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The attitudes of pharmacists and physicians in Bosnia and Herzegovina towards adverse drug reaction reporting

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ABSTRACT

Introduction: Adverse drug reactions (ADRs) are threat to the patient's safety and the quality of life, and they increase the cost of health care. Spontaneous ADR reporting system mainly relies on physicians, but also pharmacists, nurses, and even patients. The aim of this study was to explore attitudes, barriers, and possible improvements to ADR reporting practices in Bosnia and Herzegovina.

Methods: A self-reported questionnaire was developed to collect data on the perception of pharmacovigilance practice and ADR reporting. The survey was conducted in the period between September, 2014 and October, 2014.

Results: The response rate was 73% (44 of 60) and 93% (148 of 160) among the pharmacist and family medicine physician groups, respectively. Regarding the attitudes to pharmacovigilance practice and reporting, both the pharmacists and physicians found the practices important. The majority of pharmacists and physicians in year 2014 did not report any ADR, while 18% of the pharmacists and 12% of the physicians, who participated in this study, reported one ADR. Reporting procedure, uncertainty, and their exposure were the main barriers to reporting ADRs for the pharmacists. The physicians claimed lack of knowledge to whom to report an ADR as the main barrier. A significant number of the respondents thought that additional education in ADR reporting would have a positive impact, and would increase the ADR reporting rate.

Conclusions: Despite the overall positive attitude towards ADR reporting, the reporting rate in Bosnia and Herzegovina is still low. Different barriers to the ADR reporting have been identified, and there is also the need for improvements in the traditional education in this field.

Keywords: pharmacovigilance; ADR-reporting; social pharmacy

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INTRODUCTION

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" (1).

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After thalidomide disaster in 1961, the WHO established the Program for International Drug Monitoring.

Adverse drug reactions (ADRs) are threat to a patient's safety and the quality of life. In addition, they increase the health care costs considerably. ADRs are one of the leading causes of mortality and morbidity (2,3). It was estimated that around 2.9% to 5.6% of all hospital admissions are due to ADRs, and 35% of hospitalized patients experience an ADR during their hospitalization (4). The economic burden of ADR is also considerable. For example, in the United States $47.4 billion was reported as the annual total cost for 8.7 million drug related admissions (5). The Uppsala Monitoring Centre (UMC), located in Uppsala, Sweden, is the field name for the World Health Organization Collaborating Centre for International Drug Monitoring. The UMC works by collecting, assessing, and communicating information from member countries' national programs in regard to the benefits, harm, effectiveness, and risks of drugs.

Pharmacovigilance system was established in Bosnia and Herzegovina at the national level in 2008, when the Agency for Medicines and Medical Devices (ALIMSBiH) was initiated for collecting the ADR reports and providing information on ADR. Pharmacovigilance was introduced into the pharmaceutical legislation of Bosnia and Herzegovina, representing a mandatory activity for healthcare professionals, manufacturers, and marketing authorization holders (6,7).

The foundation of the International Society of Pharmacoepidemiology (ISPE) in 1984 and of the European Society of Pharmacovigilance (ESOP – later ISoP – the International Society) in 1992, marked formally the introduction of pharmacovigilance into the research and academic community, as well as its increasing integration into clinical practice (8). A national pharmacovigilance system is the primary way to collect the information on ADR practices, in both hospital and community settings. The effectiveness and success of any pharmacovigilance system depend highly on the participation of all healthcare professionals and the degree of co-operation and communication between practitioners and a pharmacovigilance center.

Spontaneous reporting is an important tool in pharmacovigilance. However, its success depends on cooperative and motivated prescribers (9). Although physicians, pharmacists, dentists, and nurses play a key role in pharmacovigilance programs (10,11), underreporting is very common, with an estimated median rate of 94% (the median rate is defined as the percentage of ADRs detected in extensive data collection that were not reported to relevant spontaneous reporting systems). Even though most countries have established systems for spontaneous ADR reporting, they still face low reporting rates by health care professionals (12).

In most countries, including Bosnia and Herzegovina, the spontaneous ADR reporting system mainly targets physicians as the major source for reporting. Nevertheless, there is an increasing trend in ADR reporting by hospital pharmacists, community pharmacists, nurses, and even patients (13-15).

Numerous studies have been conducted in order to assess the attitudes of health care practitioners towards their national ADR reporting programs, identifying different reasons for underreporting (16-18).

The aim of this study was to assess the knowledge and awareness of ADR reporting and pharmacovigilance system among healthcare professionals in Bosnia and Herzegovina. We analyzed attitudes, barriers, and possible improvements from the perspective of pharmacists and physicians at the primary care level.

METHODS

For this cross-sectional study, a self-reported questionnaire was developed. Demographic and data related to the perception of pharmacovigilance practice, previous reporting experience and attitudes of community pharmacists and family medicine physicians were collected. Among the pharmacist group, the questionnaires were distributed and collected during a pharmacists' continuing education course, held in October 2014. The survey of the family medicine physicians was performed during education courses, held in September 2014 and October 2014. All of the surveyed individuals received an

explanation of why the survey was being conducted and that only fully answered questionnaires will be valid for the analysis.

The survey questions were based on previously conducted studies with slight adaptations to the local practices. Each questionnaire consisted of four parts; A – demographic characteristics, B – attitudes, C – barriers to reporting ADRs, and D – factors that could improve current practices. The questionnaire comprised of 25 questions: 5 related to the section A, covering demographic, education, and work experience; 8 questions in the section B with multiple choice answers; 7 in the section C, and 5 in the section D, with dichotomous questions.

Statistical analysis

Statistical analyses were performed using MedCalc for Windows, version 12.6 (MedCalc Software, Ostend, Belgium). $p < 0.05$ was considered statistically significant.

RESULTS

The response rate was 73% (44 of 60) among the pharmacist group and 93% (148 of 160) among the family medicine physician group. The demographic and professional details of the respondents are shown in Table 1. The Chi-square test showed no significant difference in work experience between the pharmacists and physicians ($X^2 = 5.644$, df = 5.644; $p = 0.1302$).

Regarding attitudes to pharmacovigilance practice and reporting, both the pharmacists and physicians found the activities important. A detail overview of the current ADR reporting practice attitudes by the pharmacists and physicians is presented in Table 2.

In the second part of the questionnaire, barriers to the ADR reporting were identified. The responses are presented in Table 3. We found statistically significant differences between the pharmacists and physicians in terms of the most common reasons for not reporting ADR ($X^2 = 45.424$, $p < 0.0001$) and

TABLE 1. Demographic and professional details of the respondents

	N (%)		Chi-square	Significance level (*p*)
	Pharmacists	Physicians		
Total	148 (100)	44 (100)		
Sex				
Male	13 (8.8)	14 (31.8)	13.046	0.0003*
Female	135 (91.2)	30 (68.2)		
Age (years)				
24-30	45 (30.4)	2 (4.6)	12.517	0.0019*
31-41	36 (24.3)	13 (29.5)		
>40	67 (45.3)	29 (65.9)		
Work experience (years)				
<1	21 (14.6)	3 (6.8)	5.644	0.1302*
1-5	34 (23)	5 (11.4)		
6-10	16 (10.1)	7 (15.9)		
>10	77 (52.3)	29 (65.9)		
Level of education				
Graduate	141 (95.3)	10 (22.7)	108.004	<0.0001*
Specialization	4 (2.7)	28 (63.6)		
Postgraduate	3 (2)	6 (13.7)		
Work environment				
Community pharmacy	125 (84.5)	0 (0)	6.364	0.0116
Hospital pharmacy	23 (15.5)	0 (0)		
Primary care practice	0 (0)	44 (100)		
Hospital care practice	0 (0)	0 (0)		

*Statistically significant

TABLE 2. Pharmacists' and physicians' attitudes to ADR reporting

Attitude	N (%)	
	Pharmacists	Physicians
ADR reporting is		
Professional obligation	78 (37)	21 (36)
Legal obligation	81 (39)	21 (36)
Ethical Obligation	51 (24)	17 (24)
I believe that ADR reporting is important		
Yes	147 (99)	44 (100)
No	1 (1)	0 (0)
ADR reporting is obligation for		
Physicians	49 (19)	38 (58)
Pharmacists	123 (48)	9 (14)
Industry	42 (16)	9 (14)
Patients	42 (16)	10 (15)
ADR reporting is not mandatory		
Agree	8 (5)	1 (2)
Disagree	140 (95)	43 (98)
In last year I have reported		
Non ADR	126 (85)	32 (73)
1 ADR	18 (12)	8 (18)
2-5 ADRs	3 (2)	2 (5)
>5 ADRs	1 (1)	2 (5)
ADR should be reported to		
Professional association	11 (6)	1 (2)
Agency for medicines and medical devices	134 (76)	40 (78)
Manufacturer	18 (10)	7 (14)
Health/pharmaceutical inspectorate	4 (2)	2 (4)
Ministry of health	9 (5)	1 (2)
ADR related to OTC drugs should not be reported		
Agree	7 (5)	2 (5)
Disagree	141 (95)	42 (95)
Before ADR reporting I should consult with physician/pharmacist		
Agree	38 (26)	10 (23)
Disagree	110 (74)	34 (77)

ADR=Adverse drug reaction

in terms of information on where to find the official ADR reporting form (Chi^2 (3, n = 192) = 44.361, p < 0.0001). The pharmacists mainly reported that they are not familiar with the ADR reporting procedure, they are afraid of wrong reporting, and that they do not want to expose themselves. The main reason among the physicians was lack of information on whom to report ADR. The majority of the respondents from both groups quote that an ADR reporting form could be found on the Internet. The highest difference between the groups related to the source of ADR reporting form was that the pharmacists chose the National Drug Registry, published annually by the Agency for medicines and medical devices in the form of a printed book, while the physicians preferred other sources.

The attitudes towards activities that could improve the ADR reporting were examined in the third part of the questionnaire. A detail analysis of the responds is presented in Table 4.

Based on the Chi-square test, a significant difference was observed between the two groups, regarding whether the ADR reporting should be recognized by the professional chambers, and evaluated as a part of continuing education (Chi^2 (1, n = 192) = 9.901, p = 0.0017). Also, a difference between the groups was identified in the case of possible simplification of the current reporting process (Chi^2 (1, n = 192) = 7.119, p = 0.0076). The majority of the pharmacists (48%) considered that e-reporting through a website could improve the ADR reporting practice, and 35% of the physicians followed this option. The majority of the respondents from each group (51%) think that the current written reporting practice should be kept. Fifty-five percent of the pharmacists and 66% of the physicians considered that additional education in ADR reporting would have a positive impact and thus increase the ADR reporting rate.

DISCUSSION

This is the first survey based research on the current practices in ADR reporting in Bosnia and Herzegovina. The survey compared the attitudes of pharmacists and physicians towards this issue.

The pharmacists considered ADR reporting as a legal obligation in the first place, and then as a professional obligation, while the physicians equally ranked these questions. Both groups ranked ethical obligation at the same level. The attitudes to whose obligation is to report ADR were divided. The pharmacists considered that they are the first obliged to

TABLE 3. Barriers and knowledge of ADR reporting reported by the pharmacists and physicians

Barriers to ADR reporting	N (%)		Chi-square	Significance level (*p*)
	Pharmacists	Physicians		
Most common reasons for not reporting ADR				
Do not know whom to report ADR	8 (5.5)	18 (37.5)	45.424	<0.0001*
I do not know ADR reporting procedure	49 (34)	17 (35.4)		
I am afraid of wrong report and personal discredit	30 (20.8)	0 (0)		
Reporting form is complicated	17 (11.8)	6 (12.5)		
I have no time for ADR reporting	19 (13.2)	7 (14.6)		
I do not want to expose myself	21 (14.7)	0 (0)		
ADR reporting form can be found at				
Internet site	72 (40.7)	10 (22.7)	44.361	<0.0001*
Official gazette	16 (9)	3 (6.8)		
Drug registry	61 (34.5)	3 (6.8)		
I do not know	28 (15.8)	28 (63.7)		
If I report ADR I am afraid it will impact my relationships with drug manufacturer				
Yes	7 (4.7)	2 (4.5)	0.126	0.7223
No	141 (95.3)	42 (95.5)		
One ADR reported will not be noticed and does not have importance				
Agree	19 (12.8)	7 (15.9)	0.0739	0.7858
Disagree	129 (87.2)	37 (84.1)		
Patients never mention any ADR				
Agree	33 (22.3)	2 (4.5)	6.029	0.0141*
Disagree	115 (77.7)	42 (95.5)		
Known ADR should not be reported again				
Agree	47 (31.8)	18 (40.9)	1.247	0.2642
Disagree	101 (68.2)	26 (59.1)		
I do not have enough clinical knowledge to recognize ADR that should be reported				
Agree	44 (29.7)	9 (20.5)	1.558	0.2120
Disagree	104 (70.3)	35 (79.5)		

*Statistically significant, ADR=Adverse drug reaction

report, while the physicians found that the obligation is in their jurisdiction. Both groups had similar attitudes towards drug manufacturers and patients. A similar percentage of the respondents did not see the need to consult with each other (the pharmacist with physician and vice versa) before reporting ADR. The Chi-square test showed that there is a significant difference between the pharmacists and physicians with regard to the attitudes towards whose obligation is to report ADRs (Chi^2 (3, n = 192) = 44.151, p < 0.0001). Both groups of the healthcare professionals considered the Agency for medicines and medical devices of Bosnia and Herzegovina as the address to report ADR, which is correct and defined by the current legislation. They also considered other institutions for reporting ADR, such as professional associations, the Ministry of Health, and the manufacturers. The majority of the pharmacists and physicians did not report any ADR in 2014 year. Eighteen percent of the pharmacists and 12% of the physicians, who participated in this study, reported one ADR.

Even though ALIMSBIH launched pharmacovigilance department and reporting in 2009, the reporting level is still too low, especially compared to the number of adverse reactions reported

TABLE 4. Potential factors influencing improvements in ADR reporting

Potential factors influencing improvements in ADR reporting	Pharmacists	Physicians	Chi-square	Significance level (*p*)
ADR reporting should be recognized by professional chambers				
Agree	66	10	9.901	0.0017*
Disagree	82	34		
ADR reporting procedure should be simplified				
Agree	123	44	7.119	0.0076*
Disagree	25	0		
ADR reporting should be paid				
Agree	27	14	2.96	0.0855
Disagree	121	30		
ADR reporting should be possible by				
Telephone	28	6	3.205	0.2014
Written and signed form	68	22		
Internet (e-reporting)	89	15		
I need additional education about ADR reporting				
Yes	81	29	1.306	0.2532
No	67	15		

*Statistically significant, ADR=Adverse drug reaction

by the physicians in Great Britain (19), the Netherlands (20), and Spain (21). Our findings suggest that the low rate of ADR reporting still persists, since the majority of the respondents (85% of the pharmacists and 73% of the physicians) did not report any ADR in 2014 year. A study published in 2010 examined current ADR reporting practices among different South Eastern European countries. They concluded that health care professionals from Bosnia and Herzegovina had the lowest response rate to the questionnaires sent (22). A study from Serbia, a neighboring country to Bosnia and Herzegovina, published in 2010, also showed a low rate of hospital ADR reporting in Serbia in comparison to other countries (23). The results of a survey on hospital pharmacists' services conducted by the European Association of Hospital Pharmacists, showed a low rate of ADR related services in Bosnia and Herzegovina (24). The situation in Croatia is much better, since the ADR reporting is continuous and well recorded (25).

Our sample was heterogeneous and we identified significant differences among the pharmacist and physician groups in terms of the number of respondents. However, there was no significant difference in terms of working experience that could impact the attitudes and practice in ADR reporting. The majority of the respondents from both groups agreed that ADR reporting is a legal, professional, as well as ethical obligation. A significant difference was observed between the respondents with regard to whose obligation is ADR reporting. The pharmacists considered that they have the primary responsibility, while the physicians considered the same for themselves. This could be a consequence of low cooperation and communication between these two groups of health care professionals. Several studies reported physicians' attitudes towards the roles and responsibilities of community pharmacists (26,27). In our study, the respondents from both groups disagreed that consulting a pharmacist or physician before reporting ADRs should be performed. Seventy-four percent of the pharmacists and 77% of the physicians reported these answers. Although the ADR reporting rate is very low, in this study, both the pharmacists (76%) and physicians (78%) stated that ADRs should be reported to the ALIMSBIH. In addition, a significant number of them stated that ADRs should be reported to the manufacturer of the drug or other organizations. Although

previously published studies have shown positive health care professionals' attitudes to ADR reporting (28), in this study we tried to identify the most common barriers to ADR reporting. A significant difference among the two groups was observed with respect to two barriers to reporting ADRs, lack of knowledge of whom to report and where to find an ADR reporting form. The main difference between the groups was that the pharmacists were mostly concerned about making a wrong report, which could cause personal discrediting (21%), as well as concerned about exposing themselves (15%). The main barrier for the physicians (38%) was lack of information on whom to report ADR. Both, the pharmacists and physicians, similarly perceived lack of knowledge of ADR reporting procedure as a barrier. A study performed among health care professionals in Northern Cyprus, found that the main barrier was lack of knowledge of this practice. They recommended additional education in order to increase ADR reporting in their country (29). A study on the role of pharmacists in pharmacovigilance, conducted among Turkish community pharmacists, showed that the pharmacists considered their role in ADR reporting essential, even though the ADR reporting was very low. Similar to our results, in their study, the main reason for underreporting was also insufficient knowledge of pharmacovigilance (30).

The two groups in our study answered differently where to find the ADR reporting form. The majority of the pharmacists reported that an ADR reporting form could be found at ALIMSBiH website (41%), as well as a part of Drug registry (34%), a publication issued annually by the ALIMSBiH. On contrary, for the physicians, the main barrier was that they did not know where to find an ADR reporting form (64%). This discrepancy could be explained by the fact that the Drug registry is obligatory literature in each pharmacy by law, so pharmacists are more familiar with the content of this publication.

Regarding the questions related to possible improvements, the two groups showed different attitudes to whether ADR reporting should be evaluated as a part of continuing education, and recognized by the professional chambers. The pharmacists considered that this should be the case, while the physicians did not. Both groups agreed that the procedure should be simplified, which is in line with previous findings (31). Online ADR reporting is one of the ways how to increase the reporting rate, and this was mainly proposed by the pharmacists (47%). In addition, both groups proposed the written form as the means to perform ADR reporting. The respondents from both groups agreed that additional education in ADR reporting would be useful (55% of the pharmacists and 66% of the physicians). This should be a clear indication to the ALIMSBiH to popularize ADR reporting through additional education, training, and to inform the health care professionals about this issue. Some studies suggest that even the introduction of pharmacovigilance-related course in undergraduate programs could improve ADR reporting, since this would allow for future health care professionals to understand the importance of this system (32). It is also important to develop new competencies for the pharmacists in order to improve their role in a health care system and move the perception from a medicines dispenser to pharmaceutical care provider (33). This should also be incorporated into undergraduate and postgraduate curricula in order to prepare future pharmacists to be able to respond to new challenges in labor markets and health care activities.

The main limitation of this study was a significantly lower number of physicians who participated. Additionally, the study did not cover health care professionals from the entire country. Nevertheless, this is the first study that compared the attitudes of pharmacists and physicians to ADR reporting and pharmacovigilance system in Bosnia and Herzegovina.

CONCLUSION

ADR reporting is still in focus, and underreporting is an issue in many countries in the world. Although ADR reporting is established in Bosnia and Herzegovina through the ALIMSBIH, the reporting rate is still low compared to the neighboring as well as developed countries. Pharmacists and physicians, as most accessible health care professionals at the primary health care level, play important roles in this process. This study confirmed a positive attitude by these two groups of health care professionals towards the importance of ADR reporting,

but also showed different levels of knowledge of this process. We identified different barriers to the ADR reporting among the surveyed professionals, as well as significant improvement measures, like additional education, that could be performed in Bosnia and Herzegovina. Further investigations should be performed among a larger number of health care professionals in order to identify precise problems and obstacles, as well as to improve this practice through additional education.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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