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REVIEW ARTICLE

A review of patient perspectives on generics substitution: what are the challenges for optimal drug use

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Introduction: With a few exceptions, generic drug use has been promoted in western countries by allowing pharmacists to substitute drugs defined as therapeutically equivalent generics. The aim of this literature review is to summarise the research on the patients' perspectives of generics substitution in the western world between 2000 and 2011 with special emphasis on the challenges these attitudes present for optimal drug use.
Methods: A literature search was undertaken in MEDLINE (PubMed), Embase (Ovid), and SciVerse Scopus with the aim of identifying all the peer reviewed, original research articles concerning patient perspectives on generics substitution in western countries published between 1 January 2000 and 1 March 2011.
Results: The 20 studies included in this review indicate that close to one-third of all patients were uneasy about having their drug(s) substituted generically. Between 8–34% of patients reported poorer effects and/or new side effects after a change—except for antiepileptic drug users from which the number of reports was even higher. Poor awareness of generics substitution caused confusion and reduced the patients' willingness and ability to take their medication as prescribed. Patients' acceptance of generics substitution was influenced by age, educational levels, perceptions about disease, generic drug information, and who informed them about the change. The studies consistently suggested a continuing need for information directed at patients and an increased involvement of physicians.
Conclusion: This literature review suggests that although generics substitution is well accepted by the majority of patients, about one-third of the patients report negative experiences which may lead to poor adherence and medication errors.

Keywords: Cost containment, generic drugs, generics prescribing, generics substitution, patient perspectives

Introduction

With a few exceptions, e.g. Ireland and the UK, generic drug use has been promoted in western countries by allowing pharmacists to substitute drugs defined as therapeutically equivalent generics. Although this enables cost savings, which can slow growing pharmaceutical budgets, concerns have been raised regarding the possibility of such substitution leading to a higher overall healthcare expenditure [1]. The core of these concerns is that problems may arise when a brand-name drug, with which the patient is familiar, is replaced by a product with a different name and with other physical attributes, e.g. shape, size, and colour. This well-intentioned cost-containment strategy might contribute to suboptimal drug use and thereby increase morbidity and overall costs in a wider perspective depending on the extent that this strategy interferes with patients' prescription drug-taking behaviour. Currently, patients with chronic medical conditions are increasingly affected by substitution reforms because they consume more drugs over a longer period of time and the generics interchangeable markets are expanding in response to policy changes and expiration of patents.

Since the first studies of generic drug use were published in the 1970s [2, 3], the emphasis on consumer/patient perspectives has increased due to the need to explore the underlying causes for the patients' decision-making processes. In 2001, Gaither et al. published a literature review of consumers' knowledge, attitudes, and opinions about the use of generic drugs [4]. The authors summarised the results of studies, which were all American and conducted in the last century, and reported that consumers, in general, were positively inclined to generic drugs, although their views differed according to socio-demographic factors and the extent of knowledge and past experiences with drug therapy. In the conclusion, the need for more research on consumers' behaviours regarding generic drug use was emphasised [4]. Following the implementation of generics substitution in more and more countries during the last decade, it seems opportune to gather the recent evidence.

The aim of this literature review is to summarise the results of studies on the patients' perspectives of generics substitution in the western world between 2000 and 2011, with special emphasis on challenges for optimal drug use.

Methods

A literature search was undertaken in MEDLINE (PubMed), Embase (Ovid), and SciVerse Scopus with the purpose of identifying all peer reviewed, original research articles published in English on patients' perspectives of generics substitution conducted in western countries. Search terms included: 'generics substitution', 'generics prescribing', 'generic drugs', and 'generic medicines'. All articles were selected for further analysis based on title and abstract. The search was supplemented by a manual review of the reference lists of identified articles.

The time period for publication was limited to 1 January 2000 and 1 March 2011. As the review focused on the patients' perspectives

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Table 1: Articles included in the literature review

Author (Year) (n = 20)	Country	Method	Number of participants	Drug class(es)	References
Babar et al. (2010)	New Zealand	Survey with self-administered questionnaire	441 (RR: 76%)	(no particular)	[11]
Berg et al. (2008)	USA	Online survey	550 (RR: 31%)	Anti-epileptics	[14]
Bulsara et al. (2010)	Australia	Mixed (forums, focus groups, panel)	107 (*)	(no particular)	[21]
Gill et al. (2010)	Australia, Finland, Italy	Personal interviews (qualitative)	30 (*)	(no particular)	[20]
Guberman and Corman (2000)	Canada	Survey with self-administered questionnaire (pilot)	83 (*)	Anti-epileptics	[12]
Haskins et al. (2005)	Canada, France, Germany, Spain, UK	Telephone survey	974 (*)	Anti-epileptics	[13]
Hassali et al. (2005)	Australia	Personal interviews (qualitative)	16 (*)	(no particular)	[19]
Heikkilä et al. (2007)	Finland	Survey with self-administered questionnaire	758 (RR: 44/47%)	(no particular)	[6]
Heikkilä et al. (2011)	Finland	Survey with self-administered questionnaire	1,844 (RR: 62%)	(no particular)	[7]
Himmel et al. (2005)	Germany	Survey with self-administered questionnaire	804 (RR: 63%)	(no particular)	[5]
Håkonsen et al. (2009)	Norway	Personal interviews (quantitative)	174 (RR: 65%)	Antihypertensives	[16]
Håkonsen and Toverud (2011)	Norway	Personal interviews (quantitative)	83 (RR: 69%)	Antihypertensives Antidiabetics Cholesterol-lowering drugs	[17]
Kjønniksen et al. (2006)	Norway	Survey with self-administered questionnaire	281 (RR: 73%)	(no particular)	[8]
Palagyi and Lassanova (2008)	Slovakia	Survey with self-administered questionnaire	1,777 (RR: 89%)	(no particular)	[9]
Papsdorf et al. (2009)	USA	Survey with self-administered questionnaire	179 (RR: 50%)	Anti-epileptics	[15]
Roman (2009)	The Netherlands	Personal interviews (quantitative)	106 (*)	Antipsychotics	[22]
Shrank et al. (2009)	USA	Survey with self-administered questionnaire linked to administrative data	1,047 (RR: 48%)	(no particular)	[10]
Shrank et al. (2009)	USA	Survey with self-administered questionnaire linked to administrative data	1,047 (RR: 48%)	(no particular)	[24]
Toverud et al. (2011)	Norway	Focus groups	22 (*)	Antihypertensives	[18]
Vallès et al. (2003)	Spain	Personal interviews (quantitative)	4,620 (RR: -/100%)	(prescription drugs for chronic conditions)	[23]

RR: response rate; *response rate inapplicable/unavailable.

of generics *substitution*, register-based studies, and studies which investigated patient perspectives on generic drug use in general and did not include aspects of substitution, were excluded.

Twenty original research articles were included. A data extraction form was developed to systematically extract relevant data from the included articles. Table 1 provides an overview of the included articles listed according to authorship and year of publication, country where the study was undertaken, research method, number of participants (response rates if applicable), and drug class(es). The results were structured thematically and reported in the main text.

The first author of this paper conducted the search, reviewed the articles, and extracted the data; the second author reviewed the interpretation and presentation of the data. Disagreements were resolved by an additional review of the article(s) in question, followed by a discussion.

Results

Patients' attitudes towards and experiences with generics substitution

In Himmel et al. (2005) primary care patients in Germany were surveyed about their thoughts on generic drug use. One-third of the participants considered inexpensive generics to be inferior to, or different from, more expensive brand-name drugs because of their lower price. This view was more frequently expressed by patients who were more than 60 years of age, chronically ill, and/or without higher education. Of those who knew that their drugs had been switched (30% of the total sample), more than half said they were sceptical about the substitution. Twelve per cent reported a lower effect of the drug after the change, and 13% claimed that they had experienced new side effects [5].

Heikkilä et al. surveyed Finns on two occasions. In the first study, two groups were recruited: customers who had accepted (28% of the total sample), and customers who had refused (72% of the total sample), generics substitution. Of these, 83% and 66%, respectively, reported that they were satisfied with the substitution reform which took effect in 2003. The main reason for accepting substitution was a desire to save money and, secondly, that the pharmacists recommended it. Positive experiences with drugs used previously and a wish to talk with their physician before substituting were the most cited reasons for refusing substitution [6]. In the second study, 81% of the participants were of the opinion that cheaper generics were effective, and 85% did not consider generics substitution as a threat to drug safety [7]. In both of these Finnish studies, men and patients up to 60 years of age were identified as those most likely to feel positively towards generics substitution [6, 7].

In a Norwegian survey by Kjønniksen et al. (2006), one-third of the participants reported one or more negative experience with generics substitution, e.g. more side effects or a poorer effect, and 21% reported an overall negative experience with the change. The negative experiences were not associated with gender, age, or number of drugs. Forty-one per cent claimed they would only allow substitution if they achieved financial savings [8].

Palagyi and Lassanova (2008) investigated patients' attitudes towards, and experiences with, generic drugs in Slovakia. Overall, 61% of the participants (predominantly those aged 30 years or younger) did not have any issues with trust regarding generic drugs and more than 50% indicated a preference for a product with a lower co-payment. Seventeen per cent considered generics inferior to brand-name drugs in terms of quality, and 18% preferred being prescribed brand-name drugs despite a higher co-payment [9].

In an American survey, Shrank et al. (2009) reported that one-third of patients were uncomfortable with substitution to some extent. About 10% believed that generic drugs could cause more side effects than brand-name drugs. The participants revealed self-contradictory opinions about generic drugs as more than half reported that Americans should use more generics but only 38% said they would prefer generics for themselves. Female, young, and wealthier patients were the most positive. Beliefs about the use of generic drugs were investigated for the treatment of an acute symptomatic condition compared to a chronic asymptomatic condition and no significant differences were found between the two [10].

In a study from New Zealand, Babar et al. (2010) differentiated between 'minor' (such as cold, flu, or hay fever) and 'major' (such as asthma, diabetes, or heart problems) illnesses and reported that participants claimed to be more prepared to change to generic drugs for the former than for the latter (78% vs 59%). Moreover, a change was more likely to be accepted if the patient was young, educated, had sufficient knowledge about generic drugs, and/or had previous experience with generics substitution [11].

The case of generics substitution of anti-epileptic drugs

Anti-epileptic drugs (AEDs) in particular have been the cause for concern regarding the safety of generics substitution. In a Canadian survey of epileptic patients by Guberman and Corman (2000), the participants had relatively positive attitudes towards generic drugs with regard to effects and safety, although they were not fully informed about whether or not their medication had been changed. Among those who thought that their medication might have been changed, 14% reported that they had experienced a problem [12].

A larger study including several countries was conducted by Haskins et al. (2005). In this study, two-thirds of participants reported concerns about the safety and the effectiveness of generic AEDs, 58% felt uncomfortable receiving a generic drug, and 23% believed that substitution was linked to breakthrough seizures [13].

Even more concern was reported by Berg et al. (2008) where 70% of the patients thought that substitution with a generic AED could have negative treatment outcome consequences, and 34% believed that generics substitution was a reason for breakthrough seizures. Four out of five patients thought pharmacists should not be allowed to generically substitute AEDs without physician consent [14].

In a study by Papsdorf et al. (2009), 80% of the epileptic patients knew that generic versions of certain AEDs are available; 57% had taken a generics version and, among these, 28% reported breakthrough seizures which they believed were a direct consequence of the change. In addition, 34% reported experiencing side effects they believed were related to the switch [15].

The risk of non-adherence and medication errors and the significance of information

Håkonsen et al. (2009) and Håkonsen and Toverud (2011) conducted semi-structured personal interviews in two populations of chronic patients in Norway: (study I) patients from the general Norwegian population [16] and (study II) patients with a Pakistani background [17]. Twenty-nine per cent (study I) and 41% (study II) of the patients reported concerns after receiving the generically substituted drug(s). Eight per cent (study I) and 16% (study II) reported that the effects of the new drug(s) were inferior. Similar findings of new, or more severe, side effects were reported by 15% and 20%, respectively. In both groups, negative attitudes towards generics substitution were significantly associated with low educational levels and lack of information. In the Pakistani population, one in four patients thought that the generics were counterfeit drugs. Generics substitution was stated as an important reason for intentional non-adherence (especially in study II). Also, 33% and 26%, respectively, reported that it was more demanding to keep track of their medication after substitution; this resulted in erroneous drug use (simultaneous use of more than one therapeutically equivalent generics, e.g. one brand-

name and one generic drug with the same active ingredient) by 5% of the participants in study I and 10% in study II. These findings were made possible because the participants showed the interviewer the drugs they were currently using [16, 17].

Confusion and discontent due to differences in drug name and physical attributes were also detected in a focus group study by Toverud et al. (2011). Although the patients usually accepted substitution by the pharmacy, they considered the inexpensive generics to be of poorer quality than the brand-name products. The following quote illustrates the patients' concerns: 'You believe in your doctor, so when you come to the pharmacy and they give you something else than what the doctor has prescribed, you feel insecure. You sit at home and think that the new tablets don't work as the old ones, because if it is the same thing, why did not the doctor prescribe it?' [18].

Qualitative studies from other countries show similar results. In semi-structured personal interviews conducted by Hassali et al. (2005), Australian consumers reported that, in addition to the cost of medicines, a recommendation from their physician or pharmacist was decisive for their acceptance of generic drugs. The major barriers to acceptance were confusion, influence from physicians, and perceived side effects of generics. The consumers also emphasised the need for direct educational intervention by health professionals and government bodies [19].

Gill et al. (2010) conducted unstructured personal interviews with customers from Australia, Finland, and Italy. The main, recurrent theme in these interviews was 'confusion related to why they were being offered something that was different to what their doctor had prescribed'. Confusion and suspicion were associated with poor awareness of generic drugs by the participants when asked whether they were willing to accept substitution by the pharmacy personnel. The participants said that although they had agreed to substitution in the pharmacy, they would check the appropriateness of the intervention with their physician [20].

In a mixed-method study among Australian seniors by Bulsara et al. (2010), generics substitution was identified as a major issue underlying problems of drug non-adherence and erroneous drug use. Reluctance to use generics was explained by a lack of knowledge, changes in packaging, disbelief in the equivalence of generics alternatives, and mistrust in the (foreign) pharmaceutical industry and their relationship with health professionals. The participants thought that physicians should discuss generics substitution more actively with their patients as this would affect their decision to accept the change [21].

Roman (2009) hypothesised that differences in name, appearance, and packaging between brand-name and non-branded drugs would cause anxiety, confusion, and misperceptions in Dutch patients with psychoses/schizophrenia. Among the 87% of such patients who were unwilling to change their medication to a generic drug, one-half attributed this decision to different packaging while 28% said that they did not have any faith in the effect of the generics since it was not prescribed by their psychiatrist [22].

Two studies explored the effects of providing information to patients. Vallès et al. (2003) conducted a Spanish multicentre study on the effect of patient education on acceptability of generics in general practice. The patient education consisted of a session of up to five minutes and included verbal information and providing handout materials on the advantages and disadvantages of generics equivalents and brand-name drugs. The study reported that 99% of participants accepted generics substitution after this intervention, but substitution was less well accepted for drugs acting on the central nervous system [23]. Similarly, Shrank et al. (2009) found that American patients who reported that they communicated with their physician and pharmacist about generics substitution, and felt comfortable doing that, were more likely to use generic drugs than patients who did not [24].

Discussion

Firstly, the main focus of the 20 studies included in this literature review was on the patients' attitudes towards generics substitution. The studies highlighted negative attitudes in a sizeable minority of the patients—often close to one-third of study participants. Several explanations for the patients' scepticism were given. First of all, the patients sometimes believed that lower prices meant poorer quality. In fact, the percentages of patients who reported changes in effects/side effects were in the range of 8–34% (except AEDs for which the number of reports was even higher). At the same time, prospects of personal economic savings were identified in some studies as a decisive factor in the patients' acceptance of generics substitution.

Secondly, changes in physical attributes added to their uncertainty. In the case of chronic drug treatment, patients tend to know their drugs by appearance and it may be more demanding to keep track of their medications. There may also be other practical challenges such as handling different medication containers [17]. Moreover, the studies suggested that patients generally preferred the drugs prescribed by their physician. It was commonly reported that patients called for increased involvement of their physicians and requested information from their physician to support the information they received in the pharmacies. The findings of this review support hypotheses proposed elsewhere: i.e. if physicians were to prescribe by the medication's generic name, it might be possible to reduce patient insecurity [25].

In the review by Gaither et al. (2001) peoples' opinions of generic drugs varied according to socio-demographic variables such as ethnicity, educational level, income, and age [9]. The influence of these factors was also identified in this current review. Patients of younger age and/or with higher educational levels were consistently more likely to hold positive attitudes towards generics substitution, while the effects of income and gender were inconsistent. One study explored the influence of being an immigrant from a developing country. The results of that particular study suggested that generics substitution may even be more challenging for patients who may experience language problems and who may also have had previous negative experiences with counterfeit drugs and other issues with respect to pharmaceutical quality [17].

In studies on lay persons' opinions of generic drugs, people tended to report being more uneasy about generics substitution of drugs used for more serious conditions [4, 26-27]. Ganther and Kreling (2000) reported that, as the perceived risk of a condition increased, the higher the cost savings needed to be in order for

the patients to accept a generic drug [27]. This current review suggests that the data we currently have on patients' views on the relevance of medical conditions are inconclusive, with the exception of epilepsy and psychiatric diseases.

The likelihood that treatment outcome may vary with the stated monetary value of the drug therapy has been found to be significant in a randomised, controlled trial by Waber et al. [28]. Research has also indicated that tablet appearance seems to influence the effectiveness of drugs [29]. As mentioned above, confusion and misunderstanding that substitution may cause are further exacerbated by changes in physical attributes and name. As this review suggests, generics substitution may reduce the patients' ability to take drugs appropriately, e.g. the patients may erroneously take more than one therapeutically equivalent generics at the same time. It was also reported that negative attitudes towards and experiences with generics substitution were associated with intentional non-adherence. In this regard, the studies in the current review are important complements to the register-based studies performed by van Wijk et al. (2006), Chapman et al. (2009), and Briesacher et al. (2009) which, on the whole, did not find any evidence that adherence was negatively affected by generics substitution and rather tended to point in the opposite direction [30-32].

Conclusion

This literature review suggests that although generics substitution is well accepted by a majority of patients, about one-third report negative experiences which may lead to poor adherence and medication errors. Patients' acceptance of generics substitution is influenced by age, educational levels, perceptions of disease, generic drug information, and who informed them about the change. Furthermore, poor awareness of generics substitution is associated with confusion which reduces the patients' ability to take their medication as prescribed. The studies reviewed consistently suggest a continuing need for patient information and an increased involvement of physicians.

For patients

In many countries pharmacists are encouraged to substitute brand-name drugs with cheaper but equivalent drugs, produced by different companies, for cost-saving purposes. Although the drugs are equal in respect of effect as well as quality and safety, they may differ by name, shape, colour, and taste.

Research shows that many patients get confused or feel apprehensive about having their drugs changed and report negative experiences such as poorer effect or more side effects. As a consequence, patients may use their drugs inappropriately or even end up not taking their drugs at all.

More information directed at patients and increased involvement of physicians are needed.

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