

# Effect of Multi-Month Dispensing on Viral Suppression for Newly Enrolled Adolescents and Adults in Northern Nigeria

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**Purpose:** We evaluated the effect of multi-month dispensing (MMD) on viral suppression among newly enrolled adolescents and adults with HIV in 11 northern Nigerian states.

**Patients and Methods:** We conducted a retrospective analysis of longitudinal data from 75 health facilities. We abstracted electronic medical records for patients  $\geq 10$  years, initiated on ART April 1, 2019 – June 30, 2021, and with a 6- or 12-month viral load (VL) result. We categorized participants in the MMD group to see if they received antiretroviral treatment (ART) for  $\geq 84$  days at any visit within 6 months of ART initiation. We consider cut-offs for viral suppression at 50 copies/mL. The period when the VL was performed was classified as pre-COVID-19 (before April 1, 2020) or during the COVID-19 pandemic. We estimated relative risks (RR) by comparing the unsuppressed proportion of those on MMD to those not on MMD, adjusted for age, gender, and COVID-19 period.

**Results:** Overall, 19,859 participant records were abstracted. Median age was 33 years, 64% were female, 91% were started on a dolutegravir (DTG)-based regimen, and 65% were on MMD. Overall, 15,259 (77%) participants were followed for  $\geq 6$  months, 4136 (27%) had a VL at 6 months and 3640 (24%) had a VL at 12 months after ART initiation. A slightly higher proportion of patients on MMD had undetectable VL levels at 6 months (65% vs 58%) and 12 months (66% vs 62%). In the adjusted analysis, we found no significant differences in undetectable VL at 6 months and 12 months between newly enrolled patients on MMD and those not on MMD. Those on Protease inhibitor-based regimen had 54% lower likelihood of undetectable VL compared to those on DTG-based regimen.

**Conclusion:** MMD does not result in poorer viral suppression among newly enrolled patients.

**Keywords:** HIV, differentiated service delivery, PLHIV, Nigeria

## Introduction

Globally 39 million people were living with HIV (PLHIV) in 2022, 86% knew their HIV status, 89% of HIV positive people were on antiretroviral (ARV) treatment, and 92% of PLHIV on treatment had achieved viral suppression.<sup>1,2</sup> As the number of PLHIV on treatment increases in high HIV burden countries, it has become necessary to scale up differentiated service delivery models that are client-centered and reduce the burden on national health systems. In 2016, the World Health Organization (WHO) recommended 3–6 monthly ARV refills also known as multi-month dispensing (MMD) for stable PLHIV (on treatment for a minimum of 1 year, no opportunistic infections and adverse reactions to treatment, not pregnant or breastfeeding, and virally suppressed based on two consecutive viral load (VL) measurements).<sup>3</sup> By early 2020, the rollout of MMD among stable patients grew from 49% to 72% in 21 PEPFAR-supported countries<sup>4,5</sup> with high levels of demonstrable viral suppression in sub-Saharan Africa.<sup>5–7</sup> In 2020, at the start of the Coronavirus disease 2019

(COVID-19) pandemic, WHO further reiterated its call for the implementation of MMD, appealing to global leaders to maintain essential HIV services during the COVID-19 pandemic and beyond and to ensure adequate supplies of drugs.<sup>4</sup>

In 2021, Nigeria ranked fourth in the world with an estimated 1.9 million PLHIV.<sup>8</sup> By the end of 2021, Nigeria had achieved 98–96–89 of the global 95–95–95 UNAIDS targets.<sup>9</sup> The 2020 Nigerian guidelines for HIV prevention, treatment, and care by the National AIDS and STDs Control Program recommend MMD as a care package for stable clients who have achieved viral suppression and have spent over 6 months in care.<sup>10</sup>

In March 2020, the COVID-19 pandemic led to lockdowns and movement restrictions.<sup>5,11</sup> To mitigate treatment interruptions, Nigeria adopted some innovative approaches and rapidly scaled up MMD among most treatment naïve and experienced PLHIV.<sup>10,12,13</sup> Similar MMD practices were adopted by sub-Saharan African countries to avoid treatment interruptions, reduce the burden on health systems, and protect PLHIV and health providers from acquiring COVID-19.<sup>5,14</sup> As a result, by the end of 2020, MMD coverage rates increased up to four-fold in some countries.<sup>5</sup> In Nigeria, MMD coverage grew from 54% to 94% within the same period.<sup>15</sup>

The Strategic HIV/AIDS and TB Response Program Task Orders 1 and 3 (SHARP TO1 and TO3) are two-year projects funded by the US Agency for International Development (USAID) and implemented by Chemonics International to support HIV care and treatment services in 11 states and approximately 200 facilities in northern Nigeria. By March 2022, both projects had enrolled over 170,000 PLHIV on treatment, 93% of whom were receiving ARV treatment through MMD.

We conducted this study to assess the effect of MMD on viral suppression among newly enrolled and treatment naïve PLHIV in northern Nigeria.

## Materials and Methods

### Study Design and Procedures

This was a retrospective analysis of longitudinal patient records (clinic, pharmacy, and laboratory) for adolescents and adults (ages  $\geq 10$  years) newly enrolled in antiretroviral therapy (ART) from April 1, 2019 – June 30, 2021. The patients were receiving care in 75 facilities across 11 states in northern Nigeria (Adamawa, Bauchi, Borno, Jigawa, Kano, Kebbi, Kwara, Niger, Sokoto, Yobe, and Zamfara), We abstracted data for this study from the electronic medical records in the national Lafiya Management Information System.<sup>16</sup>

### Measures and Definition of Variables

VL: As per Nigerian HIV care guidelines, patients receive VL measures 6 and 12 months after ART initiation, and at least yearly thereafter.<sup>10,17</sup> Delays in VL sample collection and results processing were common in sub-Saharan African settings, especially during the COVID-19 pandemic.<sup>18–20</sup> For this analysis, we selected the first VL measure on record for each patient done between 5 and 9 months after ART initiation as the 6-month VL, and the first VL done between 9 and 15 months after ART initiation as the 12-month VL. VL results were classified as unsuppressed ( $>1000$  copies/mL), suppressed ( $<1000$  copies/mL), detectable ( $>50$  copies/mL), or undetectable ( $<50$  copies/mL).<sup>10,17</sup>

MMD group: This consisted of participants who received ART for  $\geq 84$  days during any ART refill visit within the first 6 months after ART initiation. We created a sub-category of participants who received ART for  $\geq 84$  days in the same period more than once.

The ART regimen recorded at the time of initiating treatment was classified as one of the following:

- Dolutegravir (DTG) based
- Non-nucleoside reverse transcriptase inhibitor (NNRTI)-based for those on efavirenz or nevirapine
- Protease inhibitor (PI)-based for those on lopinavir or atazanavir
- Other for those not in any of the three drug categories.

Lastly, we included a variable we named COVID-19 period to identify whether a patient started ART before April 1, 2020 (pre-COVID-19 pandemic), or after April 1, 2020 (during COVID-19).

## Analysis

We used descriptive measures (counts, proportions, medians, and interquartile ranges (IQR) to summarize the socio-demographic and HIV-related data and generalized linear models to determine their association with viral suppression at 6 and 12 months for all participants, and for participants on MMD.

The primary analyses determined the effect of MMD on undetectable viral load (VL<50 copies/mL) 6 months after initiating ART, and 12 months after initiating ART. Secondary analyses determined the effect of MMD on viral suppression (VL<1000 copies/mL) 6 months after initiating ART, and 12 months after initiating ART. In each analysis, we included only records of participants with complete data. For each analysis, we used generalized linear models (family = binomial (link=log)) and included bivariate and multivariate analysis. In the latter, we adjusted for age, gender, ART regimen, and COVID-19 period. We report relative risks (RR) from bivariate analyses and adjusted relative risks (aRR) from multivariate analyses. The 95% confidence intervals (95% CI) for the aRR, and p-values were computed using bootstrapping (1000 bootstrap samples from the full sample) to account for clustering of participants by facility. Additionally, we ran a sensitivity analysis comparing PLHIV with more than one MMD refill with PLHIV with one or no MMD refills to determine differences in achieving undetectable VL among the groups. All analyses were completed using R (Version 4.0.3, Foundation for Statistical Computing, Vienna, Austria) and R studio (Integrated Development Environment for R. RStudio, 2022, PBC, Boston, MA).

## Ethical Considerations

We received Institutional Review Board (IRB) approvals from the National Health Research Ethics Committee of Nigeria (NHREC Approval Number NHREC/01/01/2007-28/06/2021) and the University of Maryland Baltimore Institutional Review Board (HP-00097414). Individual consent, including parental consent for minors, for the abstraction of patient medical records was waived since no patient identifying information was collected. Unique patient identifiers and names were excluded from the datasets shared with the research team by the program data teams. The handling of the data was done in accordance with the ethical principles in the Declaration of Helsinki for handling human subjects, materials, and data in research. The de-identified data were stored in a secure cloud repository with access restricted to only authorized study investigators. The data managers who did the data extraction are not co-authors of this paper.

## Results

We abstracted pharmacy records for 19,859 newly enrolled adolescents and adults living with HIV. Majority (64%) of the participants were female, 91% were started on DTG-based regimen, 65% received ART refills to last  $\geq 84$  days (MMD) within the first 6 months, and 30% of PLHIV received greater than one MMD refill over the 6-month period. The median age of all the participants was 33 years (interquartile range [IQR]: 26–40). Of 19,859 participants, 15,259 (77%) were followed up for 6 months or more. Of 15,259 participants, 4136 (27%) had a VL 6 months after ART initiation, while 3640 (24%) had a VL 12 months after ART initiation. While there were no major differences between participants with a 6- or 12-month VL in the overall sample in terms of age, gender, and MMD, only 34% and 16% of those with a 6- and 12-month VL, respectively, were enrolled during the COVID-19 pandemic, compared to 53% in the overall sample, and a slightly lower proportion were on DTG (maximum difference of 7%) (Tables 1 and 2).

Of 4136 PLHIV with a 6-month VL result, 3640 (88%) were virally suppressed (<1000 copies/mL), while 2606 (63%) had undetectable VL results (<50 copies/mL) and 2962 (72%) were on MMD. Of the 3640 PLHIVS with a 12-month VL result, 3208 (88%) were virally suppressed and 2350 (65%) had undetectable VL results; 2352 (65%) were on MMD. A slightly higher proportion of patients on MMD were virally suppressed 6 months after ART initiation compared to those not on MMD (88% vs 87%), with the difference being higher in undetectable VL levels (65% vs 58%). Similarly, among PLHIVs with a 12-month VL result, those on MMD had higher viral suppression (89% vs 87%) and undetectable VL results (66% vs 62%). ART regimen was associated with viral suppression at 6 months among PLHIV on MMD. Those on PI-based regimen had 54% lower likelihood of viral suppression at 6 months compared to those on DTG-based regimen (RR: 0.46 [95% CI: 0.24–0.89]). No other factors were associated with viral suppression for the full sample (Table 1), and among those on MMD (Supplementary Table 1). We found no significant differences in

**Table 1** Characteristics of Participants Newly Initiated on Antiretroviral Therapy and Viral Load Measures at 6 Months

	Overall Sample, n (%) <sup>a</sup> N=19,859	Sample with Month 6 VL, n (%) <sup>a</sup> , N=4136	On MMD, n (%) <sup>b</sup> N=2962	Suppressed Month 6 VL, n (%) <sup>2</sup> , N=3640	RR (95% CI) <sup>c</sup>
Age (years)					
10–19	1532 (8%)	268 (6%)	193 (72)	216 (81)	Reference
20–24	2585 (13%)	503 (12%)	361 (72)	438 (87)	1.08 (0.92–1.27)
>24	15,742 (79%)	3365 (81%)	2408 (72)	2986 (89)	1.10 (0.96–1.26)
Gender					
Male	7195 (36%)	1408 (34%)	1026 (73)	1242 (88)	Reference
Female	12,664 (64%)	2728 (66%)	1936 (72)	2398 (88)	1.00 (0.93–1.07)
ART Regimen					
DTG	18076 (91%)	3637 (88%)	2686 (74)	3219 (89)	Reference
NNRTI	1658 (8%)	468 (11%)	256 (55)	403 (86)	0.97 (0.88–1.08)
PI	81 (<1%)	22 (<1%)	12 (55)	9 (41)	0.46 (0.24–0.89)
Other	34 (<1%)	7 (<1%)	6 (86)	7 (100)	1.13 (0.54–2.37)
Enrollment period					
Pre-COVID-19	9397 (47%)	2723 (66%)	1707 (63)	2393 (88)	Reference
During COVID-19	10,462 (53%)	1413 (34%)	1255 (89)	1247 (88)	1.00 (0.94–1.08)

**Notes:** <sup>a</sup>Column percentages. <sup>b</sup>Row percentages. <sup>c</sup>RR (95% CI): Relative risk (95% confidence interval) for the association between the socio-demographic/ HIV-related factor and having an undetectable viral load at month 6.

**Abbreviations:** VL, Viral load; ART, Antiretroviral therapy; DTG, Dolutegravir; NNRTI, Non-nucleoside reverse transcriptase inhibitors; PI, Protease inhibitors; MMD, Multi-month dispensing.

**Table 2** Characteristics of Participants Newly Initiated on Antiretroviral Therapy and Viral Load Measures at Month 12

	Overall Sample, n (%) <sup>a</sup> , N=19,859	Sample with Month 12 VL, n (%) <sup>a</sup> , N=3640	On MMD, n (%) <sup>b</sup> , N=2352	Suppressed Month 12 VL, n (%) <sup>b</sup> , N=3208	RR (95% CI) <sup>c</sup>
Age (years)					
10–19	1532 (8%)	229 (6%)	143 (62)	184 (80)	Reference
20–24	2585 (13%)	408 (11%)	249 (61)	354 (87)	1.08 (0.90–1.29)
>24	15,742 (79%)	3003 (83%)	1960 (65)	2670 (89)	1.11 (0.95–1.28)
Gender					
Male	7195 (36%)	1244 (34%)	819 (66)	1093 (88)	Reference
Female	12,664 (64%)	2396 (66%)	1533 (64)	2115 (88)	1.00 (0.93–1.08)
ART Regimen					
DTG	18076 (91%)	3068 (84%)	2043 (67)	2717 (89)	Reference
NNRTI	1658 (8%)	535 (15%)	285 (54)	461 (86)	0.97 (0.88–1.07)
PI	81 (<1%)	20 (<1%)	9 (45)	17 (85)	0.96 (0.60–1.55)
Other	34 (<1%)	13 (<1%)	12 (92)	9 (69)	0.78 (0.41–1.50)

(Continued)

**Table 2** (Continued).

	Overall Sample, n (%) <sup>a</sup> , N=19,859	Sample with Month 12 VL, n (%) <sup>a</sup> , N=3640	On MMD, n (%) <sup>b</sup> , N=2352	Suppressed Month 12 VL, n (%) <sup>b</sup> , N=3208	RR (95% CI) <sup>c</sup>
Enrollment period					
Pre-COVID-19	9397 (47%)	3062 (84%)	1870 (61)	2686 (88)	Reference
During COVID-19	10,462 (53%)	578 (16%)	482 (83)	522 (90)	1.03 (0.94–1.13)

**Notes:** <sup>a</sup>Column percentages. <sup>b</sup>Row percentages. <sup>c</sup>RR (95% CI): Relative risk (95% confidence interval) for the association between the socio-demographic/ HIV-related factor and having an undetectable viral load at month 12.

**Abbreviations:** VL, Viral load; ART, Antiretroviral therapy; DTG, Dolutegravir; NNRTI, Non-nucleoside reverse transcriptase inhibitors; PI, Protease inhibitors; MMD, Multi-month dispensing.

**Table 3** Effect of Multi-Month Dispensing on Viral Loads at 6 Months and 12 Months After Initiation of Antiretroviral Therapy

6 months after ART initiation (N=4136)					
Outcome: viral suppression (VL<1000 copies/mL)					
	Suppressed/Undetectable	RR (95% CI)	P value	Adjusted RR (95% CI)	P value
Not on MMD	1022 (87%)	Reference		Reference	
On MMD	2614 (88%)	1.01 (0.94–1.09)	0.781	1.01 (0.97–1.04)	0.749
Outcome: Undetectable VL (VL<50 copies/mL)					
Not on MMD	684 (58%)	Reference		Reference	
On MMD	1919 (65%)	1.11 (1.05–1.17)	<0.001	1.08 (0.99–1.19)	0.096
12 months after ART initiation (N=3640)					
Outcome: viral suppression (VL<1000 copies/mL)					
Not on MMD	1112 (87%)	Reference		Reference	
On MMD	2089 (89%)	1.02 (0.95–1.10)	0.537	1.02 (0.98–1.05)	0.306
Outcome: undetectable VL (VL<50 copies/mL)					
Not on MMD	790 (62%)	Reference		Reference	
On MMD	1555 (66%)	1.07 (1.02–1.13)	0.009	1.05 (0.97–1.15)	0.240

**Notes:** In the multivariable model, we adjusted for age, gender, ART regimen, and the period of enrollment (pre/during the COVID-19 pandemic) and accounted for clustering by facility.

**Abbreviations:** VL, Viral load; ART, Antiretroviral therapy; MMD, Multi-month dispensing; RR, Relative risk.

viral suppression or undetectable VL results at 6 months (*aRR*: 1.01 [95% CI: 0.97–1.04], and *aRR*: 1.08 [95% CI: 0.99–1.19] respectively); and at 12 months (*aRR*: 1.02 [95% CI: 0.98–1.05], and *aRR*: 1.05 [95% CI: 0.97–1.15]) (Table 3) between newly enrolled patients on MMD and not on MMD, respectively. We found similar results [no significant differences in viral suppression or undetectable VL results at 6 months (*aRR*: 1.01 [95% CI: 0.98–1.04], 0.602, and *aRR*: 1.02 [95% CI: 0.96–1.10], *p*=0.477, respectively); and at 12 months (*aRR*: 1.03 [95% CI: 0.99–1.06], *p*=0.053, and *aRR*: 1.07 [95% CI: 0.98–1.16], *p*=0.110)] from the analysis comparing PLHIV who had more than one MMD refill with those who had one or no MMD refills.

## Discussion

This study demonstrates MMD of ART is feasible and does not result in poorer treatment outcomes among adolescents and adults newly enrolled in HIV care. However, despite more than 90% of participants having been initiated on DTG-

based regimen, over one-third of patients did not attain an undetectable VL at 6 and 12 months, while approximately 10% of PLHIV did not achieve VL suppression below the 1000 copies/mL level. The uptake of VL testing at 6 and 12 months after ART initiation was low, with over 70% of the eligible participants missing VL testing, likely due to the logistical barriers experienced in many settings during the COVID-19 pandemic.<sup>13</sup> However, we noted that a slightly higher number of patients were initiated on ART during the pandemic, demonstrating the resilience of the program in ensuring HIV testing and treatment services were accessible.

Two-thirds of patients received MMD of ART within the first 6 months of treatment initiation. Notably, this practice existed in the year preceding the COVID-19 pandemic with 63% of newly initiated ART patients receiving their medications through MMD within the first 6 months. This finding demonstrates that providers in Nigeria had embraced MMD before COVID-19, contrary to local treatment guidelines. This is likely to have been informed by studies from other countries that showed it was a feasible strategy for HIV care and treatment.<sup>21–23</sup>

In 2020, MMD was rapidly scaled up among PLHIV in Nigeria to improve access and mitigate treatment interruptions, due to the COVID-19 pandemic. Despite beliefs from the HIV community that MMD could adversely affect treatment outcomes among newly initiated ART patients,<sup>24,25</sup> we found that patients on MMD were more likely to achieve undetectable VL at 6 and 12 months comparable to patients who were not on MMD and similar to previous studies among treatment-experienced and stable patients.<sup>26</sup> Our study also showed that the number of MMD refills does not have an effect on viral suppression. The benefits of MMD for HIV programs such as decongesting clinics and reducing the cost of care for patients<sup>21</sup> can be extended to the care of newly enrolled PLHIV without fear of poorer treatment outcomes. Our results align with evidence from recent studies that show MMD is feasible among newly diagnosed patients.<sup>27</sup>

We assessed the effect of other key factors on VL suppression and undetectable VL levels among newly diagnosed PLHIV. Due to better tolerability, we expected PLHIV on DTG to maintain better VL suppression rates than patients on PIs at 6 and 12 months.<sup>28,29</sup> Overall, patients initiated on PI-based regimen had a lower likelihood of VL suppression compared to those on DTG at 6 months. However, we did not observe a lower likelihood of VL suppression for patients on PI-based regimen at 12 months. The early advantages of DTG including more rapid declines in VL have been established in previous studies. Moreover, when conducting further analysis for PLHIV on MMD, we were not able to observe the advantages of being on DTG-based regimen even at 6 months, likely due to the smaller sample size and a lack of power to detect small differences.

The high DTG (>90%) coverage in 2021 speaks to how successful Nigeria has been in transitioning PLHIV to a more effective ART that is well tolerated, easy to take, less toxic and has a higher barrier to resistance.<sup>11</sup> Unlike previous studies among ART-experienced PLHIV, factors like lower age (especially adolescent stage)<sup>30,31</sup> and male gender were not associated with a lower likelihood of viral suppression.<sup>32–34</sup>

The study population was heavily skewed towards adults (79%), which reflects the population of PLHIV in Nigeria.<sup>35,36</sup> High levels of missing VL results were a concern, however there were no major differences between the overall PLHIV population and patients with a VL in terms of the variable, suggesting this might have been random. In our study, we used routine clinical data to abstract a limited number of variables and were unable to identify the full range of possible factors that could influence viral suppression including social factors like stigma and mental health.<sup>37,38</sup>

## Conclusion

In this study, we found similar treatment outcomes between newly diagnosed patients on multi-month dispensing and PLHIV not on MMD within the first 6 months after initiating ART. The findings from our study suggest that MMD can be adopted and promoted for new PLHIV on ART without concern that patients will experience poorer outcomes.

## Disclosure

The authors report no conflicts of interest in this work.



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