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Assessment of knowledge and perceptions of generic medicines among pharmacy students in Yemeni universities

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Abstract

Prescription of substitute generic medicines was encouraged by most policy makers in developed and developing countries across the world. Maintaining the confidence of patients in using generics is the main challenge, whichever policy - generic prescribing or generic substitution - is adopted. This is the place where the role of the pharmacist becomes crucial. The availability of different brands of the same drug at the equivalent strength and in the unchanged dosage form creates a special challenge to healthcare professionals, making these issues very relevant to pharmacists in all practice settings. Therefore, a cross-sectional survey was undertaken to evaluate pharmacy pre-registrants' perceptions and knowledge of generic medicines. Data were collected through a standard pre-tested questionnaire. More than 70% of study participants from private universities thought that generic medicines are inferior, less effective and produce more side effects compared to brand name medicines. These findings highlight that private universities' pharmacy pre-registrants require an enhanced understanding of the concepts and principles of bioavailability and bioequivalence of health system to prevent pre-registrants to contribute inappropriately to generic medicine use.

Keywords: *Generic substitution, generic medicines, bioequivalence, perceptions*

Introduction

In recent years, the roles of pharmacists have been expanded beyond their traditional role of preparing and dispensing medications to include influencing the prescribing process and delivery of pharmaceutical care services, making them more involved in patient care (Farrell *et al*., 2010; Liekweg *et al*., 2012; Schröder *et al*., 2012). The pharmacists' role has previously been defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes for improved patients' quality of life" (Hepler & Strand, 1990).

As drug experts, pharmacists are equipped with skills to recognise, resolve and avoid drug-related problems. Additionally, pharmacists have the ability to recommend cost-effective therapy and counsel patients on drug therapy (Merten *et al*., 2013). The escalating cost of prescription medicines to both the government and patients has placed pharmacists in a position to advise both prescribers and patients on the availability of cheaper generic medicines (Black *et al*., 2013). Generic drugs are medicines that are manufactured without licence from the innovator companies and marketed after the expiration of the patent and other exclusive rights. They are usually prescribed and dispensed as alternatives to the branded products whose names are given by the parent drug manufacturers. The use of the name is reserved exclusively for its owner (WHO, 2015). According to the Center for Drug Evaluation and Research (CDER), a generic drug is defined as a drug product that is comparable to a brand l drug product in dosage form, strength, quality and performance characteristics, and intended use. Generic and brand medications generate similar clinical outcomes. The generic medications may however differ from branded ones in shape, colour, test, and names (Mccormack & Chmelicek, 2014). Several studies have suggested that pharmacists are generally supportive in promoting the use of generic medicines by their customers but, in terms of their knowledge of issues relating to bioequivalence, many pharmacists have inadequate knowledge on the criteria used by their respective country's drug regulatory bodies in the assessment and registration of generic medicines (Kirking *et al.*, 2001; Mott & Cline, 2002; Chua *et al*., 2010; Babar *et al*., 2011, Hassali *et al*., 2013).

Yemen is a developing country with a very low income per GDP and the Yemeni authority does not object to the practice of substituting branded medicines with the generic ones, however, there are no specific guidelines to regulate this practice in different parts of the health sector. The Yemeni drug regulatory agency is in fact encouraging the registration and marketing of generic medicines that fulfil the regulatory requirements.

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Patents for a number of commonly used medications are scheduled to expire in the near future in developed countries and the generic versions of these medications will come onto the market. Pharmacists need to be well trained to advise both patients and prescribers on not only the availability of these cheaper alternative brands, but also issues relating to their safety and efficacy (Ganiyu Kehinde & Suleiman Ismail, 2012).

In Australia, a study was carried out to determine any differences in knowledge and perceptions of generic medicines among final year medical students and pharmacy pre-registrants (Hassali *et al*., 2007). The response rate for both medical student and pharmacy pre-registrants showed 26.7% and 30.5% respectively. Both groups admitted having insufficient knowledge about the quality, safety and effectiveness of generic medicines (Hassali *et al*., 2007). A recent study on the perceptions and knowledge of generic medicines among final year medical students was conducted in six public universities in Iraq. This study clearly showed that the medical students have a deficit of understanding on issues relating to the use of generic medicine use and the application of principles and concepts of bioavailability and bioequivalence (Sharrad & Hassali, 2011).

To date, no study has been conducted in Yemen where the household income is very low, to determine people's perceptions and knowledge about substituting branded medicines in favour of the generic medicines. We hypothesise that the generic names will favourably replace the brand medicines and that pharmacists should have the necessary knowledge and skills to substitute branded medications for the generic ones. Thus, the aims of this study, were to evaluate pharmacy pre-registrants' perceptions and knowledge about generic medicines and their substitution as well as to explore factors that may influence the pharmacy pre-registrants' future generic substitution practices.

Methodology

A cross-sectional survey was conducted between 1st February 2013 and 31st June 2013, in six selected universities (public and private) in Yemen. Only the final-year pharmacy students in the six universities were enrolled for the study. Official permission was obtained from the respective university authorities. Data was collected using a pre-tested standard questionnaire that included 21 questions divided into four sections. The first part consisted of three demographic questions, about age, gender and university. The second part contained four items about knowledge of the bioequivalence of generic medicines and questions were framed into a 5-point Likert-scale format (5=strongly agree, 4=agree, 3=neutral, 2=disagree, and 1=strongly disagree).

The third part of the questionnaire contained eight questions that sought to evaluate understanding of brand-name medicines versus generic medicines, also using the 5-point Likert scale. The fourth part of the questionnaire consisted of six questions that sought to evaluate perceptions of current medical and pharmacy education. Three pharmacy lecturers in pharmacology and social pharmacy were asked to evaluate the relevance, clarity, and conciseness of the questions included in the questionnaire. Modifications were thereafter made to the questions according to observations and comments of the lecturers. In order to test the validity and reliability of the survey form, the revised questionnaire was pilot-tested by administering it to a sample of ten pharmacy students who did not participate in the main study. A Cronbach's alpha reliability coefficient value of 0.823 was obtained which is closer to 1.0, an acceptable value that confirms the internal consistency of the items in the survey form.

The sampling frame included all final-year (fifth year) pharmacy students who were enrolled for full-time studies at three public universities and three private universities. The list of enrolled students for the study was obtained from the respective academic coordinators of the universities. Students were informed about the objectives of the survey by means of an explanatory letter attached to the survey questionnaire that was distributed to all the participants. The students received the survey questionnaire through the respective academic coordinators of their university. Anonymity and confidentiality were ensured. Consent for participation was implied by the completion and return of the survey instrument. Descriptive statistical analyses, such as frequencies and percentages, were used to represent the respondents' demographic information. Student *t*-test was used for data analysis, to compare the responses of pharmacy students from public and private universities. A statistical significance level of $p<0.05$ was used in all analysis.

Results

Out of the 301 final-year pharmacy students from the public and private universities enrolled for the study, 200 participated in the survey. The response rate was therefore 60%. Among the respondents, 64 (32%) were females and 136 (68%) were males with an average age of 22.7 years (Table I).

Table I: Number of student in universities enrolled in the study

Current universities	Male	Female
Public universities	92	36
Private universities	43	28
Total	**136 (68%)**	**64 (32%)**

Pre-registrant pharmacy in public and private universities agreed that the generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to the innovator brand product and generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to each other (Table II). Both groups generally stated that they had not been introduced to the issues of bioequivalence for generic drugs during pharmacy education and generally agreed that they needed more

information on how bioequivalence tests are conducted for generic medicines.

Table II: Knowledge and perceptions about generic equivalent according to university

Survey question/ students	University type	SA %	A %	N %	DS %	SD %	*p*-value
All generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to the innovator brand product	Public	17.0	36.4	17.9	21.7	7.0	0.251
	Private	20.0	37.1	24.3	11.4	7.1	
All generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to each other	Public	10.3	43.7	17.5	20.6	7.9	0.134
	Private	22.5	33.8	25.4	11.3	7.0	
I have not been introduced to the issues of bioequivalence for generic drugs during my pharmacy education	Public	17.5	20.6	22.2	34.9	4.8	0.061
	Private	36.6	19.7	9.9	23.9	9.9	
I need more information on how bioequivalence tests are conducted for generic medicines	Public	50.4	33.1	13.4	2.4	0.8	0.064
	private	49.3	22.5	12.7	12.7	2.8	

Table III: of the quality, safety and efficacy of generic medicines versus brand name medicine according to university

Survey question/ students	University type	SA %	A %	N %	DS %	SD %	*p*-value
A generic medicine is bioequivalent to a brand name medicine	Public	7.8	56.3	7.0	24.2	4.7	0.114
	Private	15.5	46.5	11.3	16.9	9.9	
Generic medicine must be in the same dosage form as the brand name medicine.(*e.g.* tablet, capsule)	Public	31.1	42.2	10.9	13.3	2.3	0.633
	Private	35.2	42.3	7.0	12.7	2.8	
Generic medicine must be the same dose as the brand name medicine	Public	47.2	29.1	10.2	7.9	5.5	0.228
	Private	38.0	32.4	11.3	11.3	7.0	
Generic medicines are of inferior quality to branded drugs	Public	21.7	34.9	19.4	17.8	6.2	0.045
	Private	32.4	39.4	12.7	9.9	5.6	
Generic medicines are less effective than brand name medicines.	Public	10.9	33.6	25.8	18	11.7	0.021
	Private	31.6	29.6	9.9	23.9	5.6	
Generic medicines produce more side-effects than brand name medicine	Public	10.1	21.7	29.5	28.7	10.1	0.152
	Private	21.1	19.7	22.5	29.6	7.0	
Generic medicines are less expensive than brand name medicines.	Public	47.3	37.2	8.5	6.2	8	0.456
	Private	53.5	26.8	4.2	9.9	5.6	
Brand name medicines are required to meet higher safety standards than generic brand	Public	49	38.8	7.8	14.0	1.6	0.631
	Private	50.7	22.5	12.7	9.9	4.2	

A higher proportion of pre-registrant pharmacy in private universities compared to public universities either agreed or strongly agreed that generic medicines are of inferior quality compared to branded drugs (Table III: p=0.045 of student t-test). They also tended to believe that generic medicines are less effective than brand medicines (p=0.021 of student t-test). Pre-registrant pharmacy from private and public universities are in agreement that generic medicines are bioequivalent to the branded counterparts and must therefore be in the same dosage form and the same dose as the brand medicines. Both groups of students also agreed that generic medicines are less expensive than brand name medicines and that the branded medicines are required to meet higher safety standards than generic medicines. There was no significant difference between the pre-registrant pharmacy students of private universities and those of public universities on their perceptions regarding the differences in side-effects between generic and branded medicines.

Responses to questions evaluating the perceptions of students regarding generic medicines are shown in Table IV. About 53.5% of pre-registrant pharmacy in the private universities compared with 34.6% in the public universities reported that the pharmacy school curriculum covers the topic on cost-effectiveness of medicines (p=0.05 of student t-test). Both groups express lack of confidence in substituting branded medicine with a generic one and that they need to be more informed on issues pertaining to the safety and efficacy of generic medicines. Furthermore, they found it easier to recall a medicine's therapeutic class using generic names rather than brand names. About 66.2% of students in the private universities strongly agreed, compared with 47.6% from the public universities who agreed that the product bonuses being offered by pharmaceutical companies will influence their choice of alternative brands in the future, however, the difference between the two on this issue was not significant (p=0.06 of student t-test). Pre-registrant pharmacy students in public and private universities collectively reported that their dispensing patterns will be affected by drug advertising made by pharmaceutical companies.

Discussion

In this study the 65.5 percentage response rate obtained was reasonable. Although female students far outnumber the male students in the pharmacy colleges, there were more male students participating in the study than the female students. At university level, the number of participants from public universities was higher than the participants from private universities. This is likely because pharmacy students in public universities far outnumber those in private universities.

The pharmacy pre-registrants (n=110; 55.2%) provided the right answer on knowledge of the limits of

bioequivalence for the approval of generic medicine by the Ministry of Public Health and Population. In Yemen, a generic medicine is considered bioequivalent to a brand product if the 90% confidence interval for the ratio

Table IV: Perceptions of students about generic medicines according to university

Survey question/ students	University type	SA %	A %	N %	DS %	SD %	*p*-value
I need more information on the issues pertaining to the safety and efficacy of generic medicines	Public	53.9	28.1	10.9	7	0	0.111
	Private	43.7	32.4	12.7	8.5	2.8	
From the knowledge I have, I'm confident in substituting an innovator brand with a generic brand	Public	15.6	56.3	14.8	12.5	8	0. 20
	Private	50.7	32.4	5.6	7.0	4.2	
I find it easier to recall a medicine's therapeutic class using generic names rather than brand names.	Public	10.2	48.8	17.3	21.3	2.4	0.051
	Private	29.6	38.0	16.9	8.5	7.0	
Pharmaceutical companies' product bonuses will influence my choice of alternative brands in the future	Public	7.8	39.8	17.2	25.8	9.4	0.06
	Private	32.4	33.8	8.5	14.1	11.3	
I believe advertisement by the drug companies will influence my future dispensing pattern	Public	17.8	29.5	18.6	20.9	13.2	0.133
	Private	24.3	35.7	12.9	17.1	10.0	
My pharmacy school education covers the topic of cost-effective use of medicines well	Public	6.3	28.3	27.6	24.4	13.4	0.05
	Private	21.1	32.4	18.3	21.1	7.0	

(generic/brand) of the means of area under the curve (AUC) and maximum peak concentration (Cmax) are within the 80–125% (Morais & Lobato, 2010; European Medicines Agency, 2010). Response to the question on knowledge of bioequivalence limits for generic medicine clearly shows that the majority of pharmacy pre-registrants understand the concept of bioequivalence determination for generic medicines. Although the pharmacy pre-registrants generally responded correctly to this question, the majority of pre-registrants (94.4%) disagreed that they had been introduced to the issues of bioequivalence during their pharmacy education. Although no significant differences were found between universities, the small numbers disagreeing with the statement make it difficult to draw a useful conclusion in this regard. Most respondents indicated that they would like more information on how bioequivalence tests are conducted for generic medicines. This may be a reflection of the general tendency to be willing to accept more information when it is offered.

The participant's response may be due to limitation in scope and the shallow explanation of bioequivalence for generic medicines in current pharmacy curricula. Furthermore, bioavailability and bioequivalence of medicines may be perceived by students as a difficult and complex area of applied pharmacokinetics (McLachlan *et al*., 2004; Hassali *et al*., 2007). Although the majority of pharmacy pre-registrants especially in private universities were clear about bioequivalence of generic and brand medicines as well as the requirements for equivalence in doses and dosage forms, many of them reported that generic medicines are inferior in quality, less effective and produce more side effects compared to their branded counterparts. According to the Supreme Commission for Drugs and Medical Appliances in Yemen, companies that produce generic medicines, must adhere to the same quality standards and have the same GMP manufacturing controls as companies making the original brand medicines (Talap *et al*., 2008). A possible explanation for these misconceptions among the pre-registrants may be differences in formulation between a generic and a branded medicine, as some respondents commented about differences in properties like taste and the possibility of adverse reactions to different inactive ingredients. Furthermore, differences in the presentation and packaging might also have influenced the pre-registrants to think that the generic medicines are inferior in terms of quality.

The fact that 81% of the respondents reported that branded medicines have higher safety standards than generic medicines, may reflect their perceptions of inferior quality and efficacy. In Yemen, both generics and brand medicines must follow rigorous testing and safety standards recommended by United States- and/or British-Pharmacopoeias before they can be marketed. The responses from the pre-registrants clearly show that they are unaware of the controls used in the manufacture and marketing of medicines in Yemen. The majority of pre-registrants pharmacy were however aware that generic medicines generally cost less than brand medicines. Some key areas were recognised that require reconsideration when reviewing educational curriculum on generic medicines for pre-registrants. For example, the majority of respondents indicated that they would like more information on the issue of safety and efficacy of generic medicines. It is of concern, given their current level of familiarity, that the majority of respondents do not feel confident in the prospective substitution of an innovator brand with a generic product. One conceivable explanation for this may be that they have not been exposed to the practice of brand substitution in pharmacies where they are working or have undertaken experiential placement and therefore did not accept it as the norm, despite their lack of understanding (Toklu *et al*., 2012). Moreover, the students may have observed that the patient willingness to accept the generic substitution is based on the physicians or prescribers preference for the generic drugs (Hermansyah, 2013).

More than half of the respondents agreed that the bonuses being offered by pharmaceutical companies would likely influence their selection of medicine brands. This finding is consistent with previous studies conducted by Segal *et al*., (1989) and Hassali *et al*., (2007), showing that 35% and more than 50%

respectively of the pharmacists surveyed used product bonus as a measure to stock the appropriate brands of generic pharmaceuticals for maximising their pharmacy profits respectively. More than half of the pre-registrants agreed that pharmaceutical promotions would likely influence their future dispensing habits. This finding shows that, like medical doctors, pharmacists are also prone to drug promotions and therefore need to be trained on how to objectively evaluate drug information from literature materials of pharmaceutical companies to be evidenced base (Mansfield & Henry, 2004).

Our present study has shown that 34.7% and 53.5% of respondents from public and private universities respectively are well satisfied with the coverage of the topic on cost-effective use of medicines during their pharmacy education. Interestingly, more than half of the respondents were from private universities. This clearly reflects the inclusion of pharmacoeconomics as a standard subject in pharmacy curricula in the private universities. In many parts of the world, pharmacoeconomics is a standard subject in pharmacy curricula (Gafa *et al*., 2002) and that the acceptance of a medicine on the PBS requires pharmacoeconomic evaluation. This is a disappointing result, particularly when 90% of respondents reported that they had been adequately taught about the process of medicine substitution under the PBS. About three quarters of the pre-registrants indicated that they thoroughly understand the PBS guidelines on brand substitution, which may reflect on the education they received in pharmacy schools, however, this comprehension is also likely to have been heavily influenced by their practical experiences.

Although the response rate was reasonable, the number of students who participated in this study was small compared to the total number of students enrolled in pharmacy colleges in Yemen. Clearly, this study was limited to a restricted number of pharmacy students and the results may not be generalizable to the wider population. Nonetheless, the present study signifies a sectional view of generic substitution in Yemen.

Conclusion

This study is the first national survey on pharmacy pre-registrants' knowledge and perception on generic medicines and their substitution. It suggests that pharmacy pre-registrants in Yemen lack an in-depth understanding of the perceptions regarding generic medicines. The study further exposes the students need for more information on how bioequivalence tests are conducted for generic medicines and about the quality, safety and efficacy of generic medicines compared with innovator brands. These issues should therefore be addressed by the relevant stakeholders, such as pharmacy educators, government agencies, and generic manufacturers, since pharmacists play an important role in optimising the use of generic medicine through their interactions with both prescribers and consumers.

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