Knowledge, attitude and practice towards pharmacovigilance and reporting of adverse drug reactions among health care professionals in Albania: A cross-sectional study

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Abstract: In both developed and developing nations, the rising prevalence of adverse drug reactions (ADRs) and underreporting of ADRs in pharmacovigilance centers have become major problems. The goal of this study was to access the overall knowledge, attitude and practices toward pharmacovigilance and ADRs reporting among Albanian healthcare professionals. A cross-sectional questionnaire-based study was conducted from December 2021 to February 2022 including physicians, community pharmacists and nurses in Tirana, Albania. There were distributed a total of 511 questionnaires to healthcare professionals, where 410 of them were returned, resulting in an 80.23 percent response rate. Physicians and pharmacists compare to nurses had better knowledge about pharmacovigilance and its main purpose. Pharmacists had better knowledge regarding the establishment of the pharmacovigilance law (67.62%) and how to report ADRs (51.43%), Of all, 85.42% of physicians, 74.29% of pharmacists and 40.38% of nurses resulted had a positive attitude towards ADR reporting as a professional obligation, as well as 57.29% of physicians, 58.57% of pharmacists and 22.12% (p < 0.05) of nurses, declared that they have reported ADRs. Only physicians have reported ADRs to the national pharmacovigilance center. The findings of this study show that most of the healthcare professionals in Tirana do not have a thorough understanding of pharmacovigilance techniques.

Keywords: Knowledge, pharmacovigilance, attitude and practice, adverse drug reactions, health care professionals.

INTRODUCTION

Medicines have the potential to cause adverse drug reactions (ADRs). According to the World Health Organization, an adverse drug reaction (ADR) is "any unpleasant, unexpected and undesired result of a drug, which occurs at doses administered by humans for prevention, diagnosis, or therapy" (WHO 2006). Findings of the previous studies showed that opioid analgesic, systemic corticosteroid, diuretic, antibiotic, cytotoxic, immunosuppressant, anticoagulants and antidiabetic medications have all been specifically linked to ADRrelated hospital admissions (Coleman et al., 2016, Davies et al., 2009). According to Bouvy et al., 2015, up to 10% of in-patients encounter ADRs while in hospital and 3.6% of all hospital admissions in Europe are attributable to Adverse drug reactions (ADRs) hospitalizations of 2.9 -5.6% in Iran (Baniasadi et al., 2008), 8.4% in South Africa (Mouton et al., 2016), and 4.8 % in Germany (Stausberg et al., 2016). Two prospective studies that were conducted in the UK showed that 6.5% of hospitalized patients were experiencing an ADR (Pirmohamed et al., 2004; Howard et al., 2003). The percentage of hospital admission with ADRs in the UK was 6.5% which resulted in lower than in the USA which was 10-20%. Moreover, 6.7% of hospital patients suffer serious ADRs in the UK which

was higher compared to 3% in India (Shepherd *et al.*, 2012; Gor and Desai, 2008).

Pharmacovigilance, identified as PV, is the science and activities relating to the detection, evaluation, understanding, prevention, and management of adverse drug reactions or any other problem that are related to the security and efficacy of medicines (Darshna *et al.*, 2021). By discovering and reporting ADRs, low-quality drugs can be taken off the market. Patients are given safe and efficient drugs thanks to ADR monitoring (Khan 2013).

The identification and reporting of the important ADRs is the main responsibility of healthcare professionals (HCPs). They will be more likely to recognize and report significant ADRs if they are confident in their capacity to diagnose, manage and avoid such responses (Varallo et al., 2014; Olsson et al., 2010; Moinuddin et al., 2018; Gaude and De Sa, 2018). However, according to some researchers, ADRs are not widely reported. The studies have shown that the lack of decent knowledge, attitude and practice (KAP) about pharmacovigilance (PV) activities and ADRs reporting is one of the main reasons for the under-reporting of ADRs (AlShammari and Almoslem 2018; Kassa and Biru 2019; Gidey et al., 2020). In Nigeria, the common factors responsible for under-reporting were a lack of knowledge of the availability of reporting forms and reporting procedure

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(Okezie and Olufunmilayo, 2008). In Malaysia, a lack of awareness about the existence, purpose and function of national ADR reporting was the main reason for underreporting (Aziz et al., 2007). It is crucial to enhance the knowledge, attitude and practice (KAP) of healthcare professionals regarding ADRs reporting pharmacovigilance, this way the reporting rate improves.

The Pharmacovigilance Center in Albania was established in 2011. Even though all the HCPs and patients are encouraged to report suspected ADRs to the pharmacovigilance monitoring center using the reporting form still the underreporting problem is present. Very few studies have explored the viewpoints of Albanian medical professionals on pharmacovigilance (Napuce et al., 2019, Shkreli et al., 2018, Vito et al., 2009). These studies stated that the reasons for underreporting were lack of reporting format, reporting practice, and what ADRs to be reported.

Also, it was necessary to improve the curriculum of pharmacovigilance in all public and private universities.

The purpose of this study was to investigate the knowledge, attitudes and practice of Albanian healthcare professionals towards pharmacovigilance and ADRs reporting, as well as the factors influencing their practice.

MATERIALS AND METHODS

There was performed a cross-sectional study in Tirana region, the capital city of Albania, which was carried out between December 2021 and February 2022. It was delivered a self-administered questionnaire to the following randomly selected HCPs, respectively: 250 pharmacists working full time in community pharmacies, 129 physicians and 132 nurses working full time in "Mother Teresa" University Hospital Center in Tirana. The total number of participants was 410 resulting in response rates: 84% for the pharmacists, 74.4% for the physicians and 78.8% for the nurses. The survey was totally confidential and anonymous.

The questionnaire was modified and adapted referring to the previous study carried out in different developing countries. It was designed to gather data on sociodemographic factors, questions about knowledge, attitudes, practices and reporting ADRs from healthcare professionals (Adisa and Omitogun, 2019; Tekel et al., 2021; R. Behera et al., 2022; Acharya et al., 2022). The questionnaire was composed of eight main sections covering 31 items with the components regarding (a) sociodemographic data, (b) knowledge about the law of PV, the aim of PV and practice of ADR reporting, (c) attitude about ADR reporting, (d) practice regarding ADRs reporting, (e) recommendation to patient with ADR, (f) obstacles for not reporting ADRs. Both were involved in the questionnaire, open-ended and closeended questions.

The questionnaire was validated through a pilot study of 53 randomly selected healthcare professionals from community pharmacies, hospitals, academia pharmaceutical wholesalers. It was finalized after unsuitable and ambiguous questions were modified based on the pretest result. Cronbach's α was calculated using the reliability scale which resulted in an overall α , the value was 0.815. The used questionnaires and study protocol were ethically evaluated and approved by the Ethical Council of Aldent University.

STATISTICAL ANALYSIS

The data from the survey was immediately entered into the Statistical Package for the Social Sciences (SPSS) version 21 (IBM 2013) and checked again for any errors. Descriptive statistics were used to characterize demographic factors and percentages and frequencies were used to represent categorical variables. The comparison between variables was analyzed using the Pearson Chi-Squared test, and p-values <0.05 were considered statistically significant.

RESULTS

Socio-demographics data

Table 1 lists the socio-demographic information about the HCPs (physicians, pharmacists and nurses) who participated in the study. Community pharmacists made up 51.21% of HCPs, followed by nurses at 25.38% and physicians at 23.41%. Among all the participants who replied to the questionnaire the majority were female, 67.57% and the average age of participants was 37.36 years old (SD±3.11). The working experience average number was 8.78 years (SD±2.33), 41.46% of participating HCPs had less than 5 years of professional experience, while 5.62% had more than 31 years of experience.

Table 1: Socio-demographics data of HCPs (n=410)

Category	Subcategory	n(%)			
Healthcare	Physicians	96 (23.41)			
professionals	Community pharmacists	210 (51.21)			
professionals	Nurses	104 (25.38)			
Gender	Male	133 (32.43)			
Gender	Female	277 (67.57)			
	below 25	75 (18.29)			
	25-30	88 (21.46)			
A co (voore)	31-35	56 (13.66)			
Age (years)	36-40	48 (11.7)			
	41-45	35 (8.54)			
	above 45	108 (26.35)			
	Less than 5 years	170 (41.46)			
	6-10 years	59 (14.39)			
	11-15 years	41 (10.0)			
Experience	16-20 years	47 (11.46)			
	21-25 years	34 (8.29)			
	26-30 years	36 (8.78)			
	Over 31 years	23 (5.62)			
n- number. %- percentage					

HCPs' knowledge regarding pharmacovigilance, pharmacovigilance law and ADRs reporting process HCPs' knowledge of PV

When participants were asked about the definition of PV, 41.69% of physicians, 36.19% of pharmacists and 35.58% of nurses gave the correct response stating PV as the detection, assessment, understanding and prevention of ADRs and the association between professions was found significant with a p-value 0.035. Of the participants, 56.25% of physicians, 42.38% of pharmacists and 30.77% of nurses responded correctly about the main purpose of pharmacovigilance which ensures the safety of the drugs, the p-value was 0.018 which indicated a significative difference between professional groups. The data about the definition of pharmacovigilance and its main purpose are presented in table 2.

HCPs' knowledge regarding pharmacovigilance law and ADRs reporting

This part of the questionnaire contains two closed-ended questions. As shown in table 3, more than half of the participating physicians and pharmacists, respectively 52.08% and 67.62% responded correctly about the existence of PV law in Albania, while more than half of the participating nurses, 59.62% responded incorrectly, there is a significant difference among professional groups (p=0.034). Among all the participants, the majority of physicians 50% and pharmacists, 66.66% had knowledge about the establishment of the PV center, while 52.9% of participating nurses had no knowledge about it. As shown in fig. 1, 68.9% of the pharmacists were aware that the PV center was established at the National Agency of Drugs and Medical Devices, Albania.

Regarding the knowledge of participants about adverse drug reaction reporting, when the participants were asked if they know how to report 46.88% of physicians and 51.43% of pharmacists responded positively, meanwhile 47.12% of nurses significantly (p=0.018) didn't know how to report ADRs.

Majority of physicians and pharmacists, 58.33% and 68.57% respectively, as well as 35.58% of nurses gave correct answers that types of ADRs that should be reported were unknown reactions and susceptible reactions to life. As presented in table 4, 51% of physicians, 54.29% of pharmacists and 49.04% of nurses responded correctly that ADRs should be reported by phone, by mail, etc.

The majority of participants thought that increasing ADR reporting would increase the safety of drugs. About 85.42% of physicians, 74.29% of pharmacists and 40.38% of nurses agreed that medical staff is obliged to report ADRs. Related to the question if ADRs reporting will help the patient's health, the majority of physicians and pharmacists, 82.29% and 79.52% and 42.73% of nurses had a positive attitude. Similarly, 66.67% of physicians,

75.71% of pharmacists and 63.46% of nurses agreed that if they would be trained, they would practice the ADRs reporting. As shown in table 4, significantly the majority of the professionals, specifically 79.17% of physicians, 91.43% of pharmacists and 59.42% of nurses declared that ADRs reporting is an essential role of the HCPs.

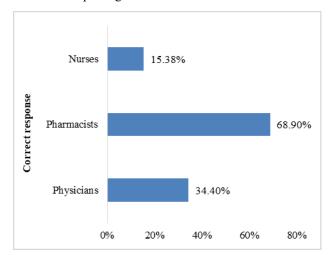


Fig. 1: Percentages of correct responses about the institution where PV center is established (*percentage within the professional group)

HCPs' practice regarding pharmacovigilance ADRs reporting

To the next question, if HCPs, personally, have reported ADRs, the majority of physicians 57.29% and pharmacists 58.57% stated that they have reported ADRs during their working experience, whereas 49.04% of nurses significantly (p=0.044) haven't had any experience on ADRs reporting. Of all physicians and pharmacists, 71.88% and 60% stated that there is a form of ADRs reporting in their workplace, significantly (p = 0.032) the majority of nurses 53.85% did not know about this topic. Shifting to the next question if the medical staff (doctors, pharmacists and nurses) meet to discuss ADRs, about fifty percent responded negatively. As presented in table 5, practices related to organized meetings are rarely documented.

Fig. 2 presents the practice related to the mode of ADRs reporting; only 11.46% of physicians that have had experience with ADRs reporting, responded they have reported ADRs to the National Pharmacovigilance Center. Contrary, none of the other professional groups (pharmacists and nurses) have reported ADRs to PV Center. Pharmacists stated to address the ADRs reporting to the doctor and specialist for ADRs and to the branch of the drug production company; nurses to the doctors and patient's medical record. As shown in fig. 3, 79.17% of physicians, 78.57% of pharmacists and 79.8% of nurses responded that when the patient has ADRs they advise to stop taking the medication, whereas 20.83% of physicians, 21.43% of pharmacists and 20.2% of nurses

recommend the consultation to a doctor and the specialist for ADRs.

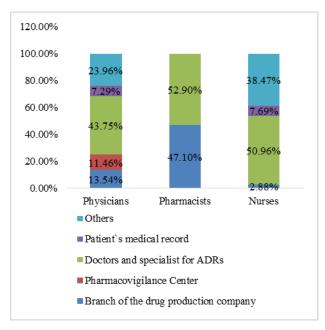


Fig. 2: Practice related to ADRs reporting* (*percentage within the professional group)

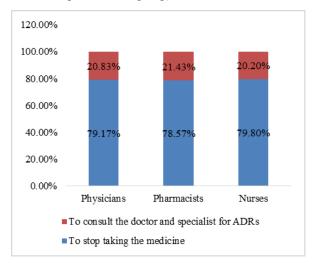


Fig. 3: Recommendation to patients with ADRs* (*percentage within the professional group)

HCPs' perceived obstacles

Majority of the HCPs who took part in this study think there are challenges in reporting ADRs. 43.52% of physicians, 42.86% of pharmacists and 41.6% of nurses admitted that they are uncertain about ADRs reporting. Whereas, 7.4% of physicians, 19.05% of pharmacists and 25.55% of nurses encountered difficulties as they did not have enough knowledge on how to report. Lack of reporting format (cited by 18.54% of respondents), not sure if ADR (cited by 5.12% of respondents) and lack of time (cited by 16.1% of respondents) are reported barriers as well (fig. 4).

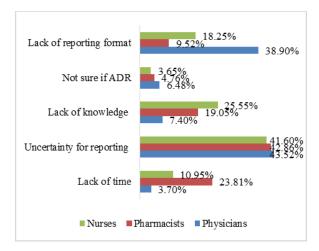


Fig. 4: Barriers to HCPs reporting of ADRs* (*percentage within the professional group)

DISCUSSION

This study is the first report from Albania that evaluated the perception, attitudes and behaviors of healthcare professionals, respectively: physicians, community pharmacists and nurses towards pharmacovigilance.

The survey's response rate was 80.23%, which is lower compared to findings on the same topic (Alsaleh *et al.*, 2017; Suyagh *et al.*, 2015; Abdel-Latif and Abdel-Wahab, 2015) and more or less the same with other publications (Gordhon *et al.*, 2020, Gidey *et al.*, 2020).

Majority of respondents were female and community pharmacists. The same findings carried out in Brazil 2020 (Romeo *et al.*, 2020) could be related to the fact that community pharmacists have a clinical background and interact closely with prescribers and patients, consequently, they are in a better position to understand the aim of the survey.

In the current study, physicians had more knowledge of PV definition and its aim compare to pharmacists and nurses. The results were found to be similar to studies conducted by Shrestha *et al.* 2022 and Shakya-Gurung *et al.*, 2019 where respectively 50% and 47.3% of professionals had a thorough comprehension of the broad concept of pharmacovigilance.

Among the professional groups, majority of pharmacists had information about the existence of the PV law and PV center establishment. Similarly, a study carried out by Hussain *et al.*, 2021 showed that the majority of pharmacists had better knowledge about the definition and aim of PV, establishment of PV system, compare to nurses and physicians. Only 39.6% of HCPs were aware of the pharmacovigilance center, according to a research by Abdel-Latif *et.*, 2015. Of them, 27.2% were nurses, 39.2% were doctors and 70.27 percent were pharmacists.

Table 2: HCPs' knowledge of pharmacovigilance

	Professional category						
Statement	Physicians	Pharmacists	Nurses	Total	p-value		
	n(%)	n(%)	n(%)	n(%)			
	tion of PV						
The science of detecting the incidence of ADRs after the drug is marketed.	46 (47.91)	41 (19.53)	43 (41.35)	130 (31.7)	0.713		
The science of monitoring ADRs occurring in hospitals.	5 (5.2)	59 (28.09)	18 (17.3)	82 (20.0)	0.002*		
The process of improving the safety of the drug	5 (5.2)	34 (16.19)	6 (5.77)	45 (10.98)	0.07		
The detection, assessment, understanding and prevention of ADRs**	40 (41.69)	76 (36.19)	37 (35.58)	153 (37.32)	0.035*		
The main purpose of pharmacovigilance							
Identifying the safety of the drug**	54 (56.25)	89 (42.38)	32 (30.77)	175 (42.68)	0.018*		
Calculation of the incidence of ADRs	15 (15.63)	40 (19.05)	10 (9.62)	65 (15.85)	0.023*		
Identifying predisposing factors to ADRs	11 (11.46)	44 (20.95)	18 (17.3)	73 (17.8)	0.012*		
Identifying previously unrecognized ADRs	16 (16.66)	37 (17.62)	44 (42.31)	97 (23.67)	0.441		

n- number, %- percentage within the professional group

Table 3: HCPs' knowledge about the establishment of pharmacovigilance law and ADRs reporting process

	Professional category					
Statements	Physicians	Pharmacists	Nurses	Total	p-value	
Statements	n (%)	n (%)	n (%)	n (%)	1	
		Knowledge about	PV law			
1. Has the pharmacovi	gilance law been app	proved in our country				
Positive	50 (52.08)	142 (67.62)	42 (40.38)	234 (57.07)		
Negative	5 (5.2)	6 (2.86)	6 (5.77)	17 (4.15)	0.034*	
Don't know	41 (42.72)	62 (29.52)	56 (53.85)	159 (38.78)	7	
Has a pharmacovigi	lance center been est	ablished				
Positive	48 (50.0)	140 (66.66)	44 (42.3)	232 (56.58)		
Negative	6 (6.25)	20 (9.52)	5 (4.8)	31 (7.56)	0.469	
Don't know	42 (43.75)	50 (23.82)	55 (52.9)	147 (35.86)	7	
	Kno	wledge about ADRs r	eporting process			
1. Do you know how t	o report ADRs?					
Positive	45 (46.88)	108 (51.43)	34 (32.69)	187 (45.6)		
Negative	30 (31.25)	82 (39.04)	49 (47.12)	161 (39.27)	0.018*	
Don't know	21 (21.87)	20 (9.53)	21 (20.19)	62 (15.13)	7	
2. What types of ADR	s do you think should	d be reported?				
Correct	56 (58.33)	144 (68.57)	37 (35.58)	237 (57.8)		
Incorrect	39 (40.63)	27 (12.86)	42 (40.38)	108 (26.34)	0.639	
Don't know	1 (1.04)	39 (18.57)	25 (24.04)	65 (15.86)	7	
3. How are ADRs repo	orted?					
Correct	49 (51)	114 (54.29)	51 (49.04)	214 (52.2)		
Incorrect	3 (3.13)	28 (13.33)	13 (12.5)	44 (10.73)	0.267	
Don't know	44 (45.87)	68 (32.38)	40 (38.46)	152 (37.07)	7	

n- number, %- percentage within the professional group

Since drugs are the most popular form of treatment, they must be used responsibly. If the safety of a drug is not properly taken into account, it could have negative effects, from fatality to permanent handicap. Likewise, by reporting drug-related ADRs, drug safety can be increased. Even though ADRs reporting is a professional obligation for healthcare workers in many countries, HCPs level of knowledge on ADRs reporting in the study was found to be significantly different: about 50% of physicians and pharmacists have knowledge of ADR reporting process compare to 30% of nurses. However,

the findings suggested that regular sensitization campaigns, trainings and drug safety notifications should be carried out among all HCPs and should be distributed to medical facilities. Several studies have attributed low knowledge (Toklu *et al.*, 2008, Guner *et al.*, 2019), while others studies concluded that pharmacists have acceptable knowledge (Srisuriyachanchai *et al.*, 2022; Shanko *et al.*, 2018) of ADRs reporting among the HCPs. According to a Kuwaiti study, pharmacists are more knowledgeable than primary care doctors in pharmacovigilance and ADR reporting (Lemay *et al.*, 2018).

^{*}the level of significance difference p<0.05, **correct answer,

^{*} the level of significance difference p < 0.05

Table 4: HCPs' attitudes towards ADRs reporting

	Professional category					
Statements	Physicians	Pharmacists	Nurses	Total	p-Value	
	n (%)	n (%)	n (%)	n (%)	p-value	
1. Is the medical staff	is obliged to report	ADRs?				
Positive	82 (85.42)	156 (74.29)	42 (40.38)	280 (68.29)		
Negative	8 (8.33)	35 (16.66)	22 (21.15)	65 (15.85)	0.771	
Don't know	6 (6.25)	19 (9.05)	40 (38.47)	65 (15.86)		
2. Reporting of ADRs	will help patients					
Positive	79 (82.29)	167 (79.52)	44 (42.3)	290 (70.73)		
Negative	5 (5.2)	18 (8.57)	29 (27.88)	52 (12.68)	0.342	
Don't know	12 (12.51)	25 (11.91)	31 (29.82)	68 (16.59)		
3. Will practice PV if	I am trained					
Positive	64 (66.67)	159 (75.71)	66 (63.46)	289 (70.49)		
Negative	26 (27.08)	27 (12.86)	13 (12.5)	66 (16.1)	0.9	
Don't know	6 (6.25)	24 (11.43)	25 (24.04)	55 (13.41)		
4. Reporting is an essential role of HCPs						
Positive	76 (79.17)	192 (91.43)	62 (59.42)	330 (80.48)		
Negative	19 (19.79)	5 (2.38)	10 (9.62)	34 (8.29)	0.007*	
Don't know	1 (1.04)	13 (6.19)	32 (30.96)	46 (11.23)		

Table 5: HCPs' practice regarding pharmacovigilance and ADR reporting

	Professional category					
Practices	Physicians	Pharmacists	Nurses	Total	n volue	
	n (%)	n (%)	n (%)	n (%)	p-value	
1. Are ADRs reported	, in the institution w	here you work (hospita	al, ambulance, phari	macy)?		
Positive	60 (62.5)	134 (63.8)	41 (39.42)	235 (57.31)		
Negative	15 (15.63)	45 (21.43)	50 (48.08)	110 (26.83)	0.868	
Don't know	21 (21.87)	31 (14.77)	13 (12.5)	65 (15.86)		
2. Have you reported	these ADRs?					
Positive	55 (57.29)	123 (58.57)	23 (22.12)	201 (49.02)		
Negative	37 (38.54)	87 (41.43)	51 (49.04)	175 (42.68)	0.044*	
Don't know	4 (4.17)	=	30 (28.84)	34 (8.3)	1	
3. Is there any form of	f ADR reporting in y	our institution?				
Positive	69 (71.88)	126 (60)	23 (22.11)	218 (53.17)		
Negative	22 (22.91)	36 (17.14)	25 (24.04)	83 (20.24)	0.032*	
Don't know	5 (5.21)	48 (22.86)	56 (53.85)	109 (26.59)		
4. If the medical staff (physicians, pharmacists, nurses) meet to discuss ADRs						
Positive	12 (12.5)	57 (27.14)	14 (13.46)	83 (20.24)		
Negative	46 (47.92)	107 (50.95)	50 (48.07)	203 (49.51)	0.073	
Don't know	38 (39.58)	46 (21.91)	40 (38.47)	124 (30.25)		
5. If the organized meetings are documented						
Positive	9 (9.4)	20 (9.52)	7 (6.73)	36 (8.78)		
Negative	-	27 (12.86)	5 (4.8)	32 (7.8)	0.068	
Don't know	3 (3.13)	10 (4.76)	2 (1.92)	15 (3.65)		

n- number, %- percentage within the professional group

The present study showed that HCPs had a positive attitude towards PV activities in general and ADRs reporting in particular. The study stated that the majority of the respondents thought that reporting ADRs can benefit public health. It was good to notice that majority of the participants in this study considered ADR reporting as important and must be obligatory. Although HCPs had knowledge of ADR reporting, about 50% of physicians and pharmacists and 35% of nurses still had inadequate knowledge on how to report ADRs and what kind of

ADRs to be reported. Findings from the current study showed that pharmacists and nurses do not report ADRs to the national pharmacovigilance center but report to other places. A less favorable opinion about ADR reporting was carried out in 2021 in Libya (Yousef *et al.*, 2021) where 34.37% of participants stated ADRs report necessary, whereas 36.25% of them thought it should be obligatory. Similar results were also recorded from the study carried out in India (Srinivasan *et al.*, 2017).

^{*} the level of significance difference p<0.05

Positive attitudes and knowledge, however, were not reflected so well in practice. About 58% of ADR reports obtained by Albanian HCPs showed how knowledge and practice need to be improved; as majority of ADR reports were not submitted to the national pharmacovigilance center, this data can not officially be taken into consideration. To enhance the current pharmacovigilance system and make it fully operational in the nation, health professionals, regulatory agencies, patients and other pharmacovigilance stakeholders should collaborate closely.

This bad practice is found to be in line with the previous studies performed among pharmacists in New Zealand (Zolezzi and Parsotam, 2005) and Hong Kong (Lee *et al.*, 1994) where pharmacists and other healthcare professionals were sending their ADR reports to hospitals, doctors, pharmaceutical companies, etc., but contrary to the findings in Canada, Australia, Netherlands, Japan, Spain and Portugal were the majority of the pharmacists and other healthcare professionals submitted their ADRs reports to their national reporting centers (Sweis and Wong, 2000).

In the present study, it was found that the main reasons that might have contributed to underreporting of ADRs among the participants were such as uncertainty on how to report, lack of time, lack of feedback and unavailability of reporting forms. In a survey conducted in Malaysia doctors felt uncertain about ADR discouraged reporting 76.6% (Agarwal *et al.*, 2013), a similar outcome was obtained in Sweden 75% (Backstrom and Miorndal, 2006) and Romania 40.2% (Pavelin *et al.*, 2013). The reasons for not reporting ADR declared by the healthcare workers were quite similar to the above-mentioned reasons, indicating that the results were consistent with the previous studies.

Majority of all HCPs recommended to stop taking the medication or to consult the doctor and specialist of ADRs, in case with patient with ADRs.

Promoting pharmacovigilance procedures requires communication between Albanian pharmacovigilance center and the stakeholders in that field. The system will be more effective if the reporting mechanism and channel are well established. The patients, pharmaceutical corporations and all other healthcare experts must work closely together to accomplish this. The prevention, management and thorough understanding of ADRs will ultimately improve patient safety.

The limitation of the study is that the findings were restricted to only healthcare professionals working in one city only, also hospital pharmacists were not part of the study. However, the findings of this study do provide insight into aspects that should be further investigated as a part of a larger study in the future in our country.

CONCLUSIONS

The results of the present study show that the majority of the healthcare professionals in Tirana city had a lack of knowledge about pharmacovigilance practices. Since there is a demand in healthcare units, under and postgraduate educational programs about ADR reporting and pharmacovigilance practice need to be improved towards ADR reporting. In order to reinforce the role of pharmacovigilance in guaranteeing patient safety, it is necessary to raise the frequency and intensity of public awareness campaigns and recurring training programs.

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