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INTERCHANGEABILITY OF MEDICINES USING METFORMIN AS A SURROGATE PRODUCT (I)

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ABSTRACT

Medicines are necessities to every patient, therefore whenever the need arise, the patient have little option but to obtain whatever is available and affordable. The study was aimed at assessing the rationale for medicines substitution and to determine the level of compliance of pharmacists in Jos University Teaching Hospital (JUTH), to WHO principles on interchangeability of medicines. Metformin Hydrochloride was used as a surrogate product. The study was carried out in two phases, with the first phase involving the use self-completion structured questionnaires administered to the pharmacists in the hospital. A total of 63 pharmacists (47males and 16 females) participated in the study. 36.7% affirmed that their selection of generic medicines depends on quality and safety, while 82.53% of the respondent considered cost and 96.8% considered availability a priority. 68% used bioequivalence data if available and 44.2% of the respondent based selection on product popularity, local demands and company's reputation. Finally, 63.5% based their substitution on patients consent or demand. The pharmacists showed excellent level of compliance to WHO policy on interchangeability and pharmaceutical care principles.

KEYWORDS: Interchangeability, Metformin, Generic.

INTRODUCTION

Medications are necessary to the patients to gain and maintain a healthy state. Therefore whenever the need arise, patient do not have much options but to obtain whatever is available and affordable. A worldwide increase in healthcare costs poses a burden of affordability of medicines. In developing countries out-of-pocket payment is as high as 80% of healthcare spending.[1] Innovator medicines are generally expensive particularly when the patent rights are still on. The Food and Drug Administration FDA of USA approved generic versions of marketed innovator medicines on the basis of established bioequivalence and pharmaceutical equivalence. The Act was aimed at providing the public with affordable medications which are therapeutically equivalent to the innovator products and also to increase access to medicines.[2] Generic drugs tend to imitate innovator products, in safety, efficacy, strength, route of administration, and quality.[3,4] Regulatory authorities therefore demand for studies to prove adequate comparison according to their specifications. As the word implies any generic drug that is bioequivalent to its brand named counterpart may be interchanged with it. Hence they can be defined as drugs that contain the same amount of the same active ingredients and the same dosage forms.[5,6]

It is therefore, paramount for the physician and the pharmacist to be familiar with drugs on the interchange-ability list (Essential Drug List). Also the pharmacists need to have knowledge of the cost, safety, efficacy and patients specific differences.

The objective of this study is therefore to assess the rationale for medicines substitution in a tertiary hospital setup.

METHOD

Study Area

The study was conducted in Jos University Teaching Hospital located in Jos, Lamingo in Plateau State, Nigeria.

Study Population/ Sample Size

The study group comprises of Pharmacists in Jos University Teaching Hospital located in Jos

Study Design

A cross-section survey was conducted using self-completed anonymous questionnaires.

Study Instrument

The questionnaire for the survey was designed using previous studies from the literature.[7,8,9] The

questionnaire consisted of five sections. The first section was design to collect demographic data. The second section assessed participants' knowledge on bioequivalence. The third section assessed the factors that influence practice as regards generic medicine substitution. Participants' current practices with respect to generic medicines were evaluated in the fourth section. Finally, the last section assessed the respondent reasons for recommending generics medicines.

Sampling/ Procedure for data collection

Respondents for this study were obtained using a convenience sampling technique. Pharmacists on seat at the time of visit were requested to participate in the study. Pharmacists' who were willing to participate in the study were administered questionnaires. Data were collected from 9th November 2015 to 23rd of January 2016.The questionnaires were self administered to the respondents and several follow-ups were done which served as reminders in order to increase the response rate.

Data Analysis

Data analysis was performed using the statistical package for the social sciences (SPSS).

RESULTS

Results from the survey on compliance to bioequivalence policies on drug substitution or interchangeability conducted in the Jos University Teaching Hospital (JUTH)

Demography

Table 1: Table contains respondent demographics.

Variable	Frequency	Percentage
Gender		
Male	47	74.6
Female	16	25.4

There are more male pharmacists respondents than females.

Table 2: Table showing factors that influence the respondent's reason when purchasing generic medicines.

Parameters for selection	Frequency	Percentage that agrees
Profit margin	25	18.1
Product popularity and local demand	61	44.2
Company's reputation	61	44.2
Quality and safety	23	36.7
Terms and conditions of payment	2	1.4
Company's marketing strategy	3	2.2

It is observed that product popularity and manufacturer reputation are important factors in decision making on purchase than profit margin. While marketing strategy and terms of payment ranked low as a determinant factor.

Table 3: Table showing the correspondent's reasons for the practice of generic drug substitution.

Parameter	Response within those with preference for branded Products (%)	Response within those with preference for generics Products (%)
Cost effectiveness	11 (17.47)	52 (82.53)
Easier to get stock	15(12.2)	48 (76.19)
Customer's satisfaction	31 (49.20)	33 (52.38)
Product popularity	9 (18.4)	52 (85.71)
Cheaper for customers	2 (1.59)	61 (98.41)
Company's reputation	13 (26.5)	15 (14.3)
Bioequivalent to brand medicine	37 (75.20)	26 (24.8)

The parameters here consider benefits to the patient. Cost (cost effectiveness or cheaper for customers) ranked high (82% and 98%), for generic products preferences. Also popularity of product followed with 85.7% for generic products over 18.4% preference for branded product. Availability (easier to get stock) is also a strong factor in favour of generic (76%) as against innovator products (18.4%).

Table 4: Table showing the respondent's considerations while recommending and substituting generic medicines to patients.

Factors	Frequency	Percentage that agree
Credibility of manufacturer	60	95.2
Cost of medicine	62	98.4
Consumer preference and demand	46	73.0
Availability of generic medicine	61	96.8
Consumer's experience	31	49.2
Cost-effectiveness of generics	62	98.4
Personal experience and confidence in the generic	60	95.2
Substitution agreement with prescriber	40	63.5
Information available on brand substitution	11	17.5
Proven bioequivalence to original brand	43	68.0
Product appearance and	10	15.9

packaging		

All the respondents consider, cost of the medicine, credibility of the manufacturer, consumers experience, consumers preference and demand, personal experience and confidence in the generic very important while making selections as evident in the percentage of respondent agreeing in Table 4. Information availability on substitution and product appearance ranked low, therefore not generally considered as important. Also agreement with patient (73.0%) to substitute is higher than agreement with the physician (63.5%).

Table 5: Table showing the percentage of pharmacists on a scale of priority factor for consideration in substitution when choice was limited to five parameters of the eleven on table.

S/N	Factors	1st	2nd	3rd	4th	5th
1	Credibility of manufacturer	6.5	12.5	12.5	18.75	31.25
2	Cost of medicine/SN 6	25.0	37.5	25.0	31.25	18.75
3	Consumer preference and demand	-	-	-	12.50	6.50
4	Availability of generic medicine	-	25.0	50.0	18.75	6.50
5	Consumer's experience	-	-	-	-	6.5
6	Cost-effectiveness of generics	-	-	-	-	-
7	Personal experience and confidence in the generic	6.5	-	12.5	12.50	18.75
8	Substitution agreement with prescriber	12.5	6.5	12.5	6.50	12.50
9	Information available on brand substitution	-	-	-	-	6.5
10	Proven bioequivalence to original brand	50.0	18.75	-	-	-
11	Product appearance and packaging	-	-	-	-	-

When the respondents were restricted to prioritize and limited to consider only five parameters from the eleven parameters, 50% considered proven bioequivalence to innovator product as a key factor while 25% considered cost/cost effectiveness as priority factor. Also at the second priority level, 37.5% considered cost/cost effectiveness, availability (25%) and bioequivalence to innovator product (18.75%) as priority. Some parameters, though can be considered while making choices, they are not considered to be high ranking, such as packaging or information insert.

DISCUSSION

Generic Substitution Practice

All the pharmacists, male or female practice generic substitution of medicines based on general principle of pharmaceutical care, though at varying degrees. Most tertiary hospital have hospital based essential drug list as obtained at the study site and pharmacies have policies on generic medicine substitution in such hospitals as obtained in other places. The generic prescribing policy in Australia for example allows the pharmacist to dispense any brand of the drug whenever the generic name is written on prescription or not,[6,9,10] therefore not restricting the pharmacist from dispensing the cheapest brand.[5,7,12] This study sought to evaluate pharmacists' generic substitution practice. In this study 82.53% make cost a priority when deciding substitution (Table 3) and is priority in decision making too (Table5). This was a similar finding in Malaysia where majority of the pharmacists were also engaged in generic substitution.[7,11] However some pharmacists in Malaysia viewed generic medicines differently such that even though they acknowledged the cost effectiveness of generics to the healthcare system, raised concerns on the safety, effectiveness and quality of generics.[1,11]

In this study, 49.20% of the respondents preferred branded over generics products on the ground of customers' satisfaction (Table 3), which was in contrast to the finding by Babar and Awasiu 2008.[7] This is to satisfy the customer and enhance compliance.[12] However customer satisfaction comes only when other important factors such as bioequivalence and availability is satisfied (Table 5).

Rationale for medicines substitution

This study sought to evaluate rationale for generic drug substitution. Tables 3, showed that the respondent have easy access (stocking, 76.19%) to generic products, and 98.41% of respondents agreed that generics are cheaper as compared to branded medicines and cost/cost effectiveness is a priority factor for pharmacists (Table 5), therefore fulfilling the pharmaceutical care principle of accessibility and affordability. This finding is similar to the study report of Chong et al 2010,[8] where over 50% pharmacists indicated that generic substitution is suitable for any prescription. From Table 3, 85.71% sustained the argument that products popularity imparts decision making on substitution. Also important is that customer's satisfaction is taken into consideration (52.38%), which might help compliance as observed by Bearden and Mason 1978.[12]

Compliance to bioequivalence policy

This study sought to investigate prescribers and dispensers compliance to bioequivalence policies as it patterns medicines substitution. In Table 4, 68% of the respondents agreed that, their substitution of generic medicines were based on proven bioequivalence of the generics to the branded medicines which most of them have access to through documents attached to products. Pharmacists prefer to use bioequivalence data when available (Table 5). However, larger population rely on

the credibility of the manufacturer and previous experience on the product (Table 4), when bioequivalent data is not available.

CONCLUSION

The practice of drug interchangeability in the hospital by pharmacists was based on acceptable principles of pharmaceutical care practices using combination of factors such as, cost of product, cost effectiveness, availability of the medicines, consent of the patient and where available, bioequivalence data.

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