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Impact of pharmaceutical care interventions on the resolution of drug therapy problems among HIV-infected patients on second-line antiretroviral therapy in a Nigerian tertiary healthcare facility

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ABSTRACT

Background: Drug Therapy Problems (DTPs) are a major obstacle to effective disease management and treatment success, especially in chronic conditions like HIV infection.

Objectives: This study evaluated the impact of pharmaceutical care interventions on the resolution of DTPs and medication adherence among HIV-infected patients on second-line antiretroviral therapy (ART) at Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria.

Methods: This was a prospective interventional study involving 107 HIV patients on second-line ART. The patients were assessed for DTPs during routine clinic visits, and interventions such as medication counselling, ADR management, and adherence support were provided and followed for 8 weeks. The identified DTPs were categorized using the Pharmaceutical Care Network Europe (PCNE) Classification System. Data were analyzed using descriptive statistics and the student t-test, with significance set at $p< 0.05$.

Results: Eighty-two DTPs were identified among 71 patients (66.4 %), with an average of 1.2 DTPs per patient. Non-adherence (81.7 %) and ADRs (18.3 %) were the most common DTPs identified, mainly due to inappropriate drug combinations and patient not taking their drugs. All the interventions were accepted by the patients and the prescribers, resulting in a 100 % acceptance rate. During follow-up, 95.1 % of the identified DTPs were resolved, and medication adherence significantly improved by 0.682 ± 0.708 ($t = 9.962$, $p< 0.001$).

Conclusion: Pharmaceutical care interventions significantly reduced DTPs and improved adherence. Incorporating such care into HIV treatment is recommended to enhance patient outcomes.

Keywords: Drug therapy problems, HIV, Pharmaceutical care interventions, Second-line antiretroviral therapy

Impact des interventions de soins pharmaceutiques sur la résolution des problèmes liés au traitement médicamenteux chez les patients infectés par le VIH sous traitement antirétroviral de deuxième ligne dans un établissement de soins tertiaires nigérian

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RÉSUMÉ

Contexte: Les problèmes liés à la pharmacothérapie (PLP) constituent un obstacle majeur à la prise en charge efficace des maladies et au succès du traitement, notamment dans les affections chroniques comme l'infection par le VIH.

Objectifs: Cette étude a évalué l'impact des interventions de soins pharmaceutiques sur la résolution des problèmes liés à la pharmacothérapie et l'observance thérapeutique chez les patients infectés par le VIH sous traitement antirétroviral de deuxième ligne au centre hospitalier universitaire Usmanu Danfodiyo, Sokoto, Nigéria.

Méthodes: Il s'agissait d'une étude interventionnelle prospective menée auprès de 107 patients séropositifs sous traitement antirétroviral de deuxième ligne. Les patients ont été évalués pour les problèmes liés à la pharmacothérapie (PLP) lors de leurs consultations de routine. Des interventions telles que des conseils sur les médicaments, la prise en charge des effets indésirables et un soutien à l'observance ont été mises en place et suivies pendant 8 semaines. Les PLP identifiés ont été classés selon la classification du Pharmaceutical Care Network Europe (PCNE). Les données ont été analysées à l'aide de statistiques descriptives et du test t de Student, avec un seuil de signification fixé à $p < 0.05$.

Résultats: Quatre-vingt-deux problèmes liés à la pharmacothérapie (PLP) ont été identifiés chez 71 patients (66.4 %), soit en moyenne 1.2 PLP par patient. La non-observance (81.7 %) et les effets indésirables (18.3 %) étaient les PLP les plus fréquents, principalement dus à des associations médicamenteuses inappropriées et à l'arrêt du traitement. Toutes les interventions ont été acceptées par les patients et les prescripteurs, soit un taux d'acceptation de 100 %. Lors du suivi, 95.1 % des PLP identifiés ont été résolus et l'observance thérapeutique s'est améliorée de manière significative (0.682 ± 0.708 ; $t = 9.962$; $p < 0.001$).

Conclusion: Les interventions pharmaceutiques ont réduit de manière significative les problèmes liés à la pharmacothérapie et ont amélioré l'observance. Il est recommandé d'intégrer ces interventions au traitement du VIH afin d'améliorer les résultats pour les patients.

Mots-clés: problèmes liés à la pharmacothérapie, VIH, interventions pharmaceutiques, traitement antirétroviral de deuxième ligne

INTRODUCTION

Human Immunodeficiency Virus (HIV) remains a major public health challenge worldwide, especially in sub-Saharan Africa. HIV gradually weakens the immune system by destroying CD4+ T lymphocytes, rendering individuals vulnerable to opportunistic infections and certain types of cancer. Without timely and effective antiretroviral therapy (ART), HIV infection can progress to acquired immunodeficiency syndrome (AIDS), leading to significant illness and death.[1] Since the advent of Highly Active Antiretroviral Therapy (HAART), the outlook for HIV-infected individuals has greatly improved, turning it from a death sentence into a manageable chronic condition.[2]

Globally, approximately 39 million people were living with HIV in 2023, with sub-Saharan Africa bearing about 65 % of this burden.[3] Nigeria alone has nearly 2 million HIV-positive individuals, making it one of the four countries with the highest HIV burden, along with South Africa, India, and Mozambique.[4] According to the 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS), the national HIV prevalence among adults aged 15-49 is 1.4%, and around 1.7 million people are currently on ART.[5]

The World Health Organization (WHO) and UNAIDS have set bold goals to eliminate the HIV epidemic by 2030, outlined in the 95-95-95 target: 95 % of people with HIV knowing their status, 95 % of those diagnosed receiving ART, and 95 % of those on ART achieving viral suppression.[1] As of 2023, global progress toward these goals stood at 86%, 77%, and 72%, respectively.[3] Reaching these targets relies not only on access to ART but also on ensuring patients adhere to their treatment, tolerate it well, and switch to alternative regimens promptly if treatment fails. When patients experience virologic failure or intolerance to first-line regimens, second-line ART becomes necessary. Typically, second-line regimens include a ritonavir-boosted protease inhibitor (PI) combined with two nucleoside reverse transcriptase inhibitors (NRTIs).[2] Although effective, these regimens often come with increased pill burden, adverse effects such as dyslipidemia and insulin resistance, and a higher risk of drug-drug interactions.[6,7] These challenges can compromise adherence and achievement of desired health outcomes.

Patients on second-line therapy are more likely to experience drug therapy problems (DTPs), including adverse drug reactions, drug interactions, medication non-adherence, etc.[8] Research has found that the prevalence of DTPs among patients on ART ranges from 21. 5 % to over 60 %, with factors like polypharmacy, comorbidities, and poor adherence contributing to this high burden.[9,10,11] Providing responsible drug therapy to achieve specific outcomes that improve a patient's quality of life is crucial in managing DTPs. Pharmaceutical care interventions, such as medication reconciliation, therapeutic drug monitoring, adherence counseling, and adverse drug reaction surveillance, have shown significant benefits in HIV care.[12-14] Specifically, integrating pharmaceutical care into multidisciplinary HIV programs has been linked to improved adherence, better viral suppression rates, reduced hospitalizations, and enhanced patient satisfaction.[15,16] However, most research on pharmaceutical care interventions focused on patients receiving first-line ART, leaving a significant evidence gap regarding the impact of pharmaceutical care on patients transitioning to or stabilized on second-line therapy. These patients often have complex treatment histories, comorbid conditions, and a higher risk of treatment-related complications. As a result, pharmacist interventions in this group are likely to have a significant impact on therapy outcomes. Therefore, this study evaluated the impact of pharmaceutical care interventions on the resolution of drug therapy problems and medication adherence among HIV-infected patients on second-line ART at Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria.

METHODOLOGY

Study design and participants

The study was a prospective, interventional, single-arm study with an 8-week follow-up conducted at the Infectious Disease Centre of Usmanu Danfodiyo University Teaching Hospital (UDUTH), Sokoto, Nigeria. It involved assessing DTPs before and after pharmaceutical care intervention in HIV-infected patients on second-line ART. The participant included adult HIV-positive patients (≥ 18 years) who were on second-line ART and receiving care at the UDUTH. Patients on first-line ART, those who declined to participate, and those lost to follow-up during the study period were excluded from the study.

Ethical considerations

Ethical approval was granted by the Health Research and Ethics Committee of Usmanu Danfodiyo University Teaching Hospital, Sokoto (Ref: UDUTH/HREC/2023/1336/V3). Written informed consent was obtained from all participants. All data were anonymized, and participation was voluntary.

Sample size and sampling technique

The sample size for the study was determined using the WHO formula for interventional studies,[17] with SD from previous studies[18] and an attrition of 30 %.[19] Therefore, the sample size for the study was 140 patients. A purposive sampling method was used to recruit eligible and consented participants who presented for routine clinic visits during the study period.

Study instrument

Data were collected using researcher-administered instruments. A structured data collection form was used to obtain participants' sociodemographic and clinical information through face-to-face interviews and review of patients' medical records. Medication adherence was assessed using the 4-Item Morisky Medication Adherence Scale (MMAS-4). Drug therapy problems (DTPs) were identified through a comprehensive review of patients' case notes, medication profiles, and information obtained during patient interviews. Identified DTPs were subsequently classified and documented using the Pharmaceutical Care Network Europe (PCNE) classification system (Version 9.1).

Data collection procedure

All the patients were assessed at baseline for DTPs and level of medication adherence. Pharmaceutical care intervention was provided to each patient depending on the level of medication adherence and identified DTPs. The intervention involved a comprehensive medication review, face-to-face medication education and counseling, ADR management, and adherence support. Follow-up phone calls were conducted biweekly to reinforce pharmaceutical interventions. After 8 weeks, participants were reassessed for resolution of previously identified DTPs and improvements in medication adherence.

Data analysis

Data were analyzed using SPSS version 27. Descriptive statistics (means, standard deviations, and frequencies) were used to summarize baseline characteristics. A p-value < 0.05 was considered statistically significant. The prevalence of drug therapy problems (DTPs) was calculated using the formula: Prevalence = (Number of patients with identified DTPs / Total number of patients) × 100.

RESULTS

Sociodemographic and clinical characteristics of the participants

Out of the 140 recruited patients, 107 completed the study, equivalent to 76.4 % participation rate. Most participants were female (n=76, 71.0 %) with no formal education (n=45, 42.1%). The majority of the participants were found to belong to stage I of the disease (n=67, 62.6%), mainly receiving TDF+3TC+ATV/r (n=81, 75.7%), while the least common regimen was AZT+3TC+ATV/r (n=9, 8.4%). About two-thirds of the participants (n=74, 69.2%) had no comorbidity. The details of the sociodemographic and clinical characteristics of the participant are presented in Tables 1 and 2, respectively.

Table 1: Sociodemographic Characteristics of People Living with HIV/AIDS on Second-line Antiretroviral Therapy in Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria, (n=107)

Variables	No.	%
Gender		
Female	76	71.0
Male	31	29.0
Age (years)		
18-28	4	3.7
29-38	30	28.0
39-48	35	32.7
49-58	28	26.2
>58	10	9.3
Level of education		
No formal education	45	42.1
Primary school	4	3.7
Secondary school	20	18.7
University	38	35.5
Marital status		
Currently married	89	83.2
Widowed	12	11.2
Separated	2	1.9
Single	4	3.7
Monthly Income		
<10,000	58	54.2
>10,000-50,000	20	18.7
>50,000-100,000	26	24.3
>100,000	3	2.8
Occupation		
Student	4	3.7
Self employed	79	73.8
Employee	23	21.5
Retired	1	0.9
Smoking status		
Non-smoker	107	100.0
Smoker	0	0.0

No. = Number of patients; % = Percentage

Table 2: Clinical Characteristics of People Living with HIV/AIDS on Second-Line Antiretroviral Therapy in Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria (n=107)

Variables	No.	%
HIV clinical stage		
Stage I	67	62.6
Stage II	33	30.8
Stage III	5	4.7
Stage IV	2	1.9
Current ART regimen		
AZT+3TC+ATV/r	9	8.4
TDF+3TC+ATV/r	81	75.7
ABC+3TC+ATV/r	17	15.9
Co-morbid state		
None	74	69.2
Diabetes	1	0.9
Hypertension	8	7.5
Peptic ulcer disease	4	3.7
Malaria within the last 4 weeks	14	13.1
Typhoid fever	6	5.6

No. = Number of patients; % = Percentage

Nature and prevalence of drug therapy problems and the interventions made

The nature and prevalence of drug therapy problems are shown in Table 3. Eighty-two DTPs were identified among 71 patients, resulting in a prevalence rate of 66.4 % and an average of 1.2 DTPs per patient. The leading DTP was non-adherence (81.7 %), followed by ADRs (18.3 %). The primary causes were inappropriate drug combination (n = 15, 18.3 %) and the patient not taking their drugs (n = 67, 81.7 %).

The various interventions made and the outcome are shown in Table 4. All the interventions were accepted, and the intervention outcomes after follow-up revealed that 78 (95.1%) of the DTPs were resolved. Also, adherence improved significantly from a pre-intervention mean of 3.25 ± 0.068 to 3.93 ± 0.248 post-intervention ($t = 9.962$, $p < 0.001$).

Table 3: Prevalence of drug therapy problems among people living with HIV/AIDS on second-line antiretroviral therapy in Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria, (n=107)

Variables/Domain	No.	%
Problem		
Adherence	67	81.7
ADR	15	18.3
Causes		
Patient does not take drugs	67	81.7
Inappropriate combination of drugs	15	18.3

Prevalence of DTPs = 66%

No. = Number of DTPs; % = Percentage,

Table 4: Outcomes of pharmaceutical care interventions among people living with HIV/AIDS on second-line antiretroviral therapy in Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria, (n=107)

Variables/Domain	No.	%
Interventions		
Patient drug counseling	67	81.7
Instructions for use changed	15	18.3
Acceptance		
Accepted	82	100.0
Not accepted	0	0.0
Outcome		
Solved	78	95.1
Partially solved	4	4.9

No. = Number of DTPs; % = Percentage

DISCUSSION

Drug therapy problems were evaluated using the PCNE classification system. The identification of 82 DTPs (an average of 1.2 DTPs per patient) aligns with findings from previous studies highlighting the high incidence of DTPs in HIV management.[22,23] Adherence issues were the most frequently reported problem in this study, affecting 81.7 % of participants. This rate is much higher than the 37.1 % seen in an Ibadan cohort, where non-adherence (< 95 %) was mainly linked to forgetfulness, feeling healthy, and nondisclosure of HIV status.[24] Another study at Nnamdi Azikiwe University Teaching Hospital in Nigeria reported an even higher non-adherence rate of 85.1%, with key reasons including forgetfulness (53.8 %), being busy (38.8 %), adverse drug effects (31.9 %), and stigma (31.9 %).[25] Adverse drug reactions (ADRs) were observed in 18.3 % of participants, similar to national ART cohort data indicating 4.6 ADR events per 100 person-years, mostly in the first six months of treatment, presenting symptoms like pain, rash, and anemia.[16] A smaller hospital-based study also identified dizziness (17.4 %), weakness (11.9 %), and anemia (11.1 %) as the most common ADRs, mostly mild in severity.[26] Acceptance of intervention was 100 %, similar to the study by Cantillana-Suárez *et al.* which reported a 93.3 % acceptance rate among PLWH.[18] Pharmaceutical care interventions proved particularly effective, with a resolution rate of 95.1 %, emphasizing their significance in HIV care.[16,27] Adherence levels significantly improved following interventions, similar to studies conducted by Schoenherr *et al.* and Dilworth *et al.*[23,29] Addressing DTPs is critical for enhancing clinical results and achieving desired health outcomes. The prevalence of drug therapy problems (DTPs) in this study was 66 %, which is consistent with the 69.4 % prevalence of drug-related problems reported in Ethiopian public healthcare settings.[28]

The results showed a significant improvement in adherence levels, increasing from a pre-intervention mean of 3.25 ± 0.068 to 3.93 ± 0.248 post-intervention ($t = 9.962$, $p < 0.001$). This is similar to the study by Cantillana-Suárez *et al.* who reported a significant improvement in adherence rate from 85.6 ± 33.7 pre-intervention to 96.4 ± 17.7 post-intervention ($p < 0.001$).[18] The results also showed a 100% improvement in poor adherence levels post-intervention ($Z = 7.467$, $p < 0.001$). This finding aligns with prior research by Dilworth *et al.* and Chatha *et al.* which demonstrated that pharmacist-led adherence clinics significantly enhance adherence and clinical outcomes among HIV patients.[27,29] The study found no significant associations between adherence improvement and sociodemographic or clinical characteristics. This finding suggests that the intervention, rather than external factors, might drive the observed adherence improvement. Similar trends have been noted in studies by Schoenherr *et al.* which highlighted the universal benefits of pharmacist-led interventions across diverse patient demographics.[23]

CONCLUSION

This study showed that pharmaceutical care interventions significantly improved treatment outcomes for HIV-infected patients on second-line antiretroviral therapy by decreasing DTPs and improving medication adherence. Most DTPs identified involved non-adherence

and adverse drug reactions, common challenges within this patient group. The intervention acceptance rate was 100 %, and 95.1 % of DTPs were resolved, highlighting the importance of pharmaceutical care interventions. These results advocate for the inclusion of pharmacists in HIV treatment teams to promote optimal medication use and adherence to second-line regimens. Increasing access to pharmaceutical care is recommended to improve the long-term success of antiretroviral therapy and support national HIV treatment objectives.

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