

# Substitution of generics for brand medicines in primary care centers

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**Objective.** To estimate the percentage of patients who change from current medication to generic medicine once properly informed.

**Design.** Observational, cross-sectional.

**Setting.** Two primary care clinics in Madrid, one rural and the other urban.

**Participants.** Patients who came for their consultation and who take prescribed drugs which have generic alternatives.

**Method.** All patients included received a standard 40 second verbal explanation about generics. Later, the researcher filled out a 18 items test. A descriptive analysis was done taking into account frequencies and applying a bivariable analysis comparing the variable «accepted change» with the others.

**Results.** 71% of the patients accepted the change to generic medicine, 29% did not. Of the latter, 67.4% said that they preferred to consult with the prescribing physician; 45.1% were of the opinion that it would not have the same effect; a 16.1% said that if it was cheaper, it must be of a worse quality; and another 16.1% said that they would only accept the change if it meant saving some money.

The researcher perceived distress and discomfort in 23.4% of the patients. He himself felt satisfied in 83.9% of the cases, indifferent in 12.9% and unsatisfied in 3.2%.

**Conclusion.** Providing the adequate information and letting the patients decide for themselves about the substitution of brand for generic drugs resulted in almost three quarters of the cases opting for the change. And this with a minimal professional effort and the added benefit of improving the patient-practitioner relationship.

**Key words:** Generic medicines. Generic substitution. Informed consent.

## SUSTITUCIÓN DE MEDICAMENTOS DE MARCA POR GENÉRICOS EN LA CONSULTA DE ATENCIÓN PRIMARIA

**Objetivo.** Determinar el porcentaje de pacientes que tras una explicación adecuada se muestran partidarios de cambiar su medicación habitual por una especialidad farmacéutica genérica (EFG).

**Diseño.** Observacional, transversal.

**Emplazamiento.** En dos centros de salud, uno urbano y otro rural, de la Comunidad Autónoma de Madrid.

**Participantes.** Pacientes que acuden a consulta y son susceptibles de cambiar alguno de los medicamentos que precisan por una EFG.

**Método.** A los pacientes incluidos se les facilitó una misma información verbal de 40 s de duración explicando qué es una EFG. Seguidamente se completó un cuestionario de 18 preguntas. Se analizó de forma descriptiva la muestra calculando frecuencias y aplicando un análisis bivariable relacionando la variable «aceptación del cambio» con las demás.

**Resultados.** El 71% de los participantes aceptó el cambio a EFG. El 29% que no lo hizo alegó en un 67,4% que prefería consultarlo con el médico que lo prescribió, en un 45,1% que no iba a tener el mismo efecto, un 16,1% creyó que al ser más barato sería peor y otro 16,1% refirió que en caso de que le supusiera más gasto cambiaría. El médico percibió malestar en el paciente en un 23,4%, y se sintió él mismo satisfecho con la entrevista en un 83,9%, indiferente en un 12,9% e insatisfecho en un 3,2%.

**Conclusiones.** Proporcionar información al paciente y permitirle participar en la decisión del cambio de medicación resulta muy ventajoso, ya que así se consigue el cambio en casi tres cuartas partes de los casos con un mínimo desgaste profesional y manteniendo una buena relación médico-paciente.

**Palabras clave:** Medicamentos genéricos. Sustitución por genéricos. Consentimiento informado.

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## Introduction

Policies to promote generic drugs, implemented in Spain and other countries during the last few years as a measure to contain health care costs and favor the rational use of medications, are now well known.<sup>1</sup> Since the legal concept of generic drugs<sup>2</sup> was introduced in Spain in 1996,<sup>2</sup> several structural measures, which have taken into account the legal framework, and the interests of pharmaceutical firms, pharmacies, users and health care professionals, have been used to foment the presence of generics on the market.<sup>3</sup>

One of the most important *legal measures* is Real Decreto 1035/1999,<sup>4</sup> which established the reference price system. This has led to reductions in the price of brand-name products and the appearance on the market of many generics. From September 1999 to September 2001 the number of active pharmaceutical ingredients available as generics has grown from 57 to 86, which translates as an increase in the number of generic products from 307 to 994.<sup>5</sup>

Agreements reached with *pharmacies* have increased their profit margin from 27.9% to 33% for generics, and *user* information campaigns have been sponsored by the Ministry of Health.<sup>5</sup>

Among the measures developed for *physicians* at some health services, two are worth special mention: a system of periodic feedback on prescribing practices (which includes information on costs to the national health system and on the percentage of generics prescribed),<sup>6</sup> and incentives (ie, the introduction of concepts such as variable productivity associated with generic prescribing).

The quality, safety and efficacy of generics are assured<sup>7,8</sup> by the strict application of current legislation regarding their authorization.<sup>2</sup> These products therefore offer the same guarantees as the original pharmaceutical,<sup>9</sup> and are made available to prescribing physicians and the health care system as an alternative that is more cost-effective, as long as the original indication for the active ingredient is correct.<sup>10</sup>

Physicians are increasingly aware of the advantages of generics.<sup>11</sup> By December 2000 generics already accounted for more than 5% of the prescription drug market, a figure that surpassed the national Health Administration's goal for the year 2002. Although regional differences were recorded, the average market share was as high as 7.6% in those parts of the country where health care services were provided by the National Institute of Health (INSALUD)<sup>5</sup> as opposed to regionally-administered health services.

Meanwhile, patients too have become better informed about the advantages of using generics. Several surveys showed that 50% of the users know what a generic

drug is, and that more than 80% of these patients know that generics are as effective as brand pharmaceuticals.<sup>5</sup> However, in daily practice at primary health care centers, it may be difficult to replace a patient's usual drug with a different product.<sup>12</sup> This situation is a further example of the key role that family physicians play,<sup>13</sup> as their daily contact with patients places them in the position of mediators between the health administration and patients themselves when new strategies are being implemented.

There is increasing awareness of the importance of informed consent<sup>14</sup> as a process in the physician-patient relationship. The present study therefore aimed to provide an appropriate volume of understandable information so that patients could decide whether it was in their interest to switch.<sup>15</sup> Moving away from paternalistic attitudes and toward more participatory processes is a current quality criterion that accompanies the paradigm shift in relationships between health care providers and users of the health care system.<sup>16</sup> The main objective of the present study was to determine which proportion of patients favored changing to a generic after they had received appropriate information, and to what degree the suggestion that they switch caused unease in the patient<sup>17</sup> or apprehension in the physician. The secondary aims were to determine whether accepting the switch to a generic was related with specific characteristics of the patient, the medication or the physician, and to analyze some causes of resistance to change.

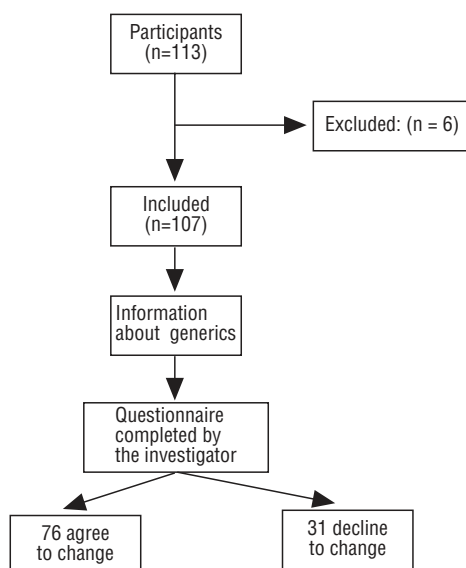
## Methods

This descriptive, cross-sectional study was carried out between July and October 2000 at the Boadilla del Monte Health Center and the Alpedrete Rural Health Center, both part of Health Area 6 in the province of Madrid (central Spain).

All 113 patients who came to the health centers and who were taking a medication for which a generic substitute was available were included. Patients with communication problems (because of language or hearing) were excluded, as were those who did not come to the center in person and whose relative declined responsibility for the decision to switch. In all, 6 patients were excluded, all for the second reason.

Three family physicians took part in the study; two saw their usual patients, and one saw patients who were temporarily residing (during their vacation) in the area served by the health center. The final sample consisted of 107 patients. All were given the same verbal information about generics in a brief explanation lasting approximately 40 to 60 s (Table 1). This was followed by a verbal questionnaire (Figure 1).

The data were analyzed with the SPSS program. An initial, descriptive (frequency) analysis of the sample was followed by analysis with chi-squared and Student's *t* tests to search for relationships between the variable «accepted change» and the other variables we recorded.



## General scheme of the study

Observational, cross-sectional study to determine the percentage of patients who, after receiving an appropriate explanation, agree to switch from their usual medication to a generic drug.

## Results

Of all patients, 71% (76 of 107) agreed to change to the generic. The physician perceived unease in 23.4% of the cases. Physicians felt satisfied with the interview 83.9% of the times, indifferent 12.9%, and unsatisfied 3.2% of the times. Slightly more than half of the patients (51%) knew what a generic is, and 12.1% of them used or had used generics before. The patient was present during the physician's talk in 73% of the cases. Mean age was 66.5 years, and 56.1% of the patients were men (43.9% women). About three-

fourths of the patients (77.6%) were receiving retirement benefits; the remaining 22.4% were actively employed. About two-thirds (67.3%) were taking two or more medications. The physician who suggested the change to generics was the patient's regular general practitioner in 24% of the cases. The medication for which a generic substitute was suggested had been initially prescribed by the patient's regular primary care physician in 41.1% of the cases, by a specialist in 54.2%, and by a different practitioner in 2.8% of the cases. The educational level of the patients was illiterate in 2%, primary education in 25%, secondary or technical education in 42%, and university-level education in 31%.

Of the 29% of the patients who opted not to switch, 67.4% said that they preferred to consult with the prescribing physician; 45.1% believed that the generic would not have the same effect; 16.1% said that if it was cheaper it must be worse than the brand-name drug; and another 16.1% said that they would accept the change if the alternative product were more expensive.

There was no statistically significant association between agreeing to change to the generic and any of the other variables we studied.

## Discussion

Medicine is the art of bringing about small changes in the patient that benefit both the patient and the community. In this study we hoped to evaluate the reasons why different persons hesitate when offered the possibility of changing their habitual treatment. Change is achieved only when the patient is given information and allowed to participate in the decision, without coercion or the imposition of authoritarian criteria. This approach leads to little practitioner apprehension and helps maintain a good physician-patient relationship based on trust and the patient's decision-making capacity. Informed consent as an ongoing process enhances the quality of medical practice and reinforces the relationship with the user. In recent years, bioethical concerns have clearly illustrated the need to transform paternalistic attitudes toward health care into more participatory approaches.

The fact that 75% of the patients were receiving retirement benefits makes the high percentage of patients who

**TABLE 1**  
**Explanation given to the patients**

«When a pharmaceutical company develops a new drug, they market it under an invented name and have exclusive sales rights for as long as their patent lasts. At the end of this period other companies can distribute the same drug and sell it under the name of the product's active ingredient. These drugs, which are the same in composition and effectiveness as the original one, are called generic drugs. This process saves money since the generic drug is cheaper, although just as effective. The Ministry of Health ensures that this is strictly enforced. Using generic drugs benefits the patient, who continues to take an equally effective drug, and benefits everybody by saving costs, which makes it possible to improve the National Health System.»

**FIGURE 1**

Data sheet

Age		
Sex	Male <input type="checkbox"/>	Female <input type="checkbox"/>
Social security coverage	General <input type="checkbox"/>	Retirement <input type="checkbox"/>
Patient present	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Prescribing physician	Regular <input type="checkbox"/>	Other <input type="checkbox"/>
Do you know what a generic drug is? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Do you think it would be okay if I changed your medication to a generic drug? Yes <input type="checkbox"/> No <input type="checkbox"/>		
If not...		
Do you think the generic is not going to have the same effect? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Do you think that because it is cheaper, it must be worse? Yes <input type="checkbox"/> No <input type="checkbox"/>		
If it were more expensive for you, would you consider changing? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Would you rather check with the doctor who prescribed the drug for you? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Use of medication (months)		
Physician who initially prescribed the drug	Regular doctor <input type="checkbox"/>	Specialist <input type="checkbox"/>
	Other <input type="checkbox"/>	
Regular use of two or more medications	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Currently using generics	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Education	Illiterate <input type="checkbox"/>	Primary <input type="checkbox"/>
	Secondary/Technical <input type="checkbox"/>	University <input type="checkbox"/>
Did the physician note any unease on the patient's part? Yes <input type="checkbox"/> No <input type="checkbox"/>		
How did the physician feel?	Satisfied <input type="checkbox"/>	Indifferent <input type="checkbox"/>
	Unsatisfied <input type="checkbox"/>	

agreed to change to a generic all the more noteworthy, as this population is assumed to be less open to change.

This study did not identify any patient-, medication- or physician-related characteristics that were associated with greater ease or difficulty in switching to a generic. If we had used a larger sample we probably would have found some statistically significant association with at least one of the variables we investigated.

The main reasons patients gave for refusing to change to a generic were doubts about its efficacy and preferring that the physician who originally prescribed the medication recommend the change. These two sources of reticence can be mitigated with additional information campaigns and with a wider use of generics in specialized care. Price was not a factor that favored change: few patients thought that the cheaper product would be less effective. The explanation for this lies in the fact that most of our sample of participants were retired persons, and the advice of a health professional was probably more important to these patients than any possible cost savings.

The main limitation of our results is that they were obtained with a closed questionnaire with four possible answers per item; patients chose one or more option for each ques-

tion. This approach was used to avoid the risk of influencing the responses. However, an open questionnaire would have made the analysis more complicated.

The accuracy of our results is supported by the fact that the percentage of patients in our sample who knew what a generic is (51%) is similar to the figure published by the Ministry of Health and Consumer Affairs.

The large percentage of patients who were taking two or more medications (67.3%) is a final point worthy of note. This population in particular stands to benefit from the switch to generics, as one of the advantages of this measure is to avoid duplicate treatments, a frequent result of the enormous variety of brand names under which the same active principle is marketed. An added value of this study is the fact that it complied scrupulously with criteria for informed consent. This endows medical practice with greater transparency, and fosters good physician-patient relations.

## Conclusion

Our data show that investing less than 1 minute during the physician-patient encounter has considerable advanta-

### What is known about the subject

- Enactment of the law that implemented a system of reference prices led to a 50% increase in the number of active pharmaceutical ingredients available as generics in Spain.
- By December 2000 generics already accounted for more than 5% of all pharmaceutical sales, a figure that surpassed the national health administration's goal for 2002.
- Information sessions and feedback about prescribing behaviors significantly increased generic prescribing.
- Half of the population in our study knows what a generic drug is.

### What this study contributes

- After receiving a brief explanation from their physician, 70% of the patients agreed to switch to a generic.
- Suggesting the change from a brand medication to a generic and involving the patient in the decision does not lead to physician apprehension.
- The main reasons patients gave for refusing to change to a generic were doubts about its efficacy and preferring that the physician who originally prescribed the medication recommend the change.

ges: the patient obtains appropriate information on generics, which facilitates the change from a habitually-used medication to a generic product in nearly three-fourths of the patients.

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## COMMENTARY

# Problems with increasing the use of generic drugs in Spain

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The interesting article in this issue by Casado Buendía and colleagues begins by recalling the novelty, in the Spanish market, of generic drugs, and by describing legislative developments in detail. These new measures are aimed at favoring the use of generic drugs, and naturally, at containing public expenditure in the pharmacies. However, the study draws attention to another novel characteristic of the generic drug market in Spain, which has been little covered in the media and rarely analyzed by physicians and pharmacists: the degree to which the citizen-user-patient actually accepts generic prescriptions, and the rate of substitution of brand-name products for generic ones. The study was designed to determine the degree of acceptance by users after they had received correct information about their health problem and about the characteristics of the medication recommended and prescribed through the public health system. This is what we now know as informed consent.

Generic drugs have been on the Spanish market for a bit longer than 5 years.<sup>1</sup> The availability of generics was followed by the establishment of reference prices for groups of pharmaceuticals. Each group listing must contain at least one generic, members must be bioequivalent, and must be identified with the initials «EQ».<sup>2</sup> These structural changes were preceded by the elimination of public financing (the negative lists) for more than 1500 pharmaceutical products. These exclusions, undertaken by both the Spanish Socialist Workers Party in 1993 and by the Popular Party in 1997, were based on the need to contain health costs for medications, and were supported by expert commission documents such as the 1991 Abril-Matorell Report and the 1993 Report on Qualitative Indicators,<sup>3</sup> which classified all medications available in the Spanish market according to potential quality or known therapeutic value. Current analyses based on evidence-based medicine establish different recommendations for each pharmaceutical on the basis of the quality of the scientific evidence.

These measures, requested by professional organizations<sup>4</sup> and by Parliament, were put in place when politicians (as in Germany, The Netherlands, Denmark, Sweden and Norway) became convinced that the provisional cost containment measures taken by the Ministry of Health and

- Generics became available on the Spanish market more than 5 years ago. This measure was followed by the creation of reference prices.
- These structural changes were preceded by the exclusion from public financing of more than 1500 pharmaceuticals. This measure was implemented by both the Spanish Socialist Workers' Party in 1993 and by the Popular Party in 1997.
- A large proportion of patients agreed to switch from a brand-name product to a generic after they had received appropriate information.
- The General Directorate of Pharmacy should be urged to take measures to prevent the expert groups that advise this body on «prescribing and dispensing» from consisting only of «experts in dispensing», ie, pharmacists themselves.<sup>6</sup>

Consumer Affairs (MHCA) by negotiating pacts with the College of Pharmacists and Farmaindustria, the organism that represents pharmaceutical firms in Spain (ie, a return of 0.7% to 1.6% on their investment), were insufficient, and that real costs were continuing to rise yearly at a rate greater than the gross national product.

These regulations and structural measures were aimed at modifying the supply of generics and reducing the cost of brand-name products by introducing another novelty: the possibility of copayment (the patient pays part of the total price of the product if he or she prefers a brand name that costs more than the reference price), or substitution, under certain circumstances, upon dispensation in the pharmacy. To favor cooperation by pharmacists, an increase in their profit margin for generics from 27.9% to 33% was agreed. In contrast to increasing the fixed profit margin, which is the same for all pharmacies in the country, a different approach was used for prescribing physicians in some autonomous communities, and in certain cases. Incentives and specific interventions were proposed to favor generic pres-

cribing, with specific goals negotiated through service contracts with the National Institute of Health (INSALUD), or through specific agreements such as that negotiated with pharmacists in Catalonia.<sup>5</sup> To favor cooperation by patients, the MHCA and autonomous communities developed a public information campaign to run for just over 20 days, at a cost of over 330 million pesetas (about 2 million euros).

One of the collateral effects of the new measures was to foment an increase in irrational dispensing at pharmacies, a result that merits a brief commentary for the purposes of stimulating debate. The most common practice is the use of a credit system in which, upon purchasing a given generic product, the buyer is given, at no extra cost, medications and other health care products whose total worth is, in some cases, more than the cost of the prescription being filled. As a result, many pharmacists fill prescriptions with a product made by a manufacturer that offers additional free products instead of the generic specified in the patient's prescription: a practice known as substitution. This confuses the consumer because of constant changes that lead to no direct benefit, and because of apathy on the part of physicians who prefer one brand over another. The INSALUD has issued several warnings, noting that substitution of one generic for another should be the exception rather than the rule. In June 2001, the General Directorate of Pharmacy reprimanded Farmaindustria a second time for encouraging the credit system in pharmacies that dispense generics covered by the national health system.

The market for generics has leveled off, and now represents 5%-6% of all pharmaceutical costs to the national health system. This has disappointed professional groups with a stake in generics, the MHCA, and the manufacturers of generics. The MHCA has expressed its apparent satisfaction over the fact that pharmaceutical costs rose by less than 10% per year during 2000 and 2001, as a result of price decreases by brand-name companies to comply with the reference prices. But an analysis of costs during the first part of 2002 has set alarm bells ringing: in comparison to 2001, increases have averaged between 12% and 13% nationwide, with some autonomous communities reporting increases of more than 16%.

From the viewpoint of prescribing physicians, the policy of incentives should be broadened and deepened. This will be necessary to generate a culture of change in deeply-rooted habits. In addition, prescribing physicians have been pleading for the administration to lay aside its permissiveness and clamp down on instances of noncompliance with current regulations on substitute dispensing in pharmacies.<sup>6</sup> Out of respect for colleagues who contribute their expertise to these advisory groups, an analysis of the problems surrounding indications and prescribing practices, and

proposals for improvement, should not be left exclusively in the hands of experts in pharmaceutical dispensation.

As the study by Casado Buendía and colleagues shows, quite a large proportion of patients agreed to switch from a brand-name product to a generic after they had received appropriate information. Their decision rarely led to unease on the patient's part or apprehension on the physician's. This study supports the favorable impressions obtained in surveys undertaken by the MHCA and autonomous communities, and in reports to the Spanish Congress and Economic and Social Council.

In summary, patients who understand and cooperate with generic prescribing once they have been adequately informed are to be commended. However, poor marks go to health authorities responsible for developing regulatory measures who use provisional, primarily economic interventions that do not emphasize or follow on from earlier, successful initiatives to create incentives for the generics market measures which have been shown to be effective and efficient.<sup>6</sup> The provisional measures do not go to the heart of the problem, when the facts are that more than half of the annual growth in pharmaceutical costs is due to the introduction of new and more expensive drugs, and that experts continue to recommend the entry of such new products in the market. We encourage the new minister of Health and Consumer Affairs to attend to the essence of measures set down in the legislation in effect since 2000<sup>2</sup> that regulates reference prices.

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