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# Intern Physicians' views of Generic Medicines in a Teaching Hospital in Southwest Nigeria

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

## Abstract

**Background:** The use of generic medicines in practice is an effective pharmaceutical cost containment strategy. However, prescribing of generic medicines has remained relatively moderate compared to that of innovator brands in many developing countries. To improve generic medicine utilization, there is a need to understand prescribers' views of generic medicines and related practices.

**Objectives:** To explore the views of intern physicians on generic medicines, generic prescription and substitution practices.

**Methods:** This study employed qualitative methods. The study participants were intern physicians in a tertiary hospital. The participants were recruited using snowballing technique and interviews were continued until an adequate sample size was attained. The method for data collection was face-to-face individual in-depth semi-structured interviews. A total of 12 interviews were conducted. The interviews were audio recorded, transcribed using a denaturalized approach. Data analysis was by thematic analysis based on the framework approach.

**Results:** Three major themes were identified on their views on generic medicines; 1) insufficient knowledge about generic medicines, 2) ambivalent dispositions to generic medicines, 3) trust of innovator brands. Their views appear not very supportive of generic substitution practice. Possibly, due to a gulf in communication between dispensing pharmacists and prescribing physicians, as well as past experiences with inappropriate substitutions.

**Conclusion:** Trust in the innovator product appears an important factor in the prescribing of medications. The participants seem to have less trust in generic medicines, hence they prescribe innovator brands more.

**Keywords**: generic medicine, generic substitutions, generic prescribing, physicians.

## INTRODUCTION

Access to essential medicines in Nigeria is limited for the treatment of many common diseases. Therefore, the main goal of the Nigerian national drug policy (NDP) is to improve access to essential medicines (Federal Ministry of Health, 2005). Access to essential medicines is tightly linked to issues surrounding uptake of generics medicines, as over 90% of essential medicines are available as generics (World Health Organization, 2010). The availability of good quality generic medicines helps to contain ever-escalating prices of medicines worldwide.

Generic medicines are readily available in Nigeria. In a national survey of public and private health clinics, the pharmaceutical products stocked were almost entirely lowest priced generic equivalent products, as innovator brands were mostly not available (The Federal Ministry of Health, 2006). There was a clear preference for low priced generics in public facilities' pharmacies and use of generic medicines reduces cost of medicines up to 89% of cost of innovator brands for patients in Nigeria (The Federal Ministry of Health, 2006).

The NDP recommended generic name in listing, procuring, prescribing and dispensing of medicines to encourage generic medicines' uptake in practice. Based on this recommendation, generic medicines uptake should be physician driven by their generic prescribing practice. But in the study setting, generic

medicine uptake is driven by generic substitution practice (Oyetunde, et al., 2014). Generic substitution is a pharmacist-initiated act, where pharmacists dispense a different brand or generic instead of the prescribed brand. This involves substitution between therapeutically equivalent products. Whereas, generic prescribing involves physicians prescribing medicines by their generic names, as pharmacists may, therefore, stock and dispense generics.

Several studies have shown generic prescribing practice is low to moderate in Nigeria (Oyetunde, et al., 2014; Adebayo & Hussain, 2010; Babalola, et al., 2010; Enwere, et al., 2007). Evidences from the literature showed that physicians prefer to prescribe branded medicines and are not favourably disposed to pharmacists' generic substitution practice (Fadare, et al., 2016; Oyetunde, et al., 2014). The main reason for low generic prescribing among physicians is fear of therapeutic failure, despite physicians' belief that generic medicines are not of lower quality than innovator brands (Fadare, et al., 2016). The reasons for their unfavourable dispositions to generic substitution practice is, however, not clear. The objective of this study was to explore intern physicians' views of generic medicines, generic prescribing and substituting practices. This explorative study gave insights into physicians' perceptions of generic medicines, generic prescribing and substituting practices as well as their views on how to improve generic medicines' utilization.

## METHODOLOGY

### Methods

This study employed qualitative research methods. Qualitative research methods provide opportunity to access the opinions and impressions of participants, which enables understanding of the meaning participants ascribe to an experience or a process. An interpretive phenomenological approach was used in the study to recruit, collect and analyse data.

### The Researchers

The researcher (AB), a pharmacy undergraduate student, collected, coded and analysed the data. She brought to the inquiry a fresh perspective into an old challenge of brand prescribing in this institution. She is knowledgeable in the National drug policy recommendations and the rationale for generic medicines based on the essential medicines concept. The other researchers are pharmacists, who supervised the study. One of the supervisors (OO), who is trained in qualitative research approach, supervised the overall governance of the study to conform to interpretive phenomenology methods. She was also involved in the coding (as second coder), data analysis and interpretation of findings. While (FA) was the peer de-briefer to reduce bias in data analysis and interpretation. All authors somewhat considered generic medicines practical alternatives to innovator brands.

All researchers were trained in the positivist medical tradition but acknowledged there is no superior research approach. An appropriate research approach should, therefore, be selected for a study based on research question. Based on this study objective, an interpretive phenomenological approach was deemed as appropriate.

### Study setting

The study setting is a foremost tertiary health institution and teaching hospital in Nigeria. It is one of the largest tertiary hospitals in Nigeria and located in the most populous State in Nigeria. Lagos University Teaching Hospital (LUTH) serves as the main tertiary referral centre for the metropolis of Lagos and its neighbouring towns.

### Study Participants

Intern physicians were invited to participate in this study. An intern physician is in the first year of medical practice and undergoing a supervised mandatory one-year post qualification training. They are often the first on call in many medical teams. It is during this supervised training that knowledge acquired in medical school usually collides with day to day practice and practice context. Therefore, these participants have insights into challenges of generic prescribing and why practice may diverge from training in medical school.

### Participants' recruitment and sampling

A purposive sampling method was adopted for the study. Intern physicians were approached individually with participants' information sheet to recruit willing participants able to articulate their views on generic medicines. A convenient time and place were scheduled for the interview. Recruitment was challenging because many willing interns were unable to schedule their interviews due to heavy work load. To recruit more participants into the study, a snowball sampling method was used, where physicians interviewed introduced data collector to colleagues, who might be willing and are able, to participate in the study.

**Adequacy of sample size**
A total of twelve (12) intern physicians participated in the study. A sample size of 5-25 participants was proposed in the protocol based on literature review of sample size for phenomenological studies. However, as the interviews, transcription and codes generation were carried out after every other interview, no new code was described after the eighth transcripts. Four more interviews were conducted to ensure adequacy of sample size.

**Data collection**
The method for data collection was by face-to-face, individual, semi-structured interview. This method was adopted because it was suitable to collect participants' rich description of their prescribing practices without censure from focus group. Semi-structured interview offers a balance between the flexibility of an open ended interview and the focus of a structured interview. A semi structure interview allows the researcher to probe cues and ask follow-up questions. The interviews were conducted with a semi-structured interview guide.

**Interview guide development**
The semi-structured interview guide which is reproduced in Table 1 was developed based on extant literature and research objectives. The guide asked open-ended questions about participants' perceptions on generics, attitudes towards generics prescribing and views on INN prescribing and generics substitution. The interview guide also included questions on their prescribing decisions, as well as their views on how to improve generic prescribing practice. The guide was piloted and needed only minor revision, as well as rearranging of questions, after the pilot. Therefore, data sets collected during pilot were part of the study data analysed.

**Interview sessions**
The interview sessions lasted for an average of 15 minutes in the physicians consulting rooms. Interview sessions were recorded with the knowledge and approval of participants. The recordings were transcribed verbatim based on the denaturalized approach (Oliver, et al., 2005). Transcripts were coded by two researchers. After the fourth transcript was coded, the coding matrix was discussed and adopted. The coded transcripts, coding matrix and initial categories were reviewed by the de-briefer. All discrepancies in coding were discussed and resolved before proceeding with further data analysis.

**Data Analysis**
Thematic analysis of data was based on the framework approach. The framework approach is a versatile analytical tool that can be adapted for use in many qualitative approaches that set out to generate themes (Gale, et al., 2013)

**Table 1: The semi-structured interview guide**

| |
|---|
| • What do you understand by generic drugs? |
| • How do you get your information on generic drugs? Were you taught about generic drugs in medical school? |
| • What are your perceptions of generic drugs? |
| • Explain your views on the safety and effectiveness of generic drugs. |
| • When you prescribe, what factors do you consider on whether to choose the innovator brand or a generic version? |
| • What are your views about pharmacists' generic substitution? |
| • In your experience with patient care, how do you perceive your patient's willingness to use generic drugs? |
| • Please describe the effect of drug marketing and promotion on your selection of medications to prescribe. |
| • What is your view on the act of the government to promote the use of generic drugs? |
| • What are your thoughts on how to improve generic prescribing in practice? |

**Table 2: Study participants' characteristics**

| | | Number of participants | Participants (P1-12) |
|---|---|---|---|
| Sex | Male | 6 | 3,4,6,7,8,11 |
| | Female | 6 | 1,2,5,9,10,12 |
| Age | 21-25 years | 10 | 1,2,5,6,7,8,9,10,11,12 |
| | 26-30 years | 2 | 3,4 |
| Number of months in inter | 1 -4 months | 2 | 2,6 |
| program as at time of inter | 5 -8 months | 2 | 7,12 |
| | 9 -12 months | 8 | 1,3,4,5,8,9,10,11 |
| Posting as at time of interv | Internal Medicine | 4 | 1,2,6,7 |
| | Obstetrics and Gynecology | 2 | 11,12 |
| | Surgery | 3 | 4,5,9 |
| | Pediatrics | 3 | 3,8,10, |

## RESULTS

A total of twelve (12) intern physicians as depicted in Table 2 participated in the study.

From the data set, 36 codes were identified and defined. From these codes, 9 initial themes emerged. The five final themes from the data set were influenced by the research questions and literature review. Some of the initial themes provided possible explanations for the final themes to answer the research questions. The findings are divided into four sections based on the main research questions of the study.

***Research question: Why do physicians prefer innovator brand?***

**Theme: Brand prescribing is often about trust in the product**

Participants often made categorical statements about their prescribing choices, *'I prefer' 'normally use' 'always prescribe'* brand. Two main reasons emerged for this preference for brands. Firstly, the participants expressed trust in the preferred brands. Participants described preferred brand products as *'trusted brands', 'old trusted drugs' or 'familiar with it'*. Familiarity with a drug product is crucial for acceptance (Patel, et al., 2012) and this was the finding of this study.

Secondly, prescription of brands is based on senior colleagues' explicit request for a specific brand medicine to be prescribed for patients.

"*...in this houseman ship, some of the consultants prefer the originator brands to shorten patients stay in the ward 'cos they are sure it would work*" [P11]

To buttress their preference for innovator products, they described instances where they actively persuade patients to go for the innovator brands. They believe the brands they trust are more effective, and on the long run will benefit their patients more than generic medicine

"*Like I said, because of finances, patients prefer to use the generic ones…But so far, as a house officer, I don't think there's anyone that I explained the difference to … that these innovator brands are more trusted due to positive stories about them. From past experiences, people that can afford it always go for the innovator drugs"* [P5]

Prescribing of branded medicines rather than generic medicines appears a deliberate and conscious decision. In their prescription writing decision making process, it seems emphasis is laid on past perceived performance of a product or the physician's experience with a product. From their experiences, generic medicines, in this study setting, seem to underperform in practice.

Many participants gave vivid descriptions of initiation of antimicrobial therapy with innovator brands, then followed by a switch to generic versions to improve affordability by patients. They later switched back to the innovator brands because the generic versions could not sustain results initially observed with the innovator brands. This process of switching back and forth between innovator and generic perpetuates perception of generic medicines as inferior (Flood, et al., 2017 ) and seemed to buttress their trust in the innovator brands.

Participants' description of their experiences suggested lack of therapeutic equivalence between innovator brands and generic medicines. Therefore, they often prescribed specific brands and avoided generic medicines to reduce the possibility of therapeutic failure. Generic medicines prescription seems reserved for patients, who absolutely could not afford innovator brands.

'*…so, if the patient cannot afford the innovator brand, then I can prescribe the generic one*' [P1]

In making decision to prescribe innovator brand, they viewed the possibility for counterfeit medicines as greater with generic medicines than innovator brands. Also, there is the belief that when a patient illness is critical, then innovator brand is needed.
Notwithstanding their preference for innovator brands, it seems that trusted brands do not only apply to the innovator brands but are sometimes branded generics. Indeed, branded generic prescriptions are prevalent in the study setting (Oyetunde, et al., 2014).

"*But then I've come to realize some other generic brands can also be trusted depending on the manufacturer*" [P6]

**Theme: Inadequate knowledge of generic medicines and generic prescribing practice**
There seems to be inadequate knowledge of generic medicines and generic prescribing practice. Participants were often unable to define generic medicines and generic prescribing practice needed to be explained in the course of the interviews. But participants appeared to understand the core concepts of generic medicines (pharmaceutical equivalent to an innovator) and were quite familiar with generic substitution in practice. Their understanding of generic medicines concept was clear in their rich descriptions of their views of generic medicines and why they insisted on innovator brands.
However, there seemed to be a knowledge gap about why generic medicines are cheaper than innovator medicines. This gap seems to buttress the belief that the more expensive innovator brands may be better. They assumed that generic medicines are for those that cannot afford innovator brands or the *'lower class',* with participants describing instances where they actively tried to persuade patients to switch to the perceived better innovator.

"*So when patients come in, even though they don't have the money for a particular drug, we try to explain to them that it's not like we are just trying to make you get the most expensive one, this is what is good for you"* [P12]

Also, there is inadequate information about the regulatory processes and the quality checks that inform generic medicines registration in Nigeria. In the course of the study, participants consistently stated '*more research'* is needed, in the public domain, to establish therapeutic equivalency of generic medicines to innovator brands. This request for more information about therapeutic equivalents is a common view among participants to improve generic prescribing practices.

"*If there's more research on these cheaper drugs, and there are publications that prove that they actually work. That could help*" [P4]

"*So I think it would help if NAFDAC [Nigeria medicine regulatory authority] creates awareness about the safety and efficacy of these drugs, apart from the fact that they already approved the drug*" [P9]

Also noted is the fact that pharmaceutical detailing appeared to provide information to fill the gap about therapeutic equivalents in favor of branded products.

"*I don't like them [generic medicines] so why would I want to improve their use. If they are effective, I would prescribe them… I know someone from [Innovator manufacturer's name] they did a study, and it was confirmed at the end of the day that they had way lower active ingredient in one brand of ciprofloxacin, even lower than half"* [P-5].

***Research question: What are their perceptions of generic medicine?***
**Theme: Ambivalent disposition to generic medicines**
From the data set, physicians seemed to have positive and negative views of generic medicines. These views suggested an ambivalent disposition to generic medicines in practice. Physicians' mixed views about generic medicines in low to middle income countries is supported in the literature (Hassali, et al., 2014). Their negative view of generic medicines was often expressed as generic medicine *'not effective', 'not as effective'* as innovator brands. There were rich descriptions of generic medicines not producing equivalent therapeutic outcomes as the innovator brands in practice, especially with antibiotics. Their positive views were based on perceived safety of generic medicines, they acknowledged that generic medicines are '*safe', 'not harmful'*. Also they were aware of their patients' preference for generic because they were affordable and available.

"*…they [generic medicines] may be less efficacious. I remember a boy we managed for posterior retrial*

*valve. We decided to go for Meropenem…So the parents of the child decided to do a round of generic drugs because it's cheaper … we had no success with that after the initial successes that the innovator brand offered us. So we ended up going back to the innovator brand and forfeiting the generic brand. So sometimes it works, sometimes you have to revert to the innovator brand. On a scale of 0 to 10 for effectiveness, I would rate them at 6. So they are fairly good*". [P-7]

Therefore, the decision to prescribe or not to prescribe generics was often a compromise between their positive and negative views. They seemed to strive for a balance between their preference for innovator brands and their patients' preference for the more affordable and available generic medicines. Patients' acceptance of and request for generic medicines seemed to drive physicians' use of generic medicines and influence their acceptance of generic substitution practice. Reported patients' acceptance of generic medicines in this study seemed to deviate from the literature. Normally, consumers in low to middle income countries often equate low price with low quality, which constitutes a barrier to generic medicines' acceptance among them (Hassali, et al., 2014).

***Research question: How do they view the generic prescription and substitution policies?***

**Theme: Conditional support for generic prescribing practice**

Participants frequently described conditional support for generic prescribing practice. The conditions attached to generic prescribing included: ability to specify brand in some situations and assurance of consistent therapeutic equivalency. Also, patients should make informed decision about the selection of generic or brand medicines.

*"…That [generic prescribing] makes a lot of sense. I like it that way, because how many brand names do I even know in my head. They tend to change, at some point you could just hear that a particular brand is not in the market again. But I would like if we could also specify the brand we want in some cases too. I want to have the freedom to be able to specify*" [P-10]

Among these participants, there were suggestions for more awareness/publicity for generic prescribing practices. Pharmacists and regulatory agency would need to engage physicians through provision of evidence-based information about generic medicines' safety and efficacy. They are of the opinion that improved awareness and provision of necessary information may improve generic prescribing practice. Participants that did not support generic prescribing believed that the final decision about what medicine a patient takes does not take into cognizance their full professional expertise.

"*If I write the active ingredient, the pharmacist would give anything, and what if I believe in a particular brand and I trust that works. So I don't support the INN prescribing*" [P-5]

**Theme: Not supportive of generic substitution practice**

Participants' views showed they were not very supportive of generic substitution practice. They think generic substitution is '*wrong', 'cheating', 'not good', 'not right'.*

"*I feel it's not right, it's not good, especially with the fact that they don't usually give us a heads up and tell us what is available and [when] they don't have the originator brand*" [P-8]

From their views, there were three main reasons they appeared unsupportive of the practice. Firstly, there seemed to be a communication gulf between pharmacists and physicians in this study location. Participants believed pharmacists do not always appreciate the reasons a particular brand is preferred and prescribed by the physicians. Also, the pharmacists' intention for substitution is not always clear to the physician. The participants believe that pharmacists substituted because the prescribed brand was not available in the pharmacy.

"*I think it is totally wrong. If I write Rocephin® for a patient and you don't have... The pharmacist should tell the patient to look for it somewhere else…*" [P-5]

Secondly, participants described instances where inappropriate substitution occurred in practice. Like medicine not being the same strength as prescribed brand. Consequently, patient received less dosage than prescribed because of the substitution. Also, frequent switches between brands served as a challenge and the physician was often not familiar with the different brands a patient received in the course of a treatment.

"*Most times, when the patient starts on Rocephin® and the next dose - because the way they supply in my institution is that they supply in bits- is something else and the third dose is something else again, so everything is just mixed up. So we can't really tell if it's a particular brand that is working or causing a deterioration in treatment*" [P-10].

Generic substitution is practiced in Nigeria without an explicit policy statement in support of the practice, or the necessary guidelines. Finally, there is the salient caution that substitution may be performed by non-pharmacist that are not always mindful of the quality

of medicines. In the study setting, patients sometimes sourced for their medicines outside the hospital pharmacy and the sources are not always registered pharmacies manned by qualified pharmacists. Participants that were supportive of generic substitution believed in the professionalism of the pharmacist, or supported it, because they knew the pharmacist in person or the institution pharmacists.

"*I think the pharmacists are professionals and they can use their own professional judgment. They are where the drugs are, and we [doctors] are somewhere else prescribing drugs, so it depends on the pharmacist that is doing the substitution. If it is a standard and properly trained pharmacist, yes it can be done. If the patient might not be able to afford the original one, yes it can be done. And if it is a brand that the pharmacist knows is good, working and is effective, yes it can be done, why not*" [P-2]

The study findings showed that the preference for innovator starts early in doctors' career and seemed fully established during the internship period. It seemed to come from positive experiences with innovators compared with generic, and as learnt habits of senior colleagues

## DISCUSSION

There were three main findings from this study, namely: trust in the drug product, whether generic or branded, is crucial for physicians to prescribe any product. Secondly, physicians have ambivalent dispositions toward generic medicines in this settings. Finally, apparent lack of physicians' support for generic substitution practice is based on their attitude towards generic medicines, as well as a communication gulf between pharmacists and physicians in this setting. To explain these findings, the theory of reasoned action (TRA) will be employed (Taylor, et al., 2006).

The TRA posits that a crucial factor to an individual's behaviour is dependent on behavioural intention. Behavioural intention is influenced by attitude and subjective norms. TRA was selected for this study because of its accuracy to explain behaviour is dependent on the extent to which the behaviour is under volitional control of individuals. As prescribing of generic medicines is under the volitional control of interns' physicians, TRA is an appropriate explanatory theory to unpack the study findings. However, the general framework of TRA limits its use in intervention designs. Therefore, to interpret the study findings for appropriate intervention design, the Trans theoretical model (TTM) will be used. The TTM is built around the six stages of change and it is purpose built for appropriate intervention for change based on the stages of change (Taylor, et al., 2006) .

From the study findings, participants' attitude to generic medicines, a core construct of TRA, is determined by their perceptions of suboptimal performance of generic products in practice. Their negative attitude is often moderated by their patients' preference for affordable generic medicines and physicians' perceptions of generic medicines' safety. The subjective norm, defined as an individual's perception of social norms in this setting, is that senior colleagues often expect and demand use of branded medicines over and above generic medicines. Therefore, they often prescribe branded products rather than generic medicines.

Their lack of support for generic substitution seem influenced by their negative attitudes towards generic medicines. These negative attitudes are based on lack of trust in generic medicines to perform optimally in practice, coupled with misunderstanding of pharmacists' intentions for generic substitution and poor generic substitution practice in the setting. A subjective norm that strongly moderate continued generic substitution practice seems to be patients' preference and acceptance of generic medicines. Participants reported that their patients often requested for generic medicines in practice and they sometime had to persuade them to purchase innovator brands. This finding is contrary to many study findings in developing countries (Kaplan, et al., 2012; Hassali, et al., 2014). However, this patient preference for generic medicines often limited physicians' lack of support for generic substitution practice in this setting.

Participants are ambivalent towards generic medicines, therefore, they appear as contemplators in the stage two of the TTM. Depending on the overruling subjective norm at the point of prescribing, like the senior colleague's request for branded medicines, or patients' preference for generic medicine, generic medicines may or may not be prescribed. In order to move this cadre of physicians toward generic prescribing, appropriate interventions for contemplators are needed.

To ensure trustworthiness of our findings, we adopted reflexivity as appropriate for interpretive phenomenological study. We stated our preconceptions, biases and assumptions *a priori* and integral part of our findings. We also utilized a peer de-briefer for the study to ensure our biases did not unduly influence our findings and to clarify interpretations. Also, many of our findings were in tune with extant literature.

Study limitations are that only intern physicians were interviewed and it is based in a single location. Therefore, the findings are not generalizable to other cadre of physicians or locations. More elicitation studies for other cadre and locations are needed to develop a comprehensive and appropriately targeted intervention to improve generic prescribing practice in Nigeria.

## CONCLUSION

Generic prescribing and substituting practices often lack support of many intern physicians because they do not trust generic medicines as much as innovator brands. However, this lack of trust is counterbalanced by patients' preference for generic medicines and physicians' perception of generic medicine safety in this setting. To improve generic prescribing and garner support for generic substitution practices, appropriate interventions for the contemplator stage for change might be necessary for this cadre of physicians.

**DECLARATIONS**

**Ethical approval**

The study protocol was submitted to The Research and Ethics committee of the Lagos University Teaching Hospital (LUTH) Health Research Ethics Committee. It was approved but exempted from a full review (ADM/DCST/HREC/APP/1548).

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