Generic Medicine Substitution: A Cross-Sectional Survey of the Perception of Pharmacists in North-Central, Nigeria

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Abstract

Objective: To investigate the views of pharmacists in North-Central Nigeria on generic medicines and generic substitution practices. ***Subjects and Method:*** A cross-sectional survey was conducted in 4 cities in North-Central Nigeria from April to June 2012 among 330 pharmacists in hospital and community pharmacy settings, recruited through a convenience sampling strategy. Data were collected using a pre-validated self-administered questionnaire and entered into SPSS version 16.0 software to generate descriptive statistics. Binary logistic regression was conducted to determine the demographic predictors of preference for generic substitution among respondents. ***Results:*** The response rate was 46.7% (n = 154). Eighty-four (54.5%) respondents reported that generic medicines were not of equivalent quality to branded ones. There was no significant difference (p > 0.05) in the perception of respondents regarding the quality of imported generic medicines over locally manufactured ones. While 143 (92.9%) respondents supported generic substitution practices, 105 (68.2%) would prefer to recommend generic medicines over branded ones. Hospital pharmacists were more likely (OR = 2.6; 95% CI 1.2–5.8) than community pharmacists to recommend generic medicines. One hundred and fifty-three (99.4%) respondents would support the implementation of a future generic substitution right for pharmacists in Nigeria. ***Conclusion:*** The present study showed a high support for generic substitution and future generic substitution rights for pharmacists in Nigeria.

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Introduction

Access to quality affordable medicines is of public health importance and has remained a major challenge in developing countries, especially in Nigeria [1]. A generic medicine is a 'pharmaceutical product that is intended to be interchangeable with the innovator product, which is manufactured without a licence from the innovator company, and marketed after the expiration of the patent or other exclusivity rights' [2]. Generic medicines are usually cheaper than innovator brands and therefore save costs on medicines [3, 4]. In a cost-saving study conducted by Cameron et al. [4] in 17 developing countries, they reported that 'an average of 9–89% could be saved by an individual country in private sector purchases by switching from originator brands to lowest-priced generics' [3].

In Nigeria, payment for medicines is mainly out of pocket and no pricing formula exists for the sale of medicines [5]. A national survey of 129 medicine outlets investigating the prices of 34 prescription medicines revealed that consumers pay up to 64 times the international reference price of the medicines and the cost of innovator brands is be-

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tween 2 and 7 times that of the lowest-priced generics [6]. A recent national survey investigating access to medicines, conducted among 1,080 households, revealed that about 30% of patients with chronic conditions do not take medicines because they are unable to afford them [1].

Even though legislation exists in Nigeria regarding generic prescribing, generic medicine prescribing is yet to be institutionalized. For example, an assessment of over 4,000 medicine items included in 1,307 patients' prescriptions at the medical out-patient clinic of a tertiary hospital in Nigeria showed that only 49.5% of medicine items were prescribed as generics [7].

Many studies have investigated pharmacists' views and practices regarding generic medicines and have reported positive benefits, including a reduction in treatment costs and an increase in access to medicines [8–10]. However, some concerns have been reported regarding generic medicines in terms of their quality and the likely impact of generic medicine substitution on patients' adherence to therapy [9, 10].

The perception of health care professionals, including doctors and pharmacists, regarding generic medicine substitution has not been investigated in Nigeria. Given the role of pharmacists in the management of medicines, including the selection and dispensing of medicines, they could be an important point of intervention for promoting generic medicine utilization in the health care system. This research was therefore carried out to investigate the views of pharmacists in North-Central Nigeria on generic medicines and generic substitution practices.

Subjects and Methods

Study Setting and Population
This study was conducted in 4 cities, i.e. Abuja, Keffi, Lafiya and Jos, located in North-Central Nigeria. These cities were chosen because they contain at least one tertiary hospital with a number of pharmacists employed as staff. In addition, there is a high presence of community pharmacies in these cities. The study population consisted of hospital and community pharmacists working in these cities. Inclusion criteria were that study participants had to be registered pharmacists and had to be working in either a community or hospital pharmacy. The hospitals used for this study consisted of government, mission (private and non-profit), and private (for-profit) hospitals while the community pharmacies used were privately owned.

Sample Size
The sample size of this study was calculated based on 95% CI, a margin of error of 5%, and the assumption that there are about 1,000 pharmacists practicing in hospitals and community pharmacies in these cities. A sample size of 278 was obtained using an on-line sample size calculator [11]. However, 330 pharmacists were recruited for this study in order to accommodate for non-response among participants.

Questionnaire Development
The questionnaire used was developed based on a review of the literature investigating generic medicine utilization among pharmacists [3, 8, 9, 12]. The initial questionnaire developed was pilot tested on 20 academic pharmacists who had worked in a hospital or community pharmacy. They were asked for feedback regarding any grey areas on the questionnaire. The questionnaire was also evaluated for its ability to meet the study objectives and adjusted as required. The final version of the questionnaire contained 28 items intended to measure respondents' perception regarding generic medicines, generic substitution, and a future generic medicine substitution policy in Nigeria. The questionnaire contained closed-ended questions, and respondents were given the opportunity to comment freely at the end of the questionnaire on how generic medicine utilization can be improved in Nigeria.

Study Design
A cross-sectional survey employing a self-administered questionnaire as the data collection tool was conducted from April to June 2012 among 330 pharmacists. The pharmacists were recruited through a convenience sampling strategy due to logistical challenges and the non-availability of a sampling frame of hospital and community pharmacists to enable a probability sampling to be carried out. Several visits were made to hospitals and community pharmacies located in the 4 cities selected, and pharmacists who were present at the time of the researchers' visit and accepted the invitation to participate in the study were given the questionnaire. Follow-up visits for collection of the completed questionnaires were made within a month of the administration of the questionnaire.

Ethical Consideration
Approval for this study was granted by the Research Review Board of the Faculty of Pharmaceutical Sciences, University of Jos, Nigeria. Written informed consent was sought from each participant, participation in the study was voluntary, and the information obtained was anonymous and treated confidentially.

Data Analysis
Data collected were entered into SPSS version 16.0 software (Chicago, Ill., USA) to generate descriptive statistics. Binary logistic regression was conducted to determine the demographic predictors of a preference for generic substitution practices among respondents. No analysis was made against hospital pharmacists in the private sector as only 14 pharmacists from this sector participated in this study because most private hospitals have no resident pharmacists.

Results

Of the 330 administered questionnaires, 154 (46.7%) were correctly filled out and returned, representing an overall response rate of 50.7% (113/223) and 38.3% (41/107) among hospital and community pharmacists,

respectively. Among the 113 hospital pharmacists, 99 (87.6%) were from government hospitals, 9 (8.0%) were from private (for-profit) hospitals, and 5 (4.4%) were from mission (private and non-profit) hospitals. Demographic data of the 154 respondents of this study revealed that 100 (64.9%) were men and 54 (35.1%) were women; 78 (50.6%) were between the ages of 30 and 39 years; 113 (73.4%) were practicing as hospital pharmacists, and 115 (74.7%) had no postgraduate degree (table 1).

Overall, 103 (66.9%) and 108 (70.1%) agreed that generic medicines were bioequivalent to and cheaper than branded medicines, respectively. Eighty-four (54.5%) respondents reported that generic medicines were not of equivalent quality to branded ones. A Likert-type scale was used to evaluate respondents' perception regarding the quality of imported and locally manufactured generics. Eighty-five (55.2%) respondents believed that imported generics were of high quality, 63 (40.9%) believed they were of moderate quality, and 6 (3.9%) believed they were of low quality. Similarly, 79 (51.3%), 63 (40.9%), and 12 (7.8%) respondents believed that locally manufactured generics were of high, moderate, and low quality, respectively. Therefore, there was no significant difference (p > 0.05) in the perception of respondents regarding the quality of imported generic medicines over locally manufactured ones.

One hundred and forty-three (92.9%) respondents were in support of generic substitution; however, 112 (72.7%) of them expressed concern that some situations exist in which generic substitution is not appropriate. Respondents reported that patients usually have psychological dissatisfaction (98; 63.6%), problems adhering to therapy (33; 21.4%), adverse/allergic reactions (27; 17.5%), and poor clinical outcomes (27; 17.5%) when their regular branded medicines are substituted with generic ones.

This study also revealed that 105 (68.2%) respondents would prefer to recommend generic medicines over branded ones, while 49 (31.8%) respondents preferred to recommend branded medicines over generics in their practice. Respondents' primary area of practice was the only identified demographic predictor of a preference for recommending generic medicines (table 1). Hospital pharmacists were more likely (OR = 2.6) than community pharmacists to recommend generic medicines (table 1). Cost-effectiveness (75.2%; 79/105) and customer satisfaction (31.4%; 33/105) were the common factors that influenced respondents' preference for generics. Similarly, these factors, i.e. customer satisfaction (63.3%; 31/49) and cost-effectiveness (34.7%; 17/49), commonly

Table 1. Predictors of respondents' preference for recommending generic medicines

Variable	n	Preference for generics, n (%)	OR (95% CI)	p value
Gender				
Male	100	68 (68.0)	referent	
Female	54	37 (68.5)	1.2 (0.5–2.8)	0.601
Age group				
20–29 years	41	29 (70.7)	referent	
30–39 years	78	51 (65.4)	0.9 (0.3–2.8)	0.921
≥40 years	35	25 (71.4)	1.4 (0.3–6.4)	0.700
Primary area of practice				
Hospital	113	84 (74.3)	2.6 (1.2–5.8)	0.018*
Community	41	21 (51.2)	referent	
Experience				
0–5 years	67	48 (71.6)	referent	
6–10 years	46	30 (65.2)	0.9 (0.3–2.6)	0.826
≥11 years	41	27 (65.9)	0.7 (0.2–2.5)	0.536
Postgraduate degree				
Yes	39	24 (61.5)	referent	
No	115	81 (70.4)	1.2 (0.5–2.9)	0.703

n = 154. * p < 0.05.

influenced those with a preference for branded medicines, too.

Twenty-three (23, 14.9%) respondents reported that they regularly document and provide follow-up services to their patients when they switch their medicines from branded ones to generics. Common reasons given (n = 131) for not documenting and following up generic substitution were the absence of regulations/guidelines to document or provide follow-up services (73; 55.7%), that the respondent did not think it was necessary (50; 38.2%), and that the clients were irregular (26; 19.8%).

The reported impacts of generic medicines on the respondents' pharmacy practice were: much time was spent explaining the reasons for generic substitution to the clients (76; 49.4%), their relationship with the patient was affected when the generic medicine did not work (57; 37.0%); it promoted drug availability (44; 28.6%); less funds were needed to stock generics (38; 24.7%), and it met their patients' demand (37; 24.0%).

When respondents' views were sought concerning extending generic substitution rights to pharmacists in Nigeria, 153 (99.4%) respondents were in support of this policy direction. Sixty (39.0%) respondents reported that pharmacists should be allowed to perform generic substitution without consulting the prescribing physician,

Table 2. Major themes on how to improve generic medicine utilization in Nigeria

Theme	Supporting quote
Regulation and policy	'generic medicine policy should be institutionalized in Nigeria to encourage the selection and use of generic medicines' (R23) 'quality control/quality assurance should be enforced so that generics will be of the same standard like their branded counterparts' (R103)
Education of health professionals	'doctors should be adequately educated on the need to prescribe using generic names' (R35)
Local manufacturing	'empower local manufacturing of generic medicines by reputable companies' (R62)
Granting pharmacists prescribing rights	'pharmacist should be given the right of prescribing as it is practised in advanced countries' (R55)
Collaborative practise between physicians and pharmacists	'doctors and pharmacists should work together in prescribing and dispensing drugs base on their generic names and not brand names' (R98)

while 72 (46.8%) respondents reported that pharmacists only need to consult the prescribing physician when substituting certain groups of medicines. Eight (5.2%) respondents were of the view that pharmacists must always consult the prescribing physician when performing generic substitution. The reasons given by respondents in support of granting pharmacists generic substitution rights were: to enhance the use of pharmacists' skills (99; 64.3%), to promote access to medicine (39; 25.3%), to reduce patients' costs (13; 8.4%), to promote the rational use of medicines (11; 7.1%), to promote pharmacists' job satisfaction (7; 4.5%), and that getting back to the physician takes time (4; 2.6%).

Respondents' comments on how to improve the use of generic medicines in the country were centred on regulation and policy, education of health professionals, local manufacturing of generic medicines, granting pharmacists prescribing rights and collaborative practice between physicians and pharmacists (table 2).

Discussion

The high support (92.9%) for generic substitution in this study is comparable to those found in New Zealand and Malaysia, where 89.4% [9] and 84.7% [13] supported generic medicine substitution. Although the respondents in this study demonstrated a high support for generic substitution, the majority of them (72.7%) were of the opinion that generic substitution is not appropriate in all situations, similar to other studies [13, 14]. In these studies, generic medicine substitution was not considered appropriate for medicines with a narrow therapeutic index, including those affecting the nervous system and those prescribed for obstructive airway diseases [13, 14]. Duerden and Hughes [15], in their review, outlined a number of situations in which generic medicine substitution may be considered inappropriate, including instances where pharmacokinetic differences may be evident, where there is a significant danger of medication error, and where modified release medicines are not interchangeable.

The present study also confirmed findings from other studies in which pharmacists reported that generic medicines were not of equivalent quality to branded ones [9, 12]. This finding has implications on the level of confidence pharmacists have in generics, and the generic medicine approval/regulatory system. Since pharmacists' perception of generic medicines can influence generic substitution, the revealed poor perception of generic medicines can be corrected by building pharmacists' confidence in the generic medicine approval system. In the case of Nigeria, building confidence in the activities of the National Agency for Food, Drug Administration and Control, the agency responsible for registering medicines in Nigeria (based on a demonstrated bioequivalence and good manufacturing practices), would enhance generic medicine utilization [16].

A low percentage (21.4%) of the respondents in this study reported difficulty adhering to therapy as one of the challenges patients encountered when their regular medicines were substituted; however, this finding is still debatable. A Norwegian study reported that one third of the patients found it difficult to keep track of their medications when their regular branded medicines were substituted, and this presented a challenge to them in adhering

Auta/Bala/Shalkur

to therapy [17]. However, a cohort study in the Netherlands demonstrated that generic substitution does not affect adherence [18].

In North-Central Nigeria, hospital pharmacies are usually stocked based on the medicines on the essential drug list which contains names of medicines in generic. Most hospitals, therefore, stock their pharmacies with generic medicines and dispensing is usually based on the generic medicines available. This practice has probably influenced the hospital pharmacists' preference for generics, as seen in this study. On the other hand, community pharmacies are profit driven, and their clients usually present to them with requests for a specific brand-name medicine. This also may account for why respondents who prefer to recommend branded medicines in this study commonly reported customer satisfaction as a major reason for their preference. Generally, these factors are likely to have influenced community pharmacists' preference for branded medicines. Hence, there is a need for targeted interventions to promote the use of generic medicines among community pharmacists.

The present study shows that documentation and follow-up of generic substitution among pharmacists in North-Central Nigeria is poor. Documentation is a core tenet of pharmaceutical care [19]. Hence, regular documentation and follow-up of patients, especially those in chronic care whose regular medicines have been substituted, should be promoted among pharmacists. This will enable pharmacists to keep track of patient therapy and monitor treatment outcomes and any adverse event following generic substitution.

Generic medicines have had positive and negative impacts on pharmacy practice, including the promotion of medicine availability, less money needed to stock pharmacies with generics, more time spent explaining the reasons for the substitution to customers, and that the pharmacist's relationship with the patient may be affected when the generic medicine does not work. These effects are more likely to be felt in community pharmacy practices. More than two thirds of the 287 community pharmacists who participated in a survey in New Zealand reported that generic medicines affect the profitability of their pharmacies because more time is spent explaining the medication changes to the patients and sales volumes had to be increased to maintain a profit [9].

There was a high support (99%) for future generic substitution rights for pharmacists in Nigeria. The overwhelming support obtained in this study is similar to that found in separate studies involving community pharmacists in France and Malaysia in which 90 and 93.6% of respondents, respectively, were in support of generic substitution rights for pharmacists in their respective country of practice [3, 20]. This new policy direction has implications for generic medicine utilization in Nigeria, as it will empower pharmacists where appropriate to substitute branded medicines with generically equivalent ones.

The convenience sampling design and the low response rate constitute a hindrance for the generalization of the findings of this study. In addition, this study was carried out in urban settings; hence, the views of pharmacists in rural settings were not captured, and they could be different from those obtained in this research.

Some issues have emerged from this study, including the confidence of pharmacists in the quality of generic medicines, factors influencing pharmacists' preference for generic medicines, conditions in which generic substitution is considered inappropriate, regulation and policy change. It will be important to further explore these concerns in a qualitative study in order to have a comprehensive understanding of the perspectives of the respondents.

Conclusions

The present study showed a high support for generic substitution in North-Central Nigeria and the implementation of future generic substitution rights for Nigerian pharmacists. Many respondents lacked confidence in the quality of the generics available on the Nigerian market. However, the convenience sampling design and the low response rate in this study affect the generalizability of this research.

Acknowledgement

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