

Evaluating, improving and monitoring generic drug prescription

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Objective. To evaluate and improve generic drug prescription by family physicians in a regional primary care district with a specially-designed intervention. Design. Uncontrolled study of an intervention, based quality evaluation and improvement methods. We selected an indicator that could be constructed with the available data (monthly reports of prescriptions dispensed through the public national health system) and determined the proportion of prescriptions for generic drugs to the total number of prescriptions dispensed, for those medications that had a generic alternative (percentage of generic prescriptions, PGP). After these data were evaluated, an intervention was implemented to increase generic prescriptions. Prescribing behavior was again evaluated and monitored at the end of the intervention period.

Setting. Forty-five primary care teams in the Murcia (Southeast Spain) regional primary care district. Participants. A total of 339 family physicians. Interventions. During 15 months, individual reports of prescribing practices, in which changes over time were graphed, were sent to each participating prescriber. Each semester the physicians received a personal letter and a specially-printed, updated card showing the generic medications available and their pharmaceutical forms. One to three face-to-face clinical outreach sessions were held with each primary care team. Specific prescribing goals for the PGP were set and incentives to attain the goals were included in the terms of the contract for clinical services signed between the regional office of primary care management and each primary care team.

Main outcome measures. The PGP increased from a pre-intervention rate of 2.7% to a postintervention rate of 17.63%. Absolute improvement was therefore 14.84%, and relative improvement was 15.27%. Variability was monitored and analyzed with control charts. There was no significant variability within the pre- and post-intervention phases, whereas variability increased significantly (indicating improvement) during the intervention phase. Conclusions. The increase in PGP showed that prescribing for generic preparations improved. Statistical quality control tests were useful in evaluating and tracking the results of the intervention, and were indispensable for monitoring and promptly detecting opportunities to improve prescribing behavior and take appropriate measures.

Key words: Generic. Quality. Primary care. Use of medications.

EVALUACIÓN, MEJORA Y MONITORIZACIÓN DE LA PRESCRIPCIÓN DE MEDICAMENTOS **GENÉRICOS**

Objetivo. Evaluar y mejorar la prescripción de medicamentos genéricos por los médicos de familia de una gerencia de atención primaria (GAP) mediante un programa de intervención.

Diseño. Estudio de intervención no controlado, basado en la metodología de evaluación y mejora de la calidad. Seleccionamos un indicador capaz de ser construido con los datos disponibles (cinta de facturación), eligiendo la proporción de genéricos prescritos sobre el total de envases en que existe alternativa genérica (PPEFG). Evaluamos, diseñamos una intervención para mejorar, reevaluamos y monitorizamos. Emplazamiento. Cuarenta y cinco EAP de la GAP de Murcia.

Participantes. Un total de 339 médicos de familia.

Intervenciones. Realizadas durante 15 meses, fueron: remisión de informe mensual personalizado mostrando la evolución del PPEFG mediante gráficos de desarrollo; edición y entrega personalizada semestral de una tarjeta con los medicamentos genéricos disponibles y sus presentaciones; realización de 1-3 sesiones/EAP, e inclusión de un objetivo en PPEFG explícito e incentivado en los contratos de gestión.

Mediciones y resultados principales. El PPEFG preintervención fue del 2,79% y el postintervención de un 17,63%. La mejora absoluta es del 14,84% y la relativa de un 15,27%. Se ha monitorizado y analizado la variabilidad mediante gráficos de control. No se detecta variabilidad significativa en las fases pre y postintervención y sí (hacia la mejora) durante la intervención.

Conclusiones. Ha mejorado la prescripción de genéricos medida en PPEFG. Las técnicas de control estadístico de la calidad aplicadas son útiles en la evaluación y seguimiento de la intervención e imprescindibles para monitorizar, detectar precozmente oportunidades de mejora y actuar en consecuencia.

Palabras clave: Genéricos. Calidad. Atención primaria. Utilización de medicamentos.

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A commentary follow this article (pág. 405)

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Introduction

rug prescription, a decision-making process that physicians must often perform, 1 is one of the largest items of health resource consumption in the Spanish National Health System.² The analysis of prescribing practices—which vary widely—is not a simple task, ^{3,4} as it involves issues of effectiveness and efficiency, as well as consideration of the patients' needs and expectations.⁵ According to the World Health Organization, the continuous evaluation of prescribing behavior should be customary practice to guarantee the quality of treatment and control iatrogenic risks.⁶ In addition, the use of drugs satisfies all three characteristics that have been suggested for measures that require evaluation and monitoring (high frequency, high risk and tendency to create problems).7 Monitoring of drug use can be approached from three standpoints, which Saturno⁸ has called pharmacologic (efficacy and effectiveness of drugs), economic (efficiency and optimization of use) and structural rationality. This systematic analysis has become a necessity in efforts to improve drug use.9 However, this approach (measuring what is done accompanied by interventions to do it better) is not the most widely known one. In Spain the health system provides mainly quantitative information aimed at controlling costs, 10 although information from a qualitative viewpoint is becoming more commonplace^{11,12} (possibly because of an awareness that better prescribing practices lead, in the long run, to cost savings).¹³ However, qualitative information seems at present to be insufficient in itself to improve practices. As a result the World Organization of family doctors developed five steps to be followed to attain and maintain improvements in the use of medications.14

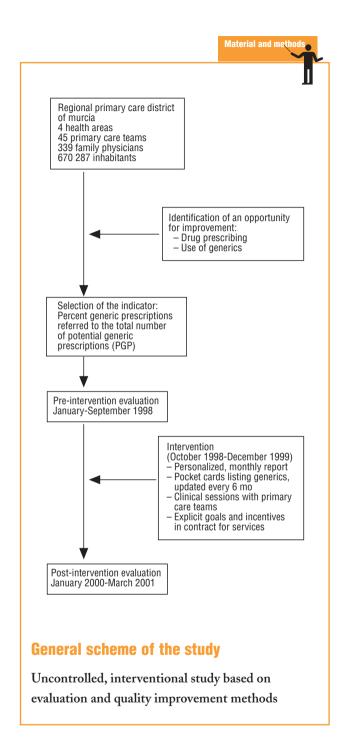
The present study reports the results of a specially-designed intervention to evaluate and improve the prescribing behavior of family physicians (FP) in a regional primary care district in Spain.

Material and methods

The regional primary care district of Murcia comprises four of the six health areas in the autonomous region of Murcia, in southeastern Spain. In 1998, when the study was begun, it employed 339 FP organized in 45 primary care teams, who provided medical care to 670 287 inhabitants.

Choice of indicator

Data on the prescriptions dispensed in the regional primary care district were obtained from the monthly reports of prescriptions sent to the Official College of Pharmacists. These lists detailed the medications prescribed by each FP that are covered by the national health system and which were dispensed through pharmacies, but did not identify the patients for whom the medications were prescribed. Of all potential indicators, we chose the



percent proportion of prescriptions for generic drugs relative to the total number of prescriptions dispensed during a given month, for those medications that had a generic alternative (percentage of generic prescriptions, PGP). We defined generic drug to mean a medication marketed under its international nonproprietary name and the name of the manufacturer, which had documented therapeutic equivalence to the reference (brand name) medication, and which cost less than the reference medication. In Spain generic drugs are designated EFG (especialidad farmacéutica genérica).¹⁵

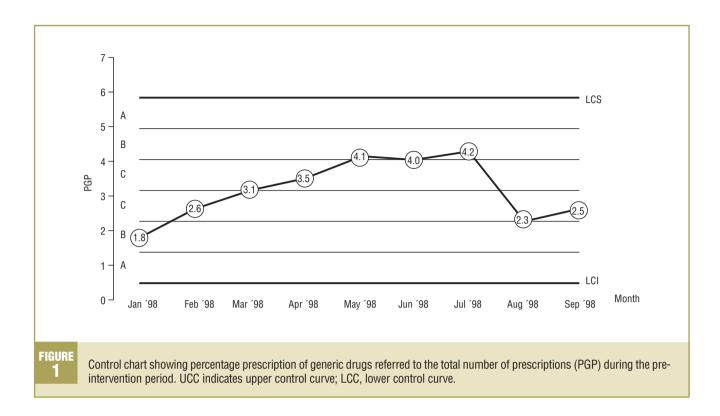
TABLE Number of packages analyzed and percentage of generic prescriptions referred to the total number of prescriptions (PGP), 1 by month. Mean PGP and standard deviation (SD) during the three phases of the study

Phase	Month	Packages dispensed		PGP	
			Per month	Mean	SD
Pre-intervention	l				
	Jan ´98	866,672	1.77		
	Feb '98	798,987	2.62		
	Mar ´98	829,810	3.13		
	Apr '98	780,539	3.46		
	May '98	800,073	4.09	3.12	0.88
	Jun '98	774,525	3.98		
	Jul '98	745,685	4.22		
	Aug '98	677,975	2.26		
	Sep '98	755,547	2.52		
ntervention					
	Oct '98	788,122	6.05		
	Nov ´98	681,272	6.05		
	Dec '98	703,090	7.77		
	Jan ´99	873,344	7.28		
	Feb '99	880,018	8.21		
	Mar ´99	847,465	9.36		
	Apr ´99	847,298	10.22		
	May '99	832,117	13.45	11.9	4.34
	Jun ´99	758,674	13.42		
	Jul '99	768,638	13.83		
	Aug '99	668,042	13.80		
	Sep '99	807,867	15.14		
	Oct '99	836,734	17.17		
	Nov '99	790,240	18.06		
	Dec '99	829,339	18.67		
Post-interventio	ın				
	Jan ´00	964,860	16.54		
	Feb '00	870,026	16.50		
	Mar ´00	874,383	19.00		
	Apr '00	794,971	17.57		
	May '00	861,630	16.20		
	Jun '00	844,479	18.82		-
	Jul '00	853,306	20.91		
	Aug '00	670,257	19.03	20.25	3.82
	Sep '00	896,530	16.35		
	Oct '00	890,840	20.41		
	Nov '00	986,740	20.75		
	Dec '00	900,588	27.97		
	Jan '01	980,640	21.34		
	Feb '01	918,352	26.88		
	Mar '01	1,035,132	25.45		

Implementation of the intervention

From October 1998 to March 2000 the office of management of the regional primary care district ran a program aimed at facilitating improvements in drug prescribing practices. The program consisted of the following actions:

1. Each FP received an individual monthly report of his or her prescribing practices, in which changes in PGP over time since January 1998 were graphed. Information about the changes in PGP for the physician's primary care team and for the entire primary health care district over the same period was also provi-



ded. Physicians and pharmacies were still required to submit monthly reports of prescriptions and pharmaceutical costs.

2. Each semester all FP received a personal letter and a speciallyprinted card listing the generic drugs available and their pharmaceutical forms, grouped according to indication (anti-infectives, neuropsychiatric drugs, cardiovascular drugs, digestive system drugs, analgesics, anti-inflammatories, miscellaneous) and arranged in alphabetical order. The cards were updated every six months to include new generics on the market, which were highlighted. Each card was sent together with a personal letter from the head of the office of management to all FP in the regional primary care district and to all physicians under temporary contract with the regional public health system. The cards were designed to be esthetically pleasing, and were printed on heavy, durable stock, then laminated. Different groups of drugs were highlighted with different colors. The cards were sized (165 × 100 mm) to fit inside the breast pocket of a lab coat or to be affixed to the computerized prescription label printer.

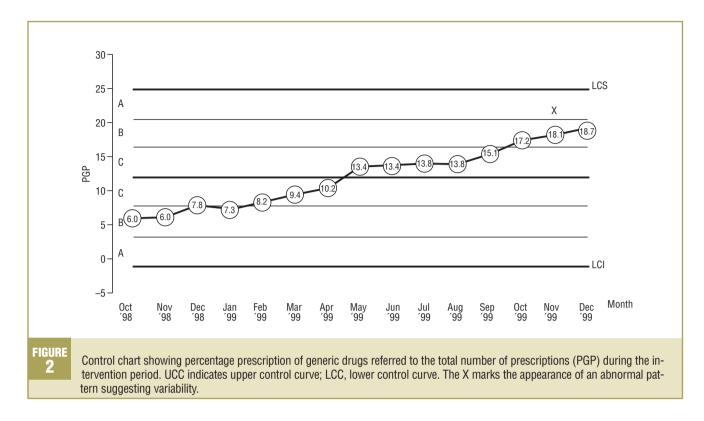
3. One to three (mode, two) face-to-face clinical outreach sessions were held with each primary care team. These meetings were called by the team member responsible for quality control, and were held during working hours. During these meetings, members of the primary care team discussed the most recent report on generic drug prescribing behavior and the best generics available as alternatives to brand-name medications.

4. Specific prescribing goals for the PGP were set for the years 1999 (12.0%) and 2000 (20.0%), and incentives to attain the goals were included in the terms of the contract for clinical services signed between the office of management of the regional primary care district and each primary care team. These contracts were signed by each FP on the primary care team, and a salary bonus of 250 000 pesetas (about 1500 euros) per practitioner was stipulated if the goals were met. The final amount of the payment for each primary care team was determined by the spe-

cific goals met with regard to (in addition to the PGP) the results for services provided, remaining within budgetary allowances for staff substitutions, drug costs, accessibility and waiting periods, and user satisfaction surveys. Payments were distributed among members of the primary care team who signed the clinical services contract on the basis of agreed-upon criteria which were ratified by the office of management.

Evaluation of effectiveness

The effectiveness of the program was evaluated in two ways. Improvements in prescribing behavior were tracked by calculating the absolute and relative differences in PGP between the 3month period immediately preceding the program (July to September 1998) and the 3 months immediately after the program (January to March 2000). To calculate relative improvement, absolute improvement was divided by total potential improvement. In addition, we monitored PGP with statistical quality control methods.¹⁶ Essentially, variability of the indicator was graphed to judge whether the indicator showed stable behavior; this analysis was done with methods similar to those traditionally used to compare hypotheses. According to the null hypothesis the indicator would remain stable. The alternative hypothesis that the indicator would show variability—was confirmed by visual analysis of the shape of the curve. We monitored PGP with control charts.¹⁷ Changes in PGP about an average value were plotted with limits at ± 3 standard deviations (SD), which represented a risk of α error <0.01. We also defined three zones above and below the average (A, B and C), delimited by ±1, ±2 and ±3 SD, to facilitate the visualization of patterns of distribution of the indicator that might suggest variability, and to increase the sensitivity of the graph. The distribution patterns were based on those described by Kume¹⁷ and Farnum¹⁸ as adapted by Saturno. 16 The same technique was used to check stability of the indicator before and after the intervention. For the pre-in-



tervention analysis we used PGP values for the period from January to September 1998, and for the post-intervention analysis the values were those for the period from January 2000 to March 2001.

Results

Prescribing practices for all FP in the Murcia regional primary care district were analyzed. A total of 24 466 872 packages of medications were dispensed, for a mean of 827 816 packages per month (maximum 1 035 132, minimum 668 042, SD 86 904).

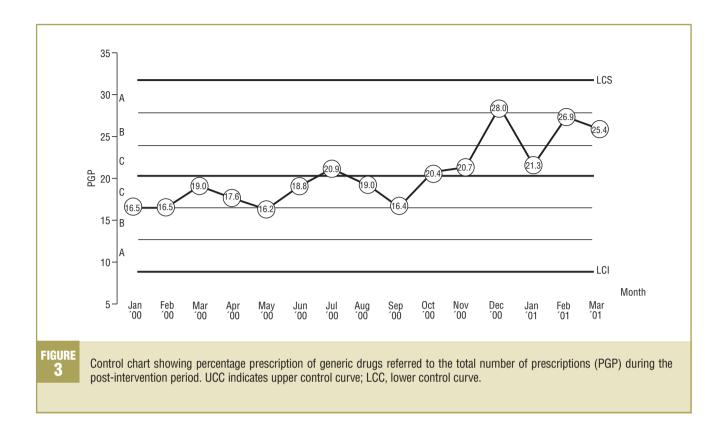
The pre-intervention PGP was 2.79%, and the post-intervention figure was 17.63%. Absolute improvement was therefore 14.84%, and relative improvement was 15.27%. Monthly PGP values ranged from 1.77% to 27.97%, with a mean of 13.08% and an SD of 7.54%. In the pre-intervention period (before October 1998) mean PGP was 3.12%. During the intervention (October 1998 to December 1999), mean PGP was 11.90%, and after the intervention (January 2000 to March 2001), mean PGP was 20.25%. Table 1 shows the changes in PGP and in the number of packages of drugs prescribed in each phase. The control charts for each phase are shown in Figures 1 to 3. We saw no signs of significant variability in the pre- and post-intervention phases based on the criteria used in this study. In the intervention phase we noted a sequence indicating significant variability, which consisted of five successively increasing values from June 1999 onward.

Discussion

The choice of indicator

The development and choice of indicators is an activity that is basic to monitoring and quality assurance programs. 19 The indicators used to measure drug prescribing or dispensation should show adequate validity and reliability, and should also be specifically focused.²⁰ In this regard, indicators developed from user reports appear to represent one of the best choices,²¹ as they have been shown to have appropriate levels of validity^{22,23} and to provide information that cannot be obtained from any other source,²⁴ because they shift the center of attention from the drug25 to the patient, which then becomes the preferential unit of study. 26,27

However, the factor most often used to decide which indicator to use has traditionally been availability of the data and ease in obtaining them.⁸ This approach, which we used here in the form of the monthly reports of packages of drugs sold through the pharmacies, may appear less than ideal as it provides indicators whose focus is global or related with efficiency. 10 Nonetheless, a high rate of generic prescribing has been related with improvements in drug use,8 and many examples of this association have been published.²⁸⁻³² There is also a recognized relationship between generic prescribing and improvements in efficiency, 33,34 one of the quality dimensions recognized by most authors. Because of its validity and because of the accessibility of the data, we decided to use generic drug pres-



cribing as an indicator to evaluate, enhance and monitor drug use, although we were aware of the existence of other features of prescribing behavior not considered here but known to be involved in the rational use of drugs.

The choice of the PGP indicator proposed by the Spanish National Institute of Health (INSALUD) on in its program for improving prescription practices, ¹¹ as opposed to other indicators traditionally used in studies of generic prescribing ^{26–32} (absolute percentage of generic drugs prescribed, prescriptions adjusted for population, daily doses per 1000 inhabitants, choice of active principles, cost savings, ect.), was motivated by the rapid appearance of new products and active principles in the form of generics during the study period. An indicator unable to take these new products into account might have shown an artificial tendency toward improved prescribing practices by greatly increasing the number of prescriptions for which a generic alternative was available.

The intervention

The measures that can be taken to improve drug utilization are many and varied. They appear to be more effective when accompanied by quality control methods, when they are preferentially internal in nature, and when they are implemented in small groups, ideally in face-to-face meetings. ^{35,36} According to some authors, measures aimed at training are the most useful; ³⁷ however, such interventions cannot be used limitlessly, as studies have shown that such measures lose their effectiveness if they are used mo-

re than two or three times a year.³⁸ Educational measures that emphasize information about prescribing practices have also been shown effective, ^{39,40} and their effectiveness is maintained with time.⁴¹ Effectiveness is influenced to a great extent by the type of indicators contained in the available information. For example, those that monitor features of prescribing-on which there is no clear consensus among FPs-or those that simply reflect prescribing patterns, ⁴² do not seem able to significantly improve prescribing quality. The use of generics, ie, the indicator we chose in the present study, is not among this group of indicators, and has been found useful on other occasions. ^{28,39}

Our intervention was intended to include characteristics that have been shown to be associated with greater effectiveness. The most important of these features are: a) personalized information about prescribing behavior and proposals to improve prescribing rates (pocket card listing generic drugs); b) control charts and graphicallypresented information used to make information more attractive and readily assimilated by FPs; c) face-to-face sessions with FPs to take advantage of positive peer pressure in favor of changing prescribing habits; d) information provided twice yearly on how to attain further improvements, supplied on pocket cards; e) use of specific goals to be reached, identifiable with the desired quality standard, and f) involving FPs in the design of incentives, which required explicit commitments from the practitioners.



What is known about the subject

- Drug prescribing, one of the most frequent activities of family physicians, is a major item in pharmaceutical costs which should be analyzed in a systematic manner.
- Improving and maintaining generic drug prescription levels can lead to greater efficiency in prescribing practices.
- The use of quality control methods together with specific types of information (specific training, information on prescribing not based on individual profiles, data on prescription drug consumption, etc.) appears to be able to improve the use of medications.

What this study contributes

- The proportion of generic drugs prescribed with reference to the total number of packages of medications for which a generic alternative is available (PGP) is a reliable indicator to evaluate generic prescribing in times of change in the availability of this type of medication.
- The interventions we propose are recognized as effective in other studies and easy to implement with the resources usually available.
- Statistical quality control techniques (control charts) promptly reveal unfavorable trends and opportunities to take appropriate measures.

Proven effectiveness

The results we obtained reflected an increase in generic prescribing both in percentage terms and as seen in the control charts (Table 1). Because we used complete records of prescriptions dispensed through the pharmacies to calculate PGP (ie, the figures reflected prescriptions actually dispensed, not estimates, for the entire regional primary care district), it was not necessary to use tests of statistical significance to document improvements. On the other hand, statistical quality control techniques showed that the indicator was stable before and after the intervention (Figures 1 and 3) and varied significantly toward improvement during the intervention (Figure 2). This is evidence that the program we designed was responsible for the improvements.

We should note that the INSALUD reported an overall increase in the use of generics for the period when our study was carried out. 10 This situation was expected in the light of the increasing number of generic drugs on the market in Spain. However, the use of raw percentages of prescriptions in the INSALUD reports means that these improvements may represent «false positives» induced by the increased availability of generics. We tried to avoid this pitfall by using the PGP, which «standardizes» the actual number of prescriptions against the number of generic drugs available.

It should be recalled, however, that this study centered on evaluating and improving prescription behavior, and was not designed explicitly to evaluate the effectiveness of our intervention. The evidence we provide is therefore insufficient to state that the improvement observed was a direct consequence of our program. Such proof will require further studies designed to compare the present results with those obtained in a control group; no such group was used here, as we included in our program all FPs in the regional primary care district under study. As in the present report, many other earlier studies also lacked a control group, and as several authors have noted, 28,43 the effectiveness of the interventions they studied should be interpreted with caution.

The statistical control techniques we used were shown to be useful, and would appear to be indispensable for the efficient monitoring of change in prescribing practices. These techniques make it possible to promptly detect opportunities for improvement (unfavorable trends) and take appropriate measures.

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COMMENTARY

Opportunities to improve generic drug prescribing

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Opportunities to improve generic drug prescribing

The international scenario in which generic drugs appeared in the 1970s was very different from the one we are currently contemplating. There were four main reasons for the appearance of generics: imminent patent expiration, a fall in the rate of important innovations, increased legislative control of new therapeutic substances, and a sudden decline in economic growth in western countries. Fifteen years later, during the mid-1980s, a new era began: that of expensive drugs based on new products that were marketed at much higher prices in comparison to older drugs.¹ The angiontensin-converting enzyme inhibitors (ACEI) that appeared for hypertension differed markedly from diuretics and beta-blockers, and currently, angiotensin receptor agonists (ARA-II) represent a further increase in costs compared to ACEI. For hypercholesterolemia, statins have supplanted fibrates; for depression, selective serotonin-reuptake inhibitors have taken the place of tricyclic antidepressants; for gastric ulcer, proton pump inhibitors have substituted H2-receptor antagonists; for benign prostate hypertrophy, finasteride and alpha-blockers are used instead of plant extracts; in psychiatry, new neuroleptics take the place of traditional neuroleptics. The differences in price between the new and the old drugs is evident both in countries with price controls and countries such as the USA, where prices are set by the manufactu-

In addition, life expectancies have increased, the economy has entered a growth phase, and generics actually appeared in Spain barely 4 years ago, in a setting very different from that of the 1970s.

On a worldwide level, the aim of the introduction of generics was --among others-- to help keep drug costs within acceptable limits. The various structural measures implemented in Spain to control drug costs since 1997 are: an agreement with Farmaindustria (the pharmaceutical industry's representative body in Spain) which led to a cost reduction of 18%; negative lists (pharmaceuticals excluded from public funding) (12% reduction in costs); reductions in wholesalers' profit margins and discounts (43% reduction in costs); reductions in price (24%); and

Key points

- The mid-1980s saw the start of a new era—the age of expensive drugs—characterized by large price differences between the newer drugs and older drugs.
- The contribution of generic drugs and reference prices to cost savings in the public health system has been rather modest to date; however, achieving these savings requires active involvement on the part of physicians.
- Although the percentage of generic prescriptions can be high, this indicator may be subject to artifacts and manipulation. The indicator of generic prescribing can provide indications of efficiency when used in conjunction with other, complementary indicators of prescribing quality.
- Information systems will improve greatly in coming years, and different health services will act as catalysts for measures to support the rational, reasoned, efficient, judicious, evidencebased use of drugs.

use of generics and reference prices (maximum amount per product the government is prepared to underwrite through the public health system).³ It will be appreciated that the contribution made by generics and reference prices to the overall savings in drug costs has been rather modest; however, of all the measures taken to date, it is the only one whose success requires active involvement on the part of physicians.

In the clinical setting, initial doubts about the quality of generics have been overcome in Spain, and the only significant difference between a generic and a brand-name equivalent is in the composition of the excipient⁴ or in morpholgy.⁵ After reference prices were introduced, the consumption of generics in Spain leveled off in 2001 despite efforts by the administration to facilitate the authorization process. Up until that same year prescribing rates varied widely between autonomous communities, with the

highest figures being recorded for Madrid, Catalunya and the Balearic Islands.⁶

Measures aimed at the clinical setting have also been proposed to keep drug costs down. Some of these measures have been linked to incentives for family physicians, the practitioners ultimately responsible for distributing primary care resources. In Spain, prescriptions written by family physicians account for 80% of pharmaceutical costs to the national health system.⁷

The article by J.J. López-Picazo and colleagues⁸ reports on a program to evaluate and improve generic prescribing practices. Their program included the use of personalized reports, pocket cards with information on available generics, clinical training sessions and economic incentives. As the authors note, statistical quality control techniques were effective in evaluating and tracking the influence of the program on generic prescribing.8 The indicator these authors propose to determine generic prescribing rates in each clinic merits interest: the percentage of packages of generics prescribed. This information can reveal opportunities for improvement at each primary care clinic. However, the indicator should be used together with other complementary indicators, as it cannot itself provide information on the quality of prescribing practices, ie, the most sought-after opportunity for improvement. True quality in prescribing begins with the correct diagnosis of the patient, which is not a simple task. The second step is selection of the best medication. When this decision is made, further decisions about the type of drug and active principle are needed. It is at this point where discussions over whether to use a brand-name product, a generic produced by a specific manufacturer, or a «wholesale» generic can begin. A further issue that deserves consideration is prescription substitution.

Although the percentage of generic prescriptions can be high, this indicator may be subject to artifacts or manipulation through the indiscriminate use of antibiotics or the use of antibiotics for viral processes; prescribing generic cephalosporins rather than brand-name penicillins; prescribing generics of doubtful therapeutic usefulness; increasing the generic prescribing rate by prescribing packages that contain smaller numbers of pills or capsules, thereby duplicating the number of packages prescribed; or prescribing very cheap generics as analgesics.

The indicator of generic prescribing can provide evidence of efficiency when used in conjunction with other, complementary indicators of prescribing quality. Computerized systems for storing and retrieving patients' records will provide the information needed for further studies of prescribing quality as it relates to diagnostic criteria, comorbidity associated treatments and individual factors.

In light of our awareness that noncompliance with treatment is frequent, ¹⁰ that up to one-third of the packages of

drugs not used by patients are intact, ¹¹ that there is always some degree of risk in any intervention, ¹² and that some drugs such as antibiotics are abused, ¹³ it is clear that the main source of savings lies in prescribing drugs in accordance with their indications. However, this requires continued training and systems or tools that provide primary care physicians with access to information in the clinic where the patients are seen, and where primary care pharmacists aim to serve as a source of support.

Information systems will improve greatly in coming years, and different health services will act as catalysts for measures to support the rational, reasoned, efficient, judicious, evidence-based use of drugs. There are no unique, magic procedures to contain pharmaceutical costs and improve prescribing quality. The contribution of generics in the current health care milieu is modest, but there is still room for expansion.

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