RESEARCH ARTICLE

Patients' attitudes towards and experiences of generic drug substitution in Norway

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Abstract

Objective   The aim of the study was to assess patients' attitudes towards and experiences of generic substitution 3 years after generic substitution of prescription medicines was permitted in Norway.

Methods Prescriptions from 2,128 consecutive patients in a Norwegian pharmacy were retrospectively reviewed to identify all patients ($n = 274$) receiving eight or more different prescription drugs on the fifth level in the Anatomical Therapeutic Chemical (ATC) classification system during the last 6 months. An age-adjusted control group ($n = 269$) of patients receiving three to seven different prescription drugs was randomly selected. Of the 543 patients, 386 were eligible for inclusion. Both groups received a mailed questionnaire addressing their experiences with and attitudes towards generic substitution.

Results   The overall response rate was 73% (281/386) and the average age of the respondents was 66 years old. The study found that patients who reported to have received information from their physician or the pharmacy about generic substitution were more likely to have switched ($P < 0.001$). About half (138/281) of the patients had experienced a generic switch, and a higher proportion of the polypharmacy patients had their medication substituted compared to the control patients ($P < 0.001$). Altogether 50 (36%) of the patients who had experienced a switch, reported one or more negative experiences connected to the substitution, and 29 of these (21%) reported an overall negative experience after the change. The experiences of the patients were not related to age, gender, or number of medications or information about generics from either the pharmacy or the physician. About 41% of the patients would not switch if they had no personal economic incentives.

Conclusions   About 1/3 of the patients who had their medication substituted reported negative experiences. Generic drug substitution for a number of patients is not considered an equal alternative to branded drugs, and these patients may need additional information and support. The lack of correlation between patient experiences and age, gender, and medical regimen complexity is interesting and should be investigated further.

Keywords   Generic substitution · Patient experience · Community pharmacy · Norway

Impact on practice

- Generic drug substitution is not perceived an equal alternative to branded drugs by all patients.
- Patients may need additional information and support from both physicians and pharmacists before accepting generic substitution.

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Introduction

Generic substitution implies that a patient receives a medicine containing the same active ingredient, dosage

form, and strength as the brand name prescribed by the doctor. The generic medicine can, however, be differently named and have another appearance, taste, shape, and color. Generic substitution is common in many countries, but is in general met with skepticism by health professionals [1–4]. It is argued that for drugs with a narrow therapeutic index, or variability in bioavailability one should exclude or limit certain medicines from generic substitution (e.g., phenytoin and carbamazepine) [5–7], however, the evidence of such risks in clinical practice is limited [3, 8]. Physicians' understanding of bioavailability requirements for generic drugs is reported to be poor [9, 10].

New pharmacy legislation implemented in March 2001 allowed Norwegian pharmacies to switch the medication originally prescribed to a generic medicine. Pharmacists in Norway are obliged to inform the patient about the cheapest available generic according to a list produced by the Norwegian Medicines Agency. The rationale behind the introduction of generic substitution in Norway was primarily cost containment. The patient and/or the doctor can refuse generic substitution, but the patient may as a result pay a higher price in some cases.

Pharmacists have reported that patients are often negative to generic substitution, and few studies have been performed in Norway investigating how patients manage their diseases or medicines following a generic switch. There is therefore a need to study how generic substitution is perceived by patients in relation to altered effects, side-effects, and confidence in their therapy. The economic incentives necessary to convince patients to switch, and their preferable source of information, also deserve attention. Our study investigates how patients with many or fewer medicines have experienced generic substitution.

Method

All 3,823 drug prescriptions for human use at Stokke Pharmacy, Norway, dispensed in September 2003 were retrospectively reviewed. The prescriptions were found to represent 2,128 different patients. The pharmacy database (FarmaPro, NAF-Data, Oslo, Norway) was used to identify the patients ($n = 274$) receiving eight or more different drugs on the fifth level in the ATC-system. An age-adjusted control group consisting of 269 randomly selected patients receiving three to seven different drugs was recruited. Three months later none of the 543 patients had changed their group status with respect to the number of medicines, and they were considered for inclusion if they were registered inhabitants

of Stokke municipality, were between the age of 18 and 85 years old, and managed their own medicines. The 404 patients meeting the inclusion criteria were mailed questionnaires regarding their attitudes and experiences towards generic substitution. The mail system found 15 addresses undeliverable, one person was without legal capacity and two were dead. Three weeks later all patients were reminded with a new questionnaire.

A total of 386 patients, 238 women and 148 men, were mailed a questionnaire. The gender, age, and number of different drugs of the respondents were the only information used in the study. The study was approved by the Norwegian Social Science Data Services (NSD) and the Regional Committee for Medical Research Ethics. We were not allowed to record information about diagnosis or the types of medicines used.

Analysis

To investigate factors influencing patients' willingness to change to a generic drug, a logistic regression analysis was performed. The independent variables were age, gender, number of drugs prescribed, whether they had been informed or not by their GP or pharmacist about generic substitution, and costs savings for themselves or the National Health Service. Following this, a logistic regression analysis was made on patients who had switched to a generic drug, investigating how experiences with generic drugs were related to the independent variables. SPSS (Statistical Package for Social Sciences, v. 11.5) was used for the analysis.

Results

The response rate was 73% (281/386), of which 59% were women (Table 1). The mean age was 65.8 years (SD = 13.7) and the number of different drugs dispensed throughout the previous 6 months was 7.5 (SD = 3.8, range 3–21). The mean number of different drugs was 4.5 in the control group ($n = 145$) and 10.8 in the polypharmacy group ($n = 136$). There were no significant differences between the genders regarding the number of different drug dispensed ($P = 0.156$). Women were evenly divided between the control and polypharmacy group. The larger proportion of men in the control group compared to the polypharmacy group was not statistically significant (Table 1).

Information provided about generic substitution

Patients were asked if they had been given information on generic substitution, and 24% of them remembered

Table 1 Basic characteristics of the study population, and comparison between patients using eight or more drugs (polypharmacy) and those using 3–7 drugs (control)

	All patients (N = 281)	Control (N = 145)	Polypharmacy patients (N = 136)	OR (95% CI)	P-trend
Mean number of drugs	7.5 (SD = 3.8)	4.5 (SD = 1.4)	10.8 (SD = 2.8)	Non-applicable	
Mean age (years)	65.8 (SD = 13.7)	65.8 (SD = 14.1)	65.8 (SD = 13.3)	Non-applicable	
Number of women	167 (59%)	78 (54%)	89 (65%)	0.62 (0.32–0.99)	P = 0.052
Patients say the GP has informed about generics*	66 (24%)	23 (16%)	43 (32%)	0.41 (0.23–0.73)	P = 0.002
Patients say the pharmacy staff has informed about generics*	150 (53%)	61 (42%)	89 (65%)	0.39 (0.24–0.63)	P < 0.001
Patients do not want to switch even if she saves money	75 (27%)	44 (32%)	31 (23%)	0.70 (0.41–1.20)	P = 0.218
Patients do not want to switch even if NHS saves money	115 (41%)	63 (46%)	52 (39%)	0.79 (0.48–1.30)	P = 0.382
Patients have changed to generic drugs*	138 (49%)	51 (35%)	87 (64%)	0.31 (0.19–0.51)	P < 0.001

* Significant differences between polypharmacy group and control group

to have received such from their physician, whereas 53% remembered being given information by the pharmacy staff (Table 1) (P < 0.001). Twice as many polypharmacy patients (32%) as patients from the control group (16%) remembered being informed by their physician (P = 0.002). Correspondingly, 65% of polypharmacy patients remembered being informed by the pharmacy staff and 42% in the control group (P < 0.001). The results show that the pharmacy employees more frequently gave information to patients who were less than 70 years of age (P < 0.005), whereas physicians did not differentiate on age (P = 0.238). There were no significant gender differences in the extent to which generic information was provided (P = 0.139).

Cost savings

Before accepting generic substitution, patients reported a median requirement for personal savings of 6–12 €, and 12–24 € as a requirement for contributing to savings on behalf of the National Health Security System. About 27% of the patients stated that they would never accept substitution, and additionally 15% would not accept substitution given that they themselves did not save money.

Exploring factors related to generic substitution

Of the 281 respondents, 138 (49%) confirmed having had their prescription drugs substituted for a cheaper generic medicine. The remaining 141 (75 women and 66 men) could not remember, or did have any of their medicines substituted. Two of the respondents failed to give information on this matter, leaving 90 women (65%) and 48 men (35%) who had experienced generic substitution to answer the remaining part of the questionnaire. A larger proportion of women than men had switched, but this difference was not statistically significant (P = 0.055).

Table 2 Logistic regression analysis of gender, age, number of drugs and information sources as predictors of generic substitution (N = 281)

	Changed to generics		Not changed to generics		OR	95% CI
	N	%	N	%		
Gender						
Female	90	65	75	47	1	
Male	48	35	66	53	0.8	0.4–1.5
Age (years)						
18–49	19	14	11	8	3.7	1.2–10.7
50–69	72	52	50	35	2.3	1.2–4.4
70+	47	34	80	57	1	
Number of drugs						
3–7	51	37	92	65	1	
8+	87	63	49	35	2.6	1.4–4.8
Information received about generic substitution						
None	22	16	103	73	1	
Pharmacist only	62	45	23	18	10.4	5.2–20.5
Doctor only	1	1	3	2	2.5	0.2–25.9
Both	53	38	9	6	23.3	9.7–56.0

In the polypharmacy group 64% had experienced generic drug exchange compared to 36% in the control group ($P < 0.001$). Patients with polypharmacy were 2.6 times more likely to have changed to a generic drug (Table 2). The difference reflects that persons using fewer different prescription drugs are less likely to have exchangeable drugs compared to persons with many different drugs. Patients younger than 50 years old were 3.7 times more likely to change than those aged 70 years or more. Moreover, there was a clear statistical correlation between generic exchange and patient recollection of having been given information regarding the subject from their physician ($P < 0.001$). A corresponding relationship was also shown between the information given at the pharmacy; however, this can be explained by the fact that the staff only gives such information in instances of interchangeable medicines (Table 1). It seems that the combined information from the GP and the pharmacy gives the largest ratio of substitution (Table 2).

The questionnaire included six questions on various aspects regarding generic substitution: (a) overall satisfaction; (b) changes in effects and (c) side-effects; (d) practical use; (e) willingness to take medication; and (f) concern on self-care. Of the 138 patients who had switched, 50 (36%, 34 women and 16 men) reported one or more negative experiences with the generic drug. The number of patients with 1, 2, 3, 4, 5, or 6 of the different negative experiences was 15, 17, 8, 4, 5, and 1, respectively. Twenty percent were overall dissatisfied, 12% reported more side-effects and 18% felt the generic alternative had a weaker effect than the branded medication. There was no significant correla-

tion between negative experiences from generic substitution and age, gender, number of different medications, information from the physician, or from the pharmacy staff (Table 3).

Discussion

Alterations in a drug regimen may raise concern and doubts about the equivalence and use of newly introduced medications. This study shows that after generic substitution approximately every third patient reported negative experiences independently of using few or many different drugs. However, most patients handled the switch without problems and 78% of the patients claimed overall satisfaction.

Our study revealed higher ratios of negative experiences compared to similar findings in Scandinavia. Health professionals and pharmacy staff making a coordinated effort to increase the proportion of generic substitution succeeded, but 21% of the patients reported problems [11]. In a study performed by the Norwegian Medicines Agency, pharmacy customers were asked about their experiences with generic medication, and 15% reported new side-effects. These side-effects were not considered by the authors to be of a serious nature. However, the customers were not questioned about any change in effect, or if they had side-effects [12]. These studies are however smaller, and had a different approach to patients inclusion than our study.

Information about generic substitution strongly affected whether patients have switched or not, where a combined effort from doctors and pharmacy staff

Table 3 Logistic regression analysis of gender, age, number of drugs, and information sources as predictors of negative experiences after generic substitution ($N = 138$)

	Negative experiences with generic drugs		No negative experiences with generic drugs		OR	95% CI
	N	%	N	%		
Gender						
Female	34	68	56	64	1	
Male	16	32	32	36	0.8	0.4–1.8
Age (years)						
18–49	11	22	8	9	2.6	0.8–7.7
50–69	22	44	50	57	0.9	0.4–1.9
70+	17	34	30	34	1	
Number of drugs						
3–7	17	34	34	39	1	
8+	33	66	54	61	1.1	0.5–2.4
Information received about generic substitution						
None	9	18	13	15	1	
Pharmacist only	18	36	44	50	0.62	0.2–1.8
Doctor only	1	2	0	0	–	–
Both	22	44	31	35	1.1	0.3–3.1

seemed to be the most effective. Previous research has shown that physicians and pharmacists play an important role when patients choose between branded or generic drugs [10, 13–15]. Only a quarter of the patients in our study were informed about generic substitution from their physician, a finding that might be related to physicians' knowledge and beliefs about bioavailability of generic drugs, or negative experiences with patients who perceive different effects or side-effects from generics [10]. Our study confirms that efforts to increase generic substitutions should be targeted first and foremost at prescribers [14]. The analysis reveals that where the GP has informed patients about generic substitution, they are also likely to have been informed at the pharmacy as well. Pharmacy employees informed patients aged 70 or older to a lesser extent than younger patients, but this could possibly be related to the patients' age and concern about confusing the patient. This is unfortunate economically, as the potential savings from generic drugs are higher for the elderly than for younger patients [16]. The higher proportion of patients informed in the polypharmacy group is no surprise, as these patients have more drugs that can potentially be switched.

In our study, 41% of patients were in opposition to generic substitution given no personal savings. The patients may need stronger financial incentives in order to increase their acceptance of generics [17, 18]. For example, patients with the right to free drugs (full reimbursement) could also be given some economic benefits from the substitution. An increase in perceived risk has also been found to be related to the increased requirements for cost savings [13]. The high percentage of patients opposing generic substitution as a result of no personal savings should raise discussions amongst health economists and representatives from the government.

The regression analysis was unable to identify independent variables such as gender, age, or the number of different medications used as indicators for negative experiences. The negative experiences should be taken seriously and be further explored to avoid non-compliance, side-effects and treatment failure.

Discussion of the method

The response rate was relatively high. This may partly be explained by coverage of the questionnaire distribution in the local newspaper and radio. The higher proportion of women participating confirms other population based prescriptions statistics. In the present study we could not control customer loyalty. As a result our control patients using 3–7 different medicines may be using more medicines bought at other pharmacies, and therefore potentially belong to the polypharmacy group. The study was limited to a restricted number of patients and generalizations to other populations may not be performed. Future studies covering the whole country and based on the newly introduced nationwide prescription database may eliminate these problems.

Conclusion

Negative experiences with generic drug substitution were not related to polypharmacy, patient age, or gender. A high percentage of patients do not allow their medicines to be substituted. Two thirds of the patients who have used generic medicines are satisfied, and about one-third of patients who have switched have negative experiences. This confirms that generic drug substitution for a number of patients is not perceived an equal alternative to branded drugs, and these patients may need additional information and support.

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