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Original article

Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait

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ABSTRACT

Introduction: Pharmacovigilance (PV) is essential to detect and prevent adverse drug reactions (ADR) after a drug is marketed. However, ADRs are significantly underreported worldwide. *Objective:* The aims of this study were to document the knowledge, attitude and practices (KAP) of pharmacists toward PV and ADR reporting and to explore the barriers to implementing a fully functional PV program in Kuwait. *Material and methods:* Pharmacists working at governmental hospitals were asked to complete a paper-based 25-item questionnaire. *Results:* A total of 414 pharmacists received the questionnaire and 342 agreed to participate, giving a response rate of 82.6%. Most pharmacists were knowledgeable about the concepts of PV (61.5%) and ADRs (72.6%) and the majority (88.6%) was willing to implement ADR reporting in their clinical practice. Despite this positive attitude, only 26.8% of participants had previously reported an ADR and the main reason for underreporting was stated as not knowing how to report (68.9%). Barriers that hinder the implementation of a PV center included lack of cooperation and communication by healthcare professionals and patients ($n = 62$), lack of time and proper management ($n = 57$), lack of awareness of staff and patients ($n = 48$) and no qualified person to report ADRs ($n = 35$). *Conclusions:* Overall this study shows that hospital pharmacists in Kuwait had good knowledge and positive attitude toward PV and ADRs reporting. However, the majority of them have never reported ADRs. These results suggest that targeted educational interventions and a well-defined policy for ADR reporting may help increase ADR reporting and support the implementation of a fully functional independent PV center in Kuwait.

1. Introduction

The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem". PV aims at enhancing patient safety by assessing the risk-benefit profile of medicines (WHO, 2002a). As such, adverse drug reaction (ADR) reporting is the foundation of any PV system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. WHO defines ADRs as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function' (WHO, 2002b). ADRs have increasingly drawn worldwide attention accounting for significant morbidity and mortality and associated with increased health costs (Pirmohamed et al., 1998, 2004). Recent estimates suggest that ADRs are the sixth leading cause of death in the United Sates of America (USA) (WHO, 2002b). In other developed countries such as the United Kingdom (UK), France and Sweden, they are responsible for 6.5%, 3.2% and 12%

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hospital admissions, respectively (Mjörndal et al., 2002; Pirmohamed et al., 2004).

On the other hand, ADRs are underreported and undisclosed in developing countries due to lack of medication monitoring and prioritization of medication safety or even lack of an ADR reporting system (Wilson et al., 2012). In South India region only, the overall incidence of the ADRs was 9.8% (Arulmani et al., 2007), while in Iran, a study documented that among 16.8% of patients, at least one had an incidence of ADRs (Gholami and Shalviri, 1999). In the Middle East region, limited data are available on the incidence and prevalence of ADRs. However, a multicenter study in Morocco showed an incidence of ADRs of 11.5 per 100 admissions in medical and surgical units (Benkirane et al., 2009). In the Kingdom of Saudi Arabia (KSA), the annual ADR reports were estimated to range from 0.07% in 1993 to 0.003% in 1999 (Al-Malaq et al., 2008).

Although ADRs data from other countries are essential to undertake medication safety decisions by a local regulatory authority and the drug manufacturer, several factors are known to influence ADRs, such as local population traditions, diets and complementary and alternative medicines (CAM) (Alshami et al., 2014). Therefore, it is crucial for every country to develop its own national PV program (WHO, 2002a). A recent survey showed that many countries in the Middle East region (e.g. KSA, Qatar, Bahrain, Oman, Yemen, Jordon, Egypt, Lebanon) are members of the WHO Programme for International Drug Monitoring; however, the existing PV programs in most of these countries are still in their infancy with limited regional collaboration (Wilbur, 2013a). Recently, important steps have been undertaken by the Kuwait Drug and Food Control (KDFC) to establish a national PV center. Although an appropriately designed online ADR reporting form is available for healthcare professionals (HCP) (KDFC, 2016), very few reports over the last two years have been received. Importantly, a functional PV center requires ongoing support from the political stakeholders for its full development and ongoing operations.

The importance of reporting ADRs cannot be understated. Studies have shown that optimizing knowledge, attitude and practices (KAP) with regard to PV is important in formulating strategies to encourage ADR reporting (Ahmad et al., 2013). In this context, there is an extensive body of literature examining KAP toward ADR reporting among pharmacists working in hospitals or community, and exploring causes of underreporting, which shows that lack of clinical knowledge and unfamiliarity of the reporting system were major discouraging factors for reporting ADRs (Sweis and Wong, 2000; Subish et al., 2008; Toklu and Uysal, 2008; Nichols et al., 2009; Vessal et al., 2009; Gavaza et al., 2010; Su et al., 2010; Elkalmi et al., 2011; Fadare et al., 2011; Palaian et al., 2011; Pérez García and Figueras, 2011; Rajesh et al., 2011; Chinenye and Michael, 2012; Ahmad et al., 2013; Irujo et al., 2013; Okeshukuwu et al., 2013; Wilbur, 2013b; Abdel-Latif and Abdel-Wahab, 2014; Afifi et al., 2014; Jose et al., 2014; Mahmoud et al., 2014; Mulatu and Worku, 2014; Varallo et al., 2014; Gupta et al., 2015; Suyagh et al., 2015). Some of these studies were conducted in the Arabic Gulf region, such as Oman, Qatar and KSA (Wilbur, 2013b; Jose et al., 2014; Mahmoud et al., 2014; Suyagh et al., 2015). However, there are no published data from Kuwait. Therefore, the objective of this study was to document KAP among pharmacists working in the government hospitals in Kuwait and to explore barriers of establishing PV activities.

2. Material and methods

A cross-sectional study was conducted among pharmacists working in the secondary and tertiary governmental hospitals in Kuwait: Al-Jahra Hospital, Al-Farwaneya Hospital, Al-Amiri Hospital, Mubarak Al-Kabeer Hospital, Al-Adan Hospital, Al-Sabah Hospital and Al-Sabah Specialized Hospitals.[1]

2.1. Sampling strategy

The sample size included the entire population of pharmacists who work in the governmental hospitals across the different Governorates in Kuwait. Preliminary fieldwork showed that there are a total of 502 pharmacists working in the secondary and tertiary hospitals. However, to ensure the study objectives were met, the following pharmacists were excluded from the study sample: pharmacists with minimal patient contact or no medication dispensing duties [e.g. those working in the total parenteral nutrition (TPN) unit, medical storage, or pharmacy laboratory ($n = 57$)]. Hence only pharmacists who manage drug distribution and dispensing on a daily basis were included in the study ($n = 445$).

2.2. Study tool

A self-administered 25-item questionnaire was used to understand pharmacists' familiarity with regard to PV and whether they were undertaking any ADR reporting practices, and to explore barriers to implementing a fully functional national PV center in Kuwait. The questionnaire consisted of questions included in previous local and international studies that examined the KAP of HCP, including pharmacists (Toklu and Uysal, 2008; Palaian et al., 2011; Rajesh et al., 2011; Chinenye and Michael, 2012; Ahmad et al., 2013; Isfahani et al., 2013; Khan, 2013; Santosh et al., 2013; Abidi et al., 2014; Jose et al., 2014; Mahmoud et al., 2014; Khan et al., 2015; Suyagh et al., 2015). The questionnaire was composed of five sections. The first section consisted of five questions to document the knowledge and awareness of PV and ADRs. The second part consisted of six questions to assess pharmacists' perception and attitude toward ADR reporting. The third part of the questionnaire had three questions, which identified practices regarding the reporting of an identified ADR. Two open-ended questions formed the fourth part of the questionnaire to investigate the barriers that exist in Kuwait toward having a PV center and any further recommendations or suggestions from the study participants. The last part of the questionnaire focused on the pharmacists' demographics. The questionnaire was distributed in English.

2.3. Validity and reliability of the study tool

The questionnaire consisted of questions that were pre-tested for reliability in previous studies (Palaian et al., 2011; Isfahani et al., 2013; Khan, 2013; Santosh et al., 2013; Khan et al., 2015). For the current study, two researchers reviewed the questionnaire and checked the questions' consistencies, clarity and relevance. Moreover, a pilot study was initially done among 10 pharmacists working in two general hospitals ($n = 5$ from Mubarak Al-Kabeer Hospital and $n = 5$ from Al-Amiri Hospital) to assess the content and face validity of the tool and whether data collection procedures were feasible or not. Slight modifications were recommended in order to clarify some of the questions without

[1] Al-Sabah Specialized Hospitals comprise 21 hospitals: Al-Razi Hospital, Kuwait Center for Mental Health, NBK Hospital, Zain Hospital, Natural Medicine & Rehabilitation Hospital, Infectious Diseases Hospital, Maternity Hospital, Chest Diseases Hospital, Pulmonary Rehabilitation Center, Ibn-Sina Hospital, Sheikhan Al-Farsi Center for rheumatic diseases, Al-Rashid Allergy Center, Islamic Medicine Center, Kuwait Cancer Control Center that include both Shaikha Badriya Al-Ahmad for oncology and stem cell transplant and Hussain Makki Juma Center for specialised surgery, Asaad Al-Hamad Dermatology Center, Khaled Al-Nafisi Center for dialysis, Center of Hamed Al-Essa for organ transplants, Al-Bahar Eye Center, Al-Babtain Center for burns and plastic surgery, and Sabah Al-Ahmad Hospital for urology.

changing their essence. Data obtained from the pilot study were excluded from the reported study results.

2.4. Ethical approval

The study protocol was approved by the Standing Committee for Coordination of Health and Medical Research, Ministry of Health (MOH) and the Health Science Center (HSC) Ethics Committee for Student Research.

2.5. Sample recruitment and data collection

Each pharmacy was visited and pharmacists were verbally invited to participate after explaining the aims of the study. For those who agreed to take part, a written consent form was obtained that clearly ensured the confidentiality and anonymity of gathered information. Data collection took place over three months (February to April 2015). Some of the pharmacists completed the questionnaire on the same day, while others were busy and their filled questionnaires were collected on a different day.

2.6. Data analysis

The statistical analysis was done using the Statistical Package for Social Science (SPSS) Software for Windows, version 21. Data from closed-ended questions were coded and entered into the SPSS. Descriptive statistics were used to analyze the data [frequency and percentages; mean ± standard deviation (SD)]. Responses to the open-ended questions from all the questionnaires were reported. Relevant issues were then grouped and presented based on the frequencies of reporting.

3. Results

3.1. Demographics

A total of 414 pharmacists working in governmental hospitals in Kuwait received the study questionnaire. Of those, 342 accepted to respond to the questionnaire, yielding a response rate of 82.6%. The main reported reason for non-participation was lack of time due to a busy schedule. Of those who responded, approximately 60% worked in general hospitals and 40% in specialized hospitals. The study population consisted of approximately 52.3% Kuwaiti nationals and had a mean age of 33 years. Most participants (45%) were within the age group of 20–29 years with 40.5% of them having 1–5 years of experience as qualified pharmacists. Details of the demographics are shown in Table 1.

Table 1
Socio-demographic characteristics of the pharmacists (n = 342).

	Numbers	(%)
Gender		
Male	142	(42.3)
Female	194	(57.7)
Nationality		
Kuwaiti	172	(52.3)
Non-Kuwaiti	157	(47.7)
Middle East (KSA, Iraq, Jordan, Syria, Lebanon, Egypt)	136	(41.3)
South Asia (India, Pakistan)	17	(5.2)
Europe (UK, Ukraine, Montenegro)	3	(0.91)
North America (Canada)	1	(0.30)
Age in years [Mean ± SD = 33.2 ± 9.3]		
20–29	143	(45.0)
30–39	112	(35.2)
40–49	33	(10.4)
⩾50	30	(9.4)
Rank		
Beginner Pharmacist	97	(28.7)
Pharmacist	88	(26.0)
Senior Pharmacist	61	(18.0)
Pharmacy Specialist	38	(11.2)
Senior Pharmacy Specialist	35	(10.4)
Head of Pharmacy Specialist	19	(5.6)
Years of experience		
<1	23	(7.0)
1–5	133	(40.5)
6–10	64	(19.5)
11–15	42	(12.8)
16–20	63	(7.0)
>20	43	(13.1)
Country of graduation		
Kuwait	115	(35.4)
Outside Kuwait	210	(64.6)
Egypt	124	(38.2)
Jordan	28	(8.6)
UK	16	(4.9)
India	12	(3.7)
Others[a]	30	(10.2)
Type of setting (hospital)		
General hospitals	204	(59.8)
Specialized hospitals	137	(40.2)

Numbers may not add to the total due to missing data.
[a] Pakistan (n = 8); United Arab Emirates, UAE (n = 7); Syria (n = 4); United States of America, USA (n = 3); Kingdom of Saudi Arabia, KSA (n = 2); Lebanon (n = 1); Italy (n = 1); Russia (n = 1); Ukraine (n = 1); Yugoslavia (n = 1); Australia (n = 1).

3.2. Knowledge about PV, ADRs and their reporting

In the questionnaire, five items were designed to assess the pharmacist's knowledge of PV, ADRs and their reporting (Table 2). When asked about the definition of PV, 61.5% of pharmacists selected the statement, which best defined PV according to the WHO definition. Participants were then asked about their knowledge regarding the purpose of PV and 74.8% provided the correct answer. Of note, 6.2% and 7.0% reported not knowing the definition or purpose of PV, respectively. A similar answer profile was observed when participants were asked about the definition of ADRs where 72.6% provided the correct answer. Several items in the questionnaire were meant to assess the knowledge and awareness of the participants about ADR reporting; 76% of respondents selected the correct answer when asked which ADRs should be reported. However, only 7% were aware of the existence of an ADR reporting system in Kuwait.

When asked to which institution ADRs should be reported, participants were provided a list of options and they could select one or more options (Fig. 1). In fact, 52.5% and 44.9% of participants selected the KDFC and the MOH, respectively, while 30.2% of participants reported not knowing where to report.

3.3. Attitudes about ADRs and their reporting

Participants in our study sample almost unanimously (98.8%) believed that it is necessary to report ADRs (Fig. 2). Our sample consisted of pharmacists working in governmental hospitals and a significant portion (85.6%) reported considering ADR reporting as a professional obligation. Similarly, almost all (97.1%) believed that ADR reporting will have a positive impact on the healthcare system. Participants were also asked who they believed should report ADRs and they were provided with a list from which they could select one or several options. As shown in Fig. 3, the majority of participants (89.5%) thought that pharmacists are responsible for reporting ADRs, followed by physicians (72.2%). The participants also believed that other HCP and patients could report ADRs, although to a lesser extent.

Table 2
Knowledge of PV and ADRs (n = 342).

	Numbers	(%)
Which of the following BEST defines PV?		
The science and activities of detecting, assessing, understanding & preventing adverse effects (**Correct**)	209	(61.5)
The science of detecting the type & incidence of ADRs after a drug is marketed.	55	(16.2)
The process of improving the safety of drugs	28	(8.2)
The science of monitoring ADRs happening in a Hospital	27	(7.9)
Do not know	21	(6.2)
The purpose of PV		
To enhance patients' safety in relation to use of drugs (**Correct**)	255	(74.8)
To identify predisposing factors to ADRs	24	(7.0)
To identify unrecognized ADRs	23	(6.7)
To calculate incidence of ADRs	15	(4.4)
Do not know	24	(7.0)
Which of the following defines an ADR correctly?		
Any noxious or undesired effect of a drug occurring at normal doses, during normal use (**Correct**)	246	(72.6)
Adverse health outcomes associated with inappropriate drug use	55	(16.2)
Harm resulting from the use of substandard/counterfeit drugs	14	(4.1)
Harm caused by drug overdose	6	(1.8)
Adverse outcomes associated with drug impurity	5	(1.5)
Other health problems associated with drug use	13	(3.8)
Which ADRs should be reported?[a]		
All serious ADRs	62	(18.2)
ADRs to herbal and non-allopathic drugs	1	(.3)
ADRs to new drugs	8	(2.3)
ADRs to vaccines	4	(1.2)
Unknown ADRs to old drugs	7	(2.1)
All of the above (**Correct**)	259	(76.0)
Any center or ADR reporting system in Kuwait?		
Yes	24	(7.0)
No	317	(93.0)

PV: Pharmacovigilance; ADRs: Adverse Drug Reactions.
Numbers may not add to the total due to missing data.
[a] Multiple responses were possible.

When asked about which reporting method would be most appropriate for them, nearly half (49.4%) preferred email or Website system, followed by 36.1% who preferred direct contact with a person. Other methods, such as telephone and post, were the least preferred methods (Table 3). The majority of pharmacists in the study (88.6%) reported being willing to implement an ADR reporting system in their practice and feel strongly that pharmacovigilance should be taught extensively to all HCP.

3.4. Practices and barriers about ADRs and their reporting

When assessing the actual practice of the study participants regarding ADR reporting, only a small proportion (26.8%) confirms having reported ADRs for their patients in the course of their practice (Table 3). Pharmacists were asked how many ADRs they recall having reported: 42.6% reported less than 5 ADRs and 29.6% reported more than 10 ADRs. Factors having a negative impact on ADR reporting were investigated and the most important barrier hindering reporting is the lack of knowledge of how to report (68.9%) (Fig. 4). This is followed, although to a significant lesser extent, by pharmacist (35.2%) believing that ADR reporting is less important than patient management and/or patient confidentiality. Only 11.4% believed that ADR reporting is not part of their job.

With the use of an open-ended question, pharmacists were also asked about their perceived barriers to establishing an ADR reporting system in their institution. About 60% (n = 204) of participants provided answers and the main barriers reported include lack of cooperation and communication between HCP and patients (n = 78), lack of time (n = 57) and qualified staff (n = 35) as well as lack of awareness by the HCP regarding ADRs and their reporting (n = 39). Other barriers were also reported but with less frequency: lack of professionalism of pharmacists e.g. lack of interest to work (n = 15); lack of financial incentives for the pharmacists (n = 5); difficulty of specifying causes of ADRs due to "poly-pharmacy" and use of over-the counter (OTC) drugs (n = 5) and reluctance by hospital administrators who usually refuse any change to the routine (n = 4). With this respect, recommendations were made by study participants to increase awareness among HCPs and patients about ADRs, their reporting and PV by providing targeted continuing professional development training. It was also recommended to establish an ADR reporting center as soon as possible in every hospital with a well-defined official policy and reporting process from the MOH.

4. Discussion

To our knowledge, this is the first study in the State of Kuwait with regard to PV and ADRs reporting among pharmacists working in the general and specialized governmental hospitals. The aim of

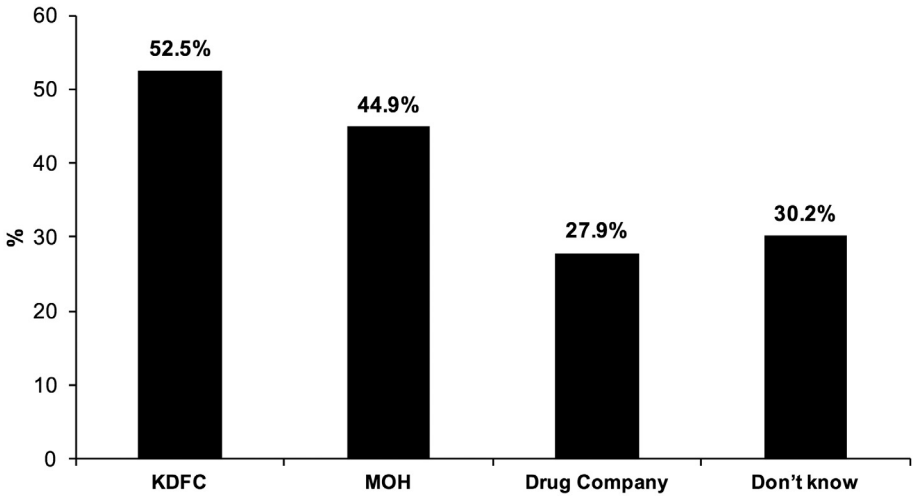

Figure 1. Participants' knowledge on where to report ADRs in Kuwait (n = 341)*. ADRs: Adverse Drug Reactions; KDFC: Kuwait Drug and Food Control; MOH: Ministry of Health Multiple responses were possible. *Data were missing from 1 participant.

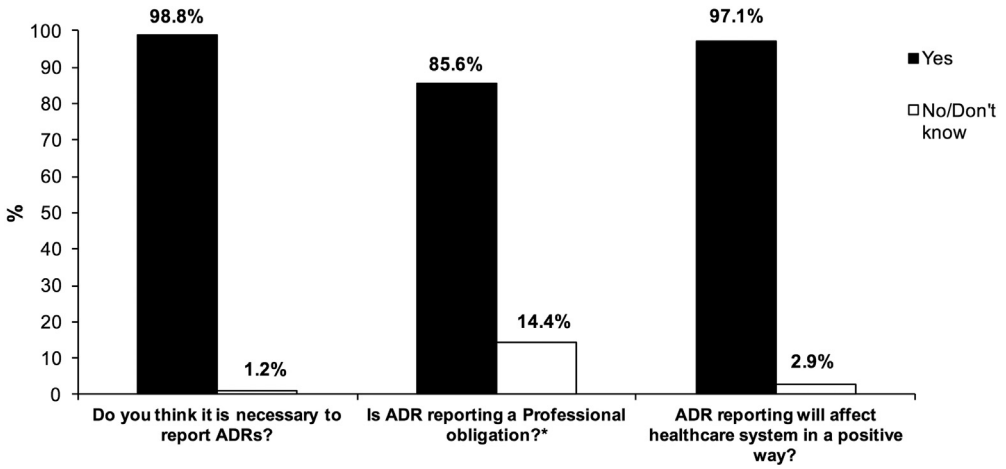

Figure 2. Pharmacists' attitudes about ADRs reporting (n = 342). ADRs: Adverse Drug Reactions. *Data were missing from 1 participant.

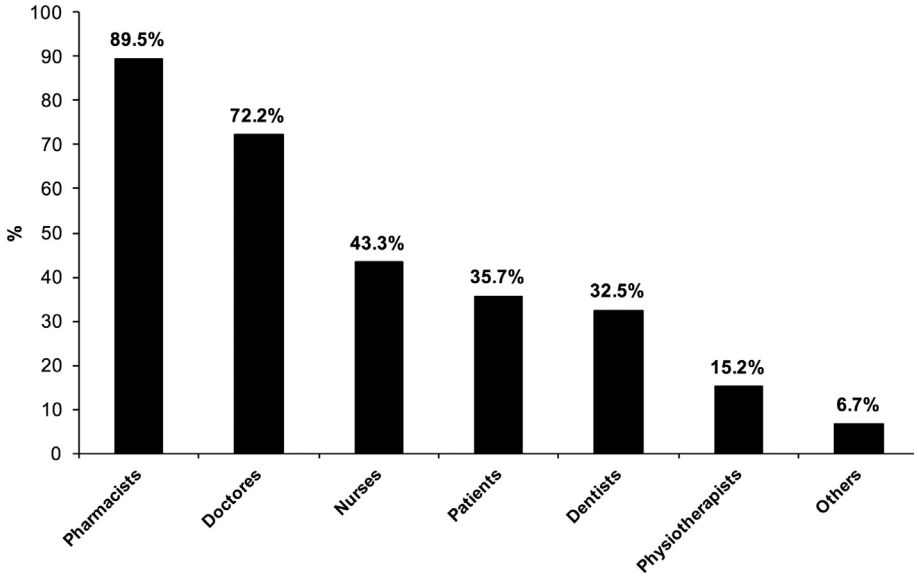

Figure 3. Participants' opinions about qualified persons to report ADRs in Kuwait (n = 342). ADRs: Adverse Drug Reactions Multiple responses were possible.

this study was to assess the pharmacists' knowledge, attitude and practices with regard to ADRs reporting, to determine the major barriers and to identify the factors that prohibit the implementation of a PV reporting center in Kuwait. Typical participant response rates for such studies vary quite extensively, from approximately 50 to 97%, as a function of the study population and how the questionnaire was administered (Green et al., 2001; Herdeiro et al., 2006; Toklu and Uysal, 2008; Vessal et al., 2009; Su et al., 2010; Abdel-Latif and Abdel-Wahab, 2014; Jose et al., 2014; Mahmoud et al., 2014; Suyagh et al., 2015). In the current study, the response rate was very good (82.6%) and was similar to those reported in other studies from the Gulf countries (Abdel-Latif and Abdel-Wahab, 2014; Jose et al., 2014; Mahmoud et al., 2014). Participants in the current study stated that the main reason for declining to participate was lack of time. As previously suggested (Toklu and Uysal, 2008), it is possible that participants felt uncomfortable in responding due to their lack of knowledge on the basic concepts of PV and ADRs and hence, declined participation. If that is the case, it is possible that only those who had adequate knowledge of PV and ADRs responded to the questionnaire and this could have influenced the study results.

Results from this study show that the majority of pharmacists had good knowledge regarding the concept of PV and ADRs in terms of their definitions and purposes. These results reflect those of other published studies from some Middle East countries on the knowledge and awareness of PV and ADRs (Abdel-Latif and Abdel-Wahab, 2014; Jose et al., 2014; Mahmoud et al., 2014; Suyagh et al., 2015). In contrast, most the pharmacists (93%) were not aware of any type of PV or ADR reporting system in Kuwait. This is a critical observation which is undoubtedly associated with the current ADR under-reporting. Lack of awareness of a national ADR reporting center or lack of knowledge of ADR reporting processes has also been reported in KSA and Jordan (Abdel-Latif and Abdel-Wahab, 2014; Mahmoud et al., 2014; Suyagh et al., 2015). This is not surprising given the fact that most national ADR reporting systems in the Middle East are in their infancy, with some countries having more developed systems (Wilbur, 2013a). For example, Oman has a national PV program which has been

Table 3
Attitudes and practices of PV and ADRs ($n = 342$).

Attitudes	Number	(%)
Which method would you prefer to send ADRs information to an ADR reporting center?		
Email/on Website	164	(49.4)
Direct contact	120	(36.1)
Telephone	31	(9.3)
Post	12	(3.6)
Other	5	(1.5)
Are you willing to implement ADRs reporting in your practice?		
No	39	(11.4)
Yes	302	(88.6)
Should PV be taught in detail to HCP?		
No	23	(6.7)
Yes	319	(93.3)
Practices	**Number**	**(%)**
Have you ever reported an ADR?		
No	249	(73.2)
Yes	91	(26.8)
Have you ever identified an ADR in any Patients?		
No	107	(31.6)
Yes	232	(68.4)
Number of identified ADRs in Patients		
<5	98	(42.6)
5–10	64	(27.8)
>10	68	(29.6)

PV: Pharmacovigilance; ADRs: Adverse Drug Reactions; HCP: Healthcare Professionals.
Numbers may not add to the total due to missing data.

established since 1995 and a recent study showed that nearly 90% of community pharmacists were aware of their national PV center. Other countries such as Jordan and KSA have well developed national PV centers; however, studies show that practicing pharmacists are not aware of them nor are they aware of the ADR reporting process. Similarly in Kuwait, efforts have been made by the KDFC to develop and implement a formal national PV center. In fact, KDFC developed an ADR reporting form based on WHO requirements and a web-based reporting system. Unfortunately, only few reports are sent because pharmacists are not aware of this Website and form. Taken together, this suggests that in addition to developing a national PV program and to ensure that the program meets its intended goals, it is critical that information be disseminated and adequate training provided to the end-users.

Pharmacists in the current study had very positive attitudes toward ADR reporting; nearly all of them thought it was necessary to report ADRs and that reporting them would have a positive impact on the healthcare system. Most also believed that it was a formal professional obligation to report ADRs. This observation is supported by similar studies with pharmacists from other countries, who concurred that reporting ADRs is a professional obligation (Su et al., 2010; Jose et al., 2014; Suyagh et al., 2015). Participants in the current study also reported that pharmacists and physicians are the most qualified individuals to undertake the role of ADR reporting, which is in line with results from other studies (Toklu and Uysal, 2008; Mahmoud et al., 2014; Suyagh et al., 2015).

Data from the current study showed that the majority of pharmacists (88.6%) are willing to implement ADR reporting in their practice and almost half of them (49.5%) would prefer using an email or a web-based reporting system. This is in contrast to another regional survey ($n = 207$) in which the pharmacists preferred reporting tools such as paper-based forms (33.3%), phone calls (23.2%), or informing verbally the drug company representative (25.6%) over using the Internet (4.3%) (Suyagh et al., 2015). However, despite the recognition of ADR reporting as an obligation, the rate of reporting is still suboptimal (Toklu and Uysal, 2008; Su et al., 2010; Abdel-Latif and Abdel-Wahab, 2014; Suyagh et al., 2015) and this could be linked to the availability and/or ease of use of the ADR reporting tools (Wilbur, 2013a).

About two thirds of pharmacists included in this study reported having identified ADRs during the course of their practice. Other studies showed that identification of ADRs by pharmacists varies significantly, from less than 20% (Abdel-Latif and Abdel-Wahab, 2014) to over 65% (Toklu and Uysal, 2008; Wilbur, 2013b). Despite the fact that the majority (68.4%) of pharmacists had identified ADRs during their practice years, these were not reported in most cases. Similarly, studies in different countries also revealed a low reporting rate: Qatar (29.3%), Istanbul (21%), Jordan (19.5%), KSA (12.5%) and Northern China (14.6%) (Toklu and Uysal, 2008; Su et al., 2010; Wilbur, 2013b; Mahmoud et al., 2014; Suyagh et al., 2015). In Kuwait, not knowing "how" to report ADRs was a major constraint in participating in PV activities and this was also documented as a major barrier for pharmacists in other Middle Eastern countries (Elkalmi et al., 2011; Jose et al., 2014; Suyagh et al., 2015). Accordingly, pharmacists emphasized the need for teaching HCP about PV, ADRs and how to undertake the reporting process. In addition to not knowing how to report, one third (30.2%) of pharmacists in the current study did not know "where" to report. However, of those who knew where to report, the majority thought ADR reports should be sent to KDFC or MOH. It is reasonable to assume that the participants believed that ADRs should be

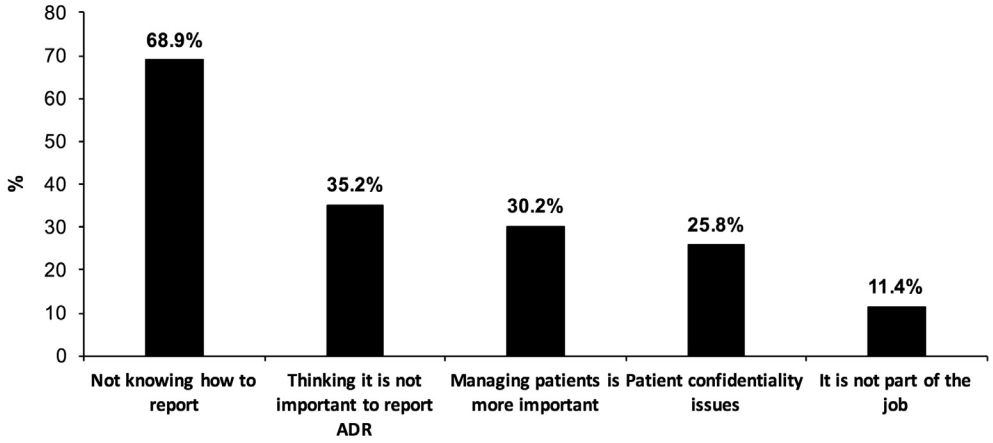

Figure 4. Discouraging factors to reporting ADRs ($n = 341$)*. ADRs: Adverse Drug Reactions Multiple responses were possible. *Data were missing from 1 participant.

reported to an official regulatory authority because in Kuwait, the KDFC is an integral part of the MOH, although it is operated by an independent administration, and perhaps this was a source of confusion for the participants. Surveyed pharmacists from other countries also thought that a governmental regulatory body should be where ADRs are reported and monitored (Mishra and Kumar, 2013; Jose et al., 2014; Mahmoud et al., 2014; Suyagh et al., 2015). Other constraints to reporting ADRs in this study were difficulty in accessing patient information and lack of time. Previously published studies reported similar constraints and in addition, they reported concerns with regard to accuracy and importance of the identified ADRs, which was also associated with underreporting (Elkalmi et al., 2011; Palaian et al., 2011; Wilbur, 2013b; Jose et al., 2014; Suyagh et al., 2015).

The current study aimed to explore the perceived barriers that exist in Kuwait to have a national reporting center. Some of these barriers included lack of cooperation and communication between HCP and patients, lack of professionalism (careless pharmacists) and lack of motivation for pharmacists, such as lack of financial incentives. A study in Jordan demonstrated the same issue with regard to the lack of financial incentives but the percentage of pharmacists who believed that it was a significant issue was very low (Suyagh et al., 2015). Another barrier for ADR reporting that was mentioned by pharmacists in Kuwait was having difficulties in specifying the cause of ADRs due to polypharmacy or the fact that patients are taking OTC. The hospital administrators also formed a barrier against changing the routine toward implementing ADR reporting. These observations suggest that raising awareness about ADRs and providing ongoing training could help both hospital administrators and pharmacists increase ADR reporting.

There are some limitations to our study. The questionnaire was administered to hospital-based pharmacists and as such, it remains to be determined whether the results can be extrapolated to pharmacists working in other settings, such as public polyclinics and community pharmacies. Similarly, it would be interesting to document knowledge, attitudes and practices toward ADR reporting with a broader population of healthcare professionals, namely physicians, in order to have a thorough understanding of the situation in Kuwait.

Our findings provide a basis to develop and implement strategies to improve ADR reporting. Results have shown that the pharmacists did not report ADRs as they were unaware of where and how to report them. This calls for the need of interventional educational programs that have been shown to effectively increase knowledge and awareness of ADR reporting in other countries (Khalili et al., 2011; Hanafi et al., 2014). Also, collaboration between academia and Health Authorities is pivotal to achieve these goals. Academic institutions, in alignment with the Health Authorities regulation, can offer targeted educational interventions, and associated ADR reporting processes, tailored to the pharmacist's workplace. To support this initiative, clear guidelines and processes from the Health Authorities are crucial to stimulate ADR reporting and improve PV practices in Kuwait. In addition, a clear mandate dictated by MoH that includes ADR reporting as an official professional obligation for pharmacists and other HCP may be useful in this regard.

5. Conclusions

Collectively, results from this study suggest that pharmacists working in governmental hospitals in Kuwait are willing to report ADRs if there is an appropriate support system in place. It remains to be seen whether such findings are also applicable to the numerous pharmacists working in public polyclinics (first line care) and private institutions. To ensure clarity regarding the professional obligations in this respect, it would be beneficial to have an official national policy regarding the responsibilities for ADR reporting from all HCP, namely pharmacists. In addition, because knowledge increases the understanding of the reporting process and requirements (Rajesh et al., 2011), we are proposing to provide formal, tailored and frequent training to pharmacists, other HCPs as well as administrators with the objectives of clearly defining 1) PV and ADRs, 2) the criteria and time frame for reporting an ADR and 3) where and how to report them. Taken together, and with the knowledge that hospital pharmacists have a positive attitude toward PV and ADR reporting, these measures may prove beneficial to increase ADR reporting in the State of Kuwait.

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