a VL greater than 1000 copies/mL, defining virologic failure according to the WHO definition [6] (Supplementary Table 3). The percentage of PWH with a second VL test performed in the case of unsuppressed VL was higher after the T&T implementation (76% vs 62.4%,  $P < .0001$ ) (Supplementary Table 3). Among those with a second VL performed, the rate of viral suppression was higher after the T&T implantation (Supplementary Table 3). In other words, a reduced percentage of participants met the definition of virologic failure after the T&T implementation.

### Factors Associated With Virologic Suppression

Regarding factors associated with virologic suppression, pregnancy (adjusted odds ratio [aOR], 0.62; 95% confidence interval [CI], .47–.81) ( $P = .0004$ ) and AHD (aOR, 0.83; 95% CI, .72–.97) ( $P = .017$ ) were associated with a lower chance of VS (Figure 5; Supplementary Table 4). In contrast, the probability of VS was higher when ART was initiated by a nurse (aOR, 1.2; 95% CI, 1.04–1.4) ( $P = .012$ ), when the initial regimen contained DTG compared with EFV (aOR, 1.2; 95% CI, 1.01–1.5) ( $P = .014$ ), and when patients were under follow up in a medium or large facility (aOR, 1.3; 95% CI, 1.04–1.5) ( $P = .017$ ). Age, gender, time to ART initiation, period of treatment for PWH, and duration of follow up did not influence on the probability of VS (Figure 5; Supplementary Table 4).

## DISCUSSION

During last years, viral load testing became the favored monitoring strategy for PWH [7]. Viral load testing enables early

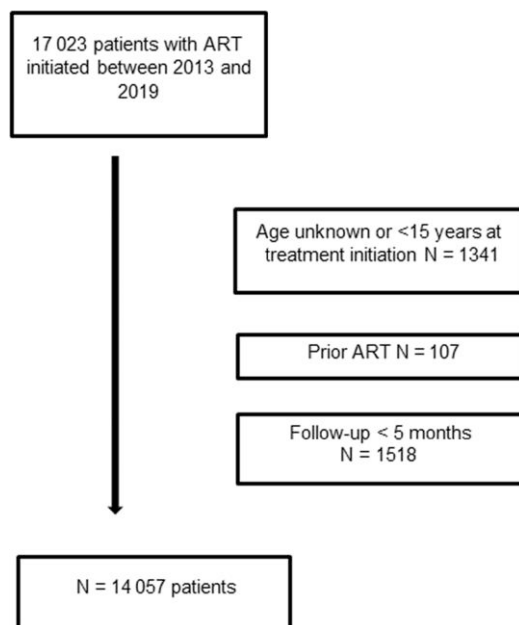


Figure 1. Flowchart. ART, antiretroviral therapy.

**Table 1. Description of PWH at ARV Treatment Initiation**

Characteristics	All (N = 14 057)		ARV Initiated From Jan 2013 to Nov 2016 (N = 3800)		ARV Initiated From Nov 2016 to Dec 2019 (N = 10 257)		Comparison P Value
	N Nonmissing	Results	N Nonmissing	Results	N Nonmissing	Results	
Gender, women	14 057	9448 (67.2)	3800	2712 (71.4)	10 257	6736 (65.7)	<.0001
Pregnant women	9271	744 (8.0)	2577	343 (13.3)	6694	401 (6.0)	<.0001
Age (years)	14 057	40.0 ± 11.4	3800	39.6 ± 11.0	10 257	40.2 ± 11.6	.0023
15–19	...	299 (2.1)	...	97 (2.6)	...	202 (2.0)	...
20–24	...	1054 (7.5)	...	258 (6.8)	...	796 (7.8)	...
25–49	...	9884 (70.3)	...	2754 (72.5)	...	7130 (69.5)	...
≥ 50	...	2820 (20.1)	...	691 (18.2)	...	2129 (20.8)	...
Height (cm)	276	164 ± 9	270	164 ± 9	6	165 ± 9	...
Weight (kg)	12 491	61.2 ± 11.1	3314	62.1 ± 12.1	9177	60.8 ± 10.7	<.0001
BMI (kg/m <sup>2</sup> )	268	22.6 ± 4.7	262	22.5 ± 4.7	6	23.2 ± 6.5	...
CD4 (cells/mm <sup>3</sup> )	2116	254 (141; 400)	1953	250 (138; 395)	163	290 (187; 480)	...
<200	...	797 (37.7)	...	752 (38.5)	...	45 (27.6)	...
200–350	...	647 (30.6)	...	597 (30.6)	...	50 (30.7)	...
351–500	...	368 (17.4)	...	339 (17.4)	...	29 (17.8)	...
>500	...	304 (14.4)	...	265 (13.6)	...	39 (23.9)	...
WHO Stage	10 651	...	2796	...	7855	...	<.0001
I	...	4834 (45.4)	...	804 (28.8)	...	4030 (51.3)	...
II	...	2472 (23.2)	...	611 (21.9)	...	1861 (23.7)	...
III	...	3028 (28.4)	...	1243 (44.5)	...	1785 (22.7)	...
IV	...	317 (3.0)	...	138 (4.9)	...	179 (2.3)	...
Advanced HIV <sup>a</sup>	11 094	3702 (33.4)	3186	1717 (53.9)	7908	1985 (25.1)	<.0001
Initial ART	14 035	...	3785	...	10 250	...	<.0001
TDF/3TC/DTG	...	2411 (17.2)	...	0 (0)	...	2411 (23.5)	...
TDF/3TC/EFV	...	9149 (65.2)	...	1674 (44.2)	...	7475 (72.9)	...
TDF/3TC/NVP	...	185 (1.3)	...	89 (2.3)	...	96 (0.9)	...
TDF/3TC/LPVr	...	29 (0.2)	...	9 (0.2)	...	20 (0.2)	...
AZT/3TC/DTG	...	1 (0.0)	...	0 (0.0)	...	1 (0.0)	...
AZT/3TC/EFV	...	433 (3.1)	...	396 (10.5)	...	37 (0.4)	...
AZT/3TC/NVP	...	1674 (11.9)	...	1569 (41.4)	...	105 (1.0)	...
AZT/3TC/LPVr	...	22 (0.2)	...	7 (0.2)	...	15 (0.1)	...
Others	...	131 (0.9)	...	41 (1.1)	...	90 (0.9)	...
Days since HIV diagnosis	10 418	0 (0; 0)	2520	7 (0; 28)	7898	0 (0; 0)	<.0001
≤7 days	...	8761 (84.1)	...	1292 (51.3)	...	7469 (94.6)	...
>7days	...	1657 (15.9)	...	1228 (48.7)	...	429 (5.4)	...
IPT	13 018	1833 (14.1)	3059	76 (2.5)	9959	1757 (17.6)	<.0001
CPT	13 925	12 117 (87.0)	3701	2837 (76.7)	10 224	9280 (90.8)	<.0001
Healthcare provider	14 001	...	3761	...	10 240	...	.0051
Doctor	...	3570 (25.5)	...	1023 (27.2)	...	2547 (24.9)	...
Nurse	...	10 431 (74.5)	...	2738 (72.8)	...	7693 (75.1)	...
Care Center	14 057	...	3800	...	10 257	...	<.0001
Small	...	1837 (13.1)	...	296 (10.4)	...	1429 (14.0)	...
Medium	...	8846 (62.9)	...	1978 (52.0)	...	6868 (67.0)	...
High	...	3374 (24.0)	...	1426 (37.5)	...	1948 (19.0)	...

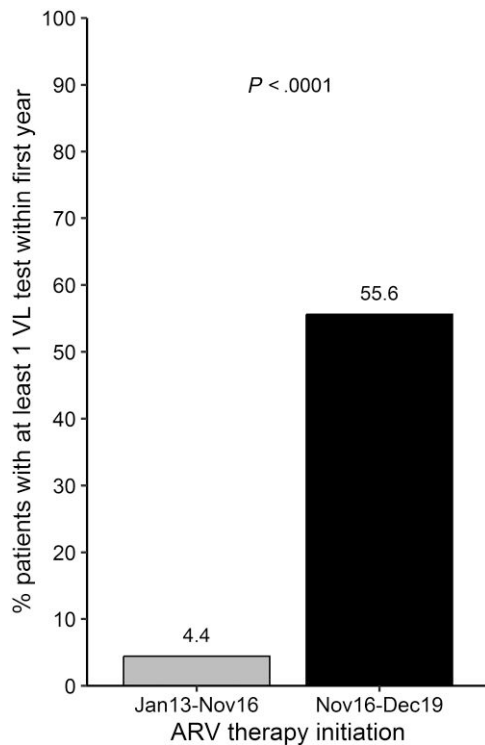
Abbreviations: 3TC, lamivudine; ART, antiretroviral therapy; ARV, antiretroviral; AZT, zidovudine; BMI, body mass index; CPT, cotrimoxazole preventive therapy; Dec, December; DTG, dolutegravir; EFV, efavirenz; HIV, human immunodeficiency virus; IPT, isoniazid preventive therapy; Jan, January; LPVr, ritonavir-boosted lopinavir; Nov, November; NVP, nevirapine; PWH, people with HIV; TDF, tenofovir disoproxil fumarate; WHO, World Health Organization.

NOTE: Results are expressed as N (%), mean ± standard deviation, or median (interquartile range), and P values as  $\chi^2$ , analysis of variance, or Kruskal-Wallis, respectively.

<sup>a</sup>Advanced HIV disease if CD4 <200 cells/mm<sup>3</sup> and/or WHO stage III/IV.

detection of treatment failure. In addition, virologic suppression is associated with reduced HIV transmission [10]. Consequently, testing all PWH for VL became a universal health priority. One key element of the UNAIDS goal to end

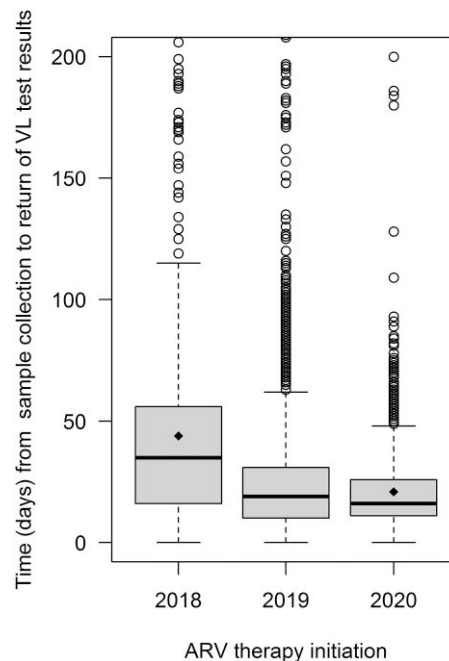
the HIV/AIDS epidemic by 2030 is that 95% of all individuals under ART reach viral suppression [11], highlighting the need for global and sustained VL monitoring. In addition, the WHO now recommends immediate initiation of ART for all people



**Figure 2.** Percentage of patients who had  $\geq 1$  viral load test within the year of antiretroviral therapy initiation ( $\leq 13$  months) before and after “test and treat” implementation (before and after November 2016).

diagnosed with HIV, regardless of CD4 T-cell count [6]. Expansions in ART eligibility criteria for PWH were followed by substantial increases in rates of timely ART initiation, with much larger increases among those newly eligible under the expanded guidelines compared with those eligible under prior guidelines [12]. Both ART expansion and switch from CD4 T-cell counts to VL to monitor ART effectiveness should be accompanied by progress on the scale up of VL testing.

In this study, we showed that there has been considerable success in increasing VL access for all PWH under therapy. Despite a huge increase in the number of PWH in Kinshasa under ART, we observed a dramatic improvement in access to VL, with more than 50% benefiting from VL testing within 1 year after ART initiation since 2016. This number rapidly increased to reach 66.9% in 2019. In the case of VL above 1000 copies/mL, a subsequent VL test is required within 6 months to define virologic failure. This control is also much more frequently performed since 2016. The increase in the number of VL tests is accompanied by a reduction in the delay from sample collection to return of VL test results during recent years, reflecting the improvement in the scale up of VL testing. Nevertheless, sustained engagement is required to hit UNAIDS targets. Efforts and progress accomplished until now remain insufficient to reach WHO guidelines related to virologic monitoring at 6 and 12 months after ART initiation and then annually.

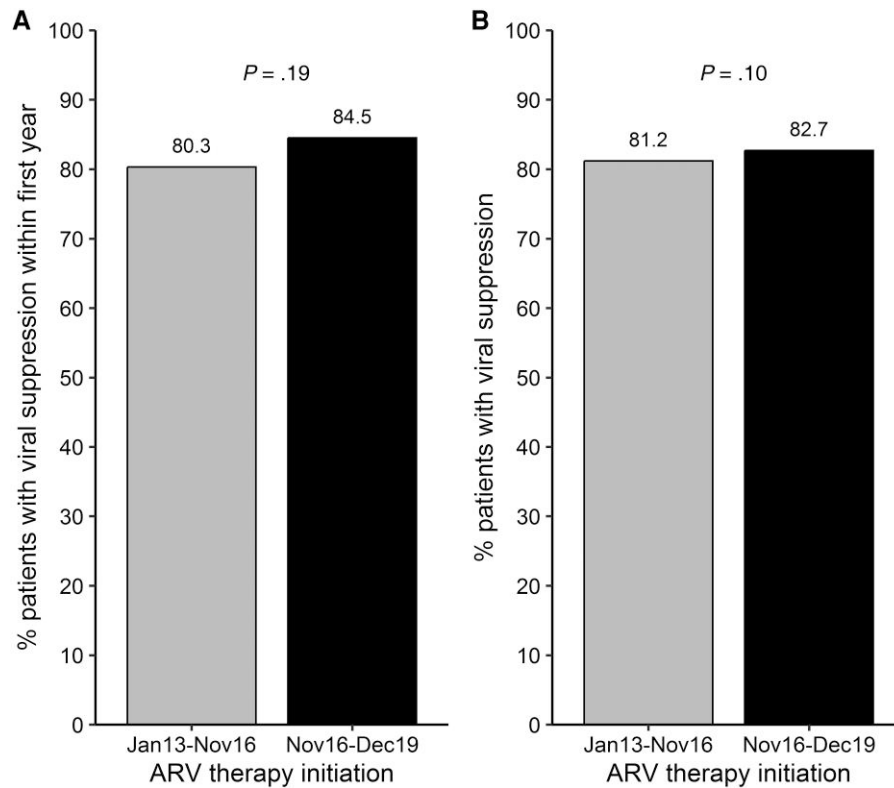


**Figure 3.** Evolution of time from sample collection to return of viral load (VL) test results to referring care center (linear regression of year impact on log-transformed time to return of results). ARV, antiretroviral.

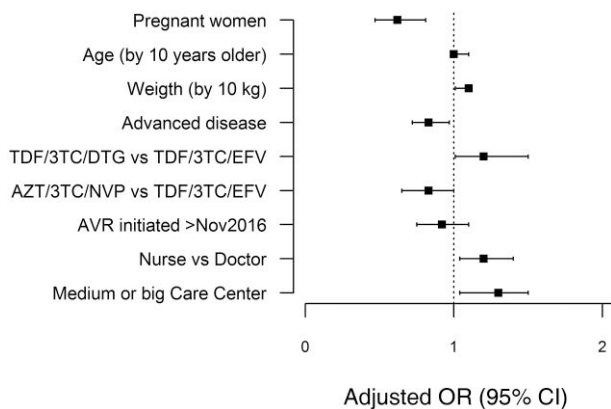
Regarding viral suppression, we observed an overall VS rate of 82.3%. This is lower than the target of 95% of UNAIDS but similar than those reported in the majority of cohorts from LMICs [8, 13–16]. Considering the first VL performed after a median delay of 12 months, this VS rate is higher (87.2%) than the overall VS rate. This difference should raise the question of the maintenance of VS in the long term. Adherence to ART seems to be a key issue because the majority of patients with a controlled VL after a first test above 1000 copies/mL achieved VS without any change in the therapeutic regimen. Those patients do not meet the definition of virologic failure.

In our study, the risk of unsuppressed viremia ( $>1000$  copies/mL) was higher in pregnant women, in PWH with AHD, and in patients treated with nevirapine-based or EFV-based regimens compared with DTG-based regimens, confirming the results of several studies in SSA [17–21]. Careful follow up should be proposed to groups at higher risk of treatment failure and lower adherence to therapy to ensure the individual and population benefits of ART. It is interesting to note that PWH who initiated ART at a medium- or large-volume center or by a nurse achieved viral suppression more often. It is reassuring that delegating the monitoring and treatment of PWH to nurses, initiated to expand access to care to a larger number of PWH, can effectively support rapid ART scale up in the era of T&T in the DRC.

We showed that PWH with low viremia (51–999 copies/mL) represent a significant proportion of our patients. Although the



**Figure 4.** Percentage of participants with viral suppression (<1000 copies/mL). (A) Percentage of participants with viral suppression during the first year from antiretroviral (ARV) initiation. (B) Percentage of participants with viral suppression (all available viral load results  $\geq$  5 months from antiretroviral therapy initiation).



**Figure 5.** Characteristics associated with the probability of viral suppression (<1000 copies/mL): multiple logistic regression. 3TC, lamivudine; AVR, antiretroviral; AZT, zidovudine; CI, confidence interval; DTG, dolutegravir; EFV, efavirenz; OR, odds ratio.

WHO guidelines do not recommend changing treatment in this condition, some studies in resource-limited settings have described low viremia as a predictor of subsequent virologic failure [22–24]. Those patients likely deserve closer monitoring.

Our results should be interpreted considering certain limitations. We used data collected in the routine management of patients, which may have several gaps. We used 2 databases for

which the cross-referencing of codes impeded the full recovery of VL data. Finally, we were not able to assess adherence to ART, which is described as the main cause of unsuppressed viremia in several cohorts [25–27]. Nevertheless, our study has some strengths. It covers a period after the implementation of T&T with enough hindsight to assess its impact on virologic suppression. The analyses relate to a large number of PWH followed in numerous healthcare centers distributed in all the health zones of the city of Kinshasa. The results of this study reflect routine clinical practice under the programmatic conditions of resource-limited settings.

## CONCLUSIONS

We showed a successful increase in VL monitoring in the DRC before and after the implementation and T&T strategy. This goes together with a reduction in the delay from sample collection to the VL results. Nevertheless, the scale up of VL testing should be intensified because the percentage of PWH with available VL tests remains insufficient. Unsuppressed viral load is mostly due to poor adherence as the majority of the participants later achieved suppressed viral load without ART modification. Pregnant women and PWH with AHD are at higher risk of viral failure and should be carefully followed.

## Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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**Author contributions.** NMN, HSN-T, MMM, MMN, MLM, EKN, BB, JOO, and GD contributed to conceptualization. NMN, HSN-T, MMM, DMS, TL, and JOO contributed to data curation. NMN, BB, NM, and GD contributed to formal analysis. NMN and EKN contributed to investigations. NMN, NM, and GD contributed to methodology. HSN-T, MMM, MLM, JOO, MM, and GD contributed to supervision. NM, BB, EKN, MM, and GD contributed to validation. NMN, MEM, and GD contributed to writing the original draft. All authors contributed to writing, reviewing, and editing.

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