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ORIGINAL ARTICLE



Résultat du Renouvellement Communautaire des Médicaments Antirétroviraux chez les Patients Stables Atteints du Virus de l'Immunodéficience Humaine Accédant Aux Soins dans un Centre Tertiaire à Abuja, Nigéria: Un Examen De 3 Ans

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ABSTRACT

INTRODUCTION: Community-based delivery of antiretroviral therapy (ART) is an innovative approach that delivers HIV treatment services closer to the people, removing logistical barriers to clinic access, thereby improving ART uptake and retention in care. The United States Emergency Plan for AIDS Relief (PEPFAR) program in Nigeria involved community-based private sector pharmacies to expand uptake of ART. We aimed at evaluating the effectiveness of this innovation by comparing the CD4 cell count, weight and viral load of stable HIV patients before and after they were devolved to community pharmacies. METHODOLOGY: This study was a facility-based retrospective study that analysed the data of HIV patients accessing care at the University of Abuja Teaching Hospital (UATH) Gwagwalada, Abuja, who were devolved to community pharmacies from June 2018 to May 2021. We compared their mean CD4 cell count, weight and viral load before they were devolved and 1 year after devolvement.

RESULTS: A total of 171 patients who met the eligibility criteria were devolved to community pharmacies during the study period. Majority (67.3%) of the patients were females. The age range was 24 years to 72 years with a median age of 42.8 years [inter-quartile range (IQR) 32, 62]. Their mean CD4 cell count (p=0.001) and weight (p=0.006) were higher after devolvement to community pharmacies compared to when they were at the clinic. They all maintained viral suppression after devolvement. **CONCLUSION:** ART refill through community pharmacies is effective in maintaining viral suppression in stable HIV patients and may lead to increase in CD4 cell count and weight. WAJM 2023; 40(1): 67-71.

Keywords: Antiretroviral therapy, Community pharmacies, HIV, Viral suppression, CD4 count, Weight.

RÉSUMÉ

INTRODUCTION: La prestation communautaire de la thérapie antirétrovirale (TAR) est une approche innovante qui permet de fournir des services de traitement du VIH plus près des gens, en éliminant les obstacles logistiques à l'accès aux cliniques, améliorant ainsi l'adoption de la TAR et la rétention dans les soins. Le programme du Plan d'urgence des États-Unis pour la lutte contre le sida (PEPFAR) au Nigéria a fait appel à des pharmacies communautaires du secteur privé pour développer l'utilisation du TAR. Nous avons cherché à évaluer l'efficacité de cette innovation en comparant le nombre de cellules CD4, le poids et la charge virale de patients VIH stables avant et après leur dévolution aux pharmacies communautaires.

MÉTHODOLOGIE: Cette étude est une étude rétrospective basée sur l'établissement qui a analysé les données des patients VIH accédant aux soins à l'hôpital universitaire d'Abuja (UATH) Gwagwalada, Abuja, qui ont été dévolus aux pharmacies communautaires de juin 2018 à mai 2021. Nous avons comparé leur nombre moyen de cellules CD4, leur poids et leur charge virale avant leur dévolution et 1 an après la dévolution.

RÉSULTATS: Un total de 171 patients répondant aux critères d'éligibilité ont été dévolus aux pharmacies communautaires pendant la période d'étude. La majorité (67,3 %) des patients étaient des femmes. La fourchette d'âge allait de 24 à 72 ans avec un âge médian de 42,8 ans [intervalle interquartile (IQR) 32, 62]. Leur nombre moyen de cellules CD4 (p=0,001) et leur poids (p=0,006) étaient plus élevés après le transfert vers les pharmacies communautaires que lorsqu'ils étaient à la clinique. Ils ont tous maintenu une suppression virale après la dévolution.

CONCLUSION: Le renouvellement de l'ART par les pharmacies communautaires est efficace pour maintenir la suppression virale chez les patients VIH stables et peut conduire à une augmentation du nombre de cellules CD4 et du poids. WAJM 2023; 40(1): 67-71.

Mots clés: Thérapie antirétrovirale, pharmacies communautaires, VIH, suppression virale, numération des CD4, poids.

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Abbreviations: AIDS, Acquired Immunodeficiency Syndrome; ART, Antiretroviral Therapy; CD4, Cluster of Differentiation 4; HIV, Human Immunodeficiency Virus; PEPFAR, United States Emergency Plan for AIDS Relief; UATH, University of Abuja Teaching Hospital; UNAIDS, Joint United Nations Programme on HIV/AIDS; WHO, World Health Organization.

INTRODUCTION

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) 2020 report, there are 38 million people living with the Human Immunodeficiency Virus (HIV) globally, and 26 million are currently receiving lifelong antiretroviral therapy (ART).¹ Of the 38 million, 36.2 million are adults while 1.8 million are children less than 15 years of age. About 1.7 million new HIV infections occurred in 2019 with a total of 690,000 AIDS-related deaths.1 Sub Saharan Africa is worst hit by the HIV epidemic with 67.4% of the global HIV burden occurring in this region. Nigeria has the second largest burden of HIV in Africa, with an estimated 1.9 million HIVpositive persons.

The introduction of combined antiretroviral therapy in 1996 ushered in a new era for HIV-infected individuals. The use of ART has remained the cornerstone of HIV treatment and prevention and has provided hope for ending the HIV epidemic in the absence of a preventable vaccine.^{2,3} In Sub-Saharan Africa, HIV care and treatment programmes have been highly donordependent and largely implemented in public hospitals. Most of these hospitals have low human resources for health, resulting in overworked staff. With the high number of HIV clients accessing services in these hospitals, and with the new WHO treatment strategy of "Test and Start" (ART is initiated immediately after testing positive, regardless of CD4 count),⁴ overcrowding is inevitable. This leads to long waiting times at ART clinics, reduced adherence and retention levels and increased patient dissatisfaction. In addition, other client barriers such as missed wages, transport cost, have all contributed to low uptake of ART.

The Community-based ART services is an innovative approach that delivers HIV treatment services closer to the people, removing logistical barriers to clinic access, thereby improving ART uptake, retention in care and decongesting overburdened public health facilities.^{5,6} The 2013 WHO consolidated guidelines on the use of antiretroviral drugs promote the use of communitybased ART in a global strategy to end HIV/AIDS by 2030.⁷ No single approach exists for community ART delivery and different approaches have been developed in sub-Saharan Africa. The success of community ART models depends on sufficient, reliable support and resources, a cadre of lay workers, a flexible and reliable medication supply, access to quality clinical management and a reliable monitoring system for patient care.^{8,9}

In Nigeria, the United States Emergency Plan for AIDS Relief (PEPFAR) program involved communitybased private sector pharmacies to expand uptake of ARTusing the differentiated care model where stable HIV patients with undetectable viral load are devolved to community pharmacies for ART refill, while ensuring that clients are not alienated from standard public sector clinical and laboratory services. Stable clients receive bi-monthly ARV refills at community pharmacies and return to the health facility semi-annually for clinical and/or laboratory assessments. Community pharmacies in Nigeria are registered private pharmaceutical premises licensed by the Pharmacists Council of Nigeria. A pilot project by Avong et al involving ten community pharmacies registered for the provision of differentiated care in Abuja, Nigeria, showed that this model improves medication adherence and retention in care.10 Another pilot study conducted by the Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) Project at FHI 360 in the Southern part of Nigeria worked with 181 community pharmacies that provided ART refill for 5,846 HIV clients who reported improved satisfaction.¹¹ The overall impact of this model has led to improved adherence to drug pick-ups as well as improved client satisfaction.10,11

The ART clinic at the University of Abuja Teaching Hospital (UATH) located in the Federal Capital Territory (FCT) adopted this new approach of devolvement of stable HIV patients to community pharmacies for ART refill in May 2018. We hypothesized that community ART refill through community pharmacies is effective in maintaining viral suppression among stable HIV clients. This study is aimed at evaluating the effectiveness of this innovation by comparing the mean CD4 cell count, weight and viral load of the clients before devolvement and 1 year after devolvement to community pharmacies.

METHODOLOGY Study Site

The study was conducted at UATH, which is a tertiary health facility located in the FCT in Nigeria. The hospital has a 520-bed capacity and doubles as a training centre for medical and nursing students as well as for post graduate fellowship training in various fields of medicine. It is one of the biggest hospitals in the North Central region of Nigeria and receives referrals from neighbouring states.

The HIV centre at UATH was established in March 2005. It is one of the largest PEPFAR-supported ART centres in the North Central zone of Nigeria that offers comprehensive HIV services and has over 5000 HIV patients currently accessing care at the centre.

Study Design

This study was a facility-based retrospective study that analysed the data of HIV patients accessing care at UATH, who were devolved to community pharmacies from June 2018 to May 2021. Prior to the implementation of this program, community pharmacies in the FCT were approached and informed about the program. Those who indicated interest and met the eligibility criteria of having a secured place for patient counselling, a temperature-regulated drug store, an efficient record keeping system and a superintendent pharmacist were requested to complete an evaluation form and provide a written informed consent. The pharmacists were then trained on ART refill, measurement of vital signs, documentation and pharmacovigilance. The community pharmacies get the ARV supplies from the PEPFAR program. The criteria for referral to a community pharmacy include patient stability, defined by duration of facilitybased ART of more than 6 months with successful suppression of viral load below detection level (20 copies/ml); patient on first line ART regimens and patient's willingness to participate,

expressed through written consent. Patients were devolved to community pharmacies closest to their place of residence. Patients devolved receive bimonthly ARV refills at community pharmacies and return to the health facility semi-annually for clinical and laboratory assessments. Vital sign parameters such as weight, temperature and blood pressure are measured and recorded both at the clinic and at the community pharmacies during each visit. Evaluation of CD4 cell count is done sixmonthly for all patients, while viral load assessment is done once a year at the clinic. We compared the mean CD4 cell count, weight and viral load of all the patients before devolvement to the community pharmacies and one year after devolvement. Though vital sign parameters were recorded both at the clinic and at the community pharmacies, only measurements taken at the clinic were included in the data analysis. The primary outcomes to be compared were mean CD4 cell count, weight and viral load before and one year after devolvement.

Data Analysis

Descriptive statistical methods were used for baseline demographic characteristics and follow-up parameters of study participants. Comparison was made between weight, viral load and CD4 count before and after devolvement, using chi-square, paired t-test and Wilcoxon signed rank tests. Statistical significance was set at p-value <0.05. IBM SPSS version 25 was used for analysis.

Ethical Approval

Data used for this study was based on secondary data analysis and ethical approval is not required. The UATH hospital management gave the approval for the release and use of the data which was de-identified to ensure anonymity.

RESULTS

A total of 171 patients were devolved to community pharmacies during the study period. The majority (67.3%) of them were females. The age range was 24 years to 72 years; the median age was 42.8 years [inter-quartile range (IQR) 32, 62]. About half (52.0%) of them have secondary level of education and about one-third (32.2%) have post-secondary level of education. Majority of the patients, 118 (69.0%), were employed (Table 1).

The mean weights before and one year after devolvement were 63.48 ± 13.20 and 66.81 ± 13.77 respectively (p=0.006). The mean CD4 cell counts before and after devolvement were 590.51 cells/ml and 679.12 cells/ml respectively (p=0.001). The median viral load before and after

devolvement was 20.00 copies/ml (p=0.612), showing that there was no change in the viral load before and after devolvement (Table 2).

DISCUSSION

In this paper, we compared the mean CD4 cell count, weight and viral load of stable HIV clients before and one year after they were devolved to community pharmacies. A total of 171 PLHIV clients who were accessing care at UATH and

Table 1: Socio-demographic Characteristics of Patients

Variable	Frequency (n=171)	Percentage (%)	
Age	42.8 (IQR 32, 62.)		
Gender			
Male	56	32.7	
Female	115	67.3	
Age Category			
21-40	76	44.4	
41-60	90	52.6	
>60	5	2.9	
Marital Status			
Married	82	48.0	
Single	77	45.0	
Widow	10	5.8	
Divorced	2	1.2	
Level of Education			
Nil	9	5.3	
Quranic	2	1.2	
Primary	16	9.4	
Secondary	89	52.0	
Post-secondary	55	32.2	
Employment			
Business	5	2.9	
Employed	118	69.0	
Farmer	1	0.6	
Retired	1	0.6	
Student	7	4.1	
Unemployed	39	22.8	

Table 2: Comparison of CD4 Cell Count, Weight and Viral Load Before and After Devolvement

Variable	Before	After	Paired	p-value
	Devolvement	Devolvement	t-test	
Weight	63.48 ± 13.20	66.81 ± 13.77	-2.788	0.006*
CD4	590.51(243.79)	679.12(285.57)	-4.828	< 0.001*
Viral load Median (IQR)	20.00 (20-20)	20.00 (20-20)	-0.508**	0.612
	(Mean=399.31)	(Mean=259.54)		

*p-value significant @ <0.05; ** Wilcoxon signed rank test.

who met the eligibility criteria were devolved to community pharmacies for ART refill from June 2018 to May 2021.

This study showed a statistically significant increase in the mean CD4 cell count of the clients after devolvement to community pharmacies when compared to their mean CD4 cell count before they were devolved. A similar study by Dakum et al in Nigeria also reported an increase in the mean CD4 cell count of the participants after they were devolved to community pharmacies, though the increase was not statistically significant.¹² Goodrich et al, however, reported no increase in the CD4 cell count of clients who had communitybased ART services in Western Kenya.13 The increased in adherence to ART associated with community-based ART services^{14,15} may explain the rise in CD4 cell count observed in this study. ART adherence is associated with immunological recovery in HIV-infected clients, and good adherence contributes to greater growth of CD4 cell counts.¹⁶ In two randomized, multicenter clinical trials, Mannheimer et al found that participants who reported 100% adherence at all study visits were more likely to achieve better virological and immunological outcomes after 12 months of treatment.¹⁷ In India, Adiga et al working with HIV clients on different ART regimens observed that the better the adherence the higher the CD4 cell count.18 Another study from Ghana demonstrated a positive correlation between adherence to ART and immunological success; the study showed that non-adherent subjects were nine times at risk of progressing to immunological failure.19

This study also showed a statistically significant increase in the mean weight of the participants after devolvement to community pharmacies and concurs with the report by Dakum *et al.*¹² Low CD4 cell count is associated with a higher risk of opportunistic infections, many of which affect the gastrointestinal system leading to poor appetite, poor food absorption and weight loss. A rise in CD4 cell count reduces the risk of opportunistic infections which will ultimately lead to weight gain. The increase in mean weight observed in this study may therefore be indirectly linked to the increase in CD4 cell count observed. Also, community-based ART delivery eliminates transport cost to the clinics and has been associated with improved client satisfaction which may also indirectly contribute to the weight gain. In addition, the reduction in waiting time associated with community ART services means that day laborers have more available time to earn a day's wages which may translate to better feeding and weight gain.

The clients in this study maintained viral suppression after devolvement to community pharmacies. This finding concurs with reports from other studies that have shown that community ART refill is comparable or even superior in some instances to clinic refill in terms of viral suppression. A clinical trial conducted in the rural and peri-urban settings in KwaZulu-Natal, South Africa and the Sheema District, Uganda showed that community-based delivery of ART significantly increased viral suppression compared with clinic-based ART, particularly among men.²⁰ Another study in Akwa Ibom and Cross River states of Nigeria also showed that HIV patients devolved to the community to receive ART through five differentiated service delivery models including community pharmacy refill had an increased viral suppression compared to those that received the standard of care at the facilities.²¹ In Uganda, Jaffar et al compared the rates of virological failure in patients treated in a home-based versus a facility-based HIV-care model and found the rates to be similar.22

Viral suppression remains the most desired outcome in the management of patients with HIV/AIDS. The main factors associated with viral suppression include adherence to ART, type of ART regimen and socioecomic status of the client.23,24 Client barriers to care, such as missed wages, transport costs, and long waiting times for clinic visits and ART refills are associated with poor adherence to ART.^{25,26} Removal of such barriers through community-based ART delivery leads to good adherence to ART and consequently leads to higher viral suppression. Our clients had undetectable viral load at the time of devolvement and maintained undetectable viral load

one year after devolvement. The findings of this study concur with other findings that have shown that decentralization of HIV services and task-shifting to community workers in low- and middleincome countries achieve the same results as facility-based services.

This study has its limitations. It is a retrospective analysis using routine data with its inherent limitations, including missing data and inconsistencies that could affect generalization of the results. Secondly the eligibility criteria for devolvement to community pharmacies required clients to be stable on treatment. These clients would more likely also have had same outcome if they had remained in the clinic.

CONCLUSION

We conclude that ART refill through community pharmacies is effective in maintaining viral suppression and may lead to increase in CD4 cell count and weight. These findings therefore add to a growing literature showing good outcomes with community-based ART refill.

Competing Interests

The authors declare no competing interest.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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