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Role of Supply Chain in the Implementation of Multi-Month Dispensing of Antiretroviral among People Living with Human Immunodeficiency Virus in Tanzania

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Abstract

Background

Globally, it is estimated that by 2020 28.2 million of all people living with HIV were accessing antiretroviral (ARV) therapy. Providing Multi-Month Dispensing (MMD) of ARV for stable clients has been reported to increase adherence and improve health outcomes in terms of death, retention, adherence, immunosuppression, and viral suppression. The objective of this study was to investigate the role of the health commodities supply chain in the implementation of MMD among people living with Human Immuno Deficiency Virus (HIV) in Tanzania.

Methods

This was a mixed-method cross-sectional study, to investigate the role of the supply chain in the roll-out of the MMD strategy. The study was carried out in 44 Care and Treatment Clinics (CTC) in Mtwara, Lindi, Morogoro, Iringa, Njombe and Ruvuma regions. A structured electronic questionnaire was administered to CTC in-charges and key informant interviews were conducted with 14 District Pharmacists. STATA software version 15 was used for quantitative data analysis and NVIVO 11 was used for qualitative data analysis.

Results

Majority of the health facilities 95.4% had enough first-line ARV medications; 59.1% had enough stock of second-line medications 70.4% had enough stock of paediatrics regimens to support MMD implementation. ARV related factors contributed to 36% of the most common challenges attributed to poor implementation of MMD (ARV stock (23%) and ARV shortage (13%)).. This study established that, the solution of running out of ARV stock is to ensure that ordering is timely done, using quality data and whenever need be, redistribution from nearby facilities to ensure uninterrupted supply of ARVs.

Conclusion

ARV supply chain is at the core of the successful implementation of MMD. The supply chain of ARV drugs should be thoroughly reviewed to ensure ARV resupply is processed timely for all health facilities to maintain appropriate stock levels. To realise and sustain MMD goals.

Keywords: Antiretroviral, Multi-Month Dispensing, HIV, HIV/AIDS, Supply Chain.



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Background

Globally, by June 2020, 84% of the people living with HIV (PLHIV) knew their HIV status and among then 87% were accessing treatment. Of these 90% were virally suppressed (1). In Tanzania as of December 2019, 78% of PLHIV knew their status, 78% of those who knew their status were accessing treatment and 88% of those accessing treatment were virally suppressed (2). Significant progress has been made in expanding access to ARV in lowand middle-income countries (LMICs). With this rapid increase of availability of HIV/AIDS care and treatment services, a critical concern is the capacity of the health system to effectively meet the needs of treatment. Providing HIV/AIDS stable patients with multi-month dispensing (MMD) of antiretrovirals (ARVs) is one differentiated service delivery model (DSDM) that has been recommended to alleviate health system challenges that may affect the efficient provision of ARV(3). Stable clients are those with 'viral suppression' defined as "two consecutive viral load measurements below 1000 copies/ml or in the absence of viral load monitoring, rising CD4 cell counts or CD4 counts above 200 cells/cubic millimetre. These clients are being given MMD of ARV medications for, either three or six months to increase adherence and hence maintain favourable health outcomes in terms of death, retention, adherence and viral suppression. Implementation of these innovative approaches for care and treatment interventions requires a stable supply chain for ARVs and health system adjustment to accommodate these changes to realize the expected outcomes (4).

One such health system adjustment is a stable supply chain that delivers a reliable, continuous supply of health commodities to its customers (5). Stock-out of ARV drugs which ultimately results in rationing of available stocks hampers both service delivery models for the distribution of ARV and achievement of the treat-all strategy (4). In Rwanda, to implement the three-monthly MMD policy necessitated a one-time procurement of additional ARVs for all health facilities so ensure availability of adequate stock to administer to stable clients. Based on procurement and supply chain systems, which considered lead-time and other uncertainties, it was estimated that six months of stock will be required to adequately meet the additional need for ARV's (6). A comprehensive review of both inventory management and distribution systems is recommended prior to the introduction of MMD to ensure adequate planning for the anticipated increase in the volume of needed ARV's (5, 7).

Little is known on the response of the ARVs supply chain following the implementation of MMD in Tanzania. Therefore, this study intended to determine the ARV supply chain in the implementation of MMD among PLHIV in Tanzania.



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Methods

Study design

The study was a mixed-method cross-sectional study employing to investigate the role of the health supply chain in the implementation of MMD.

Study Area

The study was carried out at 44 randomly selected care and treatment centres (CTC) in the southern regions of Tanzania namely Mtwara, Lindi, Morogoro, Iringa, Njombe and Ruvuma. The study area was chosen based on the convenience of access to data, due to existing monitoring and evaluation collaboration between Muhimbili University of Health and Allied Sciences (MUHAS) and Deloitte Consulting Limited.

SN	Region	District	Facility Name	Type of Facility	Facility Ownership
1	Iringa	Mafinga TC	Ihongole	Health Center	Government
2		Mufindi DC	Usokami	Health Center	Faith Based Organization
3		Mufindi DC	lfwagi	Health Center	Government
4		Mufindi DC	Kasanga	Health Center	Government
5		Iringa MC	Frelimo	Hospital	Government
6		Mafinga TC	Mafinga	Hospital	Government
7		Iringa MC	Iringa RRH	Hospital	Government
8		Iringa MC	Alamano	Dispensary	Faith Based Organization
9		Iringa MC	St Edigio	Dispensary	Faith Based Organization
10		Mufindi DC	Nyololo	Health Center	Non-Government Organization
11		Iringa DC	Nzihi	Hospital	Government
12	Lindi	Nachingwea DC	Nachingwea	Hospital	Government
13		Nachingwea DC	Mnero	Hospital	Faith Based Organization
14		Liwale DC	Liwale	Hospital	Government
15	Morogoro	Mvomero DC	Turiani	Hospital	Faith Based Organization
16		Kilombero DC	Mang'ula	Health Center	Government
17		Kilosa DC	Kidodi	Health Center	Government
18		Gairo DC	Gairo	Health Center	Government
19		Ulanga DC	Lupiro	Health Center	Government
20		Kilosa DC	St. Kizito	Hospital	Faith Based Organization
21		Ifakara TC	St. Francis	Hospital	Faith Based Organization
22		Morogoro MC	Morogoro RRH	Hospital	Government
23		Morogoro MC	Sabasaba	Health Center	Government
24	Mtwara	Mtwara MC	Ufukoni	Dispensary	Government

Table 1: Study facilities characteristics



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25		Newala TC	Newala	Hospital	Government
26		Masasi DC	Ndanda	Hospital	Faith Based Organization
27		Nanyumbu TC	Mangaka	Hospital	Government
28		Masasi DC	Nagaga	Health Center	Government
29	Njombe	Ludewa DC	Madope	Dispensary	Government
30		Njombe TC	Idundilanga	Dispensary	Government
31		Njombe TC	Njombe	Hospital	Government
32		Makete DC	Ikonda	Hospital	Faith Based Organization
33		Ludewa DC	Mlangali	Health Center	Government
34		Ludewa DC	Lugarawa	Hospital	Faith Based Organization
35		Njombe TC	Njombe	Health Center	Government
36		Makambako TC	St. Joseph Ikelu	Hospital	Faith Based Organization
37		Makambako TC	Makambako	Health Center	Government
38		Makete DC	Makete Hospital	Hospital	Government
39		Makete DC	Mfumbi	Dispensary	Government
40	Ruvuma	Mbinga TC	Мрераі	Health Center	Faith Based Organization
41		Madaba DC	Madaba	Health Center	Government
42		Madaba DC	Lilondo	Dispensary	Government
43		Nyasa DC	Liuli	Hospital	Non-Government Organization
44		Tunduru DC	Tunduru	Hospital	Government

Study Population

Quantitative data

The study population for quantitate data was all active (100%) patient files from 44 facilities. Active client files are those with at least one visit recorded in the last six months. A total of 83,142 active electronic clients' files were retrieved from CTC2 database.

Qualitative data

For qualitative data, Key informant interviews were conducted with 14 District Pharmacists from Ruvuma, Njombe, Iringa, Morogoro, Lindi and Mtwara regions. The final sample size for Key informants was determined based on theoretical saturation, which refers to the point at which no new concepts emerge from the review of data drawn from a sample that is diverse in pertinent characteristics and experiences (8, 9). In this study saturation was achieved based on daily reviews of notes and transcripts from interviews.

Sampling procedures and sample size

The study involved 146 high-volume health facilities providing care and treatment services to about eighty percent (80%) of all clients in six southern zone regions of Tanzania. To ensure

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representation of different facility levels i.e., hospitals, health centres and dispensaries depending on the proportion of PLHIV served by the strata; within each stratum, simple random sampling was employed to obtain a final sample of 44 facilities that were involved in this study. At each facility active files were retrieved for data extraction (Table 3).

Facility Level	% Proportion of clients served	Number of HF's per category
Hospitals	47.5%	21
Health Centres	36.5%	16
Dispensaries	17%	7
Total	100%	44

Table 2: Stratified random sampling of Health facilities by level

Data collection

Quantitative data

To collect data on the role of the supply chain in the implementation of MMD, a structured electronic questionnaire was administered to 44 CTC in-charges of sampled facilities. Information collected included general health facility information, laboratory services, staffing, workload and commodity availability. Data on MMD client were extracted from patient electronic files.

Qualitative data

Key informant interviews were conducted with pharmacists from districts with sampled facilities. Interview guides were used to probe respondents to acquire rich information. The question asked included How do CTCs in you council get their resupply of ARV's? With regard to MMD, how is it being implemented at facilities in your council? How MMD implementation has affected Supply chain system in your council?; Do you have any final comments or recommendations on MMD implementation? The interview was recorded using a tape recorder. Additionally, the researcher took notes during the interview.

Confidentiality

Confidentiality was maintained by de-identifying all electronic patient records, key informant interviews and supply chain information. All data was kept with utmost confidentiality in password protected electronic equipment the password was known only to the research team.

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Data management and analysis

Quantitative data

STATA software version 15 was used for quantitative data analysis. Descriptive statistics were done to determine the characteristics of PLHIV electronic files and MMD status.

Qualitative data

A thematic analytical approach was employed in the analysis of this data, this method explores for emerging themes that can describe the subject under investigation (10). All interviews were audio-recorded, transcribed verbatim into a computer Microsoft word. Transcripts were then imported to NVIVO 11 to be coded and sorted. Transcripts were initially examined to identify primary coding categories as well as the range of themes present within each category. Codes and sub-codes that were derived directly from the transcripts were used as a guideline when coding. Developed codebook contained identified coding categories and themes, new emerged themes were attached in the appropriate code as coding proceeding. The purpose of this process was to systematically group text data into fewer content-related themes that share the same meaning.

Results

Characteristics of HIV Clients

A total of 83,142 electronic clients' files were retrieved from CTC2 database of all 44 sampled health facilities. Majority of client, 54,404 (64.4%) were of females, while 28,738 (34.6%) were male clients. About 99.2% of clients were above five years of age. Clients' duration on ARV was assessed, and about 51.6% had over five years on ARV while 48.4% had less than five years on medication

Table 3:	Characteristics	of HIV	clients
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	Characteristic	N = 83,142	%
Age (Years)	< 5	633	0.8
	<u>></u> 5	82,509	99.2
Sex	Female	54,404	65.4
	Male	28,738	34.6
Days on ARV	< 180	6,838	8.2
	180+	76,304	91.8

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Characteristics of Key Informants

Key informant interviews were conducted to a total of 14 district pharmacist, all of them were degree holders with working experience ranging from three to seventeen years in their current roles. All participants had vast knowledge on how PLHIV are being managed at their supervised facilities including MMD intervention.

Facility capacity to provide ARV

Facility capacity to provide ARV was assessed based on the facility stock adequacy to serve the current pool of eligible clients at the study period. The majority (95.4) of the facilities confirmed to have enough first-line ARV medications; 59.1% had enough stock of second-line medications 70.4% had adequate stock of paediatrics regimens to support MMD implementation. (Table 4).

	Characteristic	N= 44	Percentage (%)
Enough ARV stock for 1 st line	Yes	42	95.4
	No	2	4.6
Enough ARV stock for ARV stock	Yes	26	59.1
2 nd line	No	18	40.9
Enough ARV stock for Paediatrics	Yes	31	70.4
(Above 5years)	No	13	29.6

Table 4: Facility's capacity to provide ARV for MMD clients

Compliance on MMD Service Delivery Model

This section presents the results of the compliance of MMD across the studied facilities. The study findings show that, 51,478 out of 83,142 (61.9%) clients who were analyzed by the study were eligible for receiving MMD, and 31,664 (38.1%) clients were not eligible. The key informant interviews revealed similar information on the HCW knowledge to determine clients who are eligible for MMD and those that are not, one respondent had this to say.

"...For us stable clients are those that after starting using ARV continue to demonstrate higher level of ARV treatment adherence, the correct way of using ARV's lead to lower viral load and high CD4 count ..." (Key Informant IR2 from Iringa).

Therefore, in order to gain more insights on facilities compliance to MMD, a cross tabulation analysis was performed to establish whether facilities provided MMD to stable clients. Out of



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51,478 stable clients, 82.1% were put on MMD while 17.9% did not received MMD. This is summarized in (Table 5).

	On MMD		
MMD Eligibility	Yes	No	Total
Eligible	42,259 (82.1)	9,219 (17.9**)	51,478 (100)
Not eligible	10,685(33.7) **	20,979 (66.3)	31,664(100)
Total	52,944	30,198	83,142

Table 5: Clients provided with MMD per eligibility categorizations

**Poor compliance of MMD

Some clients eligible for MMD were reluctant to be given 90 days ARVs pills as they did not want to be seen carrying those pills, as narrated by one respondent.

"...we were also receiving packages with 30 pills; therefore, we were supposed to give each client three packages to make the total of 90 pills that also bring challenges because some of the clients did not want to be seen carrying a large number of pills..." (Key Informant IR1 from Iringa).

Standard Set-Up to Provide ARVs

The findings of the study show that health facilities were in line with standards set up to provide ARVs. This is justified in the below quotation;

"...Most of the facilities now provide pills for three months, and the important thing is improvement in the packaging, mostly the ARV is tenofovir, lamivudine and dolutegravir (TLD) with a package that contains 90 pills. Clients are given after conducting thorough assessment to ensure client's stability. Also, we started to provide after receiving the guideline from the government that require us to start providing pills to the client who qualifies in the stable client criteria..." (Key Informant IR1 from Iringa).

ARV Stock Status and Ordering

To ensure smooth implementation of MMD, facilities were supposed to keep enough stock of ARVs to supply for the needy stable clients. This was done through proper forecasting and ordering of ARV's from Medical Stores Department (MSD) as it was noted from an interview from Key informant from Iringa.

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"...The first thing that we did was to identify clients who are classified as stable. This helped us to forecast our needs to be able to get the supplies because we knew demand will increase, therefore we tried to identify and get the number of the stable client then the pharmacist make some projections that will help us to meet our requirements, thereafter we would order for the pills that we think could be enough to serve the demand" (Key Informant IR2 from Iringa).

ARV availability and MMD implementation

The study further measured the influence of ARV stock in relation to adherence to MMD implementation. The most common mentioned challenges attributed to poor implementation of MMD were ARV stock-outs (23%), followed by a 19% delay of HVL results and 13% ARV shortage. Overall, the ARV-related factors contributed to 36% of all challenges (Figure 1).



Figure 1. Facility Challenges Affecting Implementation of MMD

This was corroborated by the qualitative findings whereas one of the key informants had the following excerpt to comment.



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"...Some of the clients do not prefer seen carrying the pills. This brings some challenges. The major challenge was however a shortage of supply after a while supply increased and things become better..." (Key Informant NJ1 from Njombe).

Following ARV's stock out, the quantity of drugs dispensed to clients is reduced to ensure continuity of services so that all clients get ARV medication during their visits. This was evidently captured during an interview with key informant from Njombe and Mtwara who had the following to say.

"...We look at the available stock and decide to go back to one-month dispensing system so that all the clients will be able to get the pills.... When the supply is full, stable the client would receive the three-month pills..." (Key Informant MT2 from *Mtwara*).

Thus, ARVs supply capacity depended on the capacity of the health facility to make an order to MSD. Health facilities to be able to have a stock to serve their client they should make an order based on the site category i.e., ordering site/non-ordering site.

"...CTC receives ARVs in two different ways, first there are those centres that they order directly from MSD (mother sites). We currently have four health facilities that order direct from MSD therefore MSD sends to them directly. But we also have other health facilities that are non-ordering sites, which receive their ARVs through ordering facilities that order directly to MSD." (Key Informant NJ1 from Njombe.

The absence of persistent supply to the facilities makes it hard to serve all the targeted community as per the government guideline; hence the client cannot have a clear understanding regarding their clinic appointments. This was likely to interfere with their daily schedules as they must do more clinic visits. Especially when they are given pills for one month instead of three months or more.

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"...we have met with low supply of the ARVs., Although we order the amount of the medicines required, but we receive less the amount ordered, this forces us to make more emergency order and sometimes we are told MSD is out of stock and we are forced to wait until they arrive. (Key Informant IR2 from Iringa).

The problem of ARV ordering and stock-outs is attributed to several bottlenecks. This can be viewed from the comment made by one of the key informants.

"...The challenge that we have is the geographical location of our district and the infrastructure, it hinders the distribution of ARVs that is why you may find ordering site mother sites cannot help non-ordering site..." (Key Informant IR1 from Iringa).

Nevertheless, due to poor geographical location and not meeting criteria for the site to place ARV's orders directly from MSD some of the non-ordering sites find different means to solve challenges they encounter. This includes the use of motorcycles to carry some of the pills from the mother sites. The below quotation justifies this.

"...what we are doing to rescue the situation, the non-ordering sites come with motorcycle to pick the pills for their sites...Because of the motorcycle capacity, they just take a little and when they are out of stock again motorcycle is sent again to collect from the mother site or if there is any car that it pass-by will collect for them..." (Key Informant NJ1 from Njombe).

Shelf Life of Existing Stock

Visual inspection for the shelf life of ARV medicines is normally done prior to dispensing them to the needy clients so that medicines do not expire before being consumed by the client. The study found that with the current package of default first-line ARV, healthcare providers are supposed to open the package and repackage pills to clients to reach the number of required days which can be consumed before expiry, as the packages are fixed with 90 pills each. The below excerpt describes this more clearly.

"...the challenge led us to open the packs using First Expiry First Out (FEFO) approach, then we start counting the pills enough to be consumed by clients before expiry. However, quality of pills can be compromised since they are not stored in their original containers..." (Interview with Key Informant IR2 from Iringa).

To countercheck, the setback raised by ARV's shelf life was done by facility by ensuring management of medication with short expiration dates. This was done by providing ARV

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medication with a short shelf life to clients who are not under MMD service and those with long expiration duration to MMD clients. This was narrated by one of the key informants who offered the following excerpt.

...You may find you have batches of pills some of them last for a long period of time when some are for a short period of time therefore for the short life span pills, we give them to the patient who fall under the short period of time like those who are new clients. A patient who falls under three months period and stable patient we give them pills that have longer life span..."(Interview with Key Informant IR2 from Iringa).

Discussion

The finding of the study established that supply chain factors are very important in promoting the effective implementation of MMD. The supply chain ensures the availability of ARV at alltime based on the requirement of the facility. This is the first step to ensure that the facility does not have ARV stock out. The study found that it is paramount for the facilities first to understand the standard setup to provide ARVs with a main focus on stable clients. To do so, healthcare providers have to assess the clients' criteria for MMD and make the projection of required ARV medications. A study in Ethiopia, on the supply chain management performance of HIV/ AIDS commodities and factors affecting it, corroborate these findings, narrating that a health commodity inventory control system has been important to maintain appropriate stock levels (11). In another study, it was reported that lack of proper supply chain pre-planning and stock-outs could interfere with the implementation of DSDM such as MMD (12).

The findings of this study pointed out that stock out affected the implementation of MMD at health facilities. Consequently, the lack of sufficient stock to support MMD at health facilities led to healthcare providers' failure to comply with the implementation of MMD. The available drugs will not suffice for all active clients who are on ARV, to be provided with 90 or 180 days pills. However, stock out of ARV's at health facilities is contributed by several other factors, some of which are beyond the capacity of the health facilities. These includes shortages in the national pipeline, long order fulfilment rate such as delays in ordering and or distribution. The study findings showed that some facilities order ARVs directly from MSD; these facilities are termed as mother sites, while other facilities order the ARV drugs from the mother sites. Shortage of ARVs at mother sites will also be reflected at non-ordering sites. In addition, some of the non-ordering sited can experience shortage as a result of failure of



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ordering site to deliver ARV's to these sites due to lack of required resources. Therefore, the study established that the solution of running out of ARV stock is to ensure that timely ordering using quality data and whenever need be, redistribution from nearby facilities. Similarly approach has been proposed in Uganda as a means to reduce ARV stockout(13). Supporting ordering sites with resources for distribution of ARV's to non-ordering sites remains of paramount importance, alternatively, non-ordering sites need to be equipped and order directly from MSD. A study in Uganda highlighted ARV stock out as a bottleneck in the implementation of MMD (14). Similarly, findings have been reported regarding HIV service delivery in Liberia, highlighting that, commodity supply chain disruptions are likely to hamper the achievement of the 95 95 95 targets since eligible clients will not receive MMD (15).

Another supply chain factor assessed by the study was the shelf life of ARV drugs. It was noted that the ordering process, storage and package of ARV drugs largely affect the quality of drugs over time. At first, the quality of drug is being affected by the long ordering process ranging from MSD, which order the drugs abroad from the time they reach the country, their life cycle is reduced(16, 17). With ordering of drugs taking a long time, it somehow affects the life cycle of the drug, however, the study found out that providers use First Expiry First Out (FEFO) approach to dispensing ARV drugs to manage the shelf life of the drugs. This finding was consistent with a previous study in Ethiopia which indicated that, due to storage challenges, health facilities manage their ARV stock through adaptation of the FEFO approach(13). Therefore, it is worthwhile for this study to argue that the shelf life of ARV drugs if not managed properly will result in running out of stock of required ARV medication due to expiries.

Poor ordering processes could affect the shelf life of ARV drugs because it takes a period for the drug to reach the facility. This is complemented by a recent study in Ethiopia, which showed that only 30% of health facilities received their ARV drugs orders on time. (11). Again, a review of ARV's procurement and supply chain management ascertained that the average ARV shelf life is usually 24–36 months, a product must arrive in the country within a few months of manufacture; hence manufacturers do not take the risk of keeping goods ready for stock themselves, and most ARVs are 'made to order though this can result in longer lead times and an inability to meet emergency orders (18). Additionally, it was also noted that, shelf life of ARV drugs is being attributed to poor distribution process which take long time for the drugs to reach health facilities (11). A similar finding has been documented elsewhere, such as in Uganda and Malawi (19, 20). Therefore, it is crucial that healthcare providers are provided with appropriate training on the supply chain and distribution of ARV

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drugs to clients. This will ensure consistent availability and distribution of ARVs to MMD eligible clients.

In interpreting the results of this study, should be noted that the study was conducted during the COVID-19 outbreak, this might have led to increased number of ineligible clients being put on MMD to reduce congestion at care and treatment clinics. The study was conducted in only six regions of Tanzania, and the sampling frame was based on patient volume and health facility levels. Moreover, trustworthiness of the results of this study was assured through triangulation with respondents from different settings, interviews were conducted by experienced researchers and to the saturation point, we further triangulated qualitative and quantitative results.

Conclusion

A robust supply chain system is of paramount importance to ensure uninterrupted availability of ARV's for successful implementation of MMD. The current design of the ARV ordering system with ordering and a non-ordering site causes ARV shortages at non-ordering sites due to distribution challenges. Therefore, the supply chain of ARV medications should be thoroughly reviewed to ensure ARV resupply is processed timely for all health facilities to maintain appropriate stock levels. Wherever possible, non-ordering sites should be capacitated to order ARVs directly from MSD. Adhering to criteria for assigning only stable clients to MMD is key in ensuring the forecasted ARV drugs are sufficient. The supply chain of ARV drugs should be prioritized if the achievement of the MMD intervention is to be realized and sustained.

Abbreviations

ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
СТС	Care and Treatment Centre
HVL	HIV Viral Load
MMD	Multi-Month Dispensing
OI	Opportunistic Infections
PLHIV	People Living with HIV



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Declarations

Competing interests

All authors declare that they have no competing interests.

Ethical approval and consent to participate

Ethical approval to conduct this study was obtained from MUHAS Senate Research and Publications Committee. A formal written informed consent, in Kiswahili, was used. The informed consent described the purpose of the study, the procedures to be followed, and the benefits of participation. Participants were advised that their participation in this evaluation is voluntary, and they have the right to withdraw from the study at any point in time. For secondary data, confidentiality was maintained by de-identifying all the study data at the end of data collection.

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Authors' contributions

GMR and GGM collected all the primary data, conducted the analyses and wrote the first draft. FNN contributed to the research design, interpretation of the results, and writing the manuscript. BCU,IRM MAN contributed interpretation of the results, and writing the manuscript.

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