
This version is available at https://strathprints.strath.ac.uk/54753/

Strathprints is designed to allow users to access the research output of the University of Strathclyde. Unless otherwise explicitly stated on the manuscript, Copyright © and Moral Rights for the papers on this site are retained by the individual authors and/or other copyright owners. Please check the manuscript for details of any other licences that may have been applied. You may not engage in further distribution of the material for any profitmaking activities or any commercial gain. You may freely distribute both the url (https://strathprints.strath.ac.uk/) and the content of this paper for research or private study, educational, or not-for-profit purposes without prior permission or charge.

Any correspondence concerning this service should be sent to the Strathprints administrator: strathprints@strath.ac.uk

The Strathprints institutional repository (https://strathprints.strath.ac.uk) is a digital archive of University of Strathclyde research outputs. It has been developed to disseminate open access research outputs, expose data about those outputs, and enable the management and persistent access to Strathclyde's intellectual output.
The prescribing of generic medicines in Nigeria: knowledge, perceptions and attitudes of physicians

Joseph O Fadare¹, Adekunle O. Adeoti², Olufemi O. Desalu³, Okezie O. Enwere⁴, Aliyu M. Makusidi⁵, Olayinka Ogunleye⁶, Taofeek O. Sunmonu⁷, Ilse Truter⁸, Onyinye O Akunne⁹, *Brian Godman¹⁰,¹¹

¹Department of Pharmacology, Ekiti State University, Ado-Ekiti, Nigeria. Email: jofadare@gmail.com
²Department of Medicine, Ekiti State University, Ado-Ekiti, Nigeria. Email: kadeoti2002@yahoo.com
³Department of Medicine, University of Ilorin, Ilorin, Nigeria. Email: femuy1967@yahoo.co.uk
⁴Department of Medicine, Imo State University, Orlu, Imo State, Nigeria. Email: dr.o.enwere@gmail.com
⁵Department of Medicine, Usman Danfodiyo University, Sokoto, Nigeria. Email: makusidi1@yahoo.com
⁶Clinical Pharmacology Unit, Department of Medicine, Lagos State University Teaching Hospital, Ikeja, Lagos, Nigeria. Email: yinkabode@yahoo.com
⁷Department of Medicine, Federal Medical Centre, Owo, Nigeria. Email: taosunmonu@yahoo.com
⁸Drug Utilization Research Unit (DURU), Department of Pharmacy, Nelson Mandela Metropolitan University, Port Elizabeth 6031, South Africa. Email: ilse.truter@nmmu.ac.za
⁹Onyinye O Akunne, Department of Pharmacology and Therapeutics, University of Ibadan, Nigeria. Email: onyinyeakunne@yahoo.com
¹⁰,¹¹Brian Godman, Department of Laboratory Medicine, Division of Clinical Pharmacology, Karolinska Institutet, Karolinska University Hospital Huddinge, SE-141 86, Stockholm, Sweden. Email: Brian.Godman@ki.se and Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, UK. Email: Brian.godman@strath.ac.uk

Keywords: Generics, generic substitution, Nigeria, physicians’ knowledge and attitudes, prescribing

(accepted for publication Expert Review of Pharmacoeconomics and Outcomes Research – Please keep CONFIDENTIAL).

ABSTRACT

Background: Generic medicines have the same efficacy and safety as originators at lower prices. However, there are concerns with their utilization in Nigeria. Objectives: Evaluate physicians’ understanding and perception of generics. Methods: Questionnaire among physicians working in tertiary healthcare facilities in four geo-political regions of Nigeria. Results: Response was 74.3% (191/257) among mainly males (85.9%). The mean knowledge score regarding generics was 5.3 (maximum of 9) with 36.6%, 36.1% and 27.2% having poor, average and good knowledge respectively. Cross-tabulation showed statistical significance (P = 0.047) with the duration of practice but not with position, subspecialty or sex. The majority did not agree that generic medicines are of lower quality than branded medicines. Therapeutic failure was a major concern in 82.7%, potentially discouraging prescribing of generics. Majority (63.9%) did not support generic substitution by pharmacists. Conclusion: Knowledge gaps were identified especially with the perception of generics. These need to be addressed.

INTRODUCTION

Generic medicines have the same quality, efficacy and safety properties as originator (branded) medicines while being available at more affordable prices [1-5]. According to the United States Food and Drug Administration (FDA), a generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. These are similar definitions in Europe [2,6]. As a result, published studies from these countries have shown similar effectiveness rates between generics and originators (brand name medicines) across a range of classes. These include medicines for infectious and cardiovascular diseases as well as mental health [7-13].

The increasing need for good quality low costs generic medicines has arisen with pharmaceutical expenditure growing by more than 50% in real terms among OECD (Organisation for Economic Co-
operation and Development) countries during the past decade [14], with expenditure on medicines accounting for up to 60% of total healthcare expenditure in some countries [15]. This growth in pharmaceutical expenditure has been driven by well known factors. These include the increasing prevalence of non-communicable diseases, enhanced by growing elderly populations in a number of continents including Europe, and the continued launch of new higher priced medicines [16, 17]. This has resulted in health authorities introducing measures to moderate pharmaceutical expenditure without compromising care [18, 19]. This includes initiatives to increase the prescribing and dispensing of low cost generics versus originators (brand named medicines). Measures and initiatives include educational activities among physicians and patients, reference pricing in a class with patients covering the additional costs themselves for a more expensive molecule, financial incentives for physicians, compulsory generic substitution in pharmacies, substitution targets in pharmacies as well as compulsory International Nonproprietary name (INN) prescribing; alternatively education and other measures to ensure high voluntary INN prescribing [4, 18, 20-29]. In their study, Cameron and colleagues believed up to 89% of the cost of medicines could be saved among developing countries from switching patients from originator brands to the lowest priced generics [5]. Policies to enhance the prescribing and dispensing of generics in France led to annual savings estimated at €1bn in 2007, €0.905bn in 2008 and €1.01bn in 2009 [19]. The use of generic medicines versus more expensive branded (originator) medicines has also been shown to positively impact on medication adherence, appreciably impacting on disease progression and the overall health of the population [30, 31].

There have also been initiatives across countries to increase the prescribing of low cost generics versus patented products in a class where all products in the class are seen as essentially similar at therapeutic doses. These classes include the proton pump inhibitors (PPIs), renin-angiotensin inhibitors and statins [17, 25, 32-36]. Published studies have again shown that patient care is not compromised [32, 36-39], whilst moderating or even reducing pharmaceutical expenditure despite increasing utilisation [17, 25, 36, 40-42].

However, there are countries where the prescribing and dispensing of generics versus originators is suboptimal. The reasons for this include physicians’ concerns with the safety, efficacy, and bioequivalence of generics versus originators, ease of remembering brand names as well as pharmaceutical company activities promoting concerns with generics [43-50]. These differences in perceptions regarding generics have resulted in very different utilization rates for generics across countries. For instance, there is high acceptance of generics among physicians in the UK translating into very high voluntary INN prescribing rates apart from a limited number of situations including certain combination products, lithium, theophyllines and certain medicines to treat epilepsy [24, 25, 51-53]. A variety of educational and other initiatives in the UK have resulted in INN prescribing at 98% to 99% of medicines once they are available as generics across a range of classes where there are no issues with substitution [25]. In Malaysia, 85.1% of physicians routinely prescribed generic drugs, although this figure was lower among physicians in private medical centers [43, 50]. This contrasts with Italy where a survey conducted between January and March 2011 ascertained that 87% of pediatricians do not prescribe generics due to concerns [54].

Results from several studies in Nigeria have shown that only 42% to 50% of all medications were prescribed by their generic name [55-57]. This low rate of generic medicine prescribing contradicts the National Standard Treatment Guidelines, which stipulates that medicines should be prescribed in their generic form, i.e. INN prescribing [58]. In Nigeria, the National Agency for Food and Drug Administration (NAFDAC) is the main regulatory body for medicines including biologicals, responsible for marketing authorization of all medications – generics and branded medicines - in the country [59]. At the same time, the healthcare sector in Nigeria is under-funded, accounting for less than 6% of the country’s GDP between 2010 and 2012, while the proportion of federal government revenue expended on healthcare was 3.5% in 2010 [60, 61]. Several studies have shown that out of pocket spending (OOP) in Nigeria constitutes the major form of healthcare expenditure among the population, which can be as high as 62% of total healthcare expenditure [61-64]. This will impact on available choices of medicines to treat diseases as well as potential compliance, especially in patients with chronic diseases [65-67]. The National Health Insurance Scheme (NHIS), which commenced operations in 2005, was introduced to address some of these issues and concerns; however, its coverage has remained below 5% of the total population [68].
Increased prescribing of lower cost generic medicines could lead to a reduction in healthcare costs as well as OOP for patients. In addition, offering dispensers the freedom to choose from a wide variety of available generic medicines. However, there are barriers to address including concerns with their efficacy and safety.

However, information regarding the knowledge, perception and attitude of Nigerian physicians towards generic medicines is lacking. This needs to be addressed in order to develop robust policies to overcome potential misinformation and misconceptions concerning generic medicines. Consequently, the primary objective of this study is to evaluate physicians' understanding of the concept of “generic medicines”. Additional objectives include evaluating physicians’ perception of generic medicines including their safety, efficacy and bioequivalence versus brand name (originator) medicines as well as assess physicians’ prescribing of generic medicines. Subsequently, use the findings to suggest future activities in Nigeria to enhance the prescribing of generics.

METHODS

- **Study design**

This was a cross-sectional and questionnaire-based study conducted during the months of June to December, 2014.

- **Study Sites**

The study was conducted among medical doctors working in tertiary healthcare facilities located in four geo-political regions of Nigeria: south-west, south-east, north-central and north-west Nigeria.

- **Study Instrument**

The questionnaire, comprising four sections, was adapted from a previous study [69]. It comprised sections on the general characteristics of the participants, assessment of physicians' understanding of the concept of generic medicines, their perception of their safety and efficacy as well as attitudes towards their prescribing.

The section on physicians' knowledge consisted of 9 statements regarding the concept of generic medicines to which three questions had three options - Yes, No and Don’t Know. Each correct (Yes) response was scored 1 whilst “No” and “Don’t know” were scored 0, making the total available score of 9. Physicians' knowledge (knowledge level) was subsequently classified into poor (score <5), average (score 5-6) and good (score 7-9). The questionnaire was pilot-tested among ten medical doctors from a secondary level healthcare facility and necessary adjustments made to achieve the objectives before it being administered to the study participants. The internal consistency of the three parts of the questionnaire was calculated (Cronbach’s alpha) with the knowledge, perception/attitude and practice aspects scoring 0.70, 0.62 and 0.76 respectively.

We have divided medicines into brand name (originator) medicines and generics. We accept that branded generics are common in a number of countries. However, we wanted to avoid any confusion. We have made this distinction in a number of previous studies involving some of the co-authors when researching the utilization of generics, originators and patented products in a class [34, 42, 70-72]. In addition, this was the definition of Cameron and colleagues from the WHO in their recent paper [5].

- **Sample size calculation**

The estimated sample size was 233 from a population of 1200 physicians from the four geo-political regions. Ten percent of the calculated sample size was added to cater for possible non–responders and poorly completed questionnaires, making a total of 257. The sample size was calculated using the online statistical software from Raosoft Incorporated [73].
**Sample Population/Selection**

Random sampling was used to select respondents among medical doctors working in tertiary healthcare facilities in the selected geo-political regions of Nigeria. The names of all doctors (excluding medical interns) working in the hospitals were compiled from departmental duty rosters and participants were selected using a random technique – dice rolling. Medical interns were excluded because of their lack of experience with prescribing. The selected medical doctors were approached during a departmental seminar in their different units and invited to participate in the study. Written informed consent was then obtained from those who agreed to participate in the study. The questionnaire was subsequently administered to those who agreed to take part and they were given approximately 30 minutes to complete it. The distribution and collection of the questionnaires was coordinated by a co-investigator and one research assistant in each of the participating centers.

**Ethical consideration**

Ethical approval was obtained from relevant hospital authorities before commencement of the study. Confidentiality was maintained as respondents were advised not to disclose their identities in their completed questionnaires.

The study was funded through contributions from all co-investigators

**Statistical Analysis**

The information obtained from the questionnaire was coded, entered and analyzed using IBM compatible SPSS version 19. Analysis was undertaken using descriptive statistics to obtain the general characteristics of the study participants. Chi square was used to determine the level of significance of the groups of categorical variables. P values <0.05 were considered significant.

**RESULTS**

**General characteristics of respondents**

The response rate was 74.3% (191/257) with a preponderance of males (164/85.9%). Respondents comprised medical registrars (98/51.5%), medical officers (53/27.7%), senior registrars (27/14.1%) and consultants (13/6.7%). Most respondents worked in Internal medicine, followed by Surgery and Family Medicine (Figure 1).
The median duration of work experience (time since obtaining their medical degree) was 4 years with 119 (62.3%), 50 (26.2%) and 22 (11.5%) having 1 to 5yrs, 6 to 10yrs and >10yrs work experience respectively.

- Knowledge about generic medicines

Generic medicines were recognized as copies of brand name (originator) medicines by only 44% of the respondents, whilst 47.1% were aware that generic medicines are interchangeable with brand name medicines (Table 1). The fact that generic medicines are therapeutically equivalent to brand name medicines was known by 97 (50.8%) of respondents. Sixty-seven respondents (35.1%) did not know that generic medicines must be in the same dosage form as its’ corresponding brand name medicines, with only 74 (38.7%) respondents aware of the time frame for licensing of generic medicines (Table 1).
Table 1: The association of physicians’ knowledge about generic medicines and some categorical variables

<table>
<thead>
<tr>
<th>Statements</th>
<th>Yes (%)</th>
<th>No (%)</th>
<th>Don’t know (%)</th>
<th>Position (X^2) (P-value)</th>
<th>Sex (X^2) (P-value)</th>
<th>Duration (X^2) (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic medicines are copy of brand name (originator) medicines</td>
<td>84(44)</td>
<td>88(46.1)</td>
<td>19(9.9)</td>
<td>0.29</td>
<td>0.17</td>
<td>0.18</td>
</tr>
<tr>
<td>Generic medicines are interchangeable with brand name (originator) medicines</td>
<td>90(47.1)</td>
<td>86(45.0)</td>
<td>15(7.9)</td>
<td>0.001*</td>
<td>0.94</td>
<td>0.02*</td>
</tr>
<tr>
<td>Generic medicines are therapeutically equivalent to brand name medicines</td>
<td>97(50.8)</td>
<td>76(39.8)</td>
<td>18(9.4)</td>
<td>0.008*</td>
<td>0.92</td>
<td>0.40</td>
</tr>
<tr>
<td>Generic medicines must be in the same dosage form (such as tablet, capsule) as brand name (originator) medicines</td>
<td>124(64.9)</td>
<td>49(25.7)</td>
<td>18(9.4)</td>
<td>0.72</td>
<td>0.15</td>
<td>0.63</td>
</tr>
<tr>
<td>Generic medicines are less safe than brand name (originator) medicines</td>
<td>29(15.2)</td>
<td>139(72.8)</td>
<td>23(12.0)</td>
<td>0.05*</td>
<td>0.18</td>
<td>0.28</td>
</tr>
<tr>
<td>Generic medicines are available in the market of Nigeria</td>
<td>147(77.0)</td>
<td>27(14.1)</td>
<td>17(8.9)</td>
<td>0.56</td>
<td>0.35</td>
<td>0.22</td>
</tr>
<tr>
<td>Generic medicines are manufactured after the expiration of the patent of the originator/innovator</td>
<td>74(38.7)</td>
<td>67(35.1)</td>
<td>50(26.2)</td>
<td>0.02*</td>
<td>0.17</td>
<td>0.01*</td>
</tr>
<tr>
<td>Brand name medicines are of better quality compared with generic medicines</td>
<td>68(35.6)</td>
<td>109(57.1)</td>
<td>14(7.3)</td>
<td>0.045*</td>
<td>0.22</td>
<td>0.17</td>
</tr>
<tr>
<td>Brand name (originator) medicines produce lesser side effects than generic medicines</td>
<td>33(17.3)</td>
<td>132(69.1)</td>
<td>26(13.6)</td>
<td>0.83</td>
<td>0.01*</td>
<td>0.31</td>
</tr>
</tbody>
</table>

NB: * denotes P value less than 0.05 (Statistical significance)

The mean knowledge score recorded was 5.3 (SD 1.8) out of the total obtainable score of 9, with 70 (36.6%), 69 (36.1%) and 52 (27.2%) of respondents having poor, average and good knowledge respectively. A comparison of the mean knowledge score among various categories (current position and duration of practice) showed significant statistical significance (P value of 0.02 and 0.01 respectively). A box plot comparing the means of various cadres of respondents is shown in Figure 2.
The association of respondents' knowledge, perception and practice with their positions, duration of practice and sex is shown in Tables 1 to 3.
Table 2: The physicians’ perception of generic medicines with respect to categorical variables

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree (%)</th>
<th>Don’t Agree (%)</th>
<th>No opinion (%)</th>
<th>Position $X^2$ (P value)</th>
<th>Sex $X^2$ (P value)</th>
<th>Duration $X^2$ (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic medicines are of low quality compared with brand name (originator) medicines</td>
<td>41(21.5)</td>
<td>137(71.7)</td>
<td>13(6.8)</td>
<td>0.02*</td>
<td>0.51</td>
<td>0.67</td>
</tr>
<tr>
<td>Generic medicines produce more adverse effects than brand name (originator) medicines</td>
<td>29(15.2)</td>
<td>142(74.3)</td>
<td>20(10.5)</td>
<td>0.03*</td>
<td>0.14</td>
<td>0.28</td>
</tr>
<tr>
<td>Low-priced medicines are as safe as high-priced medicines</td>
<td>90(47.1)</td>
<td>72(37.7)</td>
<td>28(18.4)</td>
<td>0.99</td>
<td>0.08</td>
<td>0.84</td>
</tr>
<tr>
<td>Drugs from multinational companies are of better quality than medicines produced by local companies</td>
<td>90(47.1)</td>
<td>82(42.9)</td>
<td>19(9.9)</td>
<td>0.001*</td>
<td>0.31</td>
<td>0.09</td>
</tr>
<tr>
<td>I believe that not all the local companies in Nigeria are following Good Manufacturing Practices (GMP) guidelines as multinationals</td>
<td>139(72.8)</td>
<td>31(16.2)</td>
<td>21(11.0)</td>
<td>0.83</td>
<td>0.65</td>
<td>0.83</td>
</tr>
<tr>
<td>Few local companies are reputable generic medicine manufacturers</td>
<td>134(70.2)</td>
<td>30(15.7)</td>
<td>27(14.1)</td>
<td>0.09</td>
<td>0.28</td>
<td>0.24</td>
</tr>
<tr>
<td>My prescribing decision is influenced by medical representatives</td>
<td>39(20.4)</td>
<td>137(71.7)</td>
<td>15(7.9)</td>
<td>0.02*</td>
<td>0.31</td>
<td>0.19</td>
</tr>
<tr>
<td>Doctors should be educated more about prices of medicines</td>
<td>169(88.5)</td>
<td>11(5.8)</td>
<td>11(5.8)</td>
<td>0.23</td>
<td>0.09</td>
<td>0.87</td>
</tr>
<tr>
<td>Doctors should be given incentives to write generic names</td>
<td>34(17.8)</td>
<td>137(71.7)</td>
<td>20(10.5)</td>
<td>0.31</td>
<td>0.02*</td>
<td>0.95</td>
</tr>
<tr>
<td>I think that confidence should be conveyed to the patient about the low-cost medicines</td>
<td>136(71.2)</td>
<td>27(14.1)</td>
<td>28(14.7)</td>
<td>0.81</td>
<td>0.15</td>
<td>0.85</td>
</tr>
<tr>
<td>I believe that it is easier to remember a brand name (originator) medicine than a generic</td>
<td>94(49.2)</td>
<td>85(44.5)</td>
<td>12(6.3)</td>
<td>0.78</td>
<td>0.53</td>
<td>0.93</td>
</tr>
</tbody>
</table>

NB: * denotes P value less than 0.05 (Statistical significance)
Table 3: The physicians’ attitude/practice of generic medicine prescribing with respect to categorical variables (continued)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree (%)</th>
<th>Disagree (%)</th>
<th>Neutral (%)</th>
<th>Position $X^2$ (P value)</th>
<th>Sex $X^2$ (P value)</th>
<th>Duration $X^2$ (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am concerned about the therapeutic failures that are associated with some locally manufactured medicines</td>
<td>158(82.7)</td>
<td>13(6.8)</td>
<td>20(10.5)</td>
<td>0.22</td>
<td>0.62</td>
<td>0.98</td>
</tr>
<tr>
<td>I am hesitant to prescribe low-priced medicines in some specific therapeutic classes in my practice</td>
<td>143(74.9)</td>
<td>29(15.2)</td>
<td>19(9.9)</td>
<td>0.41</td>
<td>0.01*</td>
<td>0.96</td>
</tr>
<tr>
<td>The socioeconomic condition of my patient sometimes influence the prescription given</td>
<td>170(89)</td>
<td>13(6.8)</td>
<td>8(4.2)</td>
<td>0.76</td>
<td>0.08</td>
<td>0.56</td>
</tr>
<tr>
<td>I am comfortable prescribing products from local manufacturers</td>
<td>79(41.4)</td>
<td>51(26.7)</td>
<td>61(31.9)</td>
<td>0.96</td>
<td>0.09</td>
<td>0.09</td>
</tr>
<tr>
<td>My personal experience with medicines influence my prescribing decisions</td>
<td>165(86.4)</td>
<td>12(6.3)</td>
<td>14(7.3)</td>
<td>0.91</td>
<td>0.09</td>
<td>0.77</td>
</tr>
<tr>
<td>I feel that patient's demand of certain medicines influence my prescription</td>
<td>43(22.5)</td>
<td>129(67.5)</td>
<td>19(9.9)</td>
<td>0.22</td>
<td>0.12</td>
<td>0.78</td>
</tr>
<tr>
<td>Medical representatives are good sources of information for me</td>
<td>85(44.5)</td>
<td>62(32.5)</td>
<td>44(23)</td>
<td>0.13</td>
<td>0.008*</td>
<td>0.86</td>
</tr>
<tr>
<td>Pharmaceutical companies’ premium offers (gifts) influence my prescribing behaviour</td>
<td>23(12.0)</td>
<td>135(70.7)</td>
<td>33(17.3)</td>
<td>0.54</td>
<td>0.01*</td>
<td>0.64</td>
</tr>
<tr>
<td>I am comfortable if the brand name (originator) medicine in prescription is substituted by the pharmacist</td>
<td>34(17.8)</td>
<td>122(63.9)</td>
<td>35(18.3)</td>
<td>0.03*</td>
<td>0.51</td>
<td>0.52</td>
</tr>
<tr>
<td>I usually prescribe generic medicines for my patients</td>
<td>117(61.3)</td>
<td>37(19.4)</td>
<td>37(19.4)</td>
<td>0.55</td>
<td>0.008*</td>
<td>0.32</td>
</tr>
</tbody>
</table>

NB: * denotes P value less than 0.05 (Statistical significance)

Cross-tabulation of the knowledge level of respondents showed significant statistical significance (P = 0.047) with duration of practice but not with position, subspecialty and sex (Table 4).
Table 4: knowledge level of respondents according to some categorical variables

<table>
<thead>
<tr>
<th>Categorical variable</th>
<th>Poor knowledge</th>
<th>Average knowledge</th>
<th>Good knowledge</th>
<th>X² (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Position</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Officer</td>
<td>20 (37.7)</td>
<td>19 (35.9)</td>
<td>14 (26.4)</td>
<td></td>
</tr>
<tr>
<td>Registrar</td>
<td>38 (38.8)</td>
<td>34 (34.7)</td>
<td>26 (26.5)</td>
<td></td>
</tr>
<tr>
<td>Senior Registrar</td>
<td>10 (37.1)</td>
<td>12 (44.4)</td>
<td>5 (18.5)</td>
<td></td>
</tr>
<tr>
<td>Consultants</td>
<td>2 (15.4)</td>
<td>4 (30.8)</td>
<td>7 (53.8)</td>
<td>0.361</td>
</tr>
<tr>
<td><strong>Duration (post qualification)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-5 years</td>
<td>45 (37.8)</td>
<td>46 (38.7)</td>
<td>28 (23.5)</td>
<td></td>
</tr>
<tr>
<td>6 – 10 years</td>
<td>19 (38.0)</td>
<td>19 (38.0)</td>
<td>12 (24.0)</td>
<td></td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>6 (27.3)</td>
<td>4 (18.2)</td>
<td>12 (54.5)</td>
<td>0.047*</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58 (35.4)</td>
<td>60 (36.6)</td>
<td>46 (28.1)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12 (44.5)</td>
<td>9 (33.3)</td>
<td>6 (22.2)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

NB: *Indicates P value less than 0.05 (Statistical significance)

- Perception of doctors towards generic medicines

The majority (71.7%) of respondents did not agree that generic medicines are of lower quality than branded medicines (Table 2). Only 29 (15.2%) respondents agreed that generic medicines produced more side-effects than brand name medicines while 90 (47.1%) felt that low-priced generic medicines are as safe as the expensive branded ones (Table 2).

Regarding the quality of generic medicines produced by local drug manufacturers, 90 (47.1%) of respondents were of the opinion that they were of lower quality than those produced by multi-national pharmaceutical companies (Table 2). On the issue of Good Manufacturing Practice (GMP), 139 (72.8%) respondents believe that few local companies observe GMP, hence only 30 (15.7%) view local manufacturers as reputable producers of generic drugs. On whether doctors should be given incentives to prescribe generic medicines, the majority (71.7%) disagreed with this suggestion; whilst71.2% felt that patients should be educated about generic medicines to boost their confidence (Table 2).

- Attitude/Practice of doctors towards prescribing generic medicines

On the issue of therapeutic failures occurring with generic medicines, 158 (82.7%) respondents were seriously concerned discouraging them from prescribing low-priced generic medicines (Table 3). In fact, 74.9% stated their reluctance to prescribe generic medicines from some specific therapeutic classes based on these concerns (Table 3). Many (89%) of the respondents were also influenced by the socio-economic class of the patients and personal experience with the medicines (86.4%) when prescribing (Table 3).

Eighty-five respondents (44.5%) believed that medical representatives are good sources of information regarding medicines whilst only 23 (12%) believed they are influenced by gifts from pharmaceutical companies (Table 3).
Finally, most of the physicians (63.9%) would not be comfortable if there was generic substitution of brand name (originator) medicines by pharmacists (Table 3).

**DISCUSSION**

This cross-national study is one of the few studies to date in Nigeria evaluating the knowledge, perception and attitude of medical doctors towards generic medicines. It has identified significant gaps in the knowledge and perception among physicians in Nigeria that may hamper the prescribing of generic medicines.

Overall, we had a response rate to the questionnaire at close to 75%. This is close to 80% obtained in a similar study among Greek physicians [74]. However, appreciably higher than a 36% response rate obtained in a questionnaire study to ascertain private physicians’ perception of generic medicines in Malaysia [50]. It was also noticed that more junior medical doctors participated in our study. This though reflects the current distribution of medical doctors in many tertiary healthcare facilities in Nigeria. Results from surveys conducted among physicians have identified lack of time as the main reason for non-response [75,76].

We will first comment on the findings before suggesting potential ways forward in Nigeria to enhance the prescribing of generics.

- **Knowledge about generic medicines**

In this study, less than half of the respondents were aware of the definition of generic medicines as copy of the original brand and being interchangeable with it (Table 1). This was higher than some published studies but lower than others. Jamshed et al in their study among general practitioners in Pakistan found that 71.8% of respondents had the correct definition [69]. However, Fabianio et al in their study found only 32.6% and 37.2% of Italian pediatricians were seen to have sufficient and good knowledge of generic medicines respectively [54]. In addition, only 2.3% to 4.6% of physicians in Malaysia correctly identified bioequivalence standards for generic medicines in recent studies [43, 50].

In this study, 63.7% of respondents had at least average knowledge about the concept of generic medicine, with those with more than 10 years post-graduation experience having a higher mean score. This finding is suggestive of a positive influence of post-graduate education and experience on physicians' knowledge about the concept of generic medicines. This was in contrast to the study by Awaisu et al among community pharmacists in Qatar, who found that work experience did not positively influence the knowledge of their respondents about generic medicines [77]. The different findings may not be surprising as our study was conducted in tertiary healthcare facilities where the majority of respondents were involved with post-graduate medical education. The pharmacist studied by Awaisu et al might not be undergoing similar continual education.

- **Perception of doctors towards generic medicines**

As mentioned, most of the concerns regarding generic medicines revolve around their safety and efficacy versus originators (brand name medicines). This was a common finding in a recent systematic review regarding attitudes towards generics among physicians from low and middle income countries [78].

In this study, 39.8% of respondents believed generic medicines were not therapeutically equivalent to brand named medicines and 35.6% believed brand named medicines were of better quality (Table 1). However, 69.1% did not believe brand named (originator) medicines produce less side-effects and only 15.2% of respondents believed generic medicines are less safe (Tables 1 and 2). This was lower than 41.3% of respondents in the study by Jamshed [69] and 42.2% of private physicians in Malaysia, who believed generic medicines produce more side-effects than brand named medicines [50]. In addition, lower than Zaoui et al in their study conducted in Morocco found that 68% of respondents believed generic drugs were not always effective [79].
The possibility of therapeutic failure is a major concern among physicians when prescribing generic medicines. In this study, 82.7% of respondents were worried about the possibility of treatment failure and 74.9% would hesitate to prescribe generics from certain therapeutic classes (Table 3). The issue of therapeutic failure is directly related to that of bioequivalence [80][81]. In the study by Zaoui in Morocco, 70% of respondents would prescribe generic drugs if bioequivalence to branded medicines is ascertained [79]. In the study among community pharmacists in Qatar, the lack of proven bioequivalence to branded medicines is a major hindrance to the prescribing of generic medicines [77].

The view of majority of respondents in this study (70.2% - Table 2) that only a few local companies are reputable manufacturers of generic drugs is a cause for concern. Building trust and capacity in the local manufacture of generics will help to lower costs and enable the manufacturers in Nigeria to compete globally.

- Attitude/Practice of doctors towards prescribing generic medicines

The relationship between the pharmaceutical industry and medical practitioners has attracted considerable debate globally [82-88].

In our study, 12.0% of respondents admitted their prescribing practices are influenced by gifts from pharmaceutical companies and 44.5% believed medical representatives were a good source of information regarding medicines (Table 3). This is similar to the study by Kersnik et al among pharmacists and prescribers in Slovenia, who found only 15.5% of prescribers considered their prescribing was influenced by pharmaceutical representatives [89]. However, lower than the study by Riaz et al in Pakistan who found that 68% to 86% of the physicians surveyed obtained their knowledge of medicines from medical representatives [90].

The importance of knowing the costs of medications being prescribed cannot be over-emphasized as it contributes to rational use of medications. In this study, 88.5% of respondents agreed that medical doctors should be educated about the costs of medicine (Table 2). Toklu et al in their study conducted in Turkey also reported that 92% of prescribers took cost of medicines into consideration when prescribing [91].

- Future suggestions and initiatives

This study identified a number of gaps especially in the areas of perception and practice of generic medicines and their prescribing by physicians in Nigeria.

The perception of poor quality of generic medicines by respondents in this study resonates with the widespread problems of sub-standard medication that has attracted a lot of attention in recent times [92][93]. The role of the World Health Organization (WHO) and other international donor agencies in ensuring the provision of quality generic medicines for diseases such as malaria, TB and HIV has positively impacted patients’ outcomes [94]. Expanding this pre-qualification process to other essential medicines, especially for non-communicable diseases like hypertension and diabetes mellitus, would most likely have a similar effect. Also, strict regulations including proven bioequivalence of medicines would promote physicians’ confidence in prescribing generics [95].

The findings suggest there is an urgent need in Nigeria to build up the trust of prescribers in generic medicines to save costs for patients and the health service. This can be achieved through instigating mandatory quality assurance programmes among local generic manufacturers, as well as the statutory provision of the bioequivalence data and standards, given that 72.8% had concerns with local manufacturers (Table 2). This mirrors practices in the US and Europe [2]. Such measures should enhance physician trust regarding local generic manufacturers, and enhance their potential for export across Africa and more widely.

The findings also suggest there is a need to instigate measures to enhance the prescribing of generics versus brand named (originator) medicines in line with the National Standard Treatment Guidelines in Nigeria [58]. Measures could include routine encouragement of INN prescribing apart from a limited number of situations, starting with training in medical school similar to the UK [25]. This
Generic substitution has also been one of the measures adopted by many countries to enhance the use of generic medicines [1]. However, the majority (63.9%) of respondents in this study did not support generic substitution by the pharmacists (Table 3). This is similar to other findings depending on the faith physicians have in their regulatory system as well as other factors. 68% of prescribers in a study conducted in Morocco rejected generic substitution because it infringed on their prescribing freedom whilst 35.6% of patients in a Nigerian study rejected generic substitution at some time [79, 96]. In a study conducted among drug retailers and community pharmacists in India, 80% of respondents rejected generic substitution[97]. However, Awaisu et al found that 72% of community pharmacists supported generic substitution [77]. Generic substitution is also generally supported by key stakeholder groups in Sweden to help conserve costs [26, 98, 99]. These differences in opinion may be due to inter-professional conflicts between physicians and pharmacists, the practice environment (country), perceived differences between generic products and brand named products as well as personal experience with generic and brand named (originator) products.

There also needs to be an increase in continual professional development activities among physicians in Nigeria, including education from Drugs and Therapeutics Committees, to reduce the reliance on the pharmaceutical industry for education about medicines (Table 3).

We are aware that there are limitations with this study. We acknowledge that this study was conducted mainly among physicians working in tertiary healthcare facilities in Nigeria and its findings may not be completely generalized to physicians in other care settings. However we believe our findings may partly reflect the prescribing behaviour and understanding of generic medicines among doctors in other settings as more than 10% of the participating physician worked in general medical/family medicine specialty. We are also aware there was a greater proportion of male physicians taking part in our study at 86% of respondents compared with the normal situation of 75% in hospitals. We also accept that using the default option in allocating equal weights to the questions in the “knowledge” domain might be associated with some problems. Finally, whilst there are difficulties in estimating the actual number of medical doctors working in different geo-political regions of Nigeria to add further depth to our analysis, data from the Nigerian Medical Association revealed that approximately 70% of medical doctors practice in urban areas where most tertiary healthcare institutions (including those where some of the study participants practice) are located [100].

However, the sample size, multi-centered nature of the study and the use of previously validated instrument in previous studies with good internal constituency are strengths that add robustness to the study results and the implications. In addition, the ability to compare findings across countries. Consequently, we are confident in the findings and their implications.

We are also aware that cost differences between generics and brand named (originator medicines) was not addressed in this study with previous published studies in Nigeria showing the importance of the cost of medicines on prescribing choices [65]. There is however ample evidence of significant cost differences between these two groups of medicines. In the study conducted by Cameron et al in Nigeria and 35 other developing and middle income countries [101], the ratio of the cost of originator (branded) to generic medicines for amoxicillin, ciprofloxacin and glibenclamide was 10, 14 and 9 respectively [101]. In addition, this will be the subject of future papers with recent findings showing prices of originator atorvastatin were four times higher in Nigeria than the generic (Onyinye Akunne personal communication). Prices of generic simvastatin in Nigeria were also considerably higher than those seen in the Netherlands, Sweden or the UK where multiple measures have resulted in generic simvastatin (20 and 40mg) costing only US$2 to US$5 per month [25, 102, 103].

Key points

- The prescribing of good quality generics saves considerable resources for patients and health care systems without compromising care. This is especially important in Nigeria where the healthcare sector is underfunded and there are considerable out-of-pocket payments.
• However, there have been low rates of generic prescribing in Nigeria contradicting the National Standard Treatment Guidelines

• A cross-sectional questionnaire among physicians in Nigeria ascertained that only 27% had good knowledge concerning generics versus 36% with average knowledge and 37% with poor knowledge. There was though statistical significance with the duration of medical practice but not with physicians’ position, subspecialty or sex

• The majority of physicians (72% and 69% respectively) did not agree that generic medicines were of lower quality than branded (originator) medicines and are associated with greater side-effects. In addition, only 15.2% believed generic medicines are less safe than brand (originator) medicines

• An appreciable proportion of physicians believed (44.5%) pharmaceutical companies were a good source of information regarding medicines although only 12% admitted being influenced by gifts from pharmaceutical companies

• There is an urgent need to address physician trust in the generics from local manufacturers as well as enhance INN prescribing generally. This will benefit local manufacturers as well as patients and the healthcare system

Acknowledgements and financial disclosure

No author has any conflict of interest to declare.

The study was funded through contributions from all co-investigators. The write up of this paper was in part support by the Karolinska Institutet as well as VR-Link grant from Swedish Research Council (VR-Link 2013-6710).

References


59. National Agency for Food and Drug Administration and Control (NAFDAC). GUIDELINES FOR REGISTRATION OF DRUGS AND RELATED PRODUCTS

MANUFACTURED IN NIGERIA. 2014.
84. Roeher B. Drug companies will have to report all payments to US doctors from March 2014. BMJ. 2013;346:f826.