Generic Medicines: Perceptions of General Practitioners in Melbourne, Australia

Article *in* Journal of Generic Medicines · April 2006

DOI: 10.1057/palgrave.jgm.4940122 · Source: OAI

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Generic medicines: Perceptions of general practitioners in Melbourne, Australia

Received (in revised form): 10th December, 2005

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Abstract The aims of this study were to investigate factors affecting generic medicine prescribing among general practitioners (GPs) in Melbourne, Australia. A qualitative approach was used. A convenience sample of GPs practising in Melbourne was interviewed using a semi-structured interview guide. Thematic content analysis of the interviews identified seven major themes: medicine prescribing patterns, knowledge and confidence with generic medicines, patient acceptance of generic medicines, issues related to 'pseudo-generics' and medicine labelling, drug advertising and marketing, brand substitution by community pharmacists and, finally, strategies to increase generics prescribing. Informants suggested some methods that could be used to increase the current rate of generics prescribing, including financial reward for GPs, patient education on generic medicines, convincing GPs of the safety and efficacy of generic medicines and educating senior medical students on issues involving generic medicines and generics prescribing. This study suggested that GPs in Melbourne have mixed attitudes to generics prescribing. The findings also show that misconceptions about safety and efficacy of generic medicines still persist among some GPs. Unless they are sufficiently educated by interested parties, such as the government and the generic medicines industry, this will have a negative impact on utilisation of generic medicines in future.

Keywords: *generic medicines, perceptions, general practitioners*

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INTRODUCTION

Expenditure on prescription medicines in Australia continues to increase significantly.[1,2] A recent report of the Commonwealth Government Budget shows that the Pharmaceutical Benefits Scheme (PBS), which is a comprehensive system for subsidy of prescription

medicines covering the whole population, is currently the fastest growing area of health expenditure.[3] Expenditure for the year ended 30th June, 2004, totalled A$5.0bn, compared with a $4.5bn for the previous year — a 9.3 per cent increase.[3] In the last decade, PBS expenditure has experienced an estimated average annual growth rate of around 14 per cent.[4,5]

The growing expense of the PBS has pushed the government towards a more rigorous prescription policy.[6] Within this context, the Commonwealth Government has attempted to encourage the use of generic medicines as a cost-containment measure.[6] In Australia, generics accounted for about 20 per cent of all prescriptions filled in 2001. When compared with other countries, such as Germany, the Netherlands, Canada, the UK, the USA, Sweden and Denmark, however, this percentage is still relatively low.[7] Prescribing drugs by generic name and encouraging pharmacists to dispense prescriptions with generic medicines is one frequently suggested means for lowering the costs of healthcare.[8–10] Various articles have discussed the implications of generic substitution and other strategies to reduce pharmaceutical expenditure.[7,11–13] The concept of prescribing, dispensing and using generic medicines has been controversial, however.[10] Concern has been expressed both in Australia and elsewhere about the efficacy of generic medication.[14,15] This debate has centred on issues related to bioequivalence and potential confusion that might arise when changes of medicine brands occur in some patient populations.[6,11]

In Australia, little is known about general practitioners' (GPs') perceptions of generic medications and generic substitution. Therefore, the aim of this study was to investigate factors affecting generic medicine prescribing among GPs.

METHODS

Since little research has been carried out in Australia to identify GPs' perceptions of the use of generic medicines, qualitative methods were used to uncover themes.[16,17] The study took place in Melbourne in the state of Victoria, Australia, upon ethics approval by the Monash University's Standing Committee on Ethics in Research Involving Humans (SCERH). Using a semi-structured questionnaire, interviews were conducted with a convenience sample of GPs until saturation of themes was reached.[18,19] The semi-structured questionnaire was developed after reviewing the literature and consultation with selected representatives from the Division of General Practice, Melbourne Branch. The ten GPs were identified following an advertisement in the weekly newsletter of the Division of General Practice, Melbourne Branch. The interviews focused on the following issues: generic medicine prescribing trends, knowledge and confidence with generics and patients' acceptance of generics. Appropriate probing questions were used when necessary to get more in-depth views from the participants.[20] In addition, to draw out more complete ideas from the participants, they were given freedom to express additional views on the topic at the end of the interview session. All interviews were conducted at a place suitable for the informants, eight at the place of practice and two at the Department of Pharmacy Practice, Monash University.

The interviews took an average of 20–30 minutes and were conducted by a trained interviewer (MAH). Interviews were audio taped, transcribed verbatim and the transcripts supplemented with field notes taken during the interview and immediately after. Two of the authors (MAH and KS) listened to all tapes and MAH analysed the transcripts for relevant content and themes, using NVivo®

Table 1: General practitioners demographic characteristics

Descriptions	*n*
Age range	
30–40	2
41–50	6
51–60	2
Gender	
Male	7
Female	3
Place of graduation	
Australian university	8
New Zealand university	2
Number of prescriptions written per day	
10–20	6
More than 20	4
Number of years practising in Australia	
Under 15 years	5
More than 15 years	5

software for qualitative data management (QSR International Pty Ltd. Melbourne, Australia). The thematic framework comprised dominant themes that were refined as associations were made in attempt to provide explanations for the findings.[21,22]

RESULTS

Ten GPs practising in various group practices were interviewed after providing informed consent. Four were practising in the inner city and the other six in suburban areas. Five GPs held fellowships of the Royal Australian College of General Practice. Demographic characteristics are summarised in Table 1.

Seven major themes were identified.

Theme 1: Medicine prescribing patterns

Informants were asked about the factors they take into consideration when prescribing a medicine to their patients. The major factors identified were safety profile of the medicine, cost and patient compliance:

> Well, cost would be a factor, whether it's on the PBS is a factor, how often it needs to be taken, interaction with the other drugs that somebody is already on and, really, whether a patient is willing to take it according to the instructions. (GP02)

There were mixed reactions among informants when asked whether they actively prescribe generic medicines. Some were opposed to generic prescribing, whereas others were more open to the concept.

Reasons for opposing generics

Some GPs believed that generic medicines are not equivalent to the innovator brand and this discouraged them from prescribing generic medicines.

> I don't prescribe generic medicines because I don't believe that they're all equivalent and I think it is a lie that they're all equivalent. (GP04)

> I don't have confidence with generics because, although they are regarded as being identical, we know that the Government allows a certain percentage above or below strength and it is still classified the same when in fact it's not the same. And I think that I'm also right in saying that there is little or no control with the excipients, which can drastically affect bioavailability and the absorption curve and the side effect profile. (GP05)

Support for research-based companies that are actively involved in discovery of new drugs was seen by some GPs as a reason for opposing generic medicines.

> I am anti generic medicines since the generic companies do not put in any research and development and that is the attitude of them and as such I think, I am ashamed that all doctors don't get

> rid of them and not prescribe them. (GP06)

Concerns were raised by some of the GPs with regard to the government move to encourage generics prescribing among Australian GPs:

> I'm very reluctant for the Government to be telling me as a practitioner what to do. I mean, I'm supposed to be an educated professional person who has done suitable training. I have on-going education and then to actually be told what I should and should not do, I feel that that is a little overstepping the mark. (GP03)

> As a doctor I work in the best interests of my patients. If my prescribing pattern is going to be changed by another person then I certainly cannot take the responsibility for the patient. (GP05)

Informants were also concerned about the drug choices made by their prescribing software:

> I think I need more training with my prescribing software before I know how to default my prescribing to generic medicines. Right now it seems quicker to refer to book rather than navigating the software. (GP02)

Some informants indicated that patients may become confused by different brands of the same medicine:

> The main disadvantages are that people don't necessarily recognise what drug they're on because usually people have been prescribed a drug by trade name and if we use generic names, sometimes they can be a bit confused. Besides that, there are too many branded generics in the market which is complicating things for us and patients. (GP02)

> I'm practising in a fairly multicultural area. There is one incident where I can recall an older Lebanese man who had been given, I think it was hypertensive medication, a different named one. Stopped taking it and got confused; came back in; had his old ones in a packet. (GP09)

The failure of patients with low income to prioritise their health needs was seen as a barrier to prescribing generically by some GPs.

> These people in low social economical groups, number one, I would be interested to know first of all how many cigarettes packets they smoke per week, how much do they drink per week and how much do they spend on Lotto tickets and when their last holiday was to Bali. And if the answers to all of those is they can't afford any of those, I would then certainly consider generic and, in fact, be happy to give them samples and help in any other way I can. But unfortunately, a lot of people are not prepared to pay for pharmaceuticals, which were considered free, but will still actually smoke, you know, one or two packet of cigarettes a day, drink alcohol, spend A$70 for a haircut every fortnight. I think it's a bit unfair. (GP03)

Reasons for supporting generic prescribing

Cost to patients was seen as advantageous in prescribing a generic medicine:

> I prescribe it more routinely to healthcare card holders and pensioners because they feel that a couple of dollars difference does make a difference to them. And there are some medicines, particularly older ones, I think all the brands are equally effective. (GP02)

Increases in pharmaceutical expenditure over recent years had prompted some doctors to prescribe less expensive generic medicines as a method of cost reduction within the healthcare system.

> There is an obligation on the government to minimise the expense. So I'm in favour of that policy; it's a good policy. (GP07)

> There is a lower price option to the consumer but I'm more interested in keeping the country's drug bill low. (GP10)

Prescribing generically was suggested as a way to overcome the complexity of the brand names available in the market:

> Generic prescribing might be better because it will actually make it clearer about what we are prescribing. I think sometimes doctors might not be aware that, you know, three or four drugs of different brand names, they will be the same drug. (GP02)

Theme 2: Knowledge and confidence with generics

Informants were questioned about the bioequivalence criteria required by the Australian drug regulatory body, the Therapeutic Goods Administration (TGA), for generic medicines and appeared to be poorly informed on this topic.

> No, I don't have a clue. (GP01)

> Differences between? No, I don't prescribe them so I've never tried to find that out, no interest. (GP06)

Despite their lack of detailed knowledge, the informants expressed strong confidence in the TGA:

> I'm really confident with all the drugs registered by TGA. (GP01)

Theme 3: Patient acceptance of generic medicines

Most of the informants who supported generic medicines felt that their patients were willing to use generic medicines due to cost reasons.

> Very good, a lot of people are very actively asking, 'Is there a cheaper version?' If the pharmacy offers them a cheaper version, 'Can I take it?' I think acceptance is very high. (GP07)

> Well, it depends on the patient's background. Some of them who are well off prefer to be prescribed branded products, whereas those who are from low socio-economic background, they prefer to go for generics. (GP09)

Theme 4: Pseudo-generics and medicine labelling

Informants expressed concerns about the tactics of innovator drug companies venturing into the generic drug market upon patent expiration. These medicines are physically identical to brand name medicines and manufactured on the same production lines; however, they are sold under a different trade name and priced to compete in the generics market.

> You can't challenge a company wanting to make the most money they can, what you can challenge is how stupid we are as a profession that we are prepared to be conned by it. For that reason it would be helpful to educate patients to say look your product is produced by the brand company, who labels one box one way and another box another way and charges twice as much for the brand. (GP01)

Some informants were concerned about inadequacies in the medicine labelling in Australia.

> I would like the drug name to be perhaps a little bit more evident and also I like that fact that, the pharmacist sticker shouldn't cover up what it is that the drug is, frequently when you look on a bottle of medication the information from the pharmacist has obscured the actual bottle and it's very hard often to work out what it is and if the typing was wrong, if the pharmacist had made an error there is no way of checking it. So yeah I think it could be improved. (GP01)

> I think labelling must change for brand substitution to work. To be more clear what the generic drug is and also some restriction on how many times a drug can be substituted. (GP09)

Theme 5: Effect of drug advertising and marketing on brand medicine choices

GPs interviewed agreed that drug advertising and marketing can influence the choice of medicine brands that they will prescribe.

> The industry tries very hard to make us use their products. All our pens have brand names on them, and also the name is often easier, it does become easier just to use the brand name that you've been exposed to. (GP07)

> Even though we don't have drug representatives at the practice, if you go to talks, there are always drug representatives from different companies; again you get exposed to their products and sometimes you just recall their product and prescribe it. (GP09)

Theme 6: Brand substitution by community pharmacists

Some informants described their dissatisfaction with the move allowing community pharmacists to substitute drugs that they had prescribed.

> I just at this point in time don't have a good understanding of what there is to keep pharmacists honest, in as much as I'm not sure, I don't like the idea of the pharmacist potentially brand substituting because it is financially suiting them versus suiting the community as a whole, which makes me a little bit concerned I guess. The ability of pharmacists to be bought out by the drug companies just like doctors are. (GP01)

> Because I feel that it is an attempt to disempower doctors. It is an attempt to say, alright you've written brand A, you've gone to the trouble of specifying brand A, the government doesn't know what my reason is, it might be blind following of a particular brand name or it might just be for a good reason. They don't know my motives but it's like they are discounting my motives as if I wouldn't know and I can prescribe brand names and the chemist will dispense brand B or C and that's awful. I find that very devaluing of me as a professional. (GP05)

On the other hand, support was expressed for the move:

> My opinion is that it's fine for a pharmacist to do that, it's fine for the government to want to spend fewer of the tax payer's dollars possible to achieve the desired affect. (GP07)

> Oh yes, they are well trained in drugs. (GP08)

Theme 7: Strategies to improve generics prescribing

GPs who were supportive of the move volunteered suggestions as to how to improve the rate of generics prescribing.

Financial reward for GPs

> I think it's a really hit and miss approach and having come from the UK we were financially rewarded, because we held our own budgets for our drug costs, we were financially rewarded. Well, not rewarded, we didn't get any money in our pockets but we had more money to spend on our patients, if we were cost effective prescribers. I felt that that was a really positive thing whereas here there is nothing like that. (GP01)

Patient education

> I think we need more patient education by the government regarding the use of generic medicines. (GP02)

Information for prescribers

> To encourage us that we can confidently prescribe a generic brand of medication and not fear that that's sort of inferior. The more information that shows generic doxycycline equivalent to the brand name item the better. (GP07)

Medical student education

> I would have thought that the government could focus very much on medical students about the importance of generic prescribing. (GP01)

> I personally believe that undergraduate medical education, especially towards the senior medical students, will be helpful because sometimes it is hard to change the existing prescribing behaviour. You have to deal with it at the early levels. Certainly it is an area that needs to be covered and have a little bit more understanding of getting out of the other side of prescribing. (GP07)

DISCUSSION

Prescribing medications to patients is one of the core activities of GPs. In Australia, the Bettering the Evaluation and Care of Health (BEACH) data from 2002 to 2003 showed that at least one medication is prescribed in about 55 per cent of GP encounters, and the overall rate was 104 per 100 encounters.[23] Generics prescribing is recognised as good prescribing practice and encouraged from an educational and cost-effectiveness point of view.[8,10] GPs in Australia are currently under increasing pressure to review prescribing habits as drug expenditure continues to rise.[6] This exploratory study provides some insights into the perceptions held by GPs when it comes to the use and prescribing of generics. From the interviews, GPs appeared to be either 'pro-generics' or 'anti-generics'.

The three main reasons given by those who opposed generics included patient confusion due to the use of different generic products from different manufacturers, concerns over the bio-inequivalence of generic medicines and the risk of less money for research-based companies to discover new drugs. These reasons are similar to those from two previous limited Australian studies that focused on GPs' and pharmacists' opinions on generic substitution.[12,24] None of the GPs interviewed in this study knew the bioequivalence acceptability criteria for generic medicines as set by the TGA. The current TGA criteria for assessing bioequivalence for generic products are based on single dose *in vivo* studies in healthy volunteers. Bioequivalence is

established based on assessments of the rate of absorption involving peak plasma concentration (C_{max}) and area under the plasma concentration–time curve (AUC).[25] The TGA's criteria are designed to achieve 90 per cent confidence that the ratios of the test product to that of a reference product under log-transformed mean values for AUC and C_{max} fall within the interval from 80 to 125 per cent.[25] This lack of knowledge could have a negative impact on the future of generics prescribing. Product quality data are also required before a generic product can be registered or listed on the Pharmaceutical Benefits Scheme (PBS).[25]

On the labelling of generics, concerns were raised about deficiencies in the current labelling requirements by the drug regulatory bodies and their impact on patient safety. The GPs' comments may also partly be a reflection of patients' general lack of familiarity with generic medicines and Australians' greater tendency to identify medicines by their makers' brand names.[14] There is a good case for Australia to adopt stricter labelling requirements, similar to those in Britain and the Philippines, which require a medicine to be labelled first by its scientific or generic name in order to avoid confusion among patients.[26,27]

Access to medication by patients was a major concern among those who supported generics. Based on the demographics of their practice setting, some of the GPs recognised that patients may not have their prescription filled if they were prescribed expensive branded medicines. Therefore, to improve access to medication, prescribing cheaper generic medicines became their preferred option. With regards to the availability of pseudo-generics, GPs felt that it was unfair for patients to pay different amounts for the same medicine manufactured by the same company with a different brand name. Currently, there has been a proliferation of pseudo-generics in the Australian market, most of which are available through the PBS.[25,28] To overcome this problem, it was suggested that patients should be told about the existence of pseudo-generics so that they are aware of the profit-making tactics employed by these types of manufacturers.

On the issue of prescribing software, some informants were unhappy with drug companies advertising their medicines via the prescribing software. They also highlighted the difficulties in prescribing generically with their current prescribing software. The uptake of computers by Australian GPs was stimulated by the Australian Government in 1999.[29] A one-off grant of around A$10,000 was offered to those practices that purchased a computer, acquired internet connectivity (an e-mail address) and promised to use computer prescribing software to write the majority of their prescriptions.[29] This increased the numbers of GPs writing prescriptions with the aid of a computer from around 50 per cent in 1999 to more than 90 per cent in 2004.[29] Legible, printed prescriptions have been one of a number of positive outcomes of this initiative; however, new problems emerged. One software vendor (Health Communication Network Ltd) became the dominant market leader because its business model relied on pharmaceutical promotion to heavily subsidise the cost of GPs purchasing and updating its prescribing software (Medical Director™).[29] This business model facilitated software uptake but also resulted in advertisements for the latest and most expensive drugs appearing on the computer screen at the time of prescribing (and elsewhere).[30,31] GPs using this software package were shown to prescribe more antibiotics per patient than those who wrote prescriptions manually. It was suggested that this may have been due to default settings in the software

automatically writing in the maximum number of repeat prescriptions allowed.[32] Another default option in this software was the automatic production of a 'Do not substitute generic drugs' message on the prescription. To overcome this problem, from February 2003, the Federal Government required all prescribing software to default to generic medicines, since the existing software — which is sponsored by the manufacturers of brand name medicines — automatically ticks the 'not for substitution' box.[33] Doctors will be able to select brand name drugs, but they will have to reset the default.

Informants' opinions of the influences of drug advertising were also explored. The importance of education for medical practitioners in how to deal ethically with information received from medical representatives was highlighted. This type of education is important because relationships involving medical practitioners and the pharmaceutical industry raise serious concerns and controversy within both the medical profession and the broader community.[34] Furthermore, most information coming from the companies is for new and usually more expensive medicines, which could contribute to financial pressure on the PBS if prescribed in higher volumes without significant judgments.[35] The potential for bias as a result of sponsorship of meetings by drug companies was also raised. There are clearly common interests between professional societies, which are usually responsible for organising conferences, and the pharmaceutical industry; the former stand to gain substantial funding from the pharmaceutical industry for their meetings and other activities, while, for the latter, targeted opportunities are provided to showcase their products.[34,36] The use of incentives — such as promotional gifts, by pharmaceutical companies to influence GPs' prescribing patterns — was also discussed during the interviews. From the GPs' feedback it appears that small gifts, such as pens and notebooks, with a pharmaceutical company logo and their medicine brand prominently written on it, can influence their prescribing patterns. This is due to the fact that it is easy for them to remember the names of the medicines from the gifts they see or use on a daily basis.

Dissatisfaction with the government policy that allows community pharmacists to perform brand substitution was raised by some informants, on the basis that their professional role as a prescriber is being threatened by the actions of the pharmacist. They were also concerned about the incentives that pharmacists might receive from the generics companies to supply their products. Furthermore, they criticised the current policy because there is no restriction on how many times pharmacists can change patients' medication brands, which, in the long term could increase the possibility of patient confusion. The same issues had been highlighted by GPs in a previous study conducted in the early phase of the implementation of brand substitution policy in Australia.[12]

Those GPs who were comfortable with generics prescribing made some recommendations on how to improve the current rate of generics prescribing, including giving financial incentives to those GPs who prescribe generically. The use of financial incentives was implemented in countries such as the UK and Ireland in the early 1990s, where GPs were set annual prescribing budgets and allowed to keep a proportion of any underspending for future health planning within the practice.[37] Evidence from the UK suggested GP fundholding led to an increase in generics prescribing.[38,39] A study by Bateman *et al*. focusing on the effect of using financial incentives to change generics prescribing behaviour of non–fundholding GPs, found that the

incentives increased generics prescribing and resulted in the achievement of target savings.[40]

Patient education on the use of generics by GPs was also seen as a method of improving the utilisation of generic medicines. An Australian study by Newby *et al.*, looking at drug information seeking behaviour among consumers, revealed that medical practitioners were more frequently the main source of prescription medication information than pharmacists.[41] Therefore GPs are in the best position to educate patients about the availability of generic medicines. One of the informants felt that there is a need for more information pertaining to the quality and efficacy of generic medicines to be relayed to GPs. This information is vital to make them confident in prescribing generic medicines. A study by McGettigan *et al.*, focusing on the level of generics prescribing among Irish GPs, identified a low level of generics prescribing in Ireland compared with England, owing to the concerns of Irish GPs about the reliability and quality of generic products.[42] In the USA, to overcome GPs' ambivalence when it comes to generic prescribing, information pertaining to issues of quality, safety and efficacy was relayed to them via the federal drug regulatory body, the Food and Drug Administration (FDA).[43,44] It was suggested in the interviews that education of senior medical students on generics prescribing issues would help to increase generic medicine use and prescribing in the future. Experience from the UK suggests that teaching medical students to prescribe medicines using the international non-proprietary name (INN) has boosted the use of unbranded generics.[45] Educational intervention strategies aimed at medical students is important because studies have shown that to change existing prescribing behaviour among practising GPs would be difficult and needs more rigorous interventions.[46,47]

STUDY LIMITATIONS

An often cited limitation of qualitative research is the inability to generalise to a larger population.[48] This study was conducted only with GPs in Melbourne and thus the findings cannot be confidently generalised to Australian GPs practising in other states. The opinions gathered from all the interviews conducted in the present study will be useful for a large follow-up quantitative survey among the GPs, however, since the prescribing process for medications under the PBS system are uniform across Australia.

CONCLUSION

Prescribing generic medicines involves complex decision-making processes that require a number of personal and professional judgments to be made about physical, psychosocial and economic dimensions of health. Perceptions of the GPs in this qualitative study show that they are interested in economic prescribing but are not being educated and reassured about generic medicines by the interested parties. Accordingly, lack of knowledge still persists about the safety and efficacy of generic medicines. These are issues which must be tackled if the current level of generics prescribing in Australia is to increase.

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