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Longitudinal Analysis to Assess the Contribution of the Multi-Month Scripting (MMS) Regime on ART Outcomes among Adult (15+) Persons Living with HIV in Zimbabwe

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Introduction

Acquired Immuno Deficiency Syndrome (AIDS) continue to be a major global public health concern. There are an estimated 1.3 million people living with in Zimbabwe and 1,100,000 million were estimated to be on Antiretroviral Therapy (ART) by 2018 [1]. As part of the continued efforts to scale up client focused ART program at a global level, WHO released guidance (the 2013 guidelines, followed by the 2016 guidelines) [2,3] focused on Differentiated Models of Care (DMC). DMC is meant to ensure that HIV services across the cascade reflect the preferences and expectations of various groups of people living with HIV, while enhancing service delivery.

In Zimbabwe, two models of differentiated care for stable patients stand out: the adjusted appointment spacing through Multi-Month Scripting (MMS) and community ART groups (CAGs). MoHCC released an updated Operational and Service Delivery Manual for the Prevention, Care and Treatment of HIV in Zimbabwe (OSDM) in February 2017. This is the second edition of the manual originally developed in 2015. It sets out 'how' to implement WHO's 2016 [3] clinical guidelines, including differentiated service delivery (DMC) across the entire HIV cascade from prevention to suppression. The aim of the study is to assess the contribution of the Multi-Month Scripting (MMS) regime on ART outcomes among adult persons living with HIV in Zimbabwe.

Methodology

Study design and data sources

This is a retrospective cohort analysis of treatment outcomes. Data were abstracted from the OI/ART patient care booklets for clients initiated on ART between October 2012 and March 2013. Data was abstracted for a 60-month period. MMS was the exposure variable, while the outcomes of interest are (clinical outcomes (weight gain, OIs, TB AEs); survival status, adherence; and retention. Below is a construct of the key outcome variables for the study (Table 1).

Study population

Site selection: Data were collected from all five MOHCC facilities in Chitungwiza; namely Chitungwiza Central Hospital, Seke North Clinic, Seke South Clinic, St Mary's Clinic and Zengeza Clinic. Data was abstracted for the period April 2013 to March 2017.

Patient inclusion criteria: All HIV positive clients 15 years and older, who were initiated on ART between the October 2012 and March 2013, at the five ART sites in Chitungwiza, regardless of treatment outcome, were included in the study. This is because clients would be put on MMS only if they have been on ART for at least 6 months and are stable.

Patient exclusion criteria: Patients initiated on ART after March 2013 was excluded from the study. Patients without a documented ART initiation date were excluded from the study.

Sample size

It is important to note that the study sought to detect the contribution of MMS on ART outcomes (Table 2). The following formula was used to come up with the sample size:

$$n = \left[p(100 - p) / \Delta\text{^}2 \times \mathrm{f}(1 - \propto) \right]$$

n = computed sample size

p = estimate of the proportion

Δ= the desired width of the confidence interval

1-∝= confidence level

Table 1: The key outcome variables.

Domain	Variable
Survival status	Dead or alive
Retention	Loss to follow up, on time pill pick up (active client)
Immunological/ Virological response	Change in CD4 count or viral load, treatment failure
Clinical outcomes	Weight gain, OIs

Table 2: Sample size per health facility.

Name of Health Facility	Proportion	Sample size (Sex Distribution (60%/40% for Females and Males on ART)
Chitungwiza Central Hospital	0.443371	137 (F=82; M=55)
Seke North Clinic	0.056729	18 (F=11; M=7)
Seke South Clinic	0.196021	60 (F=36; M=24)
St Mary's Clinic	0.127106	39 (F=24; M=15)
Zengeza Clinic	0.176786	56 (F=33; M=23)
Total	1	310 (F=186; 124)

This implied that the study needed to sample a minimum of 310 OI/ART Patient Care Booklets to generate 95% confidence intervals with +/- 2.5% bounds around the proportion of interest. The sample is distributed as follows, per site, using probability proportional to size (as per their ART volume in June 2013).

Data collection

The following process was followed.

- One team of four data abstracters worked on this process.
- When the team arrived at the clinic, the abstractors met with and oriented one to two clinic staff about the objectives of the study and sought for any adult ART patient registers.
- The study numbers on each data extraction form are different to these unique identification numbers. In this way, there were no unique identifiers on any of the data abstraction forms that will allow data, collected on the form, to be linked with a specific patient attending the clinic.
- Where registers were not available, numbers were assigned to all adult ART patient OI/ART Patient Care Booklets for the purpose of sampling.
- Once numbers were assigned to all adult ART patient OI/ART Patient Care Booklets, Microsoft Excel was used to generate a list of randomly ordered ART OI/ART Patient Care Booklets at each site. The first sequential OI/ART Patient Care Booklets in the list were then selected for review until the quota for the site is reached.
- Data was abstracted using a standard data abstraction tool.
- A "study register" was created during chart review to document which records were not found or which were discarded due to one of the different exclusion criteria. The study register will not have any patient name. The study register was used to document the number of missing records at the facility and provide recommendations to the MoHCC at the end of the study.
- Feedback was given to the clinical staff at the end of the session based on the observations of the abstractors. Feedback focused on the importance quality data for patient monitoring.
- The data was captured using tablets running on an ODK platform. After each site visit, all the data would be sync into a database.

Data analysis

All analyses were performed using STATA 13 software. Data management was performed, checking the data for completeness and consistency. Variables were managed using recode, encode, generate, destring, and tabstat commands in STATA 13 software. Univariate analysis was conducted to come with descriptive statistics and pictorial representations. The Wilcoxon matched-pairs signed-ranks test was applied to test for median difference between baseline CD4 and CD4 follow up, and baseline weight and follow-up weight, respectively. The Kaplan Meier and Nelson-Aalen methods were used to model survivorship function curves for retention and survival time, stratified by selected independent variables. The log-rank test was performed to test the significance of the difference in retention and survival for selected categorical variables.

Ethical considerations

Clearance was sought from the MOHCC Head Office, the Chitungwiza Central Hospital CEO, the Superintendent at CITIMED Chitungwiza Hospital and the Chitungwiza City Health Department. To ensure confidentiality, no personally identifiable information relating to clients, such as patient name or clinic registration, number were collected during chart extraction. All the data was kept by the principal investigator on a personal computer with a password-protected login screen.

Results

Demographic characteristics

Three hundred and five (305) respondents were considered in the study, with 196 being clients on MMS. 60% of the sample was composed of females. Seventy-six percent (76%) of the respondents were in the 25-49-year category. Majority of the females were in the 30-34-year age category. Males had a bimodal distribution in the 35-39 and 40-49-year age category. Sixty percent (60%) of the respondents were females. As shown in table 3 below, there are apparent age-sex specific differences worth mentioning. For instance, the majority of the females included in the study were in the 30-34-year age group, while for men the data shows a seemingly bimodal distribution for 35-39 and 40-44-year age groups. Sixty-four percent (64 %) of the clients were married, 18% were widowed, 10% were divorced and 7% were single. Table 3 shows other demographic characteristics of the respondents.

The majority (71%) of the clients attained a secondary level of education. Only one percent of both males and females reached tertiary level. In addition, only one percent did not have any level of education. Fifty-eight percent (58%) of the respondents were enrolled

Table 3: Marital status and level of education of respondents.

Demographic Variable	Female ART Clients		Male ART Clients		Over all Sample	
Marital Status	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Divorced	24	13%	5	4%	29	10%
Married	99	54%	96	79%	195	64%
Single	13	7%	9	7%	22	7%
Widowed	47	26%	9	7%	56	18%
Unknown Status	0	0%	3	2%	3	1%
Total	183	100%	122	100%	305	100%
Level of Education						
None	2	1%	1	1%	3	1%
Primary	27	15%	10	8%	37	12%
Secondary	123	67%	95	78%	218	71%
Tertiary	2	1%	1	1%	3	1%
Unknown Level	9	16%	15	12%	44	14%
Total	183	100%	122	10%	305	100%

Source: Study data, 2017

through VCT. Thirty-seven percent (37%) of the sampled clients were in WHO clinical stage III, see table 3 for more detail.

Of the total sample, 23% did not have a CD4 count done (42/183 women and 29/122 men) as shown in table 4 above. In 2012/13, where point of care CD4 counts was done, ART initiations were restricted to those with a CD4 cell count of 350cells/μL or less. The exceptions to this rule were pregnant women as well as those who were TB-HIV co-infected regardless of sex. The proportion of those with/without a documented CD4 result was the same for both males and females. The average CD4 count at initiation was 334cells/μL for females and 289cells/μL for males.

Treatment outcomes analysis

Survival time: As shown in table 5, the incidence rate (failure rate) was, on average, 19 per 1000 across the age groups. It was highest, at 20 per 1000, among the 40-44 year olds and lowest among the 25-29-year age group. The median survival time is 53 months (out of a possible 60) as shown below. The median survival time is lowest in the 15-19 year age group and highest in the 20-24 and 50+ year age groups. The incidence rate and survival time are not different for both gender and MMS status (Table 6).

As shown in table 4 below, there were two failures (deaths) in the first six months after ART initiation (rate of 1.1038, 95% CI: 0.28-4.41). In addition, there were 2 failures in the 42-48-month period (rate of 1.1869436; 95% CI: 0.2968518-4.745921). There was also one death in the 54-60-month period (rate of 5.4317824; 95% CI: .0.7655624-38.58191).

A further interrogation of the data shows that four of the five failures occurred among clients with no TB as shown in table 7. However, as shown in the same table, the survivor function (probability of surviving beyond time, t,) was higher among clients without TB compared to those diagnosed with TB.

Retention: For retention, the incidence rate (attrition rate) was, on average, 18 per 1000 as shown in table 8. It was highest among the 40-44-year age group (18.2 per 1000) and lowest among the 25-29-year age group (16.5 per 1000). The median retention time was 53 months. Median retention time was lowest in the 15-19-year age group compared to the other age groups. As with survival, the median retention time was the same between males and females, at 53 months, and so were the incidence rates (17 per 1000). Similarly, the data shows no differences in the median retention time between ART clients diagnosed with TB and those with no TB regardless of MMS status.

Table 4: Survival over time.

Cohort	Person-time	Failure	Rate	95% Confidence Interval	
0-6 months	1812	2	1.104	0.276	4.413
6-12 months	1788	0	-	-	-
12-18 months	1782	0	-	-	-
18-24 months	1772	0	-	-	-
24-30 months	1766	0	-	-	-
30-36 months	1760	0	-	-	-
36-42 months	1744	0	-	-	-
42-48 months	1685	2	1.187	0.297	4.746
48-54 months	254	0	0	-	-
54-60 months	184	1	5.434	0.766	38.582
Total	15561	5	0.321	-	-

Source: Study data, 2017.

Table 5: Clinical characteristics of the sampled male and female clients.

Referral source for HIV care and Treatment	Female ART Clients		Male ART Clients		Overall Sample	
VCT	89	49%	87	71%	176	58%
TB Clinics	5	3%	10	8%	15	5%
PMTCT	13	7%	0	0%	13	4%
Obstetrics Unit	10	5%	0	0%	10	3%
Hospitalization	62	34%	23	19%	85	28%
Home	1	1%	0	0%	1	0%
Other	3	2%	2	2%	5	2%
Total	183	100%	122	100%	305	100%
WHO Stage at Initiation	Number	Percent	Number	Percent	Number	Percent
Stage I	55	30%	20	16%	75	25%
Stage II	73	40%	40	33%	113	37%
Stage III	49	27%	59	48%	108	35%
Stage IV	6	3%	3	2%	9	3%
Total	183	100%	122	100%	305	100%
CD4+ Cell Count Done						
Yes	42	23%	29	24%	71	23%
No	141	77%	93	76%	234	77%
Total	183	100%	122	100%	305	100%
Pre-ART Exposure						
HAART	39	21%	21	17%	60	20%
PMTCT	7	4%	0	0%	7	2%
SD NVP	4	2%	1	1%	5	2%
None	133	73%	100	82%	233	76%
Total	183	100%	122	100%	305	100%
Exposure to OI prior to ART initiation						
TB	9	5%	21	17%	30	10%
Other OI	36	20%	16	13%	52	17%
None	138	75%	85	70%	223	73%
Total	183	100%	122	100%	305	100%

Source: Study data, 2017.

Table 6: Survival time data by age, sex and MMS status.

Variable	Time at risk	Incidence rate	Number of subjects	Survival Time		
Age Group				25%	50%	75%
15-19 years	311	0.0192	6	51	51	53
20-24 years	375	0.0187	52	53	54	55
25-29 years	1699	0.0182	32	52	53	56
30-34 years	2686	0.019	51	52	53	55
35-39 years	2952	0.019	56	51	53	55
40-44 years	2028	0.0197	42	52	52	55
45-49 years	782	0.0191	15	51	52	55
50+ years	1383	0.0188	28	52	54	55
Total	**12216**	**0.019**	**237**	**52**	**53**	**55**
Sex						
Male	6121	0.0191	121	51	53	55
Female	9440	0.0193	183	51	53	55
Total	15561	0.0192	304	51	53	55
MMS						
No	5541	0.0195	108	51	53	55
Yes	10020	0.0191	196	51	53	55
Total	**15561**	**0.0192**	**304**	**51**	**53**	**55**

Source: Study data, 2017.

Table 7: The survival function stratified by TB status.

No TB	Beginning Total	Fail	Survivor Function	Standard Error	95% Confidence Interval	
6 months	271	1	0.9964	0.0036	0.9744	0.9995
12 months	271	0	0.9964	0.0036	0.9744	0.9995
24 months	269	0	0.9964	0.0036	0.9744	0.9995
36 months	267	0	0.9964	0.0036	0.9744	0.9995
48 months	247	2	0.9887	0.0065	0.9654	0.9963
60 months	4	1	0.9768	0.0135	0.9285	0.9926
Diagnosed with TB						
6 months	29	1	0.9667	0.0328	0.7861	0.9952
12 months	29	0	0.9667	0.0328	0.7861	0.9952
24 months	28	0	0.9667	0.0328	0.7861	0.9952
36 months	28	0	0.9667	0.0328	0.7861	0.9952
48 months	27	0	0.9667	0.0328	0.7861	0.9952
60 months	1	0				

Source: Study data, 2017.

Table 8: Retention over time, by age, sex, MMS status and TB status.

Variable	Time at risk	Incidence rate	Number of subjects	Survival Time		
Age Group				25%	50%	75%
15-19 years	311	0.0161	6	51	51	53
20-24 years	375	0.0187	52	52	53	54
25-29 years	1699	0.0165	32	52	53	56
30-34 years	2686	0.0179	51	52	53	55
35-39 years	2952	0.0176	56	52	54	55
40-44 years	2028	0.01182	42	52	53	55
45-49 years	782	0.0179	15	52	52	55
50+years	1383	0.0174	28	51	54	55
Total	**12216**	**0.0176**	**237**	**52**	**53**	**5**
Sex						
Male	6121	0.0168	121	52	53	55
Female	9440	0.0175	183	52	53	55
Total	15561	0.0172	304	52	53	55
MMS						
No	5541	0.0175	108	51	54	55
Yes	10020	0.0171	196	52	53	55
	15561	0.0172	304	52	53	55
TB						
No TB	14110	0.0172	274	52	53	55
Diagnosed with TB	1451	0.0172	30	52	53	55
Total	**15561**	**0.0172**	**304**	**52**	**53**	**55**

Source: Study data, 2017.

Table 9 shows retention rates at 6, 12, 24, 36, 48, and at 60 months, by MMS status. Retention was 100% among clients who were not on MMS. For clients on MMS, retention at 12 and 24 months was 99%, dropping to 98% at 48 months. The retention rate drops further to 96% at 60 months. This could partially be explained by reporting issues i.e. how accurately the information system captures MMS.

Immunological response: Table 10 below shows the immunological response changes by sex, MMS status (i.e. on MMS or not on MMS). As shown in the table, there were statistically significant gains in CD4 among all clients, regardless of sex or MMS status (p=0.00), albeit the variation in the mean differences. However, the change in CD4 as measured by the mean difference, was higher (64.63 *vs.* 32.37) among clients who were not on MMS than those on MMS. This is not surprising given that typically MMS clients are recruited with a minimum CD4 threshold. When further stratified by TB status for both MMS and non-MMS clients, there were statistically significant gains in CD4 cell count across all the strata.

Clinical response: Overall, the median weight gains at 12, 24, 36, 48 and 60 months were 4.2, 5.1, 5.4, 5.9 and 6.1kgs respectively among MMS clients as shown in figure 1 below. For non-MMS clients, the median weight gains at 12, 24, 36, 48 and 60 months were 4.1, 5, 5.34, 5.8 and 6.1 kgs respectively. The results were not statistically different between MMS and non-MMS clients (p>0.05).

Discussion and Conclusion

Among the 305 ART clients with HIV/AIDS who initiated ART, there were five failures; two within the first 6 months, two between the 42-48-month period and one in the 54-60-month period. Overall, the median survival time (53 months) was the same among MMS and non-MMS clients. The retention rates at 12, 24, 36, 48 and 60 months were 100% for non-MMS clients. For MMS clients, retention rates were 99% at 12 and 24 months, dropping to 98% at 48 months and to 96% at 60 months. The results are higher in comparison to a retrospective study by Tsitsi Mutasa-Apollo et al (2014) [4], which showed retention at 6, 12, 24 and 36 months as 90.7%, 78.1%, 68.8% and 64.4%, respectively. The differences could partially be explained by differences in the time when the two studies were undertaken. In addition, the country's ART program has witnessed significant investments meant to enhance clinical outcomes for ART patients e.g. investments in nurse mentors at facility level, capacity development of health care workers, motivation grants (salary top ups through Global Fund), deployment of community cadres (peer navigators and health care workers) and patient follow-up resources (through both PEPFAR, Global Fund and World Bank) which all help facilitate an effective ART program.

Overall, the median weight gains at 12, 24, 36, 48 and 60 months were 4.2, 5.1, 5.4, 5.8 and 6.2kgs respectively. The results were not statistically different between MMS and non-MMS clients. The results are similar to the study by Tsitsi Mutasa-Apollo et al (2014) [4] (for adults ≥ 15 years initiated on ART from 2007 to 2009) where the median weight gains at 6, 12, and 24 months were 3, 4.5, and 5.0 kgs. There was a statistically significant change in the CD4 counts over time for both MMS and non MMS clients. The results also showed that there was no statistically significant change in mean CD4 count among the 15-19 year olds, regardless of MMS status. As highlighted earlier, this is typical of adolescent clients, hence the reason they have CD4 counts done every six-month, yet for adults, once a client is deemed stable, the CD4 or viral load is to be done once a year. The study results do not point to a statistically significant contribution of MMS to observed clinical outcomes. However, the contribution of MMS to observed ART outcomes could as well be clinically significant (Table 11).

Recommendations

The study findings suggest the need for more research to conclusively determine the contribution of each of the models of differentiated care. There is evidence on the economic benefits of MMS. The fact that it saves on time and space at health facilities is also well documented. The researcher advocates for the following:

- An expanded research, covering a wide spectrum of sites, especially the rural sites, to help understand more the actual net effect of MMS, beyond the documented financial and other resource benefits of MMS at health facility level.
- Conduct an evaluation of the various models of differentiated care individually, and in tandem with others, to assess the net effect of these differentiated models of care, controlling for other factors (e.g. other interventions already in place to enhance patient level ART outcomes).

Table 9: Retention rates over time.

MMS	Cohort period	Total	Attrition Retention rate		SE	95% CI
No						
6	6	8748	0	1	.	.
12	12	8748	0	1	.	.
24	24	8586	0	1	.	.
36	36	8505	0	1	.	.
48	48	7776	0	1	.	.
60	60	243	0	1	.	.
Yes						
6	6	15552	162	0.9898	0.0008	0.9881 0.9912
12	12	15552	0	0.9898	0.0008	0.9881 0.9912
24	24	15471	0	0.9898	0.0008	0.9881 0.9912
36	36	15390	0	0.9898	0.0008	0.9881 0.9912
48	48	14337	162	0.9792	0.0011	0.9768 0.9813
60	60	243	81	0.9604	0.0024	0.9555 0.9647

Source: Study data, 2017.

Table 10: Comparison on the changes in CD4 count at initiation with the final follow up CD4 count.

Variables	Mean	SE	SD	95% C		P-value
All clients						
Follow-up CD4 (Cells/mm³)	247.68	1.37	192.79	245	250.37	
Baseline CD4 (Cells/mm³)	204.08	0.99	138.84	202.14	206.01	
Mean difference (Cells/mm³)	43.61	1.14	160.31	41.37	45.84	0
Male						
Follow-up CD4 (Cells/mm³)	202.43	2.19	190.87	198.14	206.72	
Baseline CD4 (Cells/mm³)	163.56	1.28	111.58	161.05	166.06	
Mean difference (Cells/mm³)	38.87	1.78	155.44	35.38	42.36	0
Female						
Follow-up CD4 (Cells/mm³)	276.04	1.71	188.52	272.69	279.4	
Baseline CD4 (Cells/mm³)	229.47	1.34	147.93	226.84	232.1	
Mean difference (Cells/mm³)	46.58	1.48	163.22	43.67	49.48	0
MMS-No						
Follow-up CD4 (Cells/mm³)	243.49	2.48	205.53	238.63	248.34	
Baseline CD4 (Cells/mm³)	178.86	1.49	123.59	175.94	181.78	
Mean difference (Cells/mm³)	64.63	2.17	179.68	60.38	68.87	0
MMS-Yes						
Follow-up CD4 (Cells/mm³)	249.93	1.64	185.58	246.72	253.13	
Baseline CD4 (Cells/mm³)	217.56	1.27	144.56	215.06	220.05	
Mean difference (Cells/mm³)	32.37	1.3	147.7	29.82	34.92	0

Source: Study data, 2017.

Table 11: Comparing the changes in CD4 count at initiation with the final follow up CD4 count for ART clients with and without TB.

Variables	Mean	SE	SD	95%	CI	P-value
MMS=No & TB=0						
Follow-up CD4 (Cells/mm³)	255.056	2.673	209.716	249.816	260.296	
Baseline CD4 (Cells/mm³)	186.724	1.601	125.641	183.585	189.863	
Mean difference (Cells/mm³)	68.332	2.382	186.885	63.6627	73.0014	0
MMS=Yes & TB=0						
Follow-up CD4 (Cells/mm³)	259.588	1.719	187.616	256.218	262.958	
Baseline CD4 (Cells/mm³)	225.567	1.328	144.958	222.963	228.171	
Mean difference (Cells/mm³)	34.0204	1.403	153.064	31.2708	36.77	0
MMS=No & TB=1						
Follow-up CD4 (Cells/mm³)	145.778	4.816	130.024	136.324	155.232	
Baseline CD4 (Cells/mm³)	112.444	2.877	77.6665	106.797	118.092	
Mean difference (Cells/mm³)	33.3333	3.494	94.3456	26.4733	40.1934	0
MMS=Yes & TB=1						
Follow-up CD4 (Cells/mm³)	131.583	3.211	100.093	125.283	137.884	
Baseline CD4 (Cells/mm³)	119.417	3.057	95.293	113.419	125.415	
Mean difference (Cells/mm³)	12.1667	1.295	40.373	9.62541	14.7079	0

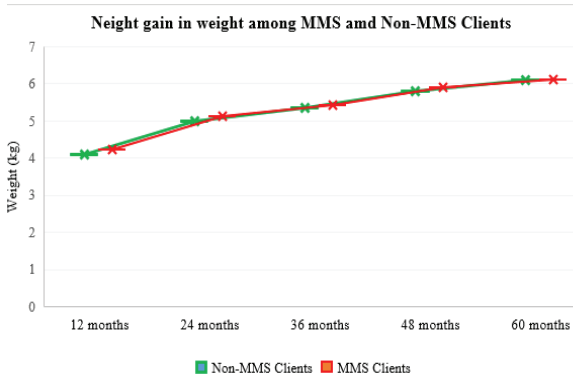

Figure 1: Changes in weight gains at 12, 24, 36, 48 and 60 months for MMS and Non-MMS clients

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