

**PHARMACISTS' INTERVENTION TO REDUCE DRUG RELATED
PROBLEMS IN HIV/AIDS PATIENTS ON HAART IN A TERTIARY
HEALTH FACILITY IN SOUTHERN NIGERIA**

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ABSTRACT

Despite advances in the use of highly active antiretroviral therapy (HAART) in the management of HIV/AIDS, drug-related problems (DRPs) still remain an issue, particularly in developing countries. This study evaluated the incidence of DRPs among HIV/AIDS patients in a HIV/AIDS care centre in southern Nigeria and the impact of pharmacist's intervention in reducing the problems. Two hundred and ninety-seven (297) HIV/AIDS out-patients (age, 41±11.3 yrs) on HAART previously for at least 2 years that were refilling their HAART drugs at Infectious Diseases Clinic in University of Benin Teaching Hospital (UBTH), Benin City based on pharmacy order form (POF), were recruited for the study. Patients' DRPs data were collected on recruitment (baseline) and the 269 patients with DRPs were followed by the pharmacist at 3, 6 and 9 months with education/counselling of patients and their prescribers were contacted as appropriate. At baseline, 652 DRPs were recorded in 90.6% of the 297 patients recruited out of which 29.4% are directly related to the use of the POF. DRPs observed were generic drug substitution (28.7%), inappropriate drug adherence (17.5%), dosing interval not indicated (12.7%), dose not indicated (10.6%), inadequate patient's knowledge of appropriate drug use (9.4%), drug-drug interactions (7.8%), side effects (7.2%), dosage too low (3.2%), dosage too high (2.0%) and wrongly prescribed drug (0.9%). In the 9th month following pharmacist's intervention 61.2% of the identified DRPs were partially solved and 38.8% were completely resolved among the 194 patients not lost to follow-up. Also, all DRPs related to the use of POF were completely resolved. Active participation of clinical pharmacists in the care of HIV/AIDS patients is vital in the prevention and reduction of DRPs in HIV/AIDS patients undergoing ambulatory care.

Keywords: Drug related problems, HIV/AIDS, generic substitution, overdose, under dose, drug

INTRODUCTION

With the complexity in progression, HIV infection has become a challenge to man (1). The global incidence of HIV infection has stabilized over the years and declining in many countries. In sub-Saha-

Ran Africa, the prevalence has declined by more than 25% from 2001 to 2009.

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Although the overall prevalence in Nigeria has declined from 4.6% in 2008 to 4.1% in 2012, the prevalence rate varies by zone, state and locality. In Edo State, the rate is 5.3% (2, 3).

The use of HAART in the treatment of HIV/AIDS has posed a number of risks and challenges, including substantial toxicity, adherence difficulties, and drug-related problems (DRPs), including drug resistance evolution, particularly in resource-poor countries of Africa. DRPs are associated with pharmacotherapy of individual patient and can actually or potentially interfere with desired health outcomes. The clinical consequences of DRPs can be anything from minor (no harm to the patient) to catastrophic (resulting in death or severe loss of bodily function) (4). These problems can originate when prescribing, dispensing or taking/administering medicines and are of major concern in view of their physical, psychological and economic burden to the patients and to society as a whole (5, 6). In 2008, Mok and Minson (7) reported drug-drug interactions and incomplete antiretroviral regimens as DRPs in HIV patients receiving HAART. Thus, optimising drug therapy – by preventing DRPs – may influence the health costs and potentially save lives (8-10).

Although prescribing of drugs in Nigeria is often carried out by physicians using their own handwriting in a prescription form, Pharmacy Order Form (POF, Plate 1) for HIV/AIDS were specifically designed for Nigeria HIV/AIDS patients on HAART based on the peculiarity of our environment using global standard. This form allow the prescribers to simply tick against the names and dosing information of the relevant HAART they

are prescribing for the patients and has other perceived advantages. First, it reduces the workload of the clinicians from the high population of HIV seropositive patients in the country. Second, it guides clinicians and pharmacists as many are still not very knowledgeable of the disease and the drugs involved, particularly in some communities, which means that special training on the disease and working tools needs to be provided to facilitate the management of the disease. Third, each form is provided in triplicate (a copy in patient's folder, one for pharmacy department and the last copy for medical record) for monitoring and evaluation of the patients to reduce loss to follow-up and encourage drug adherence. Fourth, it encourages uniformity of treatment of the patients in all the ART centres and among the donor agencies who implemented the programme. Fifth, it provides effective monitoring of HAART stock levels in ART centres as well as information on individual patients. However, the tendency for drug-related problems occurring from the use of POF has not been reported. Furthermore, although the roles of pharmacists in their participation in therapeutic plan development, implementation, monitoring and evaluation, and provision of up-to date drug literature to optimize pharmaceutical care for HIV/AIDS patients are positively perceived by other members of the health care profession (11), there is evidence that many pharmacists still concentrate their contributions to these patients in medication provision without much attention on identification of problems associated with the medications they dispense. In most hospitals, pharmacists have no direct access to patient clinical information other than the prescription

sheet for the day. There are still hardly opportunities for them to track patients' medication profiles, provide screen or monitor for adherence or adverse drug reactions, early warning signs of treatment failure and drug resistance mainly due to resistance of clinicians against patient-oriented pharmaceutical services especially in hospital wards, as well as lack of proper training and self-confidence for pharmacists (12,13). In a recent survey from 184 Global HIV/AIDS Initiative Nigeria (GHAIN) supported health facilities, only 36.5% of pharmacies were observed providing individual counselling on medication use to patients and 11.7% had evidence of monitoring and reporting of suspected adverse drug reactions (13).

This study was therefore conducted to assess the incidence of drug related problems associated with the clinical use of HAART in a major HIV/AIDS treatment Centre in Benin City, Nigeria, following the use of POF with the view to carry out interventions that will improve DRPs among the patients.

METHODS

Setting

The study was carried out in the Infectious Diseases Clinic (IDC) in University of Benin Teaching Hospital (UBTH), Benin City, Edo State which is supported by President's Emergency Plan for AIDS Relief (PEPFAR) and National Agency for the Control of AIDS (NACA). UBTH is an 800-bed tertiary health facility and as at September 2013, 14,824 HIV/AIDS patients had enrolled and were assessing care in the IDC. The turn-over rate of these patients in the

clinic is between 90 and 250 per day (Monday through Friday).

Study design

Following ethical approval from the Ethics and Research Committee of UBTH (protocol number: ADM/E 22/A/VOL.VII/833), the study was conducted between 15th October 2012 and 3rd October 2013. Eligible for inclusion in the study were patients diagnosed at least 2 years earlier to be HIV positive with both clinical and immunological data, availability in PEPFAR medical records in IDC, age from 20 to 70 years, on HAART between 2 to 8 years, must refill pharmacy prescription every three months and being willing to stay on the study for at least 12 months. Children, pregnant women and patients on hospital admission were excluded from the study.

All the participants that met inclusion criteria were comprehensively informed about the purpose of the study and verbal and written consents were obtained from them. Of the 297 HIV/AIDS patients that were enrolled into the study, DRPs data were collected on recruitment (baseline) as previously described (14, 15). DRPs were identified from the patients' case notes and through personal interview of each patient by the clinical pharmacist (researcher).

Intervention

From the baseline data of DRPs collected on recruitment, the 269 patients identified to have had DRPs were followed up for 9 months by the same clinical pharmacist with comprehensive pharmaceutical counselling every 3 months they visited the clinic for check-up and medication refill. Each patient in the study group was



Adult Pharmacy Order Form

- ☐ PEP (Check if patient is only on PEP)
☐ PMTCT only
☐ Initial Visit
☐ Follow-up Visit

Facility Name _____ Date _____ / ____ /20
 Patient Name _____
 Patient ID _____
 Surname _____
 State _____ Facility _____ Serial Enrollment Number _____
 Pharmacy Registration No. _____
 Age _____ Years Sex: M ☐ F ☐ Weight _____ kg

☐ DO NOT DISPENSE ARV'S TO PATIENT; HOLD FOR ADHERENCE STAFF PICK UP

Medications provided by: ☐ GON ☐ PEPFAR ☐ OTHER: _____

1. Indicate ARV Regimen

1st Line Regimens
☐ NVP/AZT/3TC ☐ NVP/TDF/FTC or 3TC ☐ NVP/D4T/3TC ☐ ABC/AZT/3TC
☐ EFV/AZT/3TC ☐ EFV/TDF/FTC or 3TC ☐ EFV/D4T/3TC ☐ Other: _____
2nd Line Regimens
☐ LPVr/TDF/FTC or 3TC ☐ LPVr/AZT/3TC ☐ LPVr/TDF/AZT/FTC or 3TC ☐ SQVr/TDF/FTC or 3TC
☐ Other (Only in special circumstances, under guidance of Consultant and must indicate reason): _____
 Indication: _____

2. Prescribe ARV Medications

Fixed Dose Combination	Strength	Recommended Dosing	Prescription	Frequency	Duration	Quantity Dispensed
Combipak (AZT + 3TC + NVP)	☐ 300mg/150mg/200mg	300mg/150mg/200mg BD	☐ 1 tab	☐ BD		
Triomune (D4T + 3TC + NVP)	☐ 30mg/150mg/200mg	30mg/150mg/200mg BD	☐ 1 tab	☐ BD		
Combivir (AZT + 3TC)	☐ 300mg/150mg	300mg/150mg BD	☐ 1 tab	☐ BD		
Truvada (TDF + FTC)	☐ 300mg/200mg	300mg/200mg OD	☐ 1 tab	☐ OD		

Single Drugs

Zidovudine (AZT, ZDV; Retrovir)	☐ 300mg	300mg BD	☐ 1 tab	☐ BD		
Lamivudine (3TC; Epivir)	☐ 150mg ☐ 300mg	150mg BD or 300mg OD	☐ 1 tab ☐ 1 tab	☐ BD ☐ OD		
Stavudine (D4T; Zerit)	☐ 30mg	30mg BD	☐ 1 tab	☐ BD		
Didanosine (Videx EC)	☐ 250mg ☐ 400mg	250mg OD if <60kg 400mg OD if > 60kg	☐ 1 tab (<60 kg) ☐ 1 tab (>60 kg)	☐ OD ☐ OD		
Abacavir (ABC; Ziagen)	☐ 300mg	300mg BD or 600mg OD	☐ 1 tab or ☐ 2 tab	☐ BD or ☐ OD		
Emtricitabine (FTC; Emtriva)	☐ 200mg	200mg OD	☐ 1 tab	☐ OD		
Tenofovir (TDF; Viread)	☐ 300mg	300mg OD	☐ 1 tab	☐ OD		
Nevirapine (NVP; Viramune)	☐ 200mg	200mg OD for 1st 2wks 200mg BD thereafter	☐ 1 tab or ☐ 1 tab	☐ OD or ☐ BD		
Efavirenz (EFV; Sustiva, Stocrin)	☐ 600mg ☐ 200mg	600mg Nocte Can use 800mg if >60kg and on Rifampicin	☐ 1 tab ☐ 1 tab	☐ Nocte ☐ Nocte		
Alluvia (Lopinavir + Ritonavir; LPV/r)	☐ 200mg/50mg	400mg/100mg BD	☐ 2 tab	☐ BD		
Indinavir (IDV; Crixivan) Only use boosted with Ritonavir	☐ 400mg	800mg BD (with 100mg RTV BD)	☐ 2 tabs (w/ RTV)	☐ BD (w/ RTV)		
Saquinavir (SQV; Invirase) Only use boosted with Ritonavir	☐ 200mg ☐ 500mg	1000mg BD (with 100mg RTV BD)	☐ 5 tabs (w/ RTV) ☐ 2 tabs (w/RTV)	☐ BD (w/ RTV) ☐ BD (w/ RTV)		
Ritonavir (Ritonavir; Norvir) Not to be used alone	☐ 100mg	100mg BD for boosting	☐ 1 tab	☐ BD		

Ordered by

(Physician)

Print Name

Signature

Code

/ ____ /20
Date (dd/mm/yy)

Seen by

(Nurse)

Print Name

Signature

Code

/ ____ /20
Date (dd/mm/yy)

Counseled by

(Adherence Counselor)

Print Name

Signature

/ ____ /20
Date (dd/mm/yy)

Dispensed by

(Pharmacist)

Print Name

Signature

Code

/ ____ /20
Date (dd/mm/yy)

Picked up by

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Version PMM-APO.3.02.05062009

Plate 1: Pharmacy Order Form showing names, strength, dose and dosing interval of ARV drugs

counselled on his/her medication regimens, ARV adherence, management of ARV DRPs, drug-drug interactions, drug-food interactions and authenticity of generic ARV drugs and provided up-to-date information on HIV/AIDS disease. An assessment was made on the ARV drugs during prescription refills. In addition, the prescriber was directly contacted by the researcher when any error was observed in any prescription and the error resolved with him/her. At the end of the 9th month, a post evaluation study was conducted to assess the impact of the pharmacist's intervention in resolving DRPs in the sample studied.

Study Instruments

Data collection format was designed for collection of the patient's information including DRPs. The format consisted of three sections, namely (1) sociodemographic: information on age and gender - obtained with patient biodata form, (2) data on WHO HIV clinical staging, types of antiretroviral (ARV) drugs, ARV side effects and self-reporting drug adherence - determined with standard instrument forms (POF, adult clinical evaluation and medication adherence assessment forms), (3) dose – related and patient-related problems (generic ARV drugs use, inadequate patients' knowledge on drug usage and drug-drug interactions) - derived from pharmacy order and medication-related problems evaluation forms as categorised by Cipolle *et al.* (14) and described by Mekonnen *et al.* (15).

Data collection procedure

Data were collected using the appropriate forms when the patients visited the pharmacy to refill their prescriptions.

Where any DRP was associated with the prescriber, the prescriber was contacted and the error discussed for resolution of the problem and prevention of re-occurrence. Each patient was then given proper education/counselling on the timing of pills administration, awareness on possible side effects and long-term drug toxicities of ARV drugs, the authenticity of generic ARV drugs, possibility of drug-drug and drug-food interactions, the beneficial effects of antiretroviral drugs, the importance of adhering completely to the treatment regimen and the possibility of drug resistance and therapeutic failure.

To minimize the number of patients lost to follow-up, the researcher specifically made phone call reminders to all patients taking part in the study on the last Saturday of every month and a day to appointment visit. In collaboration with each patient, a schedule on when a call should be made was drawn. At the 9th month, 73 patients (27.1%) were lost to follow-up.

Outcomes measured

The primary outcomes measured were the incidence of DRPs and the success of intervention in HIV/AIDS patients in UBTH which was defined in terms of significant reduction in number of cases of each DRP.

Data analysis

The data collected were analyzed using SPSS version-18. Data collected were summarised using descriptive statistics. Proportional data were compared using Chi-square or Fisher's Exact test. At 95% confidence interval, 2-tailed p values less

than 0.05 were considered to be significant.

RESULTS

The mean age of the patients was 41 ± 11.4 yr (range 20-70 yr). More than three quarters (75.4%) of the patients were found within the age group of 31-50 years and more than one-half (68.0%) of them were females (Table 1). Some of the patients (32.3%) enrolled into HIV/AIDS care through Preventing Mother-to-Child Transmission (PMTCT) service. Also, majority of them were in WHO clinical stage 1 and on lamivudine-zidovudine-nevirapine (LZN) combination therapy.

At baseline, 652 cases of DRPs were identified in 269 of the 297 patients recruited, giving DRPs incidence rate of 90.6%. Patients identified to have had 1, 2 or 3 DRPs were 43 (16.0%), 69 (25.6%) and 157 (58.4%), respectively. The average DRPs identified per patient was 2.4 ± 3.9 (Table 2). DRPs observed were generic drug substitution 187 (28.7%), inappropriate drug adherence 114 (17.5%), dosing interval not indicated 83 (12.7%), dose not indicated 69 (10.6%), inadequate patient's knowledge of appropriate drug use 61 (9.4%), drug-drug interactions 51 (7.8%), side effects 47 (7.2%), dosage too low 21 (3.2%), dosage too high 13 (2.0%) and wrongly prescribed drug 6 (0.9%). Of the DRPs identified, 29.4% are directly related to the use of the POF. Following the pharmacist intervention, all DRPs associated with POF were completely eliminated at the 9th month, even though wrong drug, dosage too low and dosage too high were the only problems eliminated at the 6th month. Other problems including inadequate patient's knowledge of appropriate drug use, drug

adverse effects, potential drug-drug interactions, and generic drug substitution were partially resolved at the end of the study. Also, the 82 (17.5%) cases of inappropriate drug adherence identified at baseline declined to 11 (7.1%) by the 9th month.

HIV/AIDS patients' counselling (460 out of 652, 70.6%) was the most common interventions conducted by the clinical pharmacist. Consulting the prescriber for dose related problems and change of drugs (192 out of 652, 29.4%) was the second most important intervention accomplished by the pharmacist to resolve and prevent DRPs. At the end of the 9th month, 61.2% of these problems were partially solved and 38.8% were completely resolved (Table 3).

DISCUSSION

This study has revealed high incidence of DRPs in which 29.4% are directly related to the use of the POF. Generic ARV drug substitution was the commonest DRP identified. Dose-related problems accounted for more than one quarter of all the DRPs. However, the intervention of the pharmacist led to complete elimination of the DRPs associated with the POF and 61.2% of all the DRPs were partially resolved, while 38.8% were completely resolved at the end of the 9th month of the study.

Although, our data is unique because of its association with POF, the incidence rate of DRPs obtained in the present study is comparable to that earlier reported (7, 16) but higher than that reported by Carcelero *et al.* (17). The reasons for the high incidence of DRPs in this study as identified from the prescribers by the researcher were (i)

inconvenient working space - as there were three prescribers and a nurse in the

Table 1: Demographic characteristics of HIV/AIDS patients on HAART

Variables	Number of patients (n=269) Frequency (%)
Gender	
Male	86 (32.0)
Female	183 (68.0)
Age (years)	
20-30	27 (10.1)
31-40	117 (43.4)
41-50	86 (32.0)
51-60	28 (10.4)
60+	11 (4.1)

Table 2: Clinical and treatment variables of HIV/AIDS patients on HAART

Variables	Number of patients (n=269) Frequency (%)
Entry point into HIV/AIDS care	
In-patient	5 (1.7)
Tuberculosis	3 (1.3)
Prevention of Mother-to-Child Transmission	87 (32.3)
Voluntary Counselling and Testing	58 (21.5)
Private doctor	62 (22.9)
Medical out-patient unit	54 (20.3)
WHO HIV stage	
1	268 (99.7)
2	1 (0.3)
Highly Active Antiretroviral Therapy (HAART) combinations	
Zidovudine + Lamivudine + Nevirapine	189 (70.1)
Zidovudine + Lamivudine +Efavirenz	33 (12.4)
Zidovudine + Lamivudine + Lopinavir/Ritonivir	24 (9.1)
Tenofovir+Emtricitabine+Efavirenz	18 (6.7)
Tenofovir+Emtricitabine+Nevirapine	2 (0.7)
Tenofovir+Emtricitabine+ Lopinavir/Ritonivir	3 (1.0)

Table 3: Drug Related Problems (DRPs) among HIV/AIDS patients on HAART

Types of DRPs	Frequency of DRPs (%)				
	Baseline* (n=269) ^a	Patients not lost to follow-up following intervention (n=194)			P-value
		3months ^b	6months ^c	9months ^d	
Ineffective (wrong) drug	6 (0.9)	-	-	-	
Dosage too low	21 (3.2)	-	-	-	
Dosage too high	13 (2.0)	-	-	-	
Dose not indicated	69 (10.6)	37 (11.9)	21(8.8)	-	0.002 ^{ac}
Dosing interval not indicated	83 (12.7)	40 (12.9)	28 (11.7)	-	0.027 ^{ab} , 0.002 ^{ac}
Drug adverse effects	47 (7.2)	20 (6.4)	9 (3.8)	5 (3.2)	<0.001 ^{ac, ad}
Potential drug interactions	51 (7.8)	22 (7.1)	11 (4.6)	4 (2.6)	0.047 ^{ab} , <0.001 ^{ac, ad}
Generic drug substitution	187 (28.7)	135(43.4)	135 (56.5)	135(87.1)	<0.001 ^{ab}
Inadequate patient knowledge of appropriate drug use	61 (9.4)	22 (7.1)	11 (4.6)	-	0.004 ^{ab} , <0.001 ^{ac}
Inappropriate drug adherence	114 (17.5)	35 (11.2)	24 (10.0)	11 (7.1)	<0.001 ^{ab, ac, ad}
Total	652	311	239	155	

DRPs: Drug Related Problems; *Baseline data prior to intervention

consulting room, (ii) too many forms to fill - as there were also laboratory test request forms to be completed, and (iii) rush to attend to all patients. The generic ARV drug substitution was at a much higher level (top most) in ranking of the number of DRPs observed in these patients in contrast to the earlier report by Nicholas *et al.* (18) that ranked it as the third DRP documented. The dose - related problems, accounting for more than a quarter of all the DRPs in this study, were also more than that reported by Rastegar *et al.* (19). Drug-food interaction was found to exist in patients on efavirenz, since they experienced severe nightmare on concomitant

administration of the drug with food. This corroborated an earlier study (20). Our study documented 7.2% adverse drug reactions (ADRs) as DRPs which was much lower than the 34.1% reported among newly registered patients in ART Center, RIMS Hospital, Kadapa (21).

The success of the intervention in this study is similar to that of the study carried out in Owerri, Nigeria (22), where a reduction of 55% of DRPs was reported and supports the continuous need for pharmacists in Nigeria to be fully integrated at all levels into the HIV/AIDS care programme and for education of medical doctors on the need to avoid their

frequent resistance to pharmacists having access to patients and their clinical information in hospital. Dose - related problems and wrong ARV drugs in seropositive HIV patients have several implications. First, possible development of drug resistance to HIV strains might result to new HIV and opportunistic infections. Second, increased drug toxicities could lead to organ failure and sudden death among the patients. Finally, expected inappropriate adherence to therapy might give rise to opportunistic infections, other related diseases and death. The roles of clinical pharmacists in resolving and preventing these problems can improve drug adherence and reduced cost of treatments in HIV/AIDS. As majority of the errors in prescribing originated from mistakes in ticking the correct drug, dose or dose interval in the prescription format by the prescribers (for example, some prescribers tick 200 mg OD as a daily dose of nevirapine instead of 200 mg BD for an adult on follow-up visit), a redesign of the current POF can significantly reduce the errors in medication use by HIV/AIDS patients.

CONCLUSION

A high incidence of drug-related problems has been identified in our study. Our findings indicate that the use of prescription forms where the prescriber simply ticks against names of drugs and dosing in an HIV/AIDS care centre has resulted in increase in the incidence of drug-related problems. However, the active participation of the pharmacist has led to early resolution of most of the problems.

While efforts are being made to reduce the time each HIV/AIDS patient spends with the prescribers, the need to protect

against possible increase in incidence of drug-related problems should always be a priority. This calls for continuous involvement of pharmacists in the design and implementation of programmes involving the use of drugs. In addition, clinicians should be well-trained in the proper use of POF to reduce DRPs, if the goals of HAART in enhancing quality of life and prolonging survival of HIV/AIDS patients are to be achieved.

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