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Knowledge and perceptions of recent pharmacy graduates about generic medicines

MOHAMED AZMI HASSALI[1,2], DAVID C. M. KONG[1], & KAY STEWART[1]

[1]*Department of Pharmacy Practice, Victorian College of Pharmacy, Monash University, 381 Royal Parade, Parkville, VIC 3052, Australia, and* [2]*Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, 11800 Minden, Penang, Malaysia*

Abstract

The ever-rising price of prescription medicines is a phenomenon that affects nearly every developed country across the globe. An effective strategy to contain escalating costs is by using cheaper generic medicines. Within this context, most policy makers are encouraging healthcare professionals to prescribe or substitute generic medicines whenever possible. Whichever policy—generic prescribing or generic substitution—is adopted, the main challenge is how to maintain the confidence of patients and carers in using generics. This is where the role of the pharmacist becomes vital. The availability of different brands of the same drug at the same strength and in the same dosage form poses a special challenge to healthcare professionals, making these issues very relevant to pharmacists in all practice settings. To date in Australia and elsewhere, no studies have been conducted to assess the knowledge and perceptions of recent pharmacy graduates with regard to generic medicines and generic substitution. Therefore, a national web-based survey was undertaken to evaluate pharmacy pre-registrants' perceptions and knowledge of generic medicines. More than 80% of study participants thought that generic medicines are inferior, less effective and produce more side effects compared to brand name medicines. These findings highlight that pharmacy pre-registrants need a better understanding of the principles and concepts of bioavailability and bioequivalence if they are to contribute appropriately to generic medicine use.

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

Introduction

In recent years, pharmacists have become increasingly involved in patient care and have expanded their traditional role of preparing and dispensing medication to also influencing the prescribing process and delivery of pharmaceutical care (Hepler & Strand, 1990; Greene, Cavell, & Jackson, 1996; Rodgers et al., 1999; Schumock et al., 2003). Their modern role has been defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve patients' quality of life" (Hepler & Strand, 1990). As drug experts, pharmacists are equipped with skills to prevent, identify and resolve drug-related problems; recommend cost-effective therapy; and counsel patients on drug therapy.

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. Several overseas studies have suggested that pharmacists are generally supportive in promoting generic medicines to their customers but, in terms of their knowledge of issues relating to bioequivalence, many pharmacists do not know the criteria used by their respective country's drug regulatory bodies in assessing and registering generic medicines (Cawthorne & Eckel, 1973; Smith, Monk, & Banahan, 1991; Kirking, Gaither, Ascione, & Welage, 2001; Mott & Cline, 2002). As the patents of several commonly used medications are scheduled to expire in the near future in Australia and the generic versions of these medications will come into the market, pharmacists need to be well trained to advise both

Correspondence: K. Stewart, Department of Pharmacy Practice, Victorian College of Pharmacy, Monash University, 381 Royal Parade, Parkville, VIC 3052, Australia. Tel: 61 3 9903 9618. Fax: 61 3 9903 9629. E-mail: kay.stewart@vcp.monash.edu.au

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patients and prescribers on not only the availability of these cheaper alternative brands, but also issues related to safety and efficacy.

The aims of this study, therefore, were to evaluate pharmacy pre-registrants' perceptions of and knowledge about generic medicines and generic substitution and to explore factors influencing pharmacy pre-registrants' future generic substitution practices.

Methods

For the purpose of this study, a web-based survey was developed and used to gather data. Ethical approval was sought and received from the Standing Committee on Ethics in Research Involving Humans (SCERH) of Monash University. We also received permission from the relevant pharmacy pre-registration training course coordinators to survey their participants. The initial survey items were developed using information from a literature review, consultation with several practising community pharmacists in the Melbourne metropolitan area and with several pharmacy academics experienced in teaching subjects such as pharmacy practice and pharmaceutics, in which some of the topics related to generic medicines are covered. Based on this, a total of 25 survey items were formatted as a paper based survey comprising four parts. The first part consisted of four demographic questions: age, gender, university of current enrolment and other qualifications. The second part contained five items about knowledge of bioequivalence of generic medicines. One item related to limits for bioequivalence set by the Australian authority, the Therapeutic Goods Administration (TGA), when comparing generic medicines with innovator brands. The other four questions were framed in a five-point, Likert-scale format (1 = " strongly agree", 2 = "agree", 3 = "neutral", 4 = " disagree" and 5 = "strongly disagree"). The third part of the survey contained eight items which evaluated pre-registrants' understanding of brand-name medicines versus generic medicines, again using the five-point, Likert rating scale. The fourth part of the questionnaire consisted of eight items to evaluate pharmacy pre-registrants' perceptions of their education on the topic and future practice issues related to generic substitution.

The questionnaire was tested for its face and content validity using five pharmacy academics who were also asked to comment on the relevance, clarity and conciseness of the items. After taking into consideration their comments, the revised questionnaire was pilot tested with five pharmacy pre-registrants, three of whom were undergoing their training in hospital and two in community pharmacy. Only minor changes to wording were required following the pilot; further testing of face and content validity was therefore not considered necessary. To produce the web-based survey, the final version of the paper survey was adapted into a format able to be posted online. A professional web designer was employed for this task.

The sampling frame was pharmacy graduates from Australian universities who were undertaking pre-registration training prior to being eligible to register to practice as a pharmacist. The numbers of pre-registrants during the study period were obtained from the respective pharmacy pre-registration training course co-ordinators in each state. During the study period, seven providers across Australia had been approved by pharmacy registering authorities to run programmes for pharmacy pre-registrants. The survey was conducted for a period of three months, starting at the commencement of the particular course. Overall, the survey was conducted from 30th November 2004 until the end of April 2005.

An invitational e-mail inviting pre-registrants to participate in the web-based survey was sent to them via the coordinators of each of pre-registration training course. This approach was needed to comply with privacy legislation and ethics requirements which did not permit the researchers to have access to the participants' e-mail addresses. The hyperlink and password for the survey page were provided to allow the pre-registrants access to the survey. In order to increase response rate, four follow-up reminder e-mails were sent to the participants via their coordinators, at three-week intervals. In addition, information about the survey was posted on the web course tools (webCT) page via the coordinators for students of the three courses that employed webCT as medium of teaching. In one state, as the coordinator did not have a pre-registrant e-mail list and most of the communication was conducted via ordinary mail on a monthly basis, an invitation to participate in the survey was printed and provided to the coordinator to be included as part of the monthly mailing. In the letter, the uniform resource locator (URL) for the web-survey and the password were provided to enable the pre-registrants to answer the survey online. In order to increase the response rate from pre-registrants in this state, two reminder letters were supplied to the coordinator to be included in subsequent monthly mailings. Responses were collected by the MySQL database and from this database the responses were exported to Microsoft Office Excel 2003 for Windows for data cleaning (Langer, 2004). The cleaned data were then exported to the statistical package SPSS® for Windows, version 12, for analysis (SPSS, 2003).

Data analysis

Both non-parametric statistical tests and appropriate descriptive statistics for demographic characteristics were performed using SPSS®. Responses to questions producing ordinal data were compared to detect

differences according demographic characteristics using Fisher's exact test. Fisher's exact test was used because it is considered to be more appropriate for skewed data, as were obtained in this survey (Cochran, 1954; Mehta & Patel, 1996; Pallant, 2001; Hinton, 2004). Furthermore, as a rule of thumb, if 25% or more of the cells in the table have expected frequencies less than 5, or if any expected frequency is less than 1, then Fisher's exact test is preferred over the chi-square test (Cochran, 1954; Mehta & Patel, 1996; Pallant, 2001; Hinton, 2004). For this survey data, a default Monte Carlo simulation in the SPSS software was used to estimate Fisher's exact p-values as the data set was large and normal exact computations require a great amount of computer time and memory (Agresti, 1992; Mehta & Patel, 1996). A two-sided 99% confidence level Monte Carlo estimate of Fisher's exact *p*-value was computed, with a *p*-value of 0.05 or less considered to be significant.

Results

The total number of Australian pharmacy graduates reported as being enrolled in pre-registration courses at 31st January 2005 was 948. By the end of the three-month study periods, 289 pre-registrants had responded to the survey (response rate = 30.5%) Response according to university from which the pre-registrants graduated is shown in Table I.

Response by university is more relevant than response by pre-registration training course, as some questions referred to respondents' undergraduate education. It was not possible to calculate response rates per university, as numbers were obtained per pre-registration training course, all of which are open to graduates from any university.

The average age of the respondents was 23.0 ± 3.0 years. Two-thirds of the respondents (67.1%; $n = 194$) were female. Almost all of the respondents (94.2%; $n = 272$) did not have other degree qualifications before entering their pharmacy programme. The remaining 5.8% ($n = 17$) held first degree qualifications in science-related fields.

Table I. Response rates by university.

University	Number of pre-registrants (*n*)
1	72
2	23
3	25
4	71
5	41
6	24
7	16
8	2
9	15
Total	289

The first item on the questionnaire required pre-registrants to select the correct bioequivalence limits allowed by the TGA when comparing an innovator medicine with a generic medicine. To ensure a common understanding of the concept of bioequivalence, the following explanation was provided with the question:

> In pharmacology, the term bioavailability refers to the rate (how fast) and the extent (how much) to which an active ingredient is absorbed and becomes available at the site of the drug action. The Therapeutics Goods Administration (TGA), which is the drug regulatory body involved in registering medicines in Australia, considers a generic product to be bioequivalent if its bioavailability is within an allowed range compared with the currently marketed brand product.

After this statement, the following question was asked:

> The regulatory limits applied are that the 90% confidence intervals for the ratios (generic product:brand name product) of the areas under the plasma drug concentration versus time curves and the maximum plasma drug concentrations must fall between:

Six answer options were given, the correct answer being 80–125%.

The responses are shown in Table II.

A small majority of the pre-registrants (51.4%) chose 95–105% as the bioequivalence limits and only 11.4% selected the correct limits (80–125%).

The responses to other questions on knowledge of bioequivalence are shown in Table III.

The majority of respondents correctly (according to the Schedule of Pharmaceutical Benefits (CDHA, 2004) agreed that medicines rated as being "generic equivalents" are equivalent to the innovator brand product (86.1%) but not necessarily to each other (69.5%). Just over a half of respondents (53.3%; $n = 154$) felt they did not have sufficient information about the conduct of bioequivalence tests, although pre-registrants mostly agreed that they had covered the topic of bioequivalence during their pharmacy course (90.7%). There was a statistically significant difference ($p = 0.002$) in the responses to this question according

Table II. Knowledge of TGA bioequivalence limits.

Response	Frequency	Per cent (%)
80–120%	37	12.8
80–125%	33	11.4
90–100%	11	3.8
95–100%	23	8.0
95–105%	149	51.6
Not answered	36	12.5
Total	289	100.0

Table III. Knowledge and perceptions of issues surrounding bioequivalence.

Survey question/statement	Responses					Fisher exact test *p*-values		
	SA (*n*) (%)	AG (*n*) (%)	N (*n*) (%)	DS (*n*) (%)	SD (*n*) (%)	Gender	Graduate	University
All generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to the innovator brand product.	66 22.8	183 63.3	18 6.2	18 6.2	4 1.4	0.280	0.074	0.580
All generic products of a particular medicine that are rated as "generic equivalents" are therapeutically equivalent to each other	10 3.5	42 14.5	36 12.5	146 50.5	55 19.0	0.170	0.446	0.098
I have not been introduced to the issues of bioequivalence for generic drugs during my pharmacy education.	2 0.7	17 5.9	8 2.8	139 48.1	123 42.6	0.963	0.263	0.002
I need more information on how bioequivalence tests are conducted for generic medicines.	30 10.4	124 42.9	63 21.8	48 16.6	24 8.3	0.755	0.574	0.234

Note: SA = strongly agree; A = agree; N = neutral; DS = disagree; and SD = strongly disagree.

to university, apparently due to differences in curricula, as no pre-registrants from three of the universities (6, 8 and 9 in Table I) answered either "strongly agree" or "agree" to this question.

Responses to questions about knowledge and perceptions of generic medicines compared to brand name medicines are shown in Table IV.

Over 80% of pre-registrants correctly agreed that a generic medicine is bioequivalent to the corresponding brand name medicine (86.1%), must be presented in the same dosage form (84.1%) and contain the same dose (89.9%) as the brand name medicine. With regard to quality, safety and efficacy, most pre-registrants were under the impression that generic medicines are of inferior quality (89.6%), less effective (95.8%), produce more side effects (92.7%) and need to meet lower safety standards (81.3%) than brand name medicines. They were, however, clear about the lower cost of generic medicines (91.3%).

Responses to questions exploring the pre-registrants perceptions of their future role in generic substitution are shown in Table V.

Just over half (54.4%; $n = 157$) of the pre-registrants either agreed or strongly agreed that they needed more information about safety and efficacy of generic medicines. A statistically significant difference ($p = 0.008$) was noted in responses to this question among universities. At this stage of their career, most pharmacy pre-registrants felt confident to substitute an innovator brand with a generic brand medicine. Statistically significant differences were noted in response to this question between gender ($p = 0.047$) and among universities ($p = 0.037$). A higher proportion of female students (10.3%; $n = 20$) gave a neutral response to this statement compared to their male counterparts (4.2%; $n = 4$). In three universities, no pre-registrants disagreed with the statement.

Three-quarters of respondents (76.8%) reported a thorough understanding of the pharmaceutical benefits scheme (PBS) (a comprehensive system for subsidy of prescription medicines covering the whole population) guidelines on brand substitution, and again significant differences among universities were noted ($p < 0.001$). A similar proportion (73.3%) said they found generic names more useful than brand names in recalling the therapeutic class of a drug.

With regard to the potential influence of pharmaceutical companies on their future practice of generic substitution, just over half the respondents (51.9%; $n = 150$) thought they were would be influenced by product bonuses, but only 30.1% ($n = 88$) thought they would be influenced by advertising. While most respondents (89.6%; $n = 259$) reported having been taught about how medicines are subsidised under the PBS, considerably fewer (59.1%; $n = 171$) felt that the topic of cost-effective use of medicines was well covered. In both cases, statistically significant differences ($p < 0.001$, $p = 0.001$, respectively) were noted among universities, suggesting differences in curricula.

Discussion

A web-based survey was used for this study as it was the most practical approach to reach the population of interest, who were scattered throughout Australia in hospital and community pharmacies. An overall response rate of 30.5% was achieved, which is within the range for internet based surveys (6–75%) (Sheehan & Hoy, 1999); however, it is acknowledged that this response rate carries with it the potential for

Table IV. Knowledge and perceptions of generic medicines.

Survey question/ statement	Responses					Fisher exact test *p*-values		
	SA (*n*) (%)	AG (*n*) (%)	N (*n*) (%)	DS (*n*) (%)	SD (*n*) (%)	Gender	Graduate	University
A generic medicine is bioequivalent to a brand name medicine.	73 25.3	177 61.2	17 5.9	20 6.9	2 0.7	0.146	0.378	0.868
A generic medicine must be in the same dosage form (e.g. tablet, capsule) as the brand name medicine.	104 36	139 48.1	9 3.1	29 10.0	8 2.8	0.943	0.410	0.078
A generic medicine must contain the same dose as the brand name medicine.	131 45.3	129 44.6	7 2.4	14 4.8	8 2.8	0.487	0.068	0.744
Generic medicines are of inferior quality to branded drugs.	137 47.4	122 42.2	21 7.3	9 3.1	0 0	0.577	0.750	0.412
Generic medicines are less effective than brand name medicines.	137 47.4	140 48.4	7 2.4	5 1.7	0 0	0.095	0.798	0.613
Generic medicines produce more side-effects than brand name medicines.	137 47.4	128 44.3	22 7.6	2 0.7	0 0	0.729	0.766	0.969
Generic medicines are less expensive than brand name medicines.	127 43.9	137 47.4	12 4.2	10 3.5	3 1.0	0.517	0.423	0.073
Brand name medicines are required to meet higher safety standards than generic medicines.	100 34.6	135 46.7	28 9.7	23 8.0	3 1.0	0.517	0.423	0.073

Note: SA = strongly agree; A = agree; N = neutral; DS = disagree; and SD = strongly disagree.

non-response error. This is a disadvantage of web-based surveys. Reasons for the low response rate may include lack of interest or lack of time among the participants. All reasonable attempts were made to maximise the response rate; however, because of the constraints of the Australian privacy legislation, the researchers did not have access to the contact details of the survey population and we were therefore restricted to relying on the intermediaries to pass on information and reminders to the students. Similarly, these constraints prevented us from comparing respondents to non-respondents to gauge potential bias.

The very poor response rate received from pre-registrants who qualified from University 8 can be explained by the method by which the information about the study was relayed to them. Communication with the pre-registrants in this group was conducted via normal mail. The two reminder letters did not help to increase the response rate. Another option considered was to administer the survey during a group meeting between course coordinator and the pre-registrants, but unfortunately the meeting was not held during the data collection period.

Table V. Perceptions about generic substitution.

Survey question/ statement	Responses					Fisher exact test *p*-values		
	SA (*n*) (%)	AG (*n*) (%)	N (*n*) (%)	DS (*n*) (%)	SD (*n*) (%)	Gender	Graduate	University
I need more information on the issues pertaining to the safety and efficacy of generic medicines.	12 4.2	145 50.2	45 15.6	67 23.2	20 6.9	0.063	0.108	0.008
From the knowledge I have, I'm confident in substituting an innovator brand with a generic brand	59 20.4	194 67.1	24 8.3	10 3.5	2 0.7	0.047	0.160	0.037
I find it easier to recall a medicine's therapeutic class using generic names rather than brand names.	96 33.2	116 40.1	49 17.0	23 8.0	5 1.7	0.481	0.350	0.642
Pharmaceutical companies' product bonuses will influence my choice of alternative brands in the future	29 10.0	121 41.9	54 18.7	57 19.7	28 9.7	0.296	0.079	0.062
I believe advertisement by the drug companies will influence my future dispensing pattern	10 3.5	77 26.6	66 22.8	95 32.9	41 14.2	0.770	0.253	0.266
My pharmacy school education covers the topic of cost-effective use of medicines well	29 10.0	142 49.1	61 21.1	48 16.6	9 3.1	0.146	0.426	0.001
I have been taught how medicines are subsidized in the Pharmaceutical Benefits Scheme (PBS)	91 31.5	168 58.1	13 4.5	11 3.8	6 2.1	0.288	0.246	0.000
I thoroughly understand the PBS guidelines on brand substitution	65 22.5	157 54.3	31 10.7	35 12.1	1 0.3	0.355	0.269	0.000

Note: SA = strongly agree; A = agree; N = neutral; DS = disagree; and SD = strongly disagree.

At the time of the study, no students had graduated from graduate-entry pharmacy programs hence the small proportion of respondents with prior degrees. The proportion of male to female respondents reflects the gender balance of enrolments in pharmacy courses in Australian universities.

During the release time of the survey there was potential for external factors such as media reports or articles in the professional press to have affected the nature of responses. We were not aware, however, of anything-significant happening in the area during that time. In addition, there was nothing to prevent respondents consulting reference sources or other people (including other pre-registrants and pharmacists) when answering the survey and it is possible that they may have received information about generic medicines during the course of their pre-registration training programmes. In either of these events, our results could be considered conservative.

In response to the question about knowledge of bioequivalence limits for generic medicine approval by the TGA, only 11.4% ($n = 33$) of the pre-registrants provided the right answer. In Australia, a generic medicine is considered to be bioequivalent to an innovator product if the 90% confidence interval of the geometric mean ratio of area under the curve (AUC) and peak concentration (C_{max}) between the generic and the innovator falls within 80–125% (Birkett, 2003). Response to this question clearly shows that the majority of pharmacy pre-registrants did not understand the concept of bioequivalence determination for generic medicines. Although the pharmacy pre-registrants responded poorly to this question, the majority of them were aware that medicines rated as "generic equivalents" are equivalent to the innovator brand product, but not necessarily to each other. The majority of pre-registrants agreed that they had been introduced to the issues of bioequivalence during their pharmacy education. Although 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 a general tendency to be willing to accept more information when it is offered.

Some respondents commented that they would appreciate access to bioequivalence data. One explanation for this pattern of response may be lack of depth in explanation of the topic in current pharmacy curricula, as bioavailability and bioequivalence of medicines are often perceived as an esoteric and difficult area of applied pharmacokinetics (Pearce, McLachlan, & Ramzan, 2004).

Although the majority of pharmacy pre-registrants were clear about bioequivalence of generic and innovator brands and the requirements for the same doses and dosage forms, many of them believed that generic medicines are inferior in quality, less effective and produce more side effects compared to their branded counterparts. In Australia, companies which produce generic medicines, must adhere to the same quality standards and have the same tight manufacturing controls as companies making the original brand medicines (Birkett, 2003). 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 thought that brand name medicines are required to have higher safety standards than generic medicines may underlie their perceptions of inferior quality and efficacy. In Australia, both generics and innovator brand medicines must follow rigorous testing and safety standards before they can be marketed. The responses from the pre-registrants clearly show that they are unaware of the controls on the manufacture and marketing of medicines in Australia. The majority of pre-registrants were aware that generic medicines cost less than the innovator version.

Some key areas were identified that need to be considered when planning an education programme on generic medicines for pre-registrants. For example, more than half of the 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 knowledge, that the majority of respondents feel confident in substituting an innovator brand with a generic product. An explanation for this may be that they have been exposed to the practice of brand substitution in pharmacies where they are working or have undertaken experiential placement and accept it as the norm, despite their lack of understanding.

More than half of the respondents agreed that pharmaceutical company bonuses would be likely to influence their selection of medicine brands. This finding is consistent with a previous study conducted by Segal, Wantz and Brusadin (1989) which found that 35% of the pharmacists surveyed used product bonus as a measure to stock the appropriate brands of generic pharmaceuticals for maximising their pharmacy profits. Almost one third of the pre-registrants agreed that drug advertisements would be likely to influence their future dispensing habits. This finding shows that, like medical doctors, pharmacists are prone to drug advertisement and they need to be trained on how to evaluate drug information from promotional materials (Mansfield & Henry, 2004).

About 60% of respondents felt that the topic of cost-effective use of medicines was well covered during their pharmacy education. Given that pharmacoeconomics has been included as a standard subject in pharmacy education in many parts of the world (Gafa, Bilbija, Martinova, & Bates, 2002) and that acceptance of a medicine on the PBS requires pharmacoeconomic evaluation, this is a disappointing result, particularly when 90% respondents felt that they had been adequately taught about the process of medicine subsidy under the PBS. About three quarters of the pre-registrants indicated that they thoroughly understand the PBS guidelines on brand substitution, which may be from education that they have received from pharmacy schools, but is likely to be heavily influenced by their practice experience.

Conclusion

This first national survey on generic medicine and substitution suggests that pharmacy pre-registrants in Australia may lack in-depth understanding of the facts about generic medicines and may need 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 be addressed by the relevant stakeholders, such as government agencies, pharmacy educators and generic manufacturers, because pharmacists play an important role in optimising use of generic medicine through their interactions with both prescribers and consumers.

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