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Effects of Multi-Month Dispensing on Clinical Outcomes: Retrospective Cohort Analysis Conducted in Kenya

Natalia Blanco[1,2], **MC. Lavoie**[1,2,8], **C. Ngeno**[3], **R. Wangusi**[3], **M. Jumbe**[3], **F. Kimonye**[3], **A. Ndaga**[3], **G. Ndichu**[3], **V. Makokha**[3], **P. Awuor**[3], **E. Momanyi**[3], **R. Oyuga**[3], **S. Nzyoka**[3], **I. Mutisya**[4], **R. Joseph**[3], **F. Miruka**[4], **P. Musingila**[4], **KA. Stafford**[1,2,8], **T. Lascko**[1,2], **C. Ngunu**[5], **E. Owino**[6], **A. Kiplangat**[5], **K. Abuya**[7], **E. Koech**[3]

[1]Centre for International Health, Education, and Biosecurity (Ciheb), University of Maryland School of Medicine, Baltimore, USA

[2]Institute of Human Virology, University of Maryland School of Medicine, Baltimore, MD, USA

[3]Center for International Health Education and Biosecurity (Ciheb), MGIC-an affiliate of the University of Maryland Baltimore, Nairobi, Kenya

[4]Division of Global HIV & TB (DGHT), U.S. Centers for Disease Control and Prevention (CDC), Nairobi, Kenya

[5]Nairobi Metropolitan Services Health Management Team, Nairobi, Kenya

[6]Migori County Health Management Team, Western, Kenya

[7]Kisii County Health Management Team, Western, Kenya

[8]Division of Global Health Sciences, Department of Epidemiology and Public Health, University of Maryland School of Medicine, Baltimore, MD, USA

Abstract

Multi-month dispensing (MMD) has been widely adopted by national HIV programs as a key strategy for improving the quality of HIV care and treatment services while meeting the unique needs of diverse client populations. We assessed the clinical outcomes of clients receiving MMD in Kenya by conducting a retrospective cohort study using routine programmatic data in 32 government health facilities in Kenya. We included clients who were eligible for multi-month antiretroviral therapy (ART) dispensing for ≥ 3 months (≥ 3MMD) according to national guidelines. The primary exposure was enrollment into ≥ 3MMD. The outcomes were lost to follow-up (LTFU) and viral rebound. Multilevel modified-Poisson regression models with robust standard errors were used to compare clinical outcomes between clients enrolled in ≥ 3MMD and those receiving ART dispensing for less than 3 months (< 3MMD). A total of 3,501 clients eligible

Natalia Blanco nblanco@ihv.umaryland.edu.

Declarations

Conflict of Interest The authors have no declared conflict of interest.

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for ≥ 3MMD were included in the analysis, of whom 65% were enrolled in ≥ 3MMD at entry into the cohort. There was no difference in LTFU of ≥ 180 days between the two types of care (aRR 1.1, 95% CI 0.7–1.6), while ≥ 3MMD was protective for viral rebound (aRR 0.1 95% CI 0.0–0.2). As more diverse client-focused service delivery models are being implemented, robust evaluations are essential to guide the implementation, monitor progress, and assess acceptability and effectiveness to deliver optimal people-centered care.

Keywords

HIV; Kenya; Differentiated Service Delivery; Retention; Viral Suppression

Introduction

Globally, differentiated service delivery (DSD) models have been widely adopted by national HIV programs to improve service delivery and meet the diverse needs of client populations [1–4]. The expansion of DSD models marks a shift from a “one-size-fits-all” approach to service provision to one that recognizes variability in client needs and, therefore, their levels of engagement required with the health system [5]. DSD encompasses a variety of strategies, including multi-month dispensing (MMD) of antiretroviral therapy (ART), task-shifting from physicians or nurses to other types of health providers, community or facility ART adherence groups, and community ART distribution groups [3, 6–8]. These strategies aim to improve client satisfaction and reduce lost wages and productivity [9]. At the health systems level, DSD models seek to reduce healthcare costs and burdens due to the high number of clients coming to the clinic [9]. Monitoring the implementation of DSD models is critical to addressing gaps, guiding scale-up, and ensuring quality of care irrespective of the service delivery model.

In 2016, the Kenya Ministry of Health (MOH) launched the national guidelines for the implementation of DSD [10, 11]. Under these guidelines, which align with World Health Organization (WHO) recommendations [12], clinically stable clients may elect to enroll in a facility-based, fast-track, multi-month prescription system for ART refills (≥ 3 months) [13] or receive ART dispensing for less than 3 months (< 3MMD). Several studies have been published on DSD in the context of Kenya [14–17]; however, less is known about the effects of facility-based, fast-track MMD on clinical outcomes [14] following the national guidelines for the implementation of DSD [10, 11]. This study aimed to fill this gap by assessing the effects of ART refill frequency (≥ 3MMD vs. <3MMD) on loss to follow-up (LTFU) and viral load rebound among adults living with HIV in Kenya.

Methods

Study Design

We conducted a retrospective cohort study using routine programmatic data from July 2017 to December 2019 in 32 public health facilities located in Nairobi (n = 17), Kisii (n = 7), and Migori (n = 8) counties that received support from the Center for International Health, Education, and Biosecurity (Ciheb) of University of Maryland Baltimore (UMB)

under the leadership of Kenya MOH and respective county governments. Data extraction was conducted between August and October 2020. Nairobi county includes the capital city, while Kisii and Migori counties host a predominantly rural population in the south-west of Kenya. According to the 2018 Kenya HIV population-based survey, county-level HIV prevalence among adults 15–64 years of age is 3.8% in Nairobi, 6.1% in Kisii, and 13.0% in Migori [15]. Across Kenya, among adults aged 15–64 years of age, 79.5% of HIV-infected adults have been diagnosed, 96.0% are on ART, and 90.6% are virally suppressed [15].

Sampling

The sampling frame consisted of all public health facilities with 500 or more clients on ART. A two-stage sampling approach was used to select the cohort for analysis. In the first stage, health facilities were stratified by location (Nairobi, Kisii, and Migori) and facility size based on the number of clients on ART (500–999 and 1000 and above). In total, 32 supported health facilities were randomly selected from a total of 268 supported health facilities. In the second step, files from clients were randomly selected using probability proportional to size from each of the 32 facilities using a sampling table recommended by the Kenya MOH to achieve 95% representativeness of its population [16].

Study Population

Clients were eligible to enter the cohort between July 2017 and December 2019 when they first met the pre-defined MOH criteria for being clinically stable/eligible for enrollment into ≥ 3MMD, which included: (1) aged 20 years and older; (2) receiving ART for at least 12 months; (3) virally suppressed (< 1,000 copies per milliliter (copies/ml)); and, (4) clinician determined the client was stable based on pre-defined eligibility criteria including, no active opportunistic infections, completion of 6 months of isoniazid preventive therapy, non-pregnant or breastfeeding and body mass index (BMI) ≥ 18.5 [10]. Eligible clients for ≥ 3MMD could enroll or remain on ≥ 3MMD or switch to < 3MMD based on personal preferences or due to the clinician's decisions (reasons beyond the eligibility criteria). The client's status and continuation on ≥ 3MMD were reassessed at each clinical visit. All available clinical visits from the moment clients entered the cohort up to December 2019 were included in the analysis.

Intervention

All clients received standard of care (SOC) recommended by the *2018 Kenya Guidelines on Use of Antiretroviral Drugs for Treating HIV Infection* [17]. The SOC includes a clinical evaluation every 3 months or as needed, adherence counseling and support, cotrimoxazole prophylaxis, baseline CD4 at enrollment, yearly viral load testing, ART initiation, assessment for drug toxicity, tuberculosis screening and treatment, isoniazid presumptive treatment initiation among eligible clients, sexually transmitted infections screening and treatment, and family planning services. In addition to SOC, eligible clients could receive ≥ 3MMD as part of their DSD model (Table 1). The model was referred to as a facility-based, fast-track, multi-month prescription system for ART refills (≥ 3 months), as clients could collect ART refills from the facility pharmacy directly.

Variables

The primary exposure, ≥3MMD, was defined as fast-track ART refills for 3 months or more (89 or more ART pills prescribed). We defined ART refills for less than 3 months as < 3MMD (less than 89 ART pills prescribed). The outcomes included: (1) Lost to follow-up (LTFU), defined as no clinic visit within 180 days after the scheduled appointment date (as 180 days is defined as the maximum period interval between clinical visits expected for individuals on ≥ 3MMD according to the national operational guide [10]); and (2) Viral rebound was defined as having a viral load < 1,000 copies/mL followed by a subsequent viral load ≥ 1,000 copies/ml. The cut-off value for viral suppression is aligned with Kenya MOH national guidelines [10]. A viral load value was included for each clinic visit using the most recent viral load results.

Demographic data included age, sex, marital status, type of population (general or key populations [KP] defined as female sex workers [FSW], men who have sex with men [MSM] or persons who inject drugs [PWID]), HIV diagnosis date, ART initiation date, time on ART, baseline CD4 count, viral load test results, client status (stable or unstable), quantity of ART refill, and dates of HIV-related clinical consultations were also included.

Data Collection and Management

The evaluation team extracted routine clinical data from the HIV client form and pharmacy records paper files into DHIS-2. Data quality assurance (DQA) measures included built-in validation rules and checks in DHIS-2, and the designated supervisor conducted DQA on 10% of the selected samples daily. Data concordance of less than 95% between supervisor and data officers led to further investigation to confirm values and additional training and supervision. A de-identified dataset was used for the analysis of the data and stored in a password-protected computer.

Statistical Analysis

We examined the data using univariate analysis to describe the frequency and distribution of outcomes and covariates. Client characteristics were summarized using medians and interquartile ranges (IQR) for continuous variables and proportions with a 95% confidence interval (CI) for categorical variables. We used Pearson chi-square and Wilcoxon rank-sum tests to compare outcomes between clients receiving ≥ 3MMD or < 3MMD.

As exposure and outcomes are defined at every visit, all clients' visits after entry into the cohort were included in all models. Therefore, we assigned MMD classification (≥ 3MMD vs. <3MMD) at each clinic visit. For our models, we used the MMD classification at the previous clinical visit to ensure the exposure proceeded the outcome(s). Individuals who died during the follow-up period were excluded, while individuals who had a confirmed transfer out were followed until their last clinical consultation or ART refill appointment. Multilevel modified-Poisson regression models with robust standard errors (using the "sandwich" estimation) were used to evaluate the association of ≥ 3MMD with the clinical outcomes [18]. Variables with a p-value < 0.05 in the bivariate analysis and those found to be important confounders based on the scientific literature review were included in the multivariate model. Statistically significant variables and known confounders (age, sex)

were kept in the final models. The models were adjusted for repeated measures (multiple visits from the same individual) and clustering within health facilities. Multicollinearity was assessed by estimating the variation inflation factor (VIF). If a VIF value was greater than 10, multicollinearity was observed, and the variable was removed from the model. No sub-analysis was performed. Data was analyzed using SAS 9.4 (Cary, NC) and STATA 17.0 (STATA Corporation, College Station, TX). All statistical tests were done at 5% level of significance.

Ethical Considerations

This protocol was reviewed in accordance with the U.S. Center for Disease Control and Prevention (CDC) human research protection procedures and was determined to be research, but the CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes. The Kenyatta National Hospital and University of Nairobi Ethics Review Committee (IRB) (Reference number: KNH-ERC/A/44) and the University of Maryland, Baltimore IRB (Reference number: HP-00085196) also approved the protocol. All clinical information to be analyzed is collected during routine client care or is part of good clinical practice and/or required to be reported by governmental and funding agencies. A “waiver of consent” was obtained.

Results

Clients Characteristics of the Study Sample

The final sample included 3,501 clients on ART from 32 governmental health facilities supported by Ciheb-UMB in Nairobi (n = 17), Kisii (n = 7), and Migori (n = 8) counties. Overall, the median age was 40 years (IQR, 33–48), the majority were female (69.0%), married or cohabitating (66.2%), with a median time on ART of 4.4 years (IQR = 2.7–6.8), receiving an Efavirenz (EFV)-based regimen (59.7%), on a first-line ART regimen (95.8%), and accessing HIV services in health facilities providing services to 500–999 PLHIV (58.8%) (Table 2). At the time of entry into the cohort, 64.8% (2,267/3,501) of clients were enrolled on ≥ 3MMD, while the remaining were on < 3MMD. The distribution of sex, age at entry, age at ART initiation, time on ART, current ART regimen, and year of entry differed significantly by MMD model (Table 2).

Clinical Outcomes Association with 3MMD

Lost to Follow-Up.—Based on the MMD at entry into the cohort, a total of 98 clients (2.8%) were classified as LTFU, 45 (3.7%) for < 3MMD and 53(2.3%) for ≥ 3MMD (Table S1). In the regression models, there was no difference in LTFU between the two types of care on both unadjusted and adjusted analysis [Unadjusted relative risk (uRR)1.2, 95% confidence interval (95% CI) 0.8–2.0; Adjusted relative risk (aRR) 1.1, 95% CI 0.7–1.6] (Table 3).

Viral rebound.—Based on the MMD at entry into the cohort, a total of 57 clients (2.8%) were classified as virally rebound, 53 (1.5%) for < 3MMD and 4 (0.1%) for ≥ 3MMD (Table S1). In both unadjusted and adjusted analysis, ≥3MMD was protective for viral rebound [uRR 0.1, 95% CI (0.0–0.2), aRR 0.1, 95% CI (0.0–0.2)] (Table 3).

Discussion

In this study, we observed no difference in LTFU between MMD models, while ≥ 3MMD was protective against viral rebound compared to < 3MMD. Our findings are comparable with a 2020 systematic review and meta-analysis on the effects of reduced frequency of clinical encounters and ART refills on retention (no significant difference between groups) [14]. Regarding the observed protective effects towards viral rebound, previous literature has reported either beneficial or no difference between DSD models, including MMD and viral suppression [3, 14].

Nearly two-thirds of clients were enrolled on ≥ 3MMD at entry in the cohort. Qualitative evidence suggests that clients preferred MMD due to the reduced time and financial cost associated with frequent clinic visits and increased personal freedom [12, 19, 20]. However, some clients may prefer more frequent ART refills or clinical visits due to the need for ongoing support and counseling and the fear of HIV stigma and discrimination due to the challenges of safely and privately storing several months of ART [21].

In our study, a small percentage of clients experienced LTFU (< 3%) or viral rebound (< 2%). This finding contrasts with other studies from sub-Saharan Africa, reporting LTFU between 10% and 33% within 6 months [22, 23]. The observed difference is likely due to differences in the study population. In our study, individuals who were a priori likely to be retained and suppressed were included due to eligibility criteria necessary for being on ≥ 3MMD (i.e., being on ART for at least 12 months and virally suppressed).

COVID-19 has accelerated the uptake of MMD, broader eligibility criteria, and extended ART duration refills [24]. For instance, several countries have a policy supporting 6MMD and 12MMD for specific groups and have expanded the eligibility criteria for MMD to include additional populations, including children, adolescents, adults newly initiated on ART, and pregnant and breastfeeding women [25–28]. Evidence also suggests that longer ART duration yields similar clinical outcomes compared to more frequent ART refills [14, 29]. In a cluster RCT conducted in Zambia and Malawi, Hoffman et al. found that 6-monthly clinical consultations with ART dispensing were non-inferior to 3 monthly ART dispensing for retention in care at 12 months [27]. Similarly, Fatti et al. found comparable results between 6-monthly versus 3-monthly ART refills [30]. Community-based MMD models have also shown comparable results to facility-based models for different ART refill durations (3MMD, 6MMD, and 12MMD) [31, 32]. The success of the scale-up of MMD, especially long-duration ART refills such as 6MMD, will hinge on several factors, including robust and dependable ART supply chains [26, 33] and agile monitoring and evaluation system to accommodate patient's level longitudinal follow-up irrespective of settings (e.g., facility vs. community), and duration of ART refill (3MMD, 6MMD, ≥6MMD). Monitoring the uptake of MMD across populations and assessing its effectiveness on HIV-related and patient-reported outcomes [34] to capture their perspective and experience will assist in identifying and solving implementation challenges and delivering MMD effectively. The goal for the uptake of MMD is not to reach 100% but to offer quality service delivery models, as people-centered care requires diversity and flexibility regarding service delivery models and is likely to change and fluctuate over time.

In Kenya, a previous study has assessed factors associated with MMD [35]; however, to our knowledge, few studies have assessed the effects of MMD following the launch of the DSD national guidelines in Kenya [10, 14]. The strengths of this study include a large representative sample of health facilities and clients across three counties, from both urban (Nairobi) and rural (Migori and Kisii) settings in Kenya, and its longitudinal nature. Limitations include the use of clinical programmatic data, which are subject to a higher degree of data quality errors than research studies that are collected in a more structured environment. Some clients identified as LTFU may have still been in care at a different clinic (e.g., silent transfer), contributing to an overestimation of the number of individuals who were identified as LTFU. We suspect silent transfer (without documentation) among the included stable population is similar across MMD models, leading to nondifferential misclassification of outcome. We could not assess the effects of community ≥ 3MMD model as it was not widely implemented during the period covered by the evaluation. Furthermore, our cohort population was characterized as having good adherence as they had been on ART for at least 12 months, and 99.5% had completed isoniazid TB presumptive treatment. Therefore, our results may not be generalizable to the remainder of the population. Finally, we did not disaggregate our exposure into multiple categories (e.g., 3–5MMD, 6MMD); however, 85% of those classified as ≥ 3MMD received 3–5MMD. Missing data on the ≥ 3MMD eligibility criteria, including opportunistic infections, pregnancy, and BMI status at each visit, limited our ability to confirm the client's eligibility. However, these variables are part of the criteria used by healthcare providers to classify clients as stable, which is captured under the field variable "client status" in the clinical form and was used in this analysis. Other factors may also influence the decision of healthcare providers or clients to select one MMD strategy over another beyond the eligibility criteria defined in the clinical form. Further research would contribute to a better understanding of the decision-making process for preferring more frequent ART refills from both the client's and clinician's perspectives.

In conclusion, no significant difference was found for LTFU at 6 months (180 days) between MMD models. However, ≥3MMD was found to be protective against viral rebound. The goal of providing client-centered care consists of ensuring different service delivery models are sustainable for the health system and responsive to clients' health needs. As a greater variety of service delivery models are being implemented, more robust evaluations are essential to guide the implementation, monitor progress, and assess acceptability and effectiveness to deliver optimal people-centered service delivery.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Description of intervention provided to clients accessing HIV care and treatment services by model of care at selected facilities in Kenya, July 2017-December 2019

Model of care	Components	Frequency/timing
Facility-based Fast Track System for ART Refills	ART refills	≥ 3months
	Clinical consultations	Every six months or as needed
	Psychological support	As needed
	Viral load testing	Every year or as needed
Standard of care (SOC)	ART refills	< 3 months
	Clinical consultations	Every 3 months or as needed
	Psychological support	As needed
	Viral load testing	Every year or as needed

Table 2

Characteristics of adults accessing HIV care and treatment services at selected facilities in Kenya at the time of entry into the cohort starting on July 2017-December 2019

	Overall population n (%) (N = 3,501)	< 3MMD n (%) n = 1234	≥3MMD N (%) n = 2267	*P* value*
Sex				
Male	1,086 (31.0)	306 (24.8)	780 (34.4)	< 0.01**
Female	2,415 (69.0)	928 (75.2)	1487 (65.6)	
Age at time of entry into cohort (years)				< 0.01**
20–24	161 (4.6)	75 (6.1)	86 (3.8)	
25–29	346 (9.9)	150 (12.2)	196 (8.7)	
30–34	636 (18.2)	244 (19.8)	392 (17.3)	
35–39	589 (16.8)	211 (17.1)	378 (16.7)	
40–44	620 (17.7)	195 (15.8)	425 (18.8)	
45–49	447 (12.8)	148 (12.0)	299 (13.2)	
50+	702 (20.1)	211 (17.1)	491 (21.7)	
Marital status				0.09
Single	528 (15.1)	182 (14.8)	346 (15.3)	
Married/Cohabitating	2,308 (66.2)	795 (64.6)	1513 (67.1)	
Separated/Divorced/Widows	651 (18.7)	254 (20.6)	397 (17.6)	
Type of population				< 0.01**
General population	3,329 (95.4)	1151 (93.3)	2178 (96.1)	
KPs*	162 (4.6)	83 (6.7)	89 (3.9)	
Age of ART initiation (years) median (IQR)	35.0 (28.6–42.4)	33.9 (27.4–41.3)	35.6 (29.2–42.9)	< 0.01**
Time on ART (years) median (IQR)	4.4 (2.7–6.8)	4.1 (2.4–6.7)	4.6 (2.8–6.9)	< 0.01**
Current ART regimen at time of entry to cohort				< 0.01**
DTG-based	350 (10.0)	83 (6.7)	267 (11.8)	
EFV-based	2,089 (59.7)	756 (61.3)	1333 (58.8)	
NVP-based	838 (23.9)	308 (25.0)	530 (23.4)	
Other	224 (6.4)	87 (7.0)	137 (6.0)	
Line of current ART regimen at time of entry to cohort				0.75

	Overall population n (%) (N = 3,501)	< 3MMD n (%) n = 1234	≥3MMD N (%) n = 2267	*P* value*
First-line	3,353 (95.8)	1180 (95.6)	2173 (95.8)	
Second-line	148 (4.2)	54 (4.4)	94 (4.2)	
Facility volume				0.34
500–999	2,058 (58.8)	712 (57.7)	1346 (59.4)	
≥ 1000	1,443 (41.2)	522 (42.3)	921 (40.6)	
Location type				0.74
Urban	1,808 (51.6)	642 (52.0)	1166 (51.4)	
Rural	1,693 (48.4)	592 (48.0)	11.01 (48.6)	
Year of entry into cohort				< 0.01**
2017	1,266 (36.2)	451 (36.6)	815 (35.9)	
2018	1,693 (48.4)	626 (50.7)	1067 (47.1)	
2019	542 (15.5)	157 (12.7)	385 (17.0)	

* *p* values obtained using Pearson chi-square or Wilcoxon rank-sum tests as appropriate.* represents *p* values < 0.05 and

** represents *p* values < 0.01

* Key population is composed FSW, MSM, and PWID.

Due to rounding, column sum percent may not be equal to 100%

Table 3

Outcomes associated with 3MMD in comparison to standard of care (< 3MMD) among clients receiving HIV care and treatment at selected facilities in Kenya, July 2017 – December 2019

Outcomes	Unadjusted RR (95% CI)	Adjusted RR (95% CI)
LTFU 180 days **	1.2 (0.8–2.0)	1.1 (0.7–1.6)
Viral rebound ***	**0.1 (0.0–0.2)**	**0.1 (0.0–0.2)**

* Relative risk for LTFU 90 days was adjusted by sex, age at time of visit, model of care at time of entry into the cohort, ART regimen at time of outcome

** Relative risk for LTFU 180 days was adjusted by sex, age at time of visit, ART regimen at time of outcome and location type (urban vs. rural)

*** Relative risk for viral rebound was adjusted by sex, age at time of visit, and previous switching between care models