



What do primary care patients think about generic drugs?

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Key words

generic drugs – prescriptions – cost-effectiveness – information on drug therapy – family practice

Abstract. Objective: To examine the attitude of patients towards generic drugs and prescriptions containing generic drugs as an alternative to brand-name products, with a special focus on information on patients attitude to generic drugs provided by their general practitioners (GPs). **Methods:** A total of 804 patients in 31 general practices were surveyed using a self-questionnaire. The influence of age, sex, education, disease, knowledge of generic drugs, experience with generic substitution and information provided by the GP on patient attitudes towards generic drugs and substitutions were examined. **Results:** Nearly two thirds of the patients (509/804) stated that they knew of the difference between brand-name drugs and generics; of these, one third were not satisfied with the information given by their GPs and 37% of patients expressed general skepticism towards generic drugs because of their lower price. This attitude was more frequent among those who felt that generic prescribing was “invented” to solve the financial crisis in the German health insurance system at their expense (odds ratio (OR): 6.2; 95% confidence interval: 4.0 – 9.8) and those who had not been confronted personally with a generic substitution (OR: 1.8; 1.3 – 3.0). Patients who had been skeptical when first confronted with a generic substitution were more frequently among those who considered inexpensive drugs to be inferior (OR: 4.5; 2.0 – 10.4) and they were frequently not satisfied with the information on substitution provided by their GP (OR: 2.7; 1.2 – 5.9). **Conclusion:** GPs are in an ideal position to inform their patients adequately about the equivalence of brand-name and generic drugs. However, the patient view that inexpensive drugs must be inferior may be difficult to rectify in the short term.

Introduction

In European countries as well as in the United States, expenditure on drugs is continuously rising [Heffler et al. 2003, Olson-Garewal 2001]. In Germany, costs for ambulatory prescriptions exceeded 24 billion Euro in 2003 and this is a record number in both absolute and relative terms [Schwabe 2004]. Patients could save about 10 – 30% by purchasing generic drugs as opposed to brand-name drugs [Lieberman and Rubinstein 2002]. German statutory health insurances could save another 1.5 billion Euro if the potential of generic prescribing was exploited to the full [Nink and Schröder 2004].

By definition, generics are chemically identical to their brand named counterparts and can be marketed when patents and other exclusive marketing rights on brand-name drugs expire [Bae 1997]. The major argument in favor of generic substitution has always been cost containment [Keith et al. 1998]. A drug existing as a generic may be prescribed using the brand name of the product and then be substituted by the generic by the pharmacist. Alternatively, it may be prescribed using the International Non-proprietary Name (INN) of the drug, or the proprietary name of the generic drug (“brand-name generic”) as frequently done in Germany [Mott and Cline 2002, Schwabe 2004]. At the time of the survey, the cost of a prescribed drug whether generic or otherwise, was refunded in most instances by the statutory health insurance body except, of course, when there was a fixed charge for the patient.

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Today, in contrast to the situation in the past when problems of subtherapeutic levels and/or some adverse effects due to variations in bioequivalence of a small number of generic drugs have been documented [Gleiter and Gundert-Remy 1994, Meredith 1996], the drug approval process now has required bioequivalence as well as equivalent high standards in quality and safety in the case of generic drugs [Gleiter et al. 1998, Welage et al. 2001].

Several reasons have been discussed as to why the economic potential of generic prescribing, i.e. the cost-effectiveness of drug therapy, is not fully realized [Ascione et al. 2001, Lemye 2000, McGettigan et al. 1997, Mott and Cline 2002, Suh 1999]. There is one set of reasons that refers to doctor-related factors, especially misconceptions about generic products and generic substitution [Avery et al. 2000, Banahan and Kolassa 1997, Hellerstein 1998]. There is evidence that patient preferences can also be a barrier to increased generic prescribing [Mott and Kreling 1998]. Patients may perceive brand-name products as being of higher quality compared to generic products. In one study in a British general practice, 46% of the patients questioned stated that they were dissatisfied when confronted with a drug change to a generic prescription [Dowell et al. 1995]. However, according to a study in New Jersey [McGettigan et al. 1997], nearly all patients agreed to use a generic substitute if the doctor approved of such a substitution.

The aim of this study was to examine in more detail the attitude of patients towards generic drugs and generic substitution of formerly original products. A special focus was on patient satisfaction with the information on generic drugs and substitution provided by the general practitioner (GP), since this may be an important factor in the prescribing and acceptance of generic drugs. The study was designed for a primary care setting, because GPs issue the largest number of prescriptions in the outpatient setting.

Methods

This patient survey was embedded in a larger intervention study, designed as a ran-

domized, controlled trial. GPs assigned to the "intervention arm" of the study were informed about their actual generic potential and each GP was given a small booklet with tips to ease communication with patients when talking about generic substitution. The aim of the intervention was to change the doctor's prescribing behavior. GPs in the intervention arm should better realize the economic potential of generic prescribing, compared to the GPs in the "control arm". In this paper, we report the results of the patient survey in the practices of the control arm. The study was approved by the Ethics Committee of the University of Göttingen.

Participants

A total of 46 randomly selected practices were contacted in defined regions of three German federal states (control arm of the study). The receptionists in the participating practices were instructed to recruit consecutive patients during a defined week. After completing a questionnaire on the use of generic drugs, the patients could either deposit the questionnaire in a box located at the reception or send their questionnaire in a stamped envelope to our department. Answers were not disclosed to the practice staff.

The questionnaire

The questionnaire consisted of 16 closed questions. After giving a short definition of generic drugs based on a well-known medicine (Bayer Aspirin as brand name and ASS as generic preparation), the patients were asked whether they had heard about this difference before. Further questions focused on a general assessment of generics, in contrast to brand-name drugs. A few questions referred to experience, if any, with generic drugs or generic substitution of brand-name drugs. Before eliciting some demographic data, patients were asked whether they felt appropriately informed about generic drugs and substitution by their doctor. A preliminary version of the questionnaire was piloted in 28 practices in a separate region of North Germany [Detlefsen et al. 2001].

Table 1. Factors significantly associated with respondents' opinion that inexpensive drugs are of inferior quality*.

Significant attitudes/factors	Prevalence** (%)	Adjusted odds ratio	95% confidence interval	p
Generic prescribing "devised" at the expense of the patient	49.1	6.2	4.0 – 9.8	0.0001
Generic substitution not yet experienced	41.9	1.8	1.1 – 3.0	0.0213
Generic drug not yet prescribed	46.0	1.8	1.2 – 2.8	0.0078
Costs should be no issue during consultation	45.7	1.6	1.1 – 2.3	0.0258
Chronic disease	44.3	1.8	1.2 – 2.6	0.0019
> 60 years***	53.2	1.6	1.1 – 2.4	0.0108
Education 9 years	47.5	1.5	1.1 – 2.1	0.0343

* the following variables were included in the logistic regression analysis: age, sex, disease (acute vs. chronic), education, number of drugs, doctor-patient relationship, knowledge of difference between brand-name and generic drugs, experience of generic substitution, costs as issue in the doctor-patient relation, cost savings in healthcare as additional burden for patients; selection: backward;

** "Prevalence" refers to the rate of patients in the given category who believed that inexpensive drugs are of inferior quality (e.g., 53.2% of patients older than 60 years). This figure can be compared to the overall rate of patients who deemed inexpensive drugs of inferior quality (36.7%).

*** compared to patients between 18 and 40 years, middle-aged patients did not differ in their opinion from younger ones.

The analysis is based on n = 754 patients, 50 patients were excluded due to missing variables in the response or explanatory variables.

Analysis

To analyze the association between attitudes towards generic drugs (response variable) and experience with generic substitution, degree of information, quality of the physician-patient relationship, acute versus chronic disease, age, sex and education (explanatory variables), we performed multiple logistic regressions. Backward elimination was applied to select important variables (level for elimination: $p = 0.05$). We calculated the odds ratios (ORs) with the corresponding 95% confidence intervals (CIs) as measures of effect [SAS Institute 1999].

About the quality of their doctor's information on generic drugs and substitution, 52 patients did not answer the questions. Since missing data in these cases seem to represent dissatisfaction with the doctors' performance, we treated these 52 answers as expressions of dissatisfaction with their doctor's information. For logistic regression analysis, these answers were coded as 0, in contrast to those patients who characterized their doctor's information as (very) good (= 1).

Results

Of 46 general practices addressed, 31 participated in this study. The main reasons for not participating were "no interest" and the fear that the study would be time-consuming. Most practices (66%) were solo practices, all doctors were vocationally trained GPs.

According to the study protocol, 50 consecutive patients per practice had to be addressed. Receptionists were successful in recruiting a total of 804 patients. Especially because of time pressure, it was difficult for the receptionists in some practices to address this predetermined number of people during the regular consultation hours. Considering the study protocol (i.e. addressing a total of 50 patients) as criterion, the response rate was 51.9%, considering the receptionists' report of how many patients they addressed ($n = 1,268$), the response rate was 63.4%.

Knowledge of generic drugs

After providing the participants with a short definition of generic drugs, 63% (509/804) stated that they had already heard of the dif-

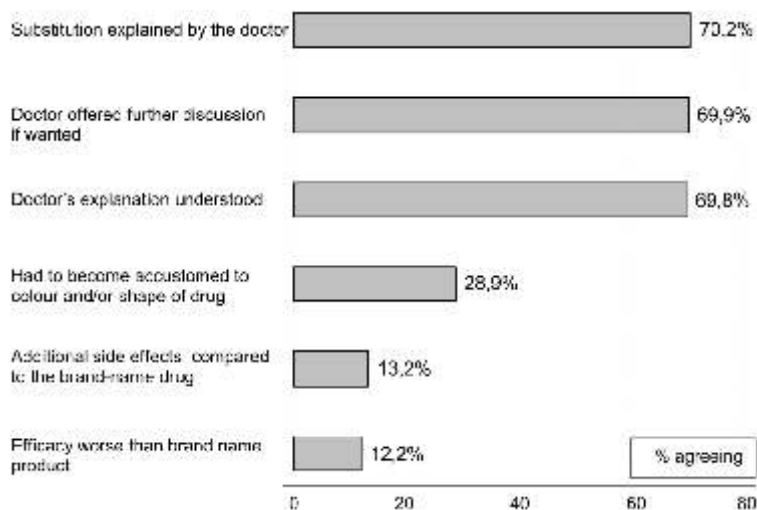


Figure 1. Processes during, and experience with, generic substitution*; * due to missing values, items were answered by 204 – 218 patients.

ference between brand-name drugs and generics before, most of them in the media (65%) and/or from their doctor (52%).

As expected, education had some influence on the knowledge of the difference between generic and brand-name products. About three quarters (303/406) of the patients with a formal education of 10 years or more reported knowing the difference, whereas only 52% (206/398) with less education did so.

General attitudes towards generic drugs

A considerable fraction (36.7%, 295/804) of the total sample of respondents considered inexpensive drugs to be inferior to, or different from, brand-name products. This attitude was more frequent among those who felt that generic prescribing was “invented” to solve the financial crisis in the German health insurance system at their expense (OR: 6.2; 95% CI: 4.0 – 9.8) and those who did not want to consider economic issues during the consultation. A negative view on generic drugs was also more frequently expressed by older people and, independently, chronically ill patients. Experience with generic drugs and/or substitution as well as a higher education were a barrier towards negative attitudes (Table 1).

Assessment of prescribed generic drugs

Of the respondents, 42% were conscious of some experience with generic drugs and nearly 30% (222/804) remembered that their doctor had changed a former prescription of a brand-name drug to a generic product; 32 patients answered several questions about their experience with generic substitution although they were not amongst the 222 patients who remembered that their doctor had substituted one or more brand-name drugs. Perhaps these patients experienced a generic substitution in another practice or at a pharmacy but since the aim of the study was, besides others, to detect associations between the doctor’s performance and the patient’s attitudes towards generic substitution, we excluded the 32 patients from further analyses.

More than half of these patients who remembered a substitution of a former brand-name drug (112/222) had been skeptical about this substitution, on principle or, at least, at the beginning. Figure 1 summarizes the patients’ reported experience with the substitution. Nearly 30% were not satisfied with the information given by their doctor. About one in three patients had to become accustomed to a different color or shape of the substituted drug. There were 12% of patients (26/213) that reported a poorer therapeutic effect of the generic drug, compared to the former brand-name preparation.

People who had been skeptical when first confronted with a generic substitution were more frequently among those who did not feel well-informed about this substitution by their doctor (OR: 2.7; 95% CI: 1.2 – 5.9) and who had to become accustomed to the new shape and/or form of the substituted drug (Table 2). Prescription of two or more drugs was also associated with skepticism about generic substitution. Most important, there was a strong association between skepticism on generic substitution and the opinion that low-cost drugs are inferior to or different than brand-name products (OR: 4.5; 95% CI: 2.0 – 10.4).

Table 2. Factors significantly associated with skepticism towards generic substitution*.

Significant attitudes/factors	Prevalence** (%)	Adjusted odds ratio	95% confidence interval	p
Inexpensive drugs deemed to be inferior	80.0	4.5	2.0 – 10.4	0.0004
Problems to become accustomed to shape/form of the drug	71.7	2.8	1.3 – 6.0	0.0085
Prescription of two drugs or more	47.1	2.5	1.2 – 5.0	0.0106
Not satisfied with doctor's information on substitution	70.6	2.7	1.2 – 5.9	0.0125
Education 9 years	61.0	2.1	1.1 – 4.2	0.0270

* the following variables were included in the logistic regression analysis: age, sex, disease (acute vs. chronic), education, number of drugs, doctor-patient relationship, knowledge of difference between brand name and generic drugs, experience of generic substitution, costs as issue in the doctor-patient relationship, cost savings in health care as an additional burden for patients, relevance of the price of a drug; selection: backward. The analysis is based on n = 186 patients, 32 patients were excluded due to missing variables in the response or explanatory variables.

** "Prevalence" refers to the rate of patients in the given category who were skeptic towards generic substitution (e.g., 71.7% of patients who had to become accustomed to shape/form of the drug). This figure can be compared to the overall rate of patients who were skeptic towards generic substitution (50.5%).

Discussion

Summary of main findings

Although the majority of patients in this study seemed to be familiar with the term "generic drug", more than one third of the respondents expressed generally negative feelings towards generics with regard to their quality and efficacy. Those who had been skeptical when first confronted with a generic substitution were more frequently among those who considered inexpensive drugs to be inferior and were not satisfied with the doctor's information on substitution. Only a small fraction of those patients who had, or remembered, some experience with generic drugs were not satisfied with the therapeutic benefit from the drug.

Strengths and limitations

In addition to previous studies [Avery et al. 2000, Pedulka et al. 1989], we compared patient attitudes towards drugs with the (perceived) quality of the doctor's information on generic drugs and substitution. Although this study included more practices and more patients than previous surveys, a sampling bias may have occurred. Doctors with low interest

in pharmacotherapy and/or low rates of generic prescribing may be underrepresented, the practice receptionists may have more frequently addressed those patients who are easier to handle and more interested in health topics. In this case, the study underestimates the frequency of critical attitudes towards generic drugs.

The doctor's information behavior was only assessed from a patient's point of view. We do not exactly know whether a negative assessment of generic drugs results from being inadequately informed or whether adequate information was negatively perceived by a very critical or skeptic patient.

Any survey of generic drugs has to consider whether patients know what the term "generic" means. In a pharmacy-based study in the Chicago area, nearly all respondents were familiar with this term [Pedulka et al. 1989]. The rate in our study was 63%. One reason may be that the public discussion about cost containment by use of generic drugs started in Germany much later than in the United States where most patients need to pay for their drugs themselves so that consumers are also more price-sensitive. Another reason for this difference may be that the respondents in our study first received a definition of generic drugs so that it was easier for them to report a knowledge gap. Nevertheless, giving

all respondents a uniform definition of generic drugs may have prevented an information bias and thus contributed to the validity of the study.

Implications of findings

Knowledge of patients' attitudes towards generic drugs and experience with generic drugs and generic substitution, may be crucial because negative attitudes might result in a larger number of prescriptions, more practice visits and emergency room consultations and additional hospitalizations as an HMO study suggested [Horn et al. 1996, Kravitz and Romano 1996]. Many patients in our study – with and without experience in generic substitution – were skeptical about generic preparations, due to their prejudice that inexpensive drugs “must” be of inferior quality. This prejudice seems to mirror what Sara Fritz from the *St. Petersburg Times* called *brand-name fetish*, encouraged by the drug manufacturers' intensive consumer advertising in the US.

The prejudice against generic drugs may be strengthened by moral hazard [Lundin 2000]: patients as well as physicians do not have the incentive to invest in low-cost treatment as long as insurance companies pay the costs of prescriptions, regardless of their generic or brand-name status. In many countries, the marginal cost of treatment, as economists put it, do not have to be covered by the patient in full insurance [de Joncheere et al. 2002, Lundin 2000]. Our study seems to reflect this moral hazard in two instances: in that many patients' dislike talking about cost with their doctor, and in their feeling that generic prescriptions are a strategy to reduce cost at the expense of patients.

In a study based on prescriptions in a US Midwestern community [Mott and Kreling 1998], generic substitution occurred significantly more often for acute than for chronic conditions. In our study, patients with chronic diseases more often showed a negative attitude towards generic drugs, confirming assumptions from different authors that chronically ill patients perceive the consequences and risks of generic substitution as more serious and have more fear of health loss [Ganther and Kreling 2000, Pedulka et

al. 1989]. From an economic point of view, particularly in chronic patients, a substitution is likely to have a remarkable effect in cost saving – at least for the statutory health insurances. From a primary care point of view, it will be more difficult for doctors to persuade these patients to accept a generic substitution without first talking to them about their aversion of taking generics for their disorder [Pedulka et al. 1989]. The same will be true in older patients and in those who regularly take several drugs. These persons, too, may have gone through several drug changes and may experience further drug changes as a threat to their health so that communication about their fears is essential but time-consuming.

Between 12% and 13% of the patients in our study having some experience of generic substitution reported a lower efficacy or side effects. So did 20% or 26% of patients who felt very unhappy or slightly unhappy, respectively, in response to a generic substitution in a British general practice [Dowell et al. 1995]. Brennan and Lee [2004] report the extreme case of a patient believing to be allergic to generic medications. Since adverse effects in generic drugs are contradictory to pharmacological findings [Gleiter and Gundert-Remy 1994, Meredith 1996], the experience of lower efficacy or non-specific side effects of generic drugs in some patients appear to be a nocebo phenomenon [Barsky et al. 2002], an “adverse placebo effect”, so to speak.

A nocebo effect may occur as a result of any intervention, even of a generic substitution. This effect is more likely if:

- drugs are primarily advocated for their low price [Rietveld and Haaijer-Ruskamp 2002],
- information on generic substitution is erroneous, or
- the physical and symbolic characteristics of the medication change [Barsky et al. 2002].

Although a “generics only” guideline is reasonable from a cost-effectiveness perspective [Brennan and Lee 2004], a too rigid generic substitution may – at least in some instances – change the physician-patient relationship for the worse, reawaken distrust and lead to the experience of a lower efficacy of generic drugs. Since a different color or form

of the generic substitution also seemed to provoke skepticism towards generic substitution in our study, doctors should also better prepare patients for such changes [Rietveld and Haaijer-Ruskamp 2002] and, thus, help to avoid much of the negative feeling generated by the drug change itself [Dowell et al. 1995]. In an intervention study in Barcelona (Spain), individual patient education in primary care was also an effective strategy for improving acceptability of the substitution of brand-name drugs by generic drugs in refill prescriptions [Vallès 2003].

Conclusions

Proper information of the patient may reduce the number of patients who are dissatisfied with the generic substitution. Substitution without provision of information may result in patient dissatisfaction, withdrawal from care or shifts to more expensive resources [Horn et al. 1996].

Considering the results of our study, physicians may adopt the following strategy, at least in some patients, when prescribing a generic drug:

- ask the patient whether they are aware that there are alternative drugs that are just as efficacious,
- ask the patient about previous experience with generic substitution,
- emphasize with any feelings expressed,
- correct any misinformation,
- make clear recommendations.

Although GPs are in an ideal position to inform patients adequately about the equivalence of brand and generic drugs, in some cases a satisfactory substitution will perhaps consume an inappropriate amount of time with regard to the costs saved because some patients' attitudes, or prejudices, seem so negative and persistent that they will be difficult to rectify.

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