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Medicine Dispensing Pattern in Management of HIV/AIDS Patients at Public Health Facilities in a North-Central State, Nigeria

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ABSTRACT

Appropriate medicine dispensing is very fundamental for optimum medicine use in the management of HIV/AIDS patients. However, there is dearth of knowledge about medicine dispensing pattern in the management of HIV/AIDS patients in North-Central Nigeria. This study assessed the medicine dispensing pattern in the management of HIV/AIDS patients at public health facilities in a North-Central State, Nigeria. This multi-center study was conducted in 7 eligible public health facilities. It comprised exit observational checks of medicines dispensed to 780 eligible HIV/AIDS patients, data abstraction from their medical folders and in-depth interviews of seven eligible dispensers using a pre-tested structured interview guide. Descriptive statistics were used for quantitative data analyses while in-depth interviews were audio-taped, transcribed verbatim, analysed and developed into ethnographic summary with illustrative quotes. Of the 1828 medicines that were dispensed, antiretroviral medicines constituted 58.9% of which Zidovudine/Nevirapine/Lamivudine as a fixed dose combination was the most dispensed while co-trimoxazole was the most dispensed non-antiretroviral medicine. Also, 96.5% of the patients were on first line ARVs regimen; 55.3% received co-trimoxazole preventive therapy and 3.5% received artemisinin-based combination therapy. One-third of dispensed medicines were inadequately labelled with regards to the name of the medicines, the dispensed quantity and the strength of the medicines. The study also revealed that six out of the seven dispensers practiced generic substitution. Dispensing pattern of medicines in the management of HIV/AIDS patients at public health facilities is below optimal regarding labelling information. Periodic training of dispensers on standard dispensing practices is recommended.

INTRODUCTION

Antiretroviral therapy (ART) has revolutionized the prognosis of HIV/AIDS and HIV - related comorbidities [1-4]. In Nigeria, some of the antiretroviral medicines (ARVs) that are used for the management of HIV/AIDS patients include tenofovir, emtricitabine, lamivudine, zidovudine, nevirapine and abacavir, (first line); and lopinavir, ritonavir and atazanavir (second line) [5]. Also, the use of non-antiretroviral medicines (NARVs) such as co-trimoxazole (co-trimoxazole preventive therapy), isoniazid (isoniazid preventive therapy) and other antimicrobial agents, as adjunct to highly active antiretroviral therapy (HAART) in HIV/AIDS patients has greatly reduced the morbidity and mortality associated with HIV infections [5].

Optimal medicine use in the management of HIV/AIDS patients is fundamentally dependent on appropriate medicine

dispensing. Appropriate dispensing is one of the core strategies for implementation of the Nigerian National Drug Policy [6]. According to the Nigerian National Drug Policy (NNDP), appropriate medicine dispensing has the objective of ensuring that "patients receive adequate information on the use of dispensed medicines so that they can derive the desired benefits" [6]. The information requirement on the label of a dispensed medicine include name of patient, generic name of dispensed drug, strength of the drug, the dose and dosage regimen [6,7]. The dosage instructions could be in symbols or words (as appropriate) [6]. Others are quantity of medicines dispensed [7], duration of treatment and date of dispensing [6,7]; expiry date and appropriate storage conditions [7]; and name of institution where the medicine(s) was/were dispensed [6].

Another core strategy for implementation of the Nigerian National Drug Policy is procurement of medicines [6]. According to the NNDP, one of the criteria for procurement is that procurement in the public sector shall be by International Non-Propriety Names or generic names only. This would result in generic substitution (GS) which involves the dispensing of a different brand or unbranded medicine product instead of the brand that was prescribed by the physician. Both products have same active pharmaceutical ingredient(s) and are in same dosage forms. GS presupposes the existence of therapeutic equivalence, equivalent safety/adverse reactions and palatability among the various brands of a medicament. Additionally, appropriate dispensing of ARVs as fixed dose combination (FDC) instead of non-fixed dose combination (NFDC) would result in reduction of pill burden which enhances patient adherence to medication.

However, reports from World Health Organization showed that more than 50% of medicines are inappropriately dispensed[8]. Inappropriate medicine dispensing (IMD) has been identified in different health facilities within and outside Nigeria. For instance, a cross-sectional survey of access to and rational use of medicines at the household level in Nigeria revealed that most of the prescribed medicines (80%) were dispensed using adequate primary packaging [8]. However, only 52% of dispensed medicines were adequately labelled with name of the medicines, dosage instructions and expiry dates [9]. Also, a study on drug use practices in teaching hospitals of Khartoum State, Sudan, showed that 37.6% of dispensed medicines were inadequately labelled [10]. Another survey of the prescribing and dispensing activities at non-governmental health facilities in West Bengal revealed that 43.8% of the dispensed medicines were inadequately labelled [11]. In addition, a study on rational drug prescribing and dispensing for outpatients in a tertiary care teaching hospital of Western Nepal, showed that only 0.4% medication envelopes were labelled with the patient's name while 82.6% and 87.0% were labelled with the name of the medicine and its strength [12]. In Kuwait, a study showed that 66.9% of the dispensed medicines were labelled [13] while a study in Cambodia revealed that none of the dispensed medicines was adequately labelled (0%) [14]. Another study in Ethiopia showed that 57% of dispensed drugs were adequately labelled [15].

In Nigeria, a study of the situation of antiretroviral drugs involving twenty-five (25) tertiary HIV treatment centers about 17 years ago, revealed that only 14% of the dispensed medicines was adequately labelled [16]. Inappropriate labelling is of serious concern since adequate labelling is a critical step in the dispensing process [7]. Moreover, inadequate labelling is a deterrent to patient adherence to medication [17].

Notwithstanding the previous studies on dispensing pattern of medicines in different health facilities in different geographical locations, the dearth of information on medicine dispensing pattern in the management of HIV/AIDS and HIV-related comorbidities has attracted concerns. In addition, none of the previous studies used triangulation of quantitative and qualitative research methods which provide more holistic findings. Hence this study assessed medicine dispensing pattern in management of HIV/AIDS patients using triangulation of research methods.

MATERIALS AND METHODS

Study Design/Setting

This multi-center cross-sectional study involved triangulation of quantitative and qualitative research methods. It comprised exit observational checks of medicines dispensed to 780 eligible HIV/AIDS patients**,** data abstraction from these patients' medical folders and in-depth interviews of seven eligible dispensers using a pre-tested structured interview guide that was developed by the researchers. It was conducted in 7 public health facilities that provided healthcare to adult HIV/AIDS patients in a North-central State, Nigeria. These hospitals were in 6 local government areas (LGAs) representing three Senatorial Districts of the state.

Inclusion and Exclusion Criteria

The inclusion criteria were: medicines dispensed to HIV/AIDS patients who were on combination antiretroviral therapy (cART); attended public health facilities in the North-Central State with age range 18 - 70 years, and gave voluntary informed consent to participate in the study. Also, Dispensers who were focal persons in the HIV Treatment Center who provided healthcare to the eligible HIV/AIDS patients and consented to participate in the study were recruited as study participants. The exclusion criteria were: medicines dispensed to HIV/AIDS patients who were too ill to participate in the study and medicines dispensed to HIV/AIDS patients who had psychiatric illness that might have impaired their ability to give voluntary informed consent. Additionally, Dispensers who provided healthcare for the eligible HIV/AIDS patients who have spent below one year in the HIV treatment center were excluded.

Sample Size Determination and Sampling

A minimum sample size of 260 was obtained through use of Fisher's formula [18,19] based on 4162 registered HIV/AIDs patients on cART, at 95% confidence level, 5% margin of error and the proportion in target population estimated to have a unique characteristic: antiretroviral therapy coverage of 23% for Nigeria [20]**.** The obtained minimum sample size was tripled so that the sample is more representative of the study population. The resultant 780 sample was proportionally allocated to the 7 study sites. Sample units were systematically obtained. Exit observational checks were then conducted on the medicines dispensed to these patients. Also, there were in-depth interviews (IDIs) of 7 purposively sampled eligible dispensers who were focal persons in the HIV Treatment Centers (HTCs).

Study Instruments

The study research instruments: dispensing indicator form, designed data extraction sheet and an interview guide were adapted from previous studies [14,16] and pre-tested in another health care facility that provided healthcare to HIV/AIDS patients. Ten percent (n =78) of the study sample size was used for the patients on which observational checks of dispensed

medicines were conducted.

Data Collection

Exit observational checks of medicines dispensed to 780 eligible HIV/AIDS patients were conducted on clinic days. The data abstraction from patients' medical folders was done on non-clinic days. IDIs were conducted in English language at a time and place convenient to the interviewees. The thematic areas were: practice of generic substitution (GS), factors that influence the dispensers' practice of GS, factors that generally influence dispensers' practice of GS and the motivations of dispensers to practice GS. The interviews were audio-taped. Notes were also taken.

Data Analyses

Statistical Package for Social Sciences version 17.00 was used for quantitative data entry and descriptive statistical analyses. The in-depth interviews were audio-taped, transcribed verbatim, analyzed and developed into ethnographic summary with illustrative quotes [21].

Ethical Issues

Institutional Ethical Review Committees granted ethical approvals for this study (ERC 1163 and MOH/KS/EU/777/41). Voluntary informed consent of the patients (signatures/finger print) and dispensers (verbally recorded) were obtained before inclusion into the study. Data and information confidentiality was ensured. Participants' anonymity and freedom to decline or consent to participate in the research were observed.

RESULTS

A total of 780 HIV/AIDS patients participated in the study, of which 25% were males (Table 1). The modal age was 35 years; 83.3% were married; 71.8% had annual income that was less than ₦120, 000.00 (USD 310.08) while about 12.6% had annual income greater than ₦240, 000.00 (USD 620.16). Additionally, more than one-third of the study participants (36.1%) had no formal education.

Table 1 : Socio-demographic Characteristics of the HIV/AIDS patients.

Variable	Frequency (%)
Gender (N = 780)	
Male	192 (25)
Female	588 (75)
Age (years) (N = 780)	
≤ 20	10 (1.3)
21 – 30	149 (19.1)
31 – 40	297 (38.1)
41 – 50	190 (24.3)
51 – 60	109 (14.0)
≥ 61	25 (3.2)
Marital Status (N = 780)	
Married	650 (83.3)
Single	44 (5.7)
Widow	65 (8.3)
Widower	5 (0.7)
Divorced	12 (1.5)
Separated	4 (0.5)
Income p.a. (₦, [N = 780)]	
< 120,000.00	560 (71.8)
120,000.00 – 239,999.00	122 (15.6)
≥ 240,000.00	98 (12.6)
Educational Status (N = 780)	
No formal education	282 (36.1)
Primary education	153 (19.6)
Secondary education	208 (26.7)
Tertiary education	137 (17.6)

Over a quarter (29.8%) of the study participants (Table 2) had less than 1.5 years' duration of illness since diagnosis (DISD). Also, 32.8% of the study participants had less than 1.5 years' duration of antiretroviral therapy (DART).

Table 2 : Durations of illness since diagnosis and antiretroviral therapy of the study participants

Variable	Frequency (%)
Duration of illness since diagnosis (years) (N = 780)	
< 1.5	232 (29.8)
1.5 – 2.999	189 (22.4)
3.0 – 4.999	192 (24.6)
≥ 4.5	167 (21.4)
Duration of antiretroviral therapy (years) (N = 780)	
< 1.5	256 (32.8)
1.5 – 2.999	191 (22.5)
3.0 – 4.999	185 (23.7)
≥ 4.5	148 (19.0)

Of the 1828 medicines that were dispensed to the 780 eligible HIV/AIDS patients, antiretroviral medicines (ARVs) constituted 58.9% (Figure 1). Regarding the non-antiretroviral medicines (NARVs), co-trimoxazole (co-trimoxazole preventive therapy [CPT]) constituted 23.6%, analgesics was 5.8% while artemisinin-based combination therapy (ACT) was 1.5%. Furthermore, 55.3%, 13.7% and 3.5% of the 780 HIV/AIDS patients received CPT, analgesics and ACT respectively. None of the patients received isoniazid preventive therapy (IPT).

With regards to the ARVs, Zidovudine/ Lamivudine/ Nevirapine (ZLN) a 3 FDC ARV was the most dispensed (Figure 2). Most of the patients (96.5%) received first line antiretroviral (ARV) treatment regimen.

The status of labelling information on labels of dispensed medicines is as shown in Figure 3. None of the dispensed medicines was labelled with regards to the names/code of patients.

Only two-third of the dispensed medicines were labelled with regards to the name of the medicines, the dispensed quantity and the strength of the medicines (Figure 3). However, all the dispensed medicines were labelled with regards to the quantity of medicines to be administered, frequency of administration and route of administration (Figure 3).

In-Depth Interviews of Dispensers

The gender ratio of dispensers was 5 males:2 females, age

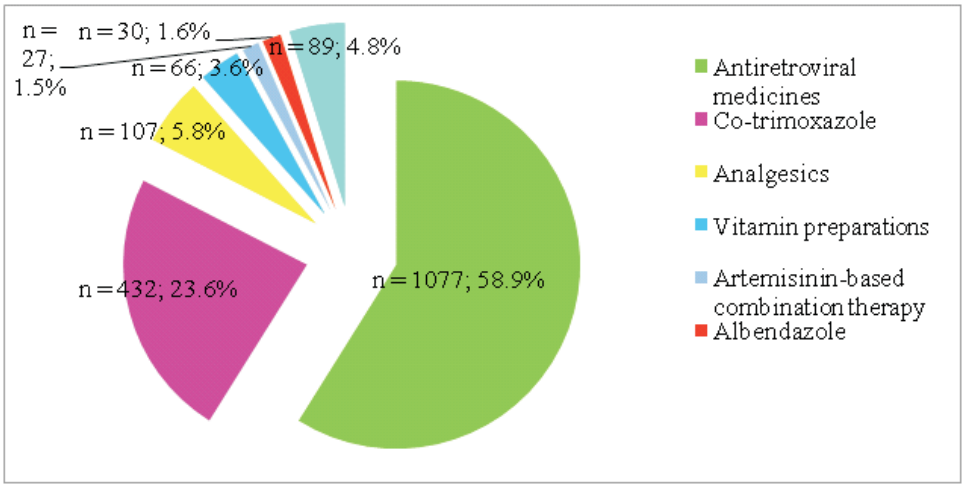

Fig **1 :** Medicines dispensed to the HIV/AIDS patients.

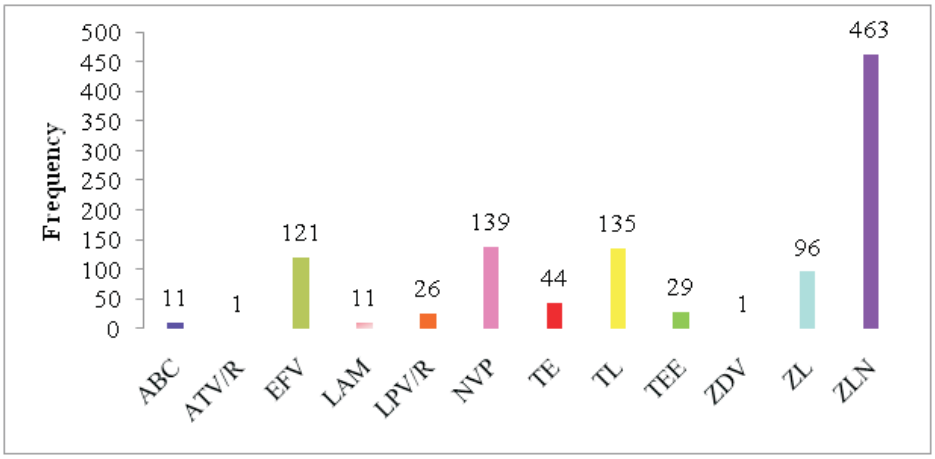

Fig **2 :** Antiretroviral medicines that were dispensed to the HIV/AIDS patients

Legend

ABC:	Abacavir;	ATV/R:	Atazanavir/Ritonavir;
EFV:	Efavirenz;	LAM:	Lamivudine;
LPV/R:	Lopinavir/Ritonavir;	NVP:	Nevirapine;
TE:	Tenofovir/Emtricitabine;	TL:	Tenofovir/Lamivudine;
TEE:	Tenofovir/Emtricitabine/Efavirenz;	ZDV:	Zidovudine;
ZL:	Zidovudine/Lamivudine;	ZLN:	Zidovudine/Lamivudine/Nevirapine.

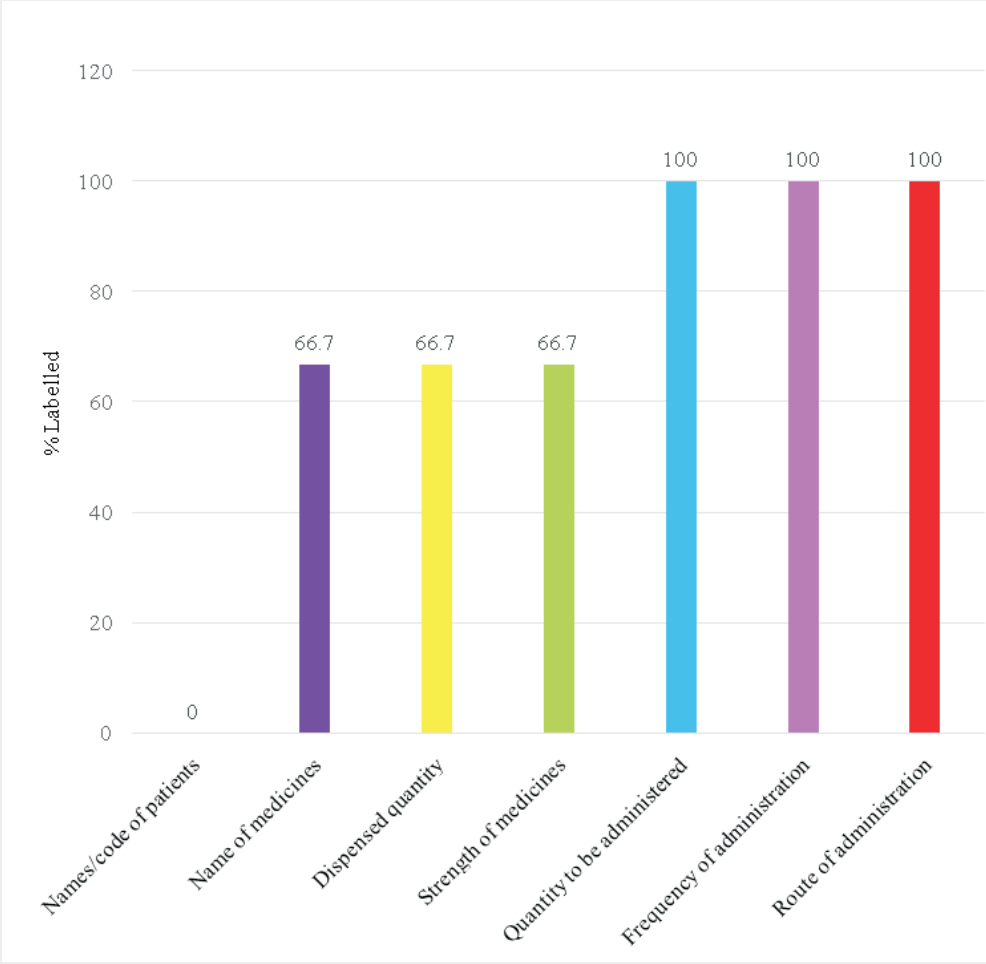

Fig 3 : Status of labelling information on labels of dispensed medicines

ranged 42 - 50 years, 57.1% obtained Bachelor of Pharmacy as the minimum tertiary education while 42.9% had Certificate in Pharmacy Technician. Only 2 of the interviewees had postgraduate qualifications. Interviewees' post qualification work experience in the hospital ranged 13 - 26 years while years of contact with HIV Treatment Center ranged 3 - 7 years. Also, 42.9% of the interviewees had worked in two HIV treatment centers.

Theme 1: Opinion about the concept of generic substitution (GS)

Six out of the seven respondents practiced GS. However, there was no documentation of the GS due to workload. Reason for practice of GS was: "*All the drugs in the HAART pharmacy are supplied by the implementing partners. Whatever is supplied whether in brand names or generic names is dispensed to the HIV/AIDS patients*" (D1 D4, D6 & D7).

Theme 2: Factors that influenced the dispensers' practice of GS

Availability, quality of the medicines and government politics were some factors that influenced the dispensers' practice of GS. According to the respondents, "*Availability and patients' clinical response to the dispensed product*" (D3); "*Government politics (some suppliers who are highly connected to government officials, convince them of the quality of a generic product), the rapport between the pharmaceutical company and the hospital management, the prescribers and the dispensers*" (D4); "*The quality of the product*" (D7).

Theme 3: Factors that generally affect dispensers' practice of GS

Availability, affordability of the medicines, pharmaceutical companies' influence on the suppliers and dispensers, patients' clinical response and patients' preference are some factors that generally affect dispensers' practice of GS. According to the respondents, "*Proliferation of drug manufacturing companies and drugs that have been registered by National Agency for Food and Drug Administration and Control (NAFDAC) resulting in availability and affordability*" (D2);

"*Patients' clinical response (absence or presence of side effects), quality of the drug and pharmaceutical companies' influence on the suppliers and dispensers affect GS*" (D3);

"*Patients' demand for a particular brand influences GS*" (D6).

Theme 4: Motivation of dispensers to practice GS

Financial incentives, availability, affordability and therapeutic efficacy of the medicines motivate dispensers to practice GS. According to the respondents, "*Availability, affordability and therapeutic efficacy of the drug*" (D2); "*Financial incentive such as it is in Health Insurance Scheme*" (D3).

DISCUSSION

Zidovudine/Lamivudine/Nevirapine (ZLN) a 3-fixed dose combination (FDC) ARV was the most dispensed. For 2-FDC, tenofovir/lamivudine was the most dispensed. Most of the dispensed ARVs were FDC. The dispensed medicines are in line with the National Guidelines for HIV and AIDS treatment and care in adolescents and adults [5]. Availability of FDCs reduced the patients' pill burden with subsequent reduction in stigmatization and improvement on medication adherence. However, the pill burden for patients on co-trimoxazole preventive therapy, ACTs, analgesics and vitamin preparations was still high due to HIV/AIDS co-morbidities and resultant poly-therapy.

The proportion of medicines labelled (PMAL) with regards to name, the strength (mg) and quantity of dispensed medicines were low. The PMAL obtained in this study is not in accordance with the NNDP minimum information requirement on the label of dispensed medicines [6], recommended standards [14] and appropriate dispensing process [7]. The 33.4% inadequate labelling found in this study is lower than that obtained from previous studies in Nigeria: 52% [9]; West Bengal: 43.8% [11] and Ethiopia: 43% [14] but higher than that obtained in Kuwait: 33.1% [13]. None (0.0%) of the dispensed medicines were labelled using patients' names. This could due to desire for anonymity. The dispensers could have used codes that provide for both anonymity and conformity to appropriate labelling requirements [15] thereby reducing/eliminating potential medication error. The non-labelling of dispensed medicines using patient names/codes is similar to the findings from the study in Cambodia [14] in which none of the dispensed medicine was labelled. These studies showed that inadequate labelling of dispensed medicines which is a deterrent to adequate adherence to medication use is a common dispensing problem. This inadequate labelling could be due to patient workload and inadequate number of dispensers. According to the in-depth interviews, the dispensers stated that patient workload is one reason for non-documentation of generic substitution. Inadequate labelling would result in inappropriate adherence (a medicine therapy problem) with consequent epidemiological, medical, social and economic implications thereby nullifying all efforts put in place to provide efficacious, safe and quality medicines. However, all dispensed medicines (1828) were labelled with regards to quantity of medicines to be administered, frequency and route of administration. This is in accordance with the NNDP minimum information requirement on the label of dispensed medicines [9] and appropriate dispensing process [7].

The practice of GS by most of the dispensers is very commendable. This is line with the requirements of the NNDP [9]. Some of the reasons for practicing GS were affordability and quality. Quality of medicines should not be compromised for affordability so that good therapeutic outcome can be achieved. However, Government Regulatory body such as NAFDAC should continually conduct market surveillance to confirm quality of generic products. This is to ensure that GS attains the aim of cost minimization of healthcare.

LIMITATIONS OF STUDY

The study was limited to the public hospitals in a North-Central State, Nigeria that provided healthcare to adult HIV/AIDS patients.The study did not include public hospitals that provided healthcare to HIV/AIDS patients who were infants and children.

CONCLUSIONS

The dispensing pattern of medicines in the management of HIV/AIDS patients at public health facilities in a North-Central state, Nigeria, did not meet up with the set standards of the Nigerian National Drug Policy regarding labelling information. However, the dispensers practiced generic substitution. Periodic training of dispensers on standard dispensing practices is

recommended to ensure that patients receive appropriate information necessary for appropriate medicine use.

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