



Research Articles

Improving Physicians' Experiences with Generic Medicines: a Roadmap for Increased Used of Generic Medicines in Practice

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SUMMARY

Objectives: Generic Medicine prescribing is a key measure in the Nigerian national drug policy to promote Generic Medicines use in Nigeria. The objectives of this study were to investigate Physicians' views of Generic Medicines and factors that might influence Generic Medicine use by Physicians in Lagos State, Nigeria.

Method: This is an exploratory cross-sectional survey of Physicians employed in public secondary and tertiary hospitals in Lagos State. Data collection was by a validated and pretested five-point bipolar Likert item structured questionnaire. A convenient sampling method was used to recruit 136 Physicians into the study. Data analysis were mainly descriptive, since this is an explorative study.

Result: Participants' knowledge of Generic Medicines seems inadequate, with less than a fifth (18.8%) 'Strongly agree' that Generic Medicines have exactly the same active constituents and amount as innovator brands. Also, Generic Medicines were perceived by participants as low quality medicines. About 9% 'strongly agree' that Generic Medicines are of comparable quality as the innovator brands.

Participants' experiences with Generic Medicines tend toward the negative position on the Likert item of this survey. One in five (20.1%) 'Frequently' experience equivalent therapeutic outcome between generic and innovator brand medicines and more than half (54.1%) think patients are 'frequently' confused by Generic Medicines substitution.

Conclusion: There is need to improve Physicians' knowledge of and experiences with Generic Medicines; its compositions, quality guarantees and therapeutic equivalency by the regulatory authority.

INTRODUCTION

Access to essential medicines is part of the fundamental human right to the highest attainable standard of health.[1] A major obstacle to essential medicines access is the high cost of medicines. Inadequate access to medicines was a foremost challenge in the Nigerian health system, when the National Drug Policy (NDP) came in to existence in 1988.[2] A key strategy to achieve the NDP goal of improved availability and affordability of medicines is the essential medicines concept. In line with the concept, the Nigerian NDP mandated use of Generic Medicines' names in listing, procuring and prescribing of medicines.[3] Adoption of Generic Medicines was a cost-containment strategy to improve access to safe, effective and affordable medicines.

Generic Medicines offer great opportunity to contain pharmaceutical expenditure, as their prices tend to be 10-80% lower than their originator equivalents.[4] However, availability of Generic Medicines does not naturally translate into optimal cost savings from generic prescription and substitution.[5] The ability of Generic Medicines to decrease cost is attributable to varying policy mix in different countries.[5] These policies are categorized into two broad groups. Firstly, supply side measures which are related to market entry and penetration of generic drugs, as well as issues around drugs pricing. Secondly, demand side measures

that are associated with interventions at Physicians', Pharmacists' and consumer levels.[6,7] Demand-side policies are critical to creating sustainable generic medicines markets.[8] The Nigerian NDP recommends generic prescribing, the only demand side measure with explicit policy backing in Nigeria.

Extant literature, however, revealed low to moderate generic prescribing in Nigeria.[9-14] Physicians' prescribing habits are important in the development of Generic Medicine markets. Their opinions about Generic Medicines will determine if they will prescribe and encourage patients' use of Generic Medicines.[6,15] Physicians' acceptance of generic pharmaceuticals, favourable disposition and appropriate incentives enhance the use of Generic Medicines in practice.[6,16-18]

The objectives of this study were to investigate Physicians' knowledge and perception of Generic Medicines as well as explore factors that might influence and improve use of Generic Medicine by Physicians in Lagos State, Nigeria.

METHODS

Study design

An explorative cross-sectional survey of Physicians employed in Lagos State-owned secondary and tertiary health

facilities.

Participants' recruitment and consent

The participants were approached in their consulting rooms, where the study was introduced to them. If they are willing to participate, the questionnaires were left with them for some days to go through and fill it. An informed consent was assumed when participants returned completed questionnaires.

Data collection

The data collection was through a validated and pre-tested structured questionnaire. The questionnaire constructs were based on identified issues associated with Medical Practitioners' views and opinions of generic drugs from a literature review. From the review, issues around Physicians' bias for or against Generic Medicines were: knowledge,[19-20] experience,[21] impact of pharmaceutical detailing on generic prescribing and difference in cost, as well as policies.[22-23] These were considered in developing the questionnaire that was used for data collection.

The questionnaire responses were in five-point bipolar Likert items. The questionnaire was reviewed for face and content validity and was pretested (n = 30) and further revised after pre-testing. The questionnaire was assessed for reliability using split halves method, with Cronbach alpha value of 0.691.

Sampling techniques

Convenient sampling was used because a sampling frame was not readily available for probability sampling. Physicians employed by Lagos State Health Service Commission and Lagos State University Teaching Hospital (LASUTH) who were available and willing filled the questionnaires. The response rate was 90.6% as 150 questionnaires were distributed to practitioners, 136 were completed and included in the data analysis which was mainly descriptive using modes and percentages.

RESULTS

Demographic Data of Participants

More participants, 65% were males. The average number and mode of years in practice were 15.3 and 1-5 years respectively (Table 1). Their areas of specialization include Paediatrics, Neurology, Internal Medicine, Haematology, Surgery, Psychiatry, Obstetrics and Gynaecology.

Physicians' Knowledge and Perception of Quality of Generic Medicines

About a quarter of the physicians surveyed (27.6%) indicated that they understood the difference between generics, branded generics and innovator brand medicines very well and 43.3% rated their knowledge as adequate (Table 2). There were definitive statements (Table 3) to rate Physicians' knowledge of Generic Medicines, 18.8% "strongly agree" that generic medicines have exactly the

same active constituents in same amount as innovator brands and 39.4% that Generics Medicines could be interchanged with innovator brands once there is assurance of bioequivalence. More respondents "somewhat agree" (Table 3) to these definitive statements about pharmaceutical and therapeutic equivalence of Generic Medicines. About 9% 'strongly agree' that Generic Medicines are of the same qualities with innovator brand and 39.1% 'strongly agree' they have the same potential as innovator brands to be faked or substandard (Table 3). Only about 37% trust registered generic medicines 'to a great extent' and more than 45% 'to a small extent' (Figure 1) compared with registered innovator brands.

Factors that Influence Physicians' Use of Generic Medicines

Less than a quarter of study respondents (20.10%) 'Frequently' experience equivalent therapeutic outcomes between generic and innovator brands (Table 4). From physicians' experiences, patients are 'Frequently' (54.1%), confused by generic medicines substitution practice (Table 4).

Less than half (43.7%) "Strongly agree" that use of generic medicines results in cost savings for patients and about half (49.3%) strongly agree that commonly used medicines in practice are available as generic medicines (Table 3). About a third of the respondents (34.8%) are 'Frequently' and less than half of the physicians (41.1 %) 'Frequently' found generic medicines acceptable for use in practice.

The statistical modes of most factors that might influence generic use is 'Sometimes' or 'somewhat agree' from this study (Tables 3 and 4). From these statistical modes of our results, more physicians' responses were in the positive position, when assessing generic medicines (Table 3).

Table1: Respondents' number of years in practice

Number of years	N (%)
1-5 years	42 (31.8)
6-10	23 (17.4)
11-15	13 (9.8)
16-20	11 (8.3)
21-30	17 (12.9)
>30 years	26 (19.7)

Table 2: Participants' Understanding of the Difference between Generics, Branded Generics and Innovator Brand Medicines

Scale	Frequency	Percentages (%)
'Not at all'	3	2.2
'Not very well'	36	26.9
'Adequately'	58	43.3
'Very well'	37	27.6
Total respondents	134	100
No response	2	

Table 3: Participants' Responses to Knowledge and View statements

Responses scale	Strongly disagree n (%)	Somewhat disagree n (%)	Neither agree nor disagree n (%)	Somewhat agree n (%)	Strongly agree n (%)
Knowledge of generic medicines					
Generic medicines have exactly the same active constituents in same amount as innovator brands	20 (15)	25 (18.8)	21 (15.8)	42 (31.6)	25 (18.8)
Generic medicines could be interchanged with innovator brands once there is assurance of bioequivalence	12 (9.1)	15 (11.4)	12 (9.1)	41 (31.1)	52 (39.4)
Perception of quality, cost savings and availability of generic medicines					
Generic medicines are of the same qualities with innovator brand	31 (23.1)	35 (26.1)	19 (14.2)	37 (27.6)	12 (9.0)
Generic medicines have the same potential as innovator brand products to be faked or substandard	21 (15.8)	20 (15)	13 (9.8)	27 (20.3)	52 (39.1)
Side effect profiles of generic medicines do not differ from that of innovator brand medicines	20 (15.2)	30 (22.7)	18 (13.6)	30 (22.7)	34 (25.8)
Use of generic medicines results in cost savings for patients	6 (4.4)	20 (14.8)	13 (9.6)	37 (27.4)	59 (43.7)
Generic medicines are readily available for most medicines commonly used in practice	7 (5.2)	8 (6.0)	11 (8.2)	42 (31.3)	66 (49.3)

Table 4: Participants' Experience, Acceptance and Use of Generic Medicines

Response scale	Never	Rarely	Not sure	Sometimes	Frequently
Physician's experiences					
I get equivalent therapeutic outcomes with Generic medicines and innovator brand	1 (0.7)	11 (8.2)	23 (17.2)	72 (53.7)	27 (20.1)
Patients are sometimes confused by the different GM supplied at pharmacy at different times	2 (1.5)	7 (5.2)	4 (3.0)	49 (36.3)	73 (54.1)
Physician's use and acceptance of generic medicines					
I am comfortable using medicines as generic medicines	0 (0)	4 (3)	6 (4.4)	78 (57.8)	47 (34.8)
I found generic medicines acceptable for use in practice	0 (0)	4 (3)	4 (3)	68 (51.5)	56 (42.4)
I am comfortable prescribing generic medicines	1 (0.8)	4 (2.9)	7 (5.3)	77 (57.9)	44 (33.1)

DISCUSSION

This study examined Physicians' knowledge about Generic Medicines and explored factors that influence and improve use of Generic Medicines in practice.

Participants Knowledge of Generic Medicines

Firstly, most of the participants (combined result of 70.9%) rated their knowledge of generic medicines as 'very well' or 'Adequate'. However, the results from definitive statements, modes at 'somewhat agree', revealed inadequate knowledge. These results suggest gaps in these Physicians' knowledge of Generic Medicines, which agree with a study that covered tertiary institutions in four geopolitical zones in Nigeria and studies from other developing countries.[25-26]

The NDP recommends training at undergraduate, post graduate and in-service for health professionals to achieve goals and targets of the policy. However, the extent of implementation of the policy, including training, is not clear. For generic prescribing to improve, prescribers should be clear on what constitute a generic medicine.

Perception of Generic Medicines as Low-Quality Medicines

Secondly, physicians perceive the quality of Generic Medicines as low, when compared with those of innovators.

This is also in agreement with the Nigerian study and also with a systematic review on the perceptive of physicians and pharmacists of generic medicines. The systematic review found that perception of Generic Medicines as low quality medicines is associated with less-matured health system.[26] The review further highlighted that lack of trust, in manufacturers and the quality of the generic drugs, affect how Pharmacists and Physicians consider generic drug use in such healthcare systems.[26] This lack of trust is buttressed by our study findings because despite the registration processes for generic medicines by national regulatory agency, NAFDAC, many physicians do not trust available Generic Medicines as much as innovator brands registered by the same body. This lack of trust needs to be addressed urgently. The NAFDAC registration number is a mark of quality assurance for registered products and promoted as such to the public. Also, the NAFDAC registration number is core to the national definition of fake and counterfeit medicines. The lack of trust and the resultant perception of low quality may be as a result of inadequate information about NAFDAC registration process for Generic Medicines or as a result of pervasive reports of high level of substandard and fake drugs in Nigeria.[27-29] Physicians need assurance on the quality of generic drugs because their views are interlinked with the consumers', if they have perception of low quality it will

ultimately affect the consumers' choice.[30] Confidence in the regulatory authority to control and effectively police pharmaceutical companies is significantly associated in its relationship with Physicians' perceptions and use of Generic Medicines.[30-31]

Perception can change over time, as reported in a study of Irish general practitioners (GPs).[32] According to that study, three quarters of General Practitioners (GPs) surveyed were concerned about quality of Generic Medicines in 1997, but a more recent study published in 2014 revealed that most GPs now believe that Generic Medicines are comparable in terms of quality to innovator brands.[32] A functioning medicine regulatory agency and appropriate policies that promote trust in regulatory activities may help overcome poor quality perception.[30] In the USA, to overcome Physicians' hesitations to prescribe generic drugs, information pertaining to issues of quality, safety and efficacy were relayed to them through Food and Drug Administration (FDA).[19] NAFDAC needs to institute measures that will improve Physicians' confidence in their regulatory activities as it concerns generic medicines.

Negative Experiences with Generic Medicines

Thirdly, Physicians' experiences with Generic Medicines tend towards negative perception on this study's Likert items. With just 20.1% reporting frequent equivalent therapeutic outcome compared with innovator brands. While, 54.1% think generic substitution practice results in confusion for patients. It is not, however, clear from this study, if experiences of therapeutic in-equivalency experienced is as result of perceived low quality of Generic Medicines or as result of pervasive reports of fake and substandard medicines in this setting. Notwithstanding the reason, this is a factor that needs thorough investigation. Therapeutic equivalency is central for safe and judicious use of Generic Medicines in practice. A few studies based on bio-waiver criteria have signalled there might be problem with bioequivalence with some pharmaceutical products in Nigeria.[33-36]

Another factor that contributes to negative experience with generic medicines is generic substitution practice. Participants indicated that current generic substitution practice results in patients' confusion and this is supported by a study in this setting.[37] The report of Fadare *et al.* [25] also corroborate the negative position of Physicians on generic substitution practice.[25] This practice is common in the study setting and is a major driver for Generic Medicines use.[38] However, the NDP is not explicit on this practice, rather it suggested enactment of legislation on a Generic Medicine prescription and substitution, which is not yet in place. Therefore, generic substitution practice is without a policy or legislative backing and without all the necessary guidelines to ensure appropriate substitution takes place. For the benefit of patients and to improve experiences of Physicians with Generic Medicines, generic substitution must be practiced conscientiously. Therefore, evidence-based guidelines for generic substitution is needed for this practice setting.

Finally, study participants had a positive perception of Generic Medicines towards other factors, acceptance, cost savings, availability and use, that contribute to its use in practice. Hence, necessary strategies are needed to keep strengthening these factors. Availability of Generic

Medicines is high and the cost savings from Generic Medicines can be as high as 88.6% if the cheapest generics is dispensed compared with the innovator brand price in this study setting.[38] These are factors that might interest physicians to improve their use of generic medicines prescribing. Generic prescribing facilitates patients' acceptance of Generic Medicines. Though the Nigerian NDP mandates generic prescribing, there are no clear strategies promoting it. Lack or ineffective policies by government promoting prescription of quality generics medicines and its cost containment capabilities hinder wide utilization of generic medicines in the health care systems.[30] There is need to develop an evidence-based Generic Medicines policy as an off-shoot of our national drug policy with appropriate strategies to promote and improve use of generic medicines.

Study limitations

This is mainly an exploratory study based on a convenient sampling technique and the results were mainly descriptive. Hence, generalization and statistical inferences were not possible. Notwithstanding these limitations, the literature supports the results from this study and strengthens the deductions from it.

CONCLUSION

This study shows inadequate Physicians' knowledge of Generic Medicines and their perception of Generic Medicines is that of very low-quality medicines. They have negative views based on their experiences, but positive views with regards to acceptance, availability, cost savings and use of generic medicines in practice. Adequate quality assurance measures, access to requisite information about therapeutic equivalence and promotion of regulatory measures for Generic Medicines' registration are necessary to improve physicians' views and of use Generic Medicines in practice.

RECOMMENDATION

An evidence based national generic medicine policy that will promote and improve generic medicine utilization in the system is needed.

The national medicine regulatory authority (MRA) needs to go beyond registration and make accessible to practitioners a list of therapeutic equivalent generic medicines. The MRA also need to provide adequate information about their quality assurance measures for Generic Medicines' registration.

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Conflict of Interest

The authors declare no competing interests.

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