ORIGINAL ARTICLE

Knowledge and attitudes of physicians and pharmacists towards the use of generic medicines in Bosnia and Herzegovina

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ABSTRACT

Aim To investigate and assess knowledge and attitudes of pharmacists and physicians towards generic drugs prescription in order to evaluate current trends, obstacles to prescribe/dispense generics and suggest possible improvements of rational and economic prescribing having in mind scarce public budgets for drugs.

Methods A cross-sectional survey among 450 primary care physicians (prescribers) and pharmacists in four major cities in Bosnia and Herzegovina (Sarajevo, Banja Luka, Tuzla and Mostar) during the period between January and March 2016 was conducted. The survey (questionnaire) was developed and physicians' and pharmacists' perception was examined using the 5-point Likert scale. Descriptive statistics was used to examine respondents' characteristics and their responses to survey questions. The respondents perception based on different characteristics was assessed using ordinal logistic regression.

Results Generally, positive attitudes towards generic drugs were found. Majority of respondents, 392 (87.0%) considered generic drugs the same as originators and they could be mutually substituted. Physicians were more likely to prescribe branded drugs, 297 (66.6%), even 391 (86.8%) were aware of generic alternatives. Respondents believed that patients considered generic drugs less effective, 204 (45.4%), and 221 (49.0%) disapproved generic substitution.

Conclusion Our findings suggest that further education and more information about benefits of generic drugs should be provided to key stakeholders including patients. Also, clearer generic drugs policies should be introduced in order to improve generic prescribing and potentially improve access and optimize pharmaceutical public expenditures.

Key words: drug substitution, practice patterns, economics, policy

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Original submission:
28 June 2016;
Revised submission:
25 July 2016;
Accepted:
19 September 2016.
doi: 10.17392/867-16

Med Glas (Zenica) 2017; 14(1):25-32

INTRODUCTION

Pharmaceutical expenditure is constantly growing worldwide due to different reasons such as growing rate of aging population, new drugs introduction into the market and an increasing trends of chronic diseases (1). Similar trends are noted in Bosnia and Herzegovina (B&H) as reported by two major health insurance funds (HIF), one from the Federation of Bosnia and Herzegovina (FB&H) and the other from Republic of Srpska (RS), which report an increasing level of drug costs contribution, around 21% in total public health care expenditures (2,3).

Majority of medicines are reimbursed by HIFs either as full coverage or through certain levels of patient co-payment. It is also noted that the level of co-payment and reimbursement differ on the local level showing huge health inequalities (4).

Pharmaceutical market in Bosnia and Herzegovina could be described as branded generic market with developed and established local/domestic generic manufacturers, which still have small market share (5,6). Innovative medicines in B&H have low penetration into the market due to reimbursements delay, so generic medicines are mainly reimbursed, especially on the primary health care level. Legislation in B&H related to drug prescriptions significantly differs among entities. In FB&H, a prescribing rule for physicians is based on a brand name, and pharmacists are obliged to dispense prescribed product without a possibility of generic switch, while in RS, since 2012 generic prescribing is allowed and pharmacist can make generic switch after prior consultation with the patient.

There are different policies implemented to control drug costs and pharmaceutical expenditures, and one of them is generic substitution and generic prescribing (7-9).

In 2006, generic medicines accounted for 42% of dispensed packs among 27 European countries, but only 18% of total pharmaceutical expenditures (10).

Prescribing physicians have substantial influence over medication selection and some physicians are more likely to prescribe generic drugs while others are more likely to prescribe brand name drugs (11).

The Government intends to ensure appropriate therapy for the patients, but ensuring supply of affordable and quality medicines. One of possible approaches is to implement generic prescribing policies, but the main barrier could be physicians' perceptions of generic medicines (12).

Understanding physicians' perceptions of the quality and efficacy of generics may help identify potential barriers to greater generic medication use. Additionally, identifying physician characteristics associated with negative perceptions about generics may help insurers and policymakers to target educational interventions or more restrictive policies.

The aim of this study was to evaluate knowledge, perception and attitude of physicians and pharmacists regarding generic medicines and compare results between these two groups of health care professionals. Another aim was to identify obstacles in prescribing generic drugs and how to improve current trends in order to improve rational and cost-effective prescribing.

EXAMINEES AND METHODS

Study design

A cross-sectional survey of practicing physicians, including primary care physicians (family practice and internal medicine) and pharmacists in four major cities in Bosnia and Herzegovina (Sarajevo, Banja Luka, Mostar and Tuzla) was conducted. A total of 450 healthcare professionals (HCPs) were selected randomly from the list of licenced HCPs provided by pharmaceutical and physician chambers. The study was conducted from January to March 2016. All participants were explained the purpose of the study and they accepted to participate voluntarily. They also signed consents stating that obtained results could be published and used for further research.

Methods

A questionnaire which was used as a survey instrument was first piloted with 10 practicing clinicians to solicit feedback and assess face validity. Clinicians, who participated in the pilot study, made some comments to the instrument and all of their recommendations were incorporated in the final questionnaire.

Self-assessed survey included demographic data and 15 questions/statements regarding physicians' and pharmacists` perception (attitudes toward cost, quality and effectiveness) of generic drug medicines (Table 1).

Table 1. Overview of surveyd question responses

	Statemnt	No (%) of respondents				
		Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	Generic drug represents pharmaceutical product identical or bioequivalent to original drug in dose, harmlessness, the way and manner of implementation, and the quality and form.	169 (37.8)	220 (49.2)	13 (2.9)	22 (4.9)	23 (5.1)
2	Generic drug has the same effects as the originator.	167 (37.3)	201 (44.9)	19 (4.2)	41 (9.2)	20 (4.5)
3	Generic drug has the same safety profile as the originator	157 (35.4)	182 (41.0)	40 (9.0)	40 (9.0)	25 (5.6)
4	Each original medicine has its generic parallel	142 (32.5)	128 (29.3)	65 (14.9)	42 (9.6)	60 (13.7)
5	Terms of production of generic drugs are of poorer quality than the conditions of originator production	34 (7.6)	100 (30.0)	122 (27.3)	58 (13.0)	133 (29.8)
6	Generic drug has exactly the same structure as the originator	102 (23.0)	181 (40.8)	59 (13.3)	65 (14.6)	37 (8.3)
7	The original drug can be substituted with generic drug during the medical treatment	219 (49.7)	151 (34.2)	40 (9.1)	18 (4.1)	13 (2.9)
8	Generic drugs are subject to clinical trials	217 (48.8)	114 (25.6)	42 (9.4)	20 (4.5)	52 (11.7)
9	Generic drugs are subject to monitoring upon market launching	217 (49.1)	142 (32.1)	58 (13.1)	11 (2.5)	14 (3.2)
10	I believe bioequivalent drug is only the one which 100% corresponds to originator in the level and width of the absorption	228 (51.7)	130 (29.5)	45 (10.2)	17 (3.9)	21 (4.8)
11	I am familiar with generic parallels of most original drugs on the market	245 (55.4)	139 (31.4)	35 (7.9)	18 (4.1)	5 (1.1)
12	In case of availability both the originator and generic parallel, I rather prescribe the original medicine	188 (42.2)	109 (24.4)	84 (18.8)	26 (5.8)	39 (8.7)
13	I believe that the generic drug causes more side effects than the original drug	41 (9.2)	127 (28.5)	104 (23.4)	51 (11.5)	122 (27.4)
14	Patients believe that the generic drug is not as effective as the original	68 (15.2)	135 (30.2)	92 (20.6)	58 (13.0)	94 (21.0)
15	Patients disapprove switch from original to generic drug during the therapy	86 (19.4)	131 (29.6)	83 (18.7)	63 (14.2)	80 (18.1)

The five-point Likert scale was used to measure the level of respondents' consent with offered statements (34). The Likert scale is the sum of responses to several statements that the respondent is asked to evaluate by giving it a quantitative value on any kind of subjective or objective dimension, with a level of agreement/disagreement being the dimension most commonly used. Each item may be analysed separately or in some cases item responses may be summed to create a score for a group of items. Physician responses regarding the efficiency, quality, safety, production and control were combined according to prevalence, and answers "absolutely agree" and "partially agree" were considered as positive responses, while answers "absolutely disagree" and "partially disagree" as negative. The response "neither agree nor disagree" was considered to be a neutral answer.

Physicians' and pharmacists' perception was examined using the 5-point Likert scale with answers ranging from positive ("strongly agree") to negative ("strongly disagree"). All responses were numerical with only one possible choice.

Statistical analysis

Data were examined, and only completed responses formed a database. Descriptive statistics to examine respondent's characteristics and their response to survey questions was used. Respondents' perception based on different characteristics was assessed using generalized ordered logit model which allows the effects of the explanatory variables to vary with the point at which the categories of the dependent variable are dichotomized.

One of outcome variables of interest were respondents' knowledge on bioequivalent drugs, attitude towards original medicine when both generic and original drug are available, and respondents' perception of patients' attitude towards generics.

Because assumptions of normality and proportional odds are violated, the most appropriate model for analysis is generalized ordered logit model. Models were fit with four explanatory variables. We followed the same procedure for each of the three models.

In model one respondents' knowledge on bioequivalent drugs was tested.

In the second model, we tested respondents' attitude toward original medicines when both generic and original drug is available.

In the third model, respondents' perception of patients' attitude towards generics was tested.

RESULTS

Of 520 physicians and pharmacists directly invited to participate, 450 (86.5%) responded and personally fulfilled the survey-questionnaire. The sample consisted of 330 (73.3%) females and 120 (26.7%) males; 207 (46%) respondents were in the age group of 30 to 50 years and 108 (24.0%) were in the group older than 50. More than one third of the sample were family medicine physi-

Table 2. Characteristics of 450 surveyed physicians and pharmacists

Characteristic	No (%) of respondents
Gender	
Male	330 (73.30)
Female	120 (26.70)
Age	
< 30	81 (18.00)
31-40	142 (29.30)
41-50	78 (16.70)
51-60	121 (24.20)
>60	28 (6.20)
Speciality	
Pharmacists	13 (2.90)
Family medicine	187 (41.50)
Internal medicine	193 (42.90)
Other	57 (12.70)
Years in practice	
< 6	151 (33.60)
6-10	69 (15.30)
11-15	41 (9.20)
16-20	45 (10.10)
> 20	143 (31.80)
Practice size	
< 30	76 (16.90)
31-50	311 (69.00)
51-70	53 (11.70)
71-100	11 (2.20)
Location	
Federation of BIH	347 (77.00)
Republic of Srpska	104 (23.00)

cians, 187 (41.5%), almost the same percentage, primary care physicians, 193 (42.9%) while only 13 (2.9%) were pharmacists. The sample represents a wide range of practical experience, volume and geographical locations (Table 2).

A total of 180 (40%) respondents disagreed with the statement that the production of generic drugs is poorer in quality than the conditions of originator production, while 270 (60%) respondents agreed. Even though 288 (64.0%) respondents reported that generic medicine had the exact same structure as the brand name drug, and that generic drug is a pharmaceutical product either identical or bioequivalent to the brand name drug in dose, harmlessness, application, form and quality (288, 87.0%) and with the exact same effect as the originator (369, 82.0%) and the security profile (344, 76.4%), 302 (67.0%) examinees reported that when available both the originator and the generics, they would prefer the originator (brand name drug) (Table 1).

A total of 176 (39.0%) respondents agreed that generics produced more side effects, and almost the same number of respondents disagreed, 171 (38.0%). A total of 333 (74.0%) respondents agreed with the statement that generic medications were subject to clinical trials, and 360 (80%) believed generics were subject to monitoring upon market launching (Table 1).

Furthermore, according to 203 (45.1%) answers, patients do not believe in equal treatment effect of generic and original drug (Table 1).

Results of generalized logistic regression assessing of the relationship between physician and pharmacists attitudes and the odds of reporting positive perception about generic medications are presented in Table 3.

In model one respondents' knowledge on bioequivalent drugs was tested. The log likelihood ratio of 24.61 with a p=0.0001 indicates that our model as a whole was statistically significant, it provides a better fit than the null model with no independent variables. The pseudo R^2 of 0.025 suggests that the relationship between our response variable and four predictors was rather small. For females, the odds of positive attitude toward bioequivalent drugs versus neutral and negative attitude were 0.684 times lower than for males, given the other variables were held constant. For a one-unit increase in average daily number of patients, the odds of positive attitude towards bioequivalent drugs and the odds of positive attitude towards original medications when both original and generic are available, versus neutral and negative attitude were 1.01 times greater, given the other variables were held constant in

Table 3. Results of generalized logistic regression assesing of the relationship between physician and pharmacists attitudes and the odds of reporting positive perception about generic medications

Variable	p (OR; 95% CI)					
	Bioequivalent drug is only one which 100% corresponds to originator in the level and width of the absorption		In case of availability both the originator and generic parallel, I rather prescribe the original medicine		Patients believe that the generic drug is not as effective as the original	
Gender	**Males**	**Females**	**Males**	**Females**	**Males**	**Females**
	0.071	0.68 (0.45-1.03)				
Average daily number of patients	0.056	1.01 (0.99-1.03)	0.050	1.01 (0.99-1.03)	0.011	1.02 (1.00-1.03)
Professional qualifications					0.063	0.79 (0.62-1.01)
Professional experience	0.000	0.97 (0.95-0.98)	0.046	0.98 (0.97-0.99)		

the model. For a one-unit increase in professional experience, the odds of positive attitude towards bioequivalent drugs versus neutral and negative attitude were 0.97 times greater, given the other variables were held constant in the model.

In the second model, respondents' attitude towards original medicines was tested when both generic and original drug is available. Again, the model showed overall statistical significance with the log likelihood ratio ($\chi 2$ =9.80; p=0.0439). The pseudo R^2 of 0.0082 suggests that given variables did not predict model at its best and more complex model specification should be considered in future researches. For a one-unit increase in average daily number of patients, the odds of positive attitude towards original medications when both original and generic are available, versus neutral and negative attitude were 1.01 times greater, given the other variables were held constant in the model, which is similar to results in the first model. Furthermore, for a one-unit increase in professional experience the odds of positive attitude towards original medications when both original and generic are available versus neutral and negative attitude were 0.98 times greater, given the other variables were held constant in the model.

In the third model, respondents' perception of patient's attitude toward generics drugs was tested.

The third model has shown overall statistical significance (log likelihood ratio ($\chi 2$ =13.57; p=0.0088), but a small pseudo R^2 of 0.010. When it comes to physicians' and pharmacists' perception of patients' opinion on generic drugs, a one-unit increase in average daily number of patients was found, the odds of positive attitude versus to neutral and negative attitude were 1.017 times greater, given the other variables were held constant in the model. Variable professional qualifications were included in the model as a factor variable and hence they were tested at each level of possible outcome when patients believed that the generic drug was not effective as the original. Results have shown that only in one case this variable was not statistically significant, e. g. with the combination of pharmacists and „strongly agree" answer.

DISCUSION

Healthcare expenditure is constantly increasing worldwide and one of possible measures that health insurance institutions can implement to reduce and control pharmaceutical expenditure is generic drug (medicine) policies (13). Generic drugs (medicines) are available at a lower cost so they provide an opportunity for savings in health care expenditure. Physicians and pharmacists have a key role in prescribing and dispensing generics and different policies have been set across the countries, while final outcome to reduce pharmaceutical expenditure sometimes fails due to insufficient control mechanisms by policy makers (14). Previous issues related to attitudes, knowledge and perception of generic drugs have been studied in different countries identifying main barriers and practices (15,19,24).

In Bosnia and Herzegovina this is the first attempt to explain current situation, so we have conducted survey among pharmacists and physicians as a first line medical professionals facing with prescription and dispensing of medicines in everyday practice. In general, the results of this study have found that surveyed health care professionals have enough knowledge about generic and branded drugs. Even though both pharmacists and physicians have found quality and efficacy of generic drugs to be the same as branded drugs, majority (67.0%) of respondents would still recommend a branded drug if it is available. This is reflected in the market since prescribing is based on trade or non-proprietary name, especially in the Federation of Bosnia and Herzegovina. One of the reasons for this is that reimbursed price is set at the same level for generic and branded drugs, so the system does not benefit from the generic switch and benefits of generic drugs are not fully captured by payers. On the other hand, this could be a signal for the generic manufacturers for better positioning and opportunity to increase the market share.

Almost 40% of respondents in this study believe that adverse events are more related to generic drugs. This is an approximation based on health care professionals' beliefs since B&H has low rate of adverse drug reporting (ADR) as shown in a recently published study (16). Such claims should be analysed in more detail and if this is the case, it should be reported and HCPs should be encouraged to do so. A study conducted among physicians in Finland showed that certain generic medicine groups were not equivalent in terms of efficacy and safety (17). Even if by definition a generic drug is equivalent to its innovator drug in

terms of active ingredients, dose, dosage form and bioequivalence, the lack of knowledge on the regulatory requirements of generic medicines could have a negative impact on confidence in generic drugs. Majority of respondents in our study stated that generic bioequivalence is met when there is a 100% match with originator, which is not the case from the legislation point of view, while the range from 80% to 130% is required from the regulatory point. Toverud et al. in their study showed that there was a certain level of knowledge about bioequivalence among prescribers and pharmacists in mature and less mature health care systems pointing out that pharmacists have slightly better knowledge on this issue (15). On the other hand, majority of respondents claim that generic drugs have the same effects and safety profile as originators.

In Ireland, a relatively low rate of generic prescribing compared to England and Northern Ireland was due to the primary concern of Irish prescribers related to reliability and quality of generic drugs (18). In our study this is not the case, since most of respondents understand that generic drugs are of the same quality as branded drugs. The issue of quality of medicines registered in B&H is regulated by the Law on Drugs and Medical Devices and each producer must prove that medicines registered in B&H meet the Good Manufacturing Practice (GMP) standards and have sustainable quality which is controlled on a regular basis. On the other hand, misconceptions on generic medicines should be corrected in order to promote cost-effective prescribing.

One of the measures to improve generic switch could be an introduction of clear guidelines on brand and generic substitution as it is proposed by other authors (19). In Australia, generic drug use has been supported by prescribing guidance and financial incentives allowing pharmacists to dispense any brand of drug whenever the non-proprietary (generic) name of the drug is written, but the pharmacist does not have to dispense the cheapest brand (20). A similar situation is found in Republic of Srpska, while in the Federation of Bosnia and Herzegovina this is not the case and pharmacists must dispense prescribed branded drugs. In order to favour generic switch and policy it would be of high importance to unify prescribing and dispensing rules. One of the obstacles is the current practice that all reimbursed drugs, either innovative or generic medicine, have the same price, so there are no financial benefits for payers or patients with generic drug switch. Other authors concluded that there was confusion and uncertainty regarding generic prescribing and substitution and there was a need for better information (15). Some studies reported that information about generic substitution should be included in education curricula (19,21) in order to have more information and be better prepared for professional work after graduation. It was reported that physicians in southern Europe depended on information provided by the brand drug manufacturers to a greater degree than physicians in northern Europe (22,23). Authors from Slovenia, the country with similar healthcare system background as B&H, having been a part of the former Yugoslavia, reported that GPs were willing to increase generic drugs prescribing under certain conditions (24).

Study by Toklu et al. concluded that healthcare providers as well as consumers had insufficient knowledge about generic drugs and they should be better educated with respect to generic substitution (25)

In our study respondents showed concerns regarding patients' perception of generic drugs. Majority of them think that patients believe that generic drugs are less effective than originators and they disapprove substitution. Studies from USA, Australia and northern Europe showed that generics have been offered to the patients from all socioeconomic backgrounds, even if they are worried about certain patient categories for whom switching to generics or switching between different generics should not be recommended (15, 26, 27). On the other hand in southern Europe and in some countries with an early-stage healthcare system, health care professionals are concerned to lose patients/customers if generics were prescribed or suggested (28-30). Frisk et al. evaluated how Swedish drug consumers experience generic substitution and concluded that thirty five percent of respondents had positive experiences, and majority of them reported the lower drug price (31). In Norway, 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 (32). An interesting study on patient attitudes towards generic drugs from Japan showed that patients have very low knowledge and under-

standing of generics but also significant interest in usage of those products in the future with significant impact of pharmacists (33). Patients in Croatia, the neighbouring country with similar cultural preferences as in B&H, showed low understanding of generic substitution, high concerns toward efficacy and safety of generics but also low resistance to generic substitution in pharmacy (34). It is expected that similar attitudes would be registered among B&H patients, and it is recommended to conduct a similar study in Bosnia and Herzegovina to get patient insight regarding this issue.

In conclusion, physicians and pharmacists in Bosnia and Herzegovina generally have positive attitudes towards generic drug prescription and recommendation. The main barrier for higher utilization of generic drugs is lack of knowledge about regulatory issues related to bioequivalence and quality. The same concerns are thought to be among patients' acceptance of generic switch. It would be recommended to increase knowledge and information about generic drugs among pharmacists and physicians. From the health policy perspective, it is recommended to bring clear generic substitution guidelines and propose new measures for generic switch. Current legal framework and reimbursement policy do not favour generic switch since reimbursed prices of originators and generics are the same and there are no clear incentives to increase generic consumption.

FUNDING

No specific funding was received for this study.

TRANSPARENCY DECLARATIONS

Competing interests: none to declare.

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Znanje i stavovi ljekara i farmaceuta u Bosni i Hercegovini o upotrebi generičkih lijekova

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SAŽETAK

Cilj Istražiti i procijeniti znanje i stavove ljekara i farmaceuta prema propisivanju generičkih lijekova u cilju procjene trenutnih trendova, barijera za njihovo propisivanje/izdavanje te predlaganje mogućih unapređenja racionalnog i ekonomičnog propisivanja u uvjetima skromnih javnih budžeta za lijekove.

Metode Provedeno je kros-sekcijsko istraživanje upitnikom među ljekarima i farmaceutima u četiri najveća grada. Upitnik je razvijen na osnovu ranije objavljenih studija iz ovog područja. Korištena je deskriptivna statistika kako bi se opisao uzorak i odgovori na pitanja iz upitnika. Percepcija ispitanika prema karakteristikama procijenjena je primjenom ordinalne logističke regresije.

Rezultati Opći stav prema generičkim lijekovima bio je pozitivan. Većina ispitanika, 392 (87,0%), smatrali su generičke lijekove jednake originatorskim te da su međusobno zamjenjivi. Ljekari su radije propisivali originatorske brendirane lijekove, 297 (66,6%), iako su bili svjesni da postoji generička zamjena, 391 (86,8%). Ispitanici su vjerovali da pacijenti generičke lijekove smatraju manje efikasnim, 204 (45,4%), te da ne odobravaju generičku supstituciju, 221 (49,0%).

Zaključci Neophodno je pružiti dodatnu edukaciju i više informacija donosiocima odluka o prednostima generičkih lijekova, uključujući i pacijente. Također, treba uvesti jasnije smjernice o propisivanju generičkih lijekova kako bi se unaprijedilo njihovo propisivanje, čime bi se potencijalno poboljšala dostupnost i optimizirala javna potrošnja za lijekove.

Ključne riječi: zamjena lijekova, propisivačka praksa, ekonomika, politika