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ORIGINAL ARTICLE

Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process

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Abstract *Background:* Adverse drug reactions (ADRs) are a major cause of drug related morbidity and mortality. Pharmacovigilance is the science that plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice.

Objectives: This study is considered the first study in the region to evaluate pharmacist's knowledge, practice and attitudes toward ADRs reporting after establishing the national ADRs reporting center in Jordan.

Method: A cross sectional study was used to evaluate pharmacist knowledge and attitude toward ADRs reporting. A structured validated questionnaire was developed for this purpose and a total of 208 pharmacists were recruited to participate in this study.

Results: The majority of pharmacists have insufficient awareness and lack of knowledge about pharmacovigilance and ADRs reporting. Also the rate of reporting of ADRs was extremely poor. Several factors were found to discourage pharmacists from reporting ADRs, which include inadequate information available from the patient, unavailability of pharmacist ADRs form when needed, unawareness of the existence of the national ADRs reporting system. Also pharmacists think that ADRs are unimportant or they did not know how to report them.

Conclusion: The results of this study suggest that pharmacists have insufficient knowledge about the concept of pharmacovigilance and spontaneous ADRs reporting. On the other hand, pharmacists had positive attitudes toward pharmacovigilance, despite their little experience with ADRs reporting. Educational programs are needed to increase pharmacist's role in the reporting process, and thus to have a positive impact on the overall patient caring process.

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1. Introduction

Adverse drug reactions (ADRs) are a major cause of patient related morbidity and mortality (Lee and Thomas, 2007), and they are associated with a high prevalence of hospital

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admission reaching about 6.5% as well as a considerable economic burden; in which around £466 million was reported as an annual total cost for drug related admissions in the united kingdom (Pirmohamed et al., 2004). Thus reporting of ADRs is considered to be an important step in maintaining and achieving a safe drug therapy use.

Most countries developed their national pharmacovigilance systems after the thalidomide disaster in 1960s (Rawlins, 1995). World Health Organization (WHO) has established the definition of pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" (WHO, 2002). Pharmacovigilance plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice. ADRs spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillance of drug-induced risks (Stricker and Psaty, 2004). These systems are inexpensive and simple to operate and they enable the generation of signals indicating potential problems, allowing the identification of new and rare ADRs, but also enable continuous monitoring of all drugs used in real life situations from the time they are first marketed. However, their strength is tightly connected to the actual reporting rate by health care professionals (Wiholm et al., 2002).

All sectors of the healthcare system would need to be involved in the reporting process, such as public and private hospitals, general practitioners, nurses, retail dispensaries, and pharmacists. Wherever medicines are being used, there should be a readiness to observe and report unwanted adverse events (both expected and unexpected) (WHO, 2002, 2004). Pharmacists were found to have an important role in ADRs reporting, and constitute a potentially valuable source for spontaneous ADRs reports (Kaboli et al., 2006; van Grootheest et al., 2004). However, under-reporting of ADRs is a main intrinsic problem, in which reporting of serious ADRs rarely exceeds 10% (Granas et al., 2007; Su et al., 2010; Toklu and Uysal, 2008; Vessal et al., 2009). It was found that the main reasons for poor reporting rate were either due to legislative restrictions or because of lack of tradition (van Grootheest and de Jong-van den Berg, 2005; van Grootheest et al., 2004).

The Jordanian Pharmacovigilance Center (JPC) was established in January 2001 in cooperation with Sweden International Development Agency (SIDA) and the Higher Council for Science and Technology (Yadav, 2008). Since that time, no studies have assessed pharmacists' knowledge and attitudes toward ADRs reporting in the hospital and community settings in Jordan. Our study was in the unique position to study pharmacist's attitudes toward ADRs reporting after the initiation of the national ADRs reporting center and their understanding and knowledge of the yellow card spontaneous ADRs reporting scheme.

2. Methodology

2.1. Study design, settings and study subjects

This is a cross-sectional study that was conducted in two of the largest cities in Jordan; Amman and Zarqa. The study commenced in July-2012 and continued for two months. Two hundred and eight pharmacists (both community and hospital pharmacists) were included in the study with a response rate of 96.7%. Each pharmacist was asked to fill a validated structured questionnaire delivered by hand. The participated pharmacists were from independent and chain pharmacies as well as from different hospitals (public and private hospitals). Sixteen hospitals in Amman and Zarqa were covered, while the community pharmacies coverage represented about 5.2 % of the total number of pharmacies in Jordan.

2.2. Questionnaire

Content validity was assessed by distributing the questionnaire to 10 pharmacists recruited to complete the validation process. The initial draft of questionnaire was hand delivered to those pharmacists to help review the structured questionnaire and perform any amendments needed.

The final form of the questionnaire consisted of pharmacist demographic data, and a total of 20 questions that covered three main areas of interest. These areas included: (1) assessment of pharmacist knowledge regarding pharmacovigilance and ADRs reporting, (2) pharmacist's attitude and practice toward ADRs reporting process and (3) pharmacists' recommendations and suggestion to improve the drawback in the system.

2.3. Statistical analysis

Data were analyzed using statistical package for social science version 17 (SPSS, Inc., Chicago, IL, USA). The descriptive analysis was done using mean and SD for continuous variables and percentage for qualitative variables. Pearson Chi- Square was used to calculate p-values for categorical variables.

3. Results

3.1. Demographics

The demographic details of the pharmacists included in the study are shown in Table 1. The mean age of pharmacist was approximately 32 years, and the average year of experience was 7.83 years. In this study, 62.5% of pharmacists were community pharmacists while 37.5 % were hospital pharmacists. Females accounted for 63.9% of pharmacists.

3.2. Pharmacist knowledge regarding pharmacovigilance and ADR reporting

This questionnaire contained two open-ended questions in which the pharmacists were asked to define the terms 'pharmacovigilance' and 'adverse drug reaction'. Of the responding pharmacists, only 25.5 % defined 'pharmacovigilance' correctly while 69.7% defined ADR correctly. Hospital pharmacists showed better awareness of the concept of pharmacovigilance compared with the community pharmacists (p-value less than 0.05), while there is no significant difference found between the two groups for the definition of ADR. Only 8.2% had attended a workshop regarding how to report an ADR.

Most of pharmacists were not aware of the presence of legal provisions in the medicines act that provide for

Table 1 Demographic characteristic of the study sample ($n = 208$).

Parameter	Results
Age [years; mean (SD)]	32.13 (8.76) [min: 22, max: 70]
Gender [female; N (%)]	133 (63.9%)
Years of practice [years; mean (SD)]	7.83 (8.07) [min: 0.1, max: 45]
Site of work; N (%)	
• Community pharmacists	130 (62.5%)
• Hospital pharmacists	78 (37.5%)
Educational level; N (%)	
• BSC. in pharmacy	162 (77.9%)
• Pharm. D	24 (11.5%)
• Masters	22 (10.6%)
• PhD	0 (0%)

pharmacovigilance activities (63.1%), and most of them did not know that we have a pharmacovigilance center in Jordan and an official standardized form for reporting adverse drug reactions (84.5% and 71.5%, respectively). Again hospital pharmacists knew significantly more than community pharmacists regarding the previous issues (p-value less than 0.05). The results are presented in Table 2.

3.3. Pharmacist practice and attitude toward ADRs reporting

The overall rate of ADRs reporting by pharmacists is shown in Table 3. It is obvious that about 91.2% of the pharmacists had noticed at least one ADR in a patient per a year, while only 19.5% had ever reported an ADR.

When pharmacists were asked about what they must do if they want to report an ADR, approximately 76% of pharmacists admitted that they did not know from where they could get the ADRs reporting forms, and almost all of them (98.5%) did not know the period within which they should report serious ADRs experienced by a patient. The questionnaire revealed that 55.1% of the pharmacists believed that if they want to report ADRs they will send their report to the Jordan food and drug administartion (JFDA) which is the authorized organization for reporting ADRs in Jordan.

When pharmacists were asked about their preferred method of reporting, 33.3% of them believed that using a specific form was their preferred method of reporting, while 23.2%, 25.6%, and 4.3% preferred to report via phone calls to the drug company, informing the representative of the drug company verbally or by using internet.

Pharmacists also were asked about their first actions if they were in a situation dealing with patients with severe ADRs. Fig. 1 shows that only 6% of the pharmacists tend to report severe ADRs immediately and the majority of them preferred to contact the physician (27%), direct the patient to an emergency room (24%) or ask the patient to contact the physician (22%).

Pharmacists were also asked to determine their degree of agreement regarding their responsibilities in reporting ADRs. This was done in order to assess their beliefs about the importance of their profession in the pharmacovigilance system, and the responsibility of the pharmacist, physician, nurses, drug company and patient in ADRs reporting. The scale consisted of three levels: (1: disagree; 2: uncertain; 3: agree). Twenty-five percent of pharmacists believed that their role in the pharmacovigilance system is important. The responsibility order was as the following: pharmacist (95.2%), physician (90.8%), drug company (86.8%), patient (74.9%) and nurses (71.3%). The results are presented in Fig. 2.

Table 4 shows the perception of pharmacists toward the importance of reporting ADRs. It is obvious that almost the

Table 2 Assessment of pharmacist knowledge about pharmacovigilance concept and policy.

Questions[$]	Community pharmacists N (%)[**]	Hospital pharmacists N (%)	P-value Pearson chi-square
Have you ever heard about the concept of pharmacovigilance?			
Yes	36 (27.7%)	35 (44.9%)	0.011[*]
What is the definition of pharmacovigilance?			
Correct Answer	25 (19.2%)	28 (35.9%)	0.008[*]
What is the definition of adverse drug reaction?			
Correct Answer	88 (67.7%)	57 (73.1%)	0.413
Have you ever had a course/attended a workshop about pharmacovigilance?			
Yes	7 (5.4%)	10 (12.8%)	0.058
In Jordan, are there legal provisions in the medicines act that provide for pharmacovigilance activities?			
Yes	41 (31.5%)	35 (46.1%)	0.037[*]
In Jordan, is there pharmacovigilance center?			
Yes	10 (7.7%)	22 (28.6%)	0.000[*]
In Jordan, is there an official standardized form for reporting adverse drug reactions?			
Yes	19 (14.6%)	40 (51.9%)	0.000[*]

[$] Question answers were either Yes or No.
[*] Significant difference.
[**] Percentage within group.

Table 3 Pharmacist practices toward ADRs reporting procedure.

Question	Number of respondent	%
How often do the patients report you ADRs of medications?	204	
More than once a week		26.5
Once a month		27.9
A few times a year		36.8
Never		8.8
Have you ever reported any ADR?	205	
Yes		19.5
No		80.5
Do you know from where can you get the ADRs reporting form?	208	
Yes		26.0
No		74.0
Do you know what is the period within which you should report a serious ADR experienced by a patient?	205	
Yes		1.5
No		98.5
Do you know to whom you should report the ADRs?	207	
The Ministry of health (MOH)		16.4
The Jordanian pharmaceutical association		6.3
The Jordanian food and drug administration		55.1
Drug Company		10.1
Prescriber		9.7
Other (specify)		2.4
How do you prefer to report the ADRs?	207	
A phone call to drug company		23.2
Verbally inform the representative of the drug company on routine visits		25.6
Mail via internet		4.3
Using adverse drug reaction reporting form		33.3
Other (specify)		13.5

majority of pharmacists believed that reporting ADRs is an important mission provided by pharmacists.

Factors influencing and encouraging the pharmacists to report ADRs were evaluated in this study. Table 5 shows that most of pharmacist preferred to report reaction of serious nature (but this was contradictory to their actual action), also most of them preferred to report unusual reactions and reactions that have been not reported before.

An interesting observation here is that nearly half of the pharmacists were reluctant to report reactions for a new drug as well as well recognized reactions.

Factors that may discourage the pharmacists to report ADRs were also evaluated. The main five reasons that discourage the pharmacists from reporting ADRs were "no enough information available from the patient (76.7%)", "Pharmacist's ADRs form is not available when needed (72.5%)", "unawareness of the existence of a national ADRs reporting system (70.7%)", "The ADR is too trivial to report (67.1%) and " they did not know how to report (66.7%)". The results are presented in Table 6.

3.4. Pharmacists' recommendations and suggestion to improve the drawback in the system

The majority of pharmacists who participated in this study (both hospital and community pharmacists), recommended that there is a need to raise pharmacists awareness toward pharmacovigilance and mainly toward ADRs reporting process. They suggested to include this topic as a part of teaching curriculum, as well as to perform a number of educational courses and workshops by the specialized authorities.

4. Discussion

The main aim of this study was to evaluate the attitudes and knowledge of pharmacists toward pharmacovigilance and spontaneous ADRs reporting. There are several reports from different countries which commonly emphasize the problem of the ADRs under-reporting among pharmacists (Generali et al., 1995; Granas et al., 2007; Green et al., 2001; Herdeiro et al., 2006; Lee et al., 1994; Sweis and Wong, 2000; Toklu and Uysal, 2008). To the best of our knowledge, this cross-sectional survey is the first study to evaluate this issue in Jordan.

The results of the present study firstly demonstrated that the majority of pharmacists have insufficient knowledge and lack of awareness about pharmacovigilance and ADRs reporting systems. The results of this study were consistent with a previous report by Toklu and Uysal in which they showed that 82.5% of the pharmacists were not aware of the concept of pharmacovigilance (Toklu and Uysal, 2008).

Despite the lack of knowledge in the majority of pharmacists, the study showed that the awareness of hospital pharmacists was better compared to community pharmacists which may be related to the fact that hospital pharmacists are in direct contact with other health care professionals such as physicians and nurses who are more often involved in the identification of potential ADRs, thus they are more exposed to situations where there is a need to manage or to report such adverse effects. In a study by Herdeiro et al., it was shown that hospital pharmacists report 20 times more frequently than community pharmacists, this was due to the fact that the hospital pharmacist was better educated and informed about pharmacovigilance practice (Herdeiro et al., 2006).

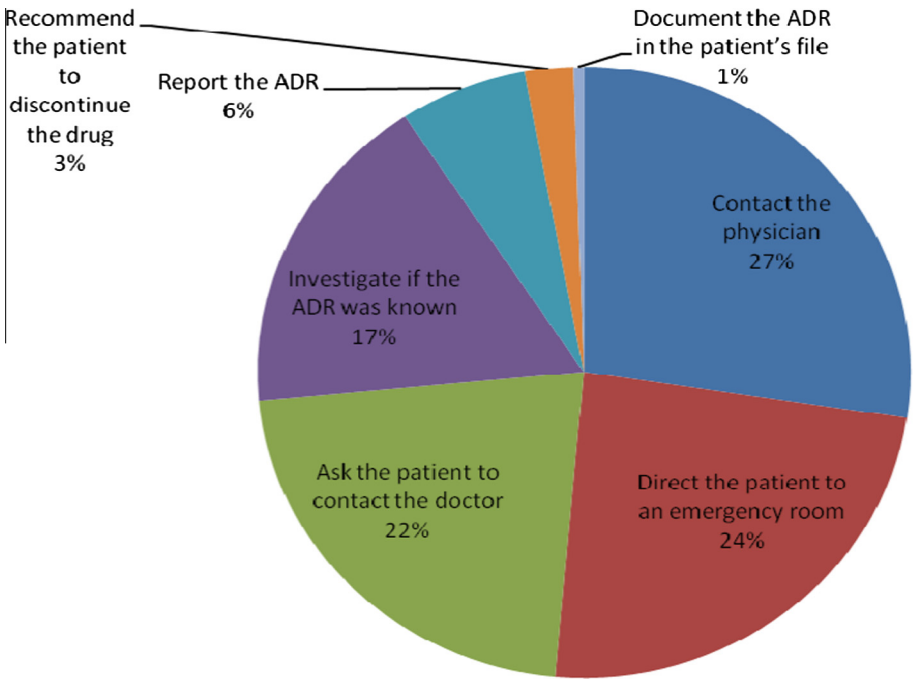
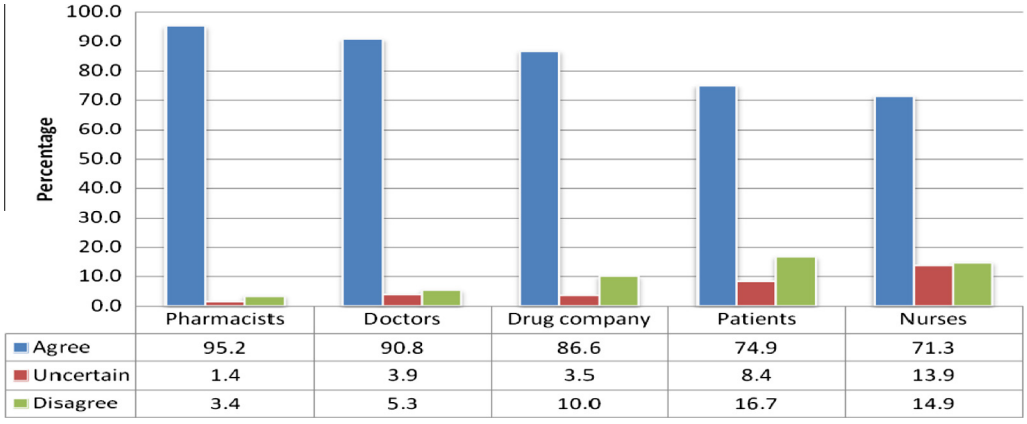


Figure 1 Initial actions that may be performed by pharmacists when dealing with patients with severe ADRs.



	Pharmacists	Doctors	Drug company	Patients	Nurses
Agree	95.2	90.8	86.6	74.9	71.3
Uncertain	1.4	3.9	3.5	8.4	13.9
Disagree	3.4	5.3	10.0	16.7	14.9

Figure 2 Pharmacist's level of agreement following asking them about health care professional's responsibility toward ADRs reporting.

Lack of knowledge is considered the starting point to deal with the problem of under reporting of ADRs, since it was previously shown that pharmacist knowledge exerted a strong influence on ADRs reporting (Herdeiro et al., 2006). Accordingly, we can expect to have a low rate of ADRs reporting secondary to poor knowledge of reporting procedures, which is consistent with what we found in our study. The rate of reporting of ADRs was extremely poor, with only 19.5% of study participants ever reporting an adverse effect. Therefore, if we suppose that those pharmacists reported only one or few ADRs during their practice, this means that the overall rate of reporting serious and actual ADRs is extremely poor.

The main reason for this low rate of reporting is the lack of knowledge, in which a large number of study participants admitted that they did not know how to report an ADR and if there is a legal authority to report to, they also did not know from where they could get the ADRs reporting forms, and the period within which they should report a serious ADRs experienced by the patient.

The majority of study participants considered ADRs reporting to be a natural task for pharmacists, as well as main responsibility of all healthcare providers, but the pharmacist was ranked to be the most important provider in preventing ADRs reporting. In the developing countries, pharmacists play an active role in patient medication management process, and patients prefer to contact them first for any consultation because they easily accessed healthcare providers. Therefore, pharmacists need to take a more active role in the assessment and decision making concerning the safety of patient medications (van Grootheest et al., 2004). Pharmacist's role in pharmacovigilance may vary from country to country, but the professional responsibility is the same, regardless of jurisdiction (Roberts et al., 1994).

Regarding pharmacist perception and attitude toward ADRs reporting, pharmacists showed almost positive attitude

Table 4 Pharmacists' perception of the importance of ADRs reporting.

Purpose	Agree %	Uncertain %	Disagree %	No. of respondent
1. To enable safe drugs to be identified	96.6	1.9	1.4	208
2. To measure the incidence of ADRs	96.6	2.4	1.0	208
3. To identify factors that might predispose to an ADR	96.1	3.9	0.0	207
4. To identify previously unrecognized ADRs	97.1	2.9	0.0	208
5. To compare ADRs for drugs in similar therapeutic classes	93.7	5.3	1.0	207
6. To compare ADRs of the same drug from different drug companies	84.1	7.7	18.2	208

Table 5 Factors that may encourage pharmacists to report ADRs.

	Agree %	Uncertain %	Disagree %	No. of respondent
1. The reaction is of a serious nature	99.0	0.0	1.0	208
2. The reaction is unusual	97.6	1.9	0.5	208
3. The reaction is to a new product	57.0	14.5	28.5	207
4. Reaction not reported before for a particular drug	87.9	9.7	2.4	207
5. Reaction is well recognized for a particular drug	57.0	14.5	28.5	208

Table 6 Factors that may discourage pharmacists to report ADRs.

	Agree %	Uncertain %	Disagree %	No. of respondent
1. Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	61.4	5.3	33.3	207
2. Uncertain association between the drug and the adverse reaction	54.3	10.7	35.0	206
3. The ADR is too trivial to report	67.1	7.3	25.6	207
4. Concern that a report will generate extra work	33.2	12.0	54.8	208
5. Pharmacist's adverse drug reaction form is not available when needed	72.5	7.7	19.8	207
6. Lack of confidence in discussing the ADRs with the prescriber	39.9	10.1	50.0	208
7. No enough information available from the patient	76.7	11.7	11.7	206
8. Lack of time to fill in a report	32.2	14.9	52.9	208
9. Unaware of the existence of a national ADR reporting system	70.7	9.8	19.5	205
10. Did not know how to report	66.7	9.2	24.2	207
11. Fear of legal liability	30.3	10.1	59.6	208
12. Unaware of the need to report an ADR	36.4	7.8	55.8	206
13. Lack of financial reimbursement	14.9	5.8	79.3	208
14. Consider it the doctors' responsibility	17.9	7.7	74.4	207

toward ADRs reporting process despite the low reporting rate, a pattern similar to other studies (Granas et al., 2007; Lee et al., 1994; Toklu and Uysal, 2008). Attitudes are potentially modifiable variables exerting a strong influence on ADRs reporting (Herdeiro et al., 2006), the greater the patient attitude the more positive influence on the overall ADRs reporting rate. This issue was proved previously by Granas et al., in which they have shown that an educational program can significantly modify pharmacists' reporting-related attitudes and influence the ADRs reporting behavior in a positive manner (Granas et al., 2007).

In this study it is obvious that among the factors that encourage pharmacists to report ADRs is the nature and severity of the ADRs. Pharmacists preferred to report reactions of serious nature as well as unusual reactions and reactions that have not been reported before. On the other hand they were reluctant to report well known ADRs, a finding that confirms results of previous studies (Eland et al., 1999; Granas et al., 2007; Hasford et al., 2002). However, the spontaneous reporting system could be used as a tool for monitoring changes of the type and/or frequency of serious known ADRs.

Several factors were found to discourage pharmacists from reporting ADRs, which include no enough information available from the patient, unavailability of pharmacists ADRs form when needed, unawareness of the existence of a national ADRs reporting system, the ADR is too trivial to report and they did not know how to report. These findings were similar to results of a study performed on pharmacists in Iran. These findings were similar to results of a study performed on pharmacists in Iran (Vessal et al., 2009), which found that the main reasons for not reporting of ADRs were uncertain association, too trivial ADRs to report, too well known ADRs to report, and yellow card not available. Also another study performed on pharmacists of the Turkish community found that the most

common reasons for not reporting ADRs were lack of knowledge of how to reach ADRs forms, and not being mandatory (Toklu and Uysal, 2008).

This study explored the urgent need for educational programs to emphasize the role and responsibility of pharmacists in pharmacovigilance practices, and to raise awareness toward ADRs reporting process. Most probably, all these perceptions, attitude and behaviors could be changed significantly by proper educational programs as was previously shown by Granas et al. 2007. However, we are aware of some methodological weaknesses of our study; as the questionnaire relied on pharmacists' self-rated assessment of their own practice and attitudes, pharmacists might have felt pressured into completing the questionnaire or might have been unwilling to reveal their practice deficiencies. Also the research has been conducted over a short period of time, which might shed doubt on the objectivity of the responses and introducing some over estimation in both pharmacist's knowledge and attitudes.

5. Conclusion

These results suggest that Jordanian pharmacists have little knowledge about the concept and process of pharmacovigilance and spontaneous ADRs reporting system. However the pharmacists had positive attitudes toward pharmacovigilance, but very little experience with reporting. Educational programs are needed to increase pharmacists' role and their knowledge about the reporting process and its requirements, and thus to have a positive impact on patient caring process.

6. Conflict of interest

None.

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