



Original article

Adverse drug reaction reporting among physicians working in private and government hospitals in Kuwait

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ABSTRACT

Introduction: To improve patient safety and care, the identification and reporting of adverse drug reactions (ADRs) should be systematic and mandatory for all healthcare professionals (HCPs). Physicians remain the main HCPs with direct patient care whose role in ADRs reporting should not be ignored.

Objective: To document the awareness and attitude of physicians working in private and government hospitals in Kuwait with regard to pharmacovigilance (PV) and ADR reporting and to identify their practices of reporting ADRs.

Material and methods: A cross-sectional study was conducted using a paper-based 25-item questionnaire. The Statistical Package for Social Science (SPSS) was used for data analysis.

Results: A total of 1017 questionnaires were distributed to the eligible physicians in the government and private hospitals, giving a response rate of 84.2% and 83.0%, respectively (an overall response rate of 83.8%). Private physicians exhibited a better knowledge profile with regards to the purpose of PV (75.2% vs 64.8%; $p = 0.002$) and the correct ADR definition (75.8% vs 65.3%; $p = 0.001$). The majority of physicians showed good attitude towards reporting ADRs, nevertheless, private physicians had a significantly stronger belief that reporting ADRs is a professional obligation (93.4% vs 85.5%; $p = 0.001$). Three quarters of the study population (74.6%) had identified an ADR during their daily practice, however, only a small proportion (34.2%) confirms having ever reported ADRs. Regardless, significantly more private physicians had done so (42.4% vs 29.6%; $p < 0.001$). ADR reporting was significantly higher in physicians who knew the correct ADRs to be reported (adjusted OR = 1.86, $p = 0.036$), and those who were aware of any center or ADR reporting system in Kuwait (adjusted OR = 2.88, $p = 0.020$).

Conclusions: A national PV center empowered by clear legislation on “how” and “what” to report should improve physicians’ reporting practices and hence is required in the country. This should be combined with constant training and education in this regard.

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1. Introduction

The State of Kuwait is an oil-producing high-income country with an approximate population of 4 million people (Bureau, 2016). Around 80% of healthcare services are provided to patients primarily through the government healthcare sector; at primary (polyclinics), secondary (delivered via six main general hospitals), and tertiary care levels (specialized hospitals) (Al-Jarallah et al., 2010). On the other hand, there is a growing body of services delivered through the private sector, represented by private hospitals and clinics scattered throughout the country. In both the government and private sectors, the healthcare delivery is governed by the Ministry of Health (MOH) which is responsible strategic planning, formulating health policies, supervising and monitoring all

health-related programs and activities within Kuwait (Al-Jarallah et al., 2010). The majority of the health workforce in Kuwait is non-Kuwaitis and is foreign-trained. However, the percentage of Kuwaiti physicians in 2005 has increased to 36.7% (out of a total of 4925 physicians in Kuwait), which is expected to grow further to reach 48.1% by the year of 2020 (Al-Jarallah et al., 2010). Of the 4925 physicians, 820 (16.6%) were working in the private sector and 74% of these 820 were non-Kuwaiti physicians.

In line with the MOH's vision to improve healthcare quality standards, Accreditation Canada International (ACI) was commissioned in 2008 to introduce a national accreditation program in Kuwait (IMTJ, 2009). The agreement allows for the provision of technical consultation to optimize the quality of healthcare services and to ensure that the national standards developed specifically for Kuwait are followed across the government hospitals and polyclinics. As part of the certification process, performance of hospitals should meet the national standards of excellence in all aspects of healthcare from patient safety and ethics to staff training and education.

Pharmacovigilance (PV) is one of the main tools used to improve patient safety and care through detecting any problems associated with the use of medicines, and assessing their benefits, effectiveness, harms and risks in order to prevent injuries and maximize patients' therapeutic outcomes (WHO, 2002a). For a PV program to be effective, the identification and reporting of adverse drug reactions (ADRs) should be systematic and mandatory. Healthcare professionals (HCPs) remain the main providers of case reports of suspected ADRs throughout the history of PV. Studies from different countries all over the world showed a strong association between ADR reporting and knowledge, attitude and practice (KAP) of the HCPs (Sweis and Wong, 2000; Herdeiro et al., 2005; Bawazir and Salama, 2006; Aziz et al., 2007; Gavaza et al., 2011). Among HCPs, physicians play a key role in ADR reporting by direct observation of the effect of a medicine or through information provided to them by patients who have been exposed to the actual ADRs of a medicine. In this context, most studies were conducted in hospital settings and have shown that ADRs under-reporting among physicians is directly associated with poor KAP (Aziz et al., 2007; John et al., 2012b; Agarwal et al., 2013; Paveliu et al., 2013; Abdel-Latif and Abdel-Wahab, 2014; Amrain and Becic, 2014; Kiran et al., 2014; Alshammari et al., 2015; Panja et al., 2015).

In a survey to inventory the status of PV among 13 countries in the Middle East, Kuwait was one among the five countries with no formal PV program in place (Wilbur, 2013). Despite the initial steps by the Kuwait Drug and Food Control (KDFC) to set up an online ADR reporting system to receive safety reports from any healthcare setting (KDFC, 2016), to date very few reports have been received. Therefore, the objective of this study is to document KAP among physicians working in the private and government hospitals in Kuwait with regard to PV and ADR reporting; compare KAP in both settings; and to investigate factors associated with ADRs reporting among this population. Information derived from these data will assist in devising strategies to improve therapeutic outcome and quality of patient care in both the private and government settings.

2. Methods

2.1. Study design

A cross-sectional study was conducted among physicians working in seven government hospitals and twelve private hospitals distributed across the six governorates of Kuwait. The government hospitals included the six general hospitals in Kuwait (Al-Amiri, Mubarak Al-Kabeer, Al-Farwaniyah, Al-Adan, Al-Jahra and Al-

Sabah General hospitals) and one specialized government hospital (National Bank of Kuwait Children's hospital). There are thirteen private hospitals across the country, among which one refused to take part in the study. The remaining twelve private hospitals included: Hadi, New Mowasat, Dar Al-Shifa, Al-Salam, Kuwait Oil Company (KOC), Taiba, London, Al-Orf, Royal Hayat, Alia, Al-Omoma, and Al-Seef hospitals.

2.2. Study tool

A self-administered 25-item questionnaire was designed using questions included in previous local and international studies that examined the KAP of HCP, including physicians (Herdeiro et al., 2005; Passier et al., 2009; Ramesh and Parthasarathi, 2009; Palaian et al., 2011; Rajesh et al., 2011; Chinenye and Michael, 2012; Adedeji et al., 2013; Agarwal et al., 2013; Santosh et al., 2013; Aithal et al., 2014; Bisht et al., 2014; Iffat et al., 2014; Kiran et al., 2014; Gupta et al., 2015; Khan 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 physicians' 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 toward developing a formal PV center or ADR reporting system in Kuwait and any further recommendations or suggestions from the participants' point of view. The last part of the questionnaire focused on the demographics. The questionnaire was distributed in English.

2.3. Validity 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). Three researchers reviewed the questionnaire and checked the questions' consistencies, clarity and relevance. To test whether the study tool questions were comprehensive and clear, a pilot study was conducted initially among ten physicians working in the medical and pediatric departments in one government general hospital (Al-Sabah General hospital) and ten physicians from different departments [internal medicine, obstetrics and gynecology, anesthesia, ear, throat and nose (ENT), pediatrics] working in four private hospitals (Al-Salam, Alia, London and Dar Al-Shifa hospitals). Minor modifications were recommended in order to clarify some of the questions without changing their essence.

2.4. Ethical approval

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

2.5. Sample size calculation and sampling strategy

All physicians working in the government and private hospitals in Kuwait were considered eligible to participate in the study.

Preliminary fieldwork carried out before actual data collection showed that there were approximately 1045 physicians working in the private hospitals in Kuwait. However, it was difficult to gather such information from the government hospitals due to the paucity of publicly available information and administrative issues. Using Raosoft sample size calculator, with a margin of error of 5% and a confidence interval of 95%, a minimum sample of 384

and 269 physicians was required from the government and private hospitals, respectively. Assuming a response rate of 80%, a larger sample size should be approached from both sectors.

Physicians working in departments with minimal medication handling, such as laboratory and surgery, and those working in departments with a busy and critical working nature, such as the emergency room, were excluded from the study.

2.6. Sample recruitment and data collection

Data was collected during periodic visits to the participating medical departments in the selected hospitals after obtaining permission from the hospitals' managers, and in some instances, from chief physicians in each department. Physicians from different departments were contacted directly and were personally invited to participate after explaining the aims of the study. For those who agreed to participate, a written informed consent form which clearly assured the participants regarding the confidentiality and anonymity of the gathered information was obtained.

Three out of the twelve participating private hospitals had strict rules that did not allow the researchers to communicate directly with the physicians. In these cases, the questionnaires were given to the hospital's human resources personnel who undertook the task of explaining the aim of the study and obtaining the written informed consent. Data collection took place over 3 months (from January to March 2016). Some of the physicians completed the questionnaire on the same day, while others were busy and their filled questionnaires were collected at a subsequent date.

2.7. Data analysis

The statistical analysis was undertaken using the Statistical Package for Social Science (SPSS) Software for Windows, version 23. Data from closed-ended questions were coded and entered into the SPSS. Descriptive statistics were used to analyze the data [frequency and percentages; mean \pm standard deviation (SD)]. Pearson Chi-Square test was used to assess the association between two categorical variables, while age in years was compared between the groups of private and government physicians using the independent sample *t*-test. To determine the factors associated with ADR reporting for physicians working in the private and government hospitals, univariate and multivariate logistic regression tests were used. The dependent variable was ADR reporting (0 = no; 1 = yes), while demographics, knowledge and attitude were included as the independent variables. Values were regarded significant at *p*-value less than 0.05 (two-tailed). Responses to the open-ended questions from all the questionnaires were documented and relevant issues were then grouped and presented based on the frequencies of reporting.

3. Results

3.1. Demographics

A total of 1017 questionnaires were distributed to the eligible physicians of which 550 (out of 653) were returned from the government hospitals and 302 (out of 364) were returned from the private hospitals, giving a response rate of 84.2% and 83.0%, respectively. The overall response rate was 83.8%. Of those who responded, 35.4% worked in private hospitals and 64.5% worked in government hospitals. Most of the study population was male (69.3%), non-Kuwaiti (75.0%), with a mean age of 41 years (Table 1).

Although the workforce in both sectors was mainly non-Kuwaiti physicians, the percentage of non-Kuwaiti physicians in

the private hospitals was significantly exceeding those who worked for government hospitals (88.4% vs 67.4%; $p < 0.001$). A significant difference was observed in the physicians' age in both settings, with the majority of private hospital physicians being above the age of 40 years compared to government hospital physicians who were younger than 40 years (mean age of 46.6 vs 37.8; $p < 0.001$). The private hospitals had significantly more senior physicians having the ranks of consultant, senior specialist, senior registrar, or specialist (63.6% vs 31.4%) and with more than 10 years of experience (90.4% vs 54.2%). Most of the study population (84.9%) obtained their basic medical degrees from abroad; mainly from Egypt ($n = 176$; 58.3% vs $n = 252$; 47.9%), followed by India ($n = 31$; 10.3% vs $n = 46$; 8.7%). The government hospitals, however, had significantly more graduates from Kuwait, (5.0% vs 20.9%; $p < 0.001$). Details of the demographics are shown in Table 1.

3.2. Knowledge about PV, ADRs and their reporting

In the study tool, five items were designed to assess the physicians' knowledge of PV, ADRs and their reporting (Table 2).

Approximately half of the study population (47.4%) recognized the WHO definition of PV, with no significant difference between the private and government physicians. A larger proportion knew the correct purpose of PV (68.5%) and correct ADR definition (69.0%). However, physicians working in the private hospital setting exhibited a better knowledge profile with regards to the purpose of PV (75.2% vs 64.8%; $p = 0.002$) and the correct ADR definition 75.8% vs 65.3%; $p = 0.001$).

Several items in the questionnaire were designed to assess the physicians' knowledge and awareness regarding ADR reporting. Regardless of the fact that most of the study population (76.8%) reported knowing which ADR should be reported, most of the participants (94.9%) were unaware of the existence of an ADR reporting system or a Center in Kuwait, with significantly more government physicians being unaware (92.1% vs 96.5%; $p = 0.004$) (Table 2). Physicians were asked to which institution they thought ADRs should be reported in Kuwait and were provided a list of options to choose from where they could select one or more options (Fig. 1). Significantly more physicians working in government hospitals did not know to whom ADRs should be reported (39.7% vs 56.0%; $p < 0.001$). However, a higher proportion of them answered that ADRs should be reported to KDFC (18.5% vs 27.8%; $p = 0.003$). There were no differences between the groups of physicians thinking ADRs should be reported to the MOH (30.5% vs 25.5%) or to drug companies (10.3% vs 12.7%).

3.3. Attitudes about ADR reporting

The majority of physicians in the current study unanimously agreed that reporting ADRs is necessary, a professional obligation and will have a positive impact on the quality of healthcare. Nevertheless, private physicians had a significantly stronger belief that reporting ADRs is a professional obligation compared to the government physicians (93.4% vs 85.5%; $p = 0.001$) (Fig. 2).

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 (Fig. 3). Physicians in both sectors shared the opinion that doctors should be the responsible HCPs to report ADRs (94% vs 88.9%), followed by pharmacists (69.2% vs 59.5%), nurses (65.6% vs 56.0%) and dentists (51.3% vs 40.5%) with physicians in the private sector exhibiting significantly higher perception about their role compared to physicians in the government sector, $p < 0.05$. A borderline significance was observed in favor of government physicians who believed in the importance of involving patients in ADR reporting ($p = 0.056$). Physiotherapists were

Table 1
Sociodemographic characteristics of the physicians working in private and government hospitals in Kuwait (n = 852).

	All		Private		Government		p-value
	n	(%)	n	(%)	n	(%)	
Gender							0.093^a
Male	584	(69.3)	220	(72.8)	364	(67.3)	
Female	259	(30.7)	82	(27.2)	177	(32.7)	
Nationality							<0.001^a
Kuwaiti	209	(25.0)	35	(11.6)	174	(32.6)	
Non-Kuwaiti	626	(75.0)	267	(88.4) ^c	359	(67.4) ^d	
Age in years							<0.001^a
20–29	98	(11.8)	2	(0.7)	96	(18.2)	
30–39	320	(38.6)	75	(24.8)	245	(46.5)	
40–49	230	(27.7)	116	(38.4)	114	(21.6)	
≥50	181	(21.8)	109	(36.1)	72	(13.7)	
Mean (SD)	41.0	(10.4)	46.6	(9.6)	37.8	(9.4)	<0.001^b
Rank							<0.001^a
Consultant/Senior specialist	183	(22.1)	107	(35.8)	76	(14.4)	
Senior Registrar/Specialist	173	(20.9)	83	(27.8)	90	(17.0)	
Registrar/General practitioner	368	(44.5)	108	(36.1)	260	(49.2)	
Assistant registrar/Resident/Trainee	103	(12.5)	1	(0.3)	102	(19.3)	
Years of experience							<0.001^a
<1	21	(2.5)	0	(0.0)	21	(4.0)	
1–5	106	(12.8)	3	(1.0)	103	(19.5)	
6–10	144	(17.3)	26	(8.6)	118	(22.3)	
11–15	195	(23.5)	62	(20.5)	133	(25.1)	
16–20	152	(18.3)	82	(27.2)	70	(13.2)	
>20	213	(25.6)	129	(42.7)	84	(15.9)	
Country of graduation							<0.001^a
Kuwait	125	(15.1)	15	(5.0)	110	(20.9)	
Outside Kuwait	703	(84.9)	287	(95.0) ^e	416	(79.1) ^f	

Numbers may not add to the total due to missing data.

^a p-values were generated using Pearson Chi-square test.

^b p-values were generated using Independent t-test.

^c Egyptian (n = 178), Indian (n = 32), British (n = 10), Lebanese (n = 9), Syrian (n = 7), Bulgarian (n = 5), Pakistani (n = 4), French (n = 3), Iraqi (n = 3), Canadian (n = 3), Jordanian (n = 3), other (n = 10).

^d Egyptian (n = 246), Indian (n = 50), Syrian (n = 20), Pakistani (n = 7), Jordanian (n = 6), American (n = 4), Palestinian (n = 3), other (n = 23).

^e Egypt (n = 176), India (n = 31), UK (n = 21), France (n = 6), Canada (n = 6), Ireland (n = 6), Syria (n = 5), Pakistan (n = 4), Bulgaria (n = 4), Jordan (n = 4), Lebanon (n = 3), Russia (n = 3), Iraq (n = 3), other (n = 15).

^f Egypt (n = 252), India (n = 46), Ireland (n = 20), Syria (n = 18), UK (n = 16), Bahrain (n = 14), USA (n = 7), Pakistan (n = 6), Russia (n = 4), Jordan (n = 4), Malta (n = 3), other (n = 26).

Table 2
Knowledge of PV and ADRs among private and government physicians (n = 852).

	All	Private	Government	p-value
	852 n (%)	302 (35.4%) N (%)	550 (64.5%) N (%)	
Know correct definition of PV ^a	404 (47.4)	147 (48.7)	257 (46.7)	0.586
Know correct purpose of PV	583 (68.5)	227 (75.2)	356 (64.8)	0.002
Know correct definition of ADRs ^b	588 (69.0)	229 (75.8)	359 (65.3)	0.001
Know ADRs that should be reported	654 (76.8)	231 (76.5)	423 (76.9)	0.890
Any center or ADR reporting system in Kuwait?				0.004
Yes	43 (5.1)	24 (7.9)	19 (3.5)	
No/Don't know	807 (94.9)	278 (92.1)	529 (96.5)	

PV: Pharmacovigilance; ADRs: adverse drug reactions. Numbers may not add to the total due to missing data. p-values were generated using Pearson Chi-square test.

^a PV is the science and activities of detecting, assessing, understanding and preventing adverse effects (WHO, 2002a).

^b ADRs are any noxious or undesired effect of a drug occurring at normal doses and during normal use (WHO, 2002b).

similarly selected as the least responsible healthcare personnel to report ADRs.

When asked about which reporting method would be most appropriate for them, physicians in both sectors preferred email or website system (61.3%), followed by direct contact with a person (25.8%), but there were significant differences ($p < 0.001$) among the two groups in their choices: email/website (73.2% vs 54.7%), direct contact (18.9% vs 29.6%), telephone (4.0% vs 6.2%), and post (1.7% vs 5.1%) (Table 3). Physicians in both settings showed willingness to implement an ADR reporting system in their practice.

However, significantly more private hospital physicians recommended that PV should be taught extensively to all HCPs (90.1% vs 84.9%; $p = 0.034$).

3.4. Practices and barriers about ADR reporting

When assessing the actual practice to report suspected ADRs, three quarters of the study population (74.6%) had identified an ADR during their daily practice, however, only a small proportion (34.2%) confirms having ever reported ADRs (Table 3). Regardless,

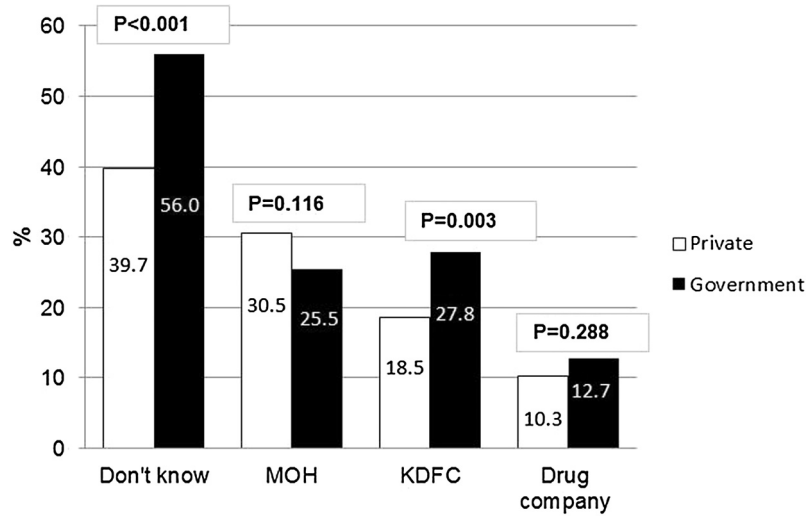


Fig. 1. Physicians' awareness on the responsible organization in Kuwait to receiving ADR reports (n = 852). ADRs: adverse drug reactions; MOH: Ministry of Health; KDFC: Kuwait Food and Drug Control Administration. *Multiple responses were possible.

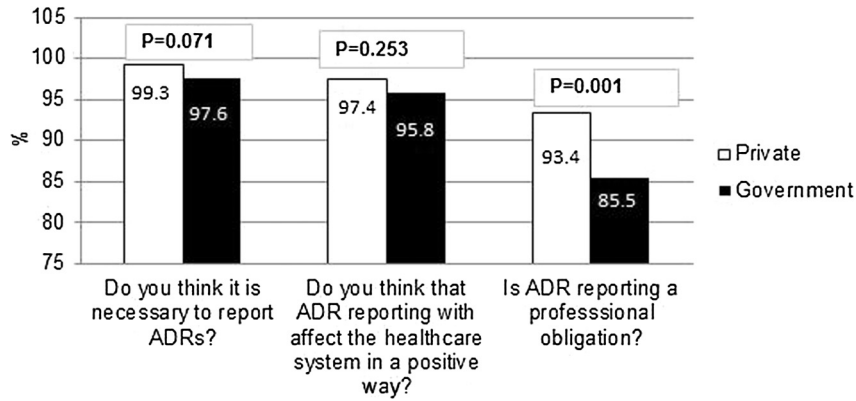


Fig. 2. Physicians' attitude toward reporting ADRs (n = 852). ADRs: adverse drug reactions.

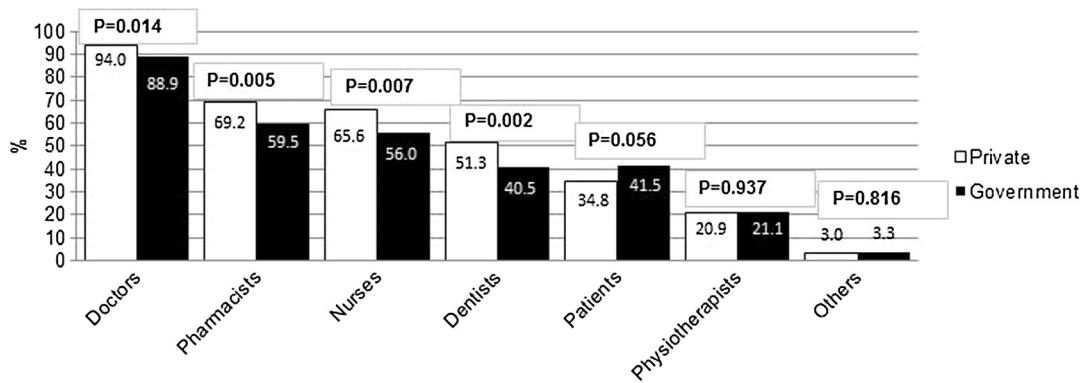


Fig. 3. Physicians' opinions on the qualified HCPs to reporting ADRs (n = 852). HCP: healthcare professionals; ADRs: adverse drug reactions. *Multiple responses were possible.

significantly more private physicians had done so compared to government physicians (42.4% vs 29.6%; $p < 0.001$).

Physicians were asked how many ADRs they recall having reported: 41.0% of the physicians documented less than 5 ADRs and 34.7% reported more than 10 ADRs. With this regard, significantly more government physicians recalled identifying greater

than 10 ADRs during their practice compared to physicians working in the private hospital setting (28.8% vs 38.2%).

Table 4 displays the results of univariate logistic regression analyses with ADR reporting (0 = No, 1 = Yes) as an outcome variable among the private and government physicians separately. Among those working in private hospitals, 'knowing the correct

Table 3
Attitudes and practices of reporting ADRs among physicians working in private and government hospitals in Kuwait (n = 852).

	All		Private		Government		p-value
	n	(%)	n	(%)	n	(%)	
Attitude							
Which method would you prefer to send ADR information to an ADR reporting center?							<0.001
Email/on Website	522	(61.3)	221	(73.2)	301	(54.7)	
Direct contact	220	(25.8)	57	(18.9)	163	(29.6)	
Telephone	46	(5.4)	12	(4.0)	34	(6.2)	
Post	33	(3.9)	5	(1.7)	28	(5.1)	
Other (e.g. mobile application)	31	(3.6)	7	(2.3)	24	(4.4)	
Are you willing to implement ADR reporting in your practice?							0.342
No/don't know	45	(5.3)	13	(4.3)	32	(5.8)	
Yes	806	(94.7)	289	(95.7)	517	(94.2)	
Should PV be taught in detail to HCPs?							0.034
No/don't know	113	(13.3)	30	(9.9)	83	(15.1)	
Yes	739	(86.7)	272	(90.1)	467	(84.9)	
Practices							
Have you ever identified an ADR in any Patients?							0.213
No	216	(25.4)	69	(22.8)	147	(26.7)	
Yes	636	(74.6)	233	(77.2)	403	(73.3)	
Number of identified ADRs in Patients							0.034
<5	261	(41.0)	109	(46.8)	152	(37.7)	
5–10	154	(24.2)	57	(24.5)	97	(24.1)	
>10	221	(34.7)	67	(28.8)	154	(38.2)	
Have you ever reported an ADR?							<0.001
No	561	(65.8)	174	(57.6)	387	(70.4)	
Yes	291	(34.2)	128	(42.4)	163	(29.6)	

PV: Pharmacovigilance; ADRs: adverse drug reactions; HCP: healthcare professionals. Numbers may not add to the total due to missing data. p-values were generated using Pearson Chi-square test.

ADRs to be reported' and 'the awareness of any center or ADR reporting system in Kuwait' were the only two significant factors associated with ADR reporting. On the other hand, the significant factors associated with ADR reporting among government doctors were: demographics (nationality, age, years of experience, country of graduation, employment rank); knowledge of the correct purpose of PV and the ADRs to be reported; the awareness of any center or ADR reporting system in Kuwait; and the willingness to implement ADR reporting in the practice.

Results of the multivariate stepwise logistic regression analyses with ADR reporting among private and government physicians are summarized in Table 5. Results showed that 'knowing the correct ADRs to be reported' and 'the awareness of any center or ADR reporting system in Kuwait' were the only two factors independently associated with ADR reporting among physicians working in private and government hospitals. ADR reporting was significantly higher in physicians who knew the correct ADRs to be reported (adjusted OR = 1.86, $p = 0.036$ vs adjusted OR = 2.55, $p = 0.002$), and those who were aware of any center or ADR reporting system in Kuwait (adjusted OR = 2.88, $p = 0.02$ vs adjusted OR = 4.72, $p = 0.003$). On the other hand, nationality and age were significantly associated with better ADR reporting among government physicians only; non-Kuwaiti and/or older physicians (≥ 40 years) reported ADRs more than Kuwaiti and/or younger physicians.

Factors having a negative impact on ADR reporting were investigated by providing a list from which physicians could select one or several options (Fig. 4). Physicians in both sectors shared the opinion that the most important barrier hindering reporting was lacking knowledge of how to report (75.8% vs 76.9%), followed by the perception that reporting ADRs is not important (16.6% vs 20.2%) and managing patients is more important (14.9% vs 18.4%) (Fig. 4). Although the difference was not statistically significant, patient confidentiality was regarded as a discouraging factor by

private physicians more than government physicians (11.6% vs 9.3%), and outside the job responsibility scope was highlighted by government physicians (8.6% vs 12.9%) more than did the private physicians.

With the use of an open-ended question, physicians were asked about their perceived barriers to establishing a formal PV center in Kuwait. With regards to the private physicians, 169 stated 'they don't know' and 17 thought that there are no barriers. Others reported lack of education/training on how to report ADRs ($n = 54$), lack of physicians' interest or commitment ($n = 33$). Communication difficulty (between private and government sectors, hospital pharmacy and administration, or between patients and physicians) was one of the issues raised by some of the physicians working in the private hospital setting ($n = 25$). Other issues highlighted were lack of a formal reporting system in Kuwait ($n = 19$), lack of law by MOH ($n = 13$), poor patient awareness ($n = 9$) and lack of staff ($n = 7$). Three hundred seventeen government physicians (57.6%) reported similar issues, however with greater emphasis on issues, such as communication challenges ($n = 118$) which was the most frequently reported barrier, followed by lack of physician knowledge/training on how to report ($n = 93$), lack of a formal reporting system ($n = 50$), lack of physician's interest or commitment ($n = 22$) and finally lack of time ($n = 20$).

Recommendations were made by the study participants to increase awareness among HCPs about ADRs, their reporting and PV by providing targeted continuing professional development training. Encouraging communication among HCPs and with the administrative department in each hospital and with different healthcare settings was highly recommended. Considering this, an emphasis was made by private hospital physicians to strengthen the communication between their institute and the MOH. It was also recommended to establish a distinct ADR reporting center in every hospital with well-defined official guidelines and reporting process from the MOH.

Table 4
Factors associated with ADR reporting (0 = No, 1 = Yes) among private and government physicians in Kuwait using univariate binary logistic regression analyses.

Factors	Private		Government	
	COR (95% CI)	p-value	COR (95% CI)	p-value
Gender				
Male	1.00		1.00	
Female	0.83 (0.49–1.39)	0.471	0.69 (0.46–1.03)	0.072
Nationality				
Kuwaiti	1.00		1.00	
Non-Kuwaiti	1.28 (0.62–2.65)	0.505	2.37 (1.53–3.66)	<0.001
Age (years)				
20–29	1.00		1.00	
30–39	0.63 (0.04–10.48)	0.748	2.64 (1.35–5.13)	0.004
40–49	0.79 (0.05–12.85)	0.865	3.78 (1.85–7.75)	<0.001
≥50	0.76 (0.05–12.44)	0.846	8.27 (3.86–17.73)	<0.001
Years of experience				
≤10	1.00		1.00	
11–20	1.54 (0.66–3.62)	0.320	2.29 (1.49–3.53)	<0.001
>20	1.93 (0.82–4.56)	0.133	4.06 (2.38–6.94)	<0.001
Country of graduation				
Kuwait	1.00		1.00	
Outside Kuwait	0.63 (0.22–1.78)	0.382	2.06 (1.23–3.46)	0.006
Rank				
Consultant/Senior Specialist	1.40 (0.81–2.42)	0.223	4.59 (2.28–9.23)	<0.001
Senior Registrar/Specialist	1.53 (0.86–2.73)	0.152	3.26 (1.65–6.46)	0.001
Registrar/General practitioner	1.00		2.06 (1.13–3.75)	0.018
Assistant registrar/Resident/ Trainee			1.00	
Know correct definition of PV				
No	1.00		1.00	
Yes	1.29 (0.82–2.04)	0.274	1.14 (0.79–1.65)	0.473
Know correct purpose of PV				
No	1.00		1.00	
Yes	1.32 (0.77–2.26)	0.308	1.93 (1.29–2.91)	0.002
Know correct definition of ADR				
No	1.00		1.00	
Yes	1.00 (0.58–1.70)	0.987	1.30 (0.88–1.92)	0.196
Know correct ADRs to be reported				
No	1.00		1.00	
Yes	1.89 (1.07–3.33)	0.028	2.10 (1.29–3.42)	0.003
Aware of any center or ADR reporting system in Kuwait				
No	1.00		1.00	
Yes	2.96 (1.23–7.16)	0.016	7.14 (2.53–20.17)	<0.001
Willing to implement ADR reporting in the practice				
No	1.00		1.00	
Yes	1.69 (0.51–5.62)	0.391	4.33 (1.30–14.43)	0.017
ADR reporting is a professional obligation				
No	1.00		1.00	
Yes	1.00 (0.58–1.70)	0.987	1.54 (0.88–2.69)	0.133
ADR reporting will affect healthcare system in a positive way				
No	1.00		1.00	
Yes	2.25 (0.45–11.33)	0.326	2.91 (0.85–9.92)	0.088

PV: Pharmacovigilance; ADRs: adverse drug reactions; COR: Crude Odds Ratio; 95% CI = 95% Confidence interval for crude odds ratio. p-values were generated using Pearson Chi-square test.

4. Discussion

Considering the fact that Kuwait is still behind other countries in the region lacking a formal ADR reporting system or PV activities (Wilbur, 2013), and that ADR under-reporting among physicians is directly related to poor KAP (Aziz et al., 2007; John et al., 2012b; Agarwal et al., 2013; Paveliu et al., 2013; Abdel-Latif and Abdel-Wahab, 2014; Amrain and Becic, 2014; Kiran et al., 2014; Alshammari et al., 2015; Panja et al., 2015), exploring physicians' KAP in this study was crucial. To date, only one study was conducted in Kuwait that explored KAP among pharmacists working in secondary and tertiary government hospitals (Alsaleh et al., 2017). Therefore, carrying out this study is timely, especially that physicians are the primary component of the healthcare system with a direct patient contact.

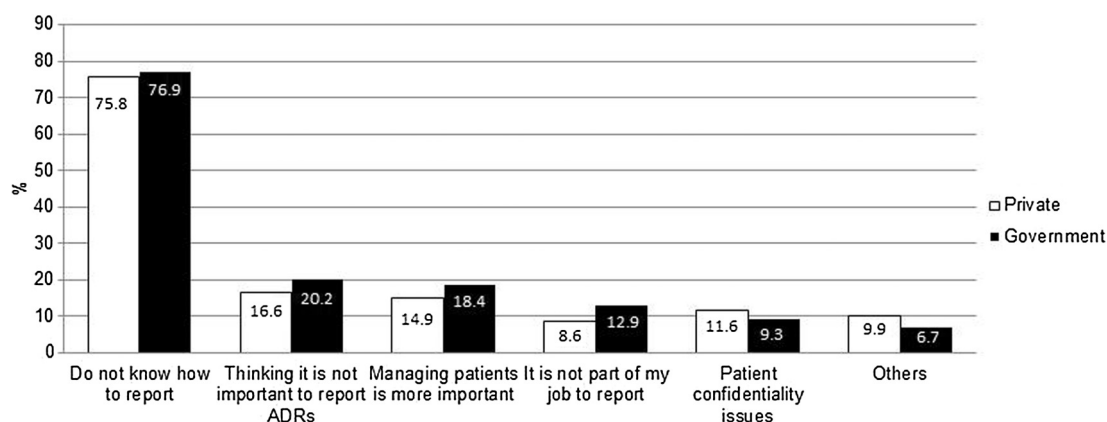
The response rate of the government and private physicians was very good (84.2% and 83.0% respectively; an overall response rate of 83.8%) and was approximately similar to the study conducted among pharmacists working in secondary and tertiary government hospitals in Kuwait (82.6%) (Alsaleh et al., 2017) and comparable to those reported in other studies among physicians working in the Gulf region (John et al., 2012a; Bakhsh et al., 2016). Results showed that the physicians in both sectors had generally good knowledge about the WHO definition of ADRs and purpose of PV (WHO, 2002a; 2002b), although less than half (47.4%) identified the correct definition of PV (WHO, 2002a). This contrasts to the pharmacists' knowledge in a recent study done in Kuwait (Alsaleh et al., 2017) where most participants identified the correct definitions of PV and ADRs and as well as the purpose of undertaking PV activities; 61.5%, 72.6% and 74.8%, respectively. Other

Table 5

Significant factors independently associated with ADR reporting among private and government physicians in Kuwait using stepwise multiple logistic regression analyses.

Factors	Private AOR (95% CI)	p-value	Government AOR (95% CI)	p-value
Nationality				
Kuwaiti			1.00	
Non-Kuwaiti			1.99 (1.17–3.40)	0.011
Age (years)				
20–29			1.00	
30–39			1.68 (0.80–3.51)	0.171
40–49			2.26 (1.01–5.04)	0.046
≥50			4.77 (2.06–11.05)	<0.001
Know correct ADRs to be reported				
No	1.00		1.00	
Yes	1.86 (1.04–3.33)	0.036	2.55 (1.40–4.64)	0.002
Aware of any center or ADR reporting system in Kuwait				
No	1.00		1.00	
Yes	2.88 (1.19–7.00)	0.020	4.72 (1.60–13.92)	0.003

ADRs: adverse drug reactions; COR: Crude Odds Ratio; 95% CI = 95% Confidence interval for crude odds ratio. p-values were generated using Pearson Chi-square test.

**Fig. 4.** Barriers towards reporting ADRs as reported by private and government physicians (n = 852). ADRs: adverse drug reactions. *Multiple responses were possible.

studies in the Middle East support this trend (John et al., 2012b; Jose et al., 2014; Alshammari et al., 2015). Private physicians in the current study showed superior knowledge over government physicians regarding the definition of ADR and the purpose of undertaking PV activities. This could be associated with the fact that our sample of physicians working in the private hospital setting had significantly more years of experience compared to those working in the government sector. Moreover, although the ACI was commissioned in Kuwait in 2008, many government hospitals and polyclinics are still in the process of obtaining the accreditation, which involves developing a formal process for incident reporting for any medical problems, including ADRs. Nonetheless, the private hospitals in Kuwait have not been required by the MOH to obtain an official accreditation, but the sense of competition toward attracting patients to use their services through delivering high standards of services stimulated many to seek the accreditation.

The current study found that most of physicians were unaware of the existence of an ADR reporting system and did not know to whom to report ADRs in Kuwait. These findings could be the reason for poor reporting practices observed in this study. In this respect, government hospital physicians showed a significantly higher level of unawareness compared to the private hospital physicians, although more of them thought that KDFC could be the main body for receiving ADR reports. Similarly, most pharmacists (Alsaleh et al., 2017) recognized the KDFC as the responsible body in Kuwait to receiving ADR reports. This can be explained by the lack of communication between the private sector and the MOH and other

government bodies, which is further supported by comments from some private physicians in this study. Therefore, KDFC should build a stronger rapport with the different healthcare settings, including private hospitals, and familiarize them with their online ADR reporting system. In comparison with other studies in the region, only 8.9% of the physicians in Jeddah were aware of an ADR reporting center and 16.6% were aware of the National PV center of Saudi Food and Drug Administration (SFDA) (Bakhsh et al., 2016). The percentage of awareness was higher (45.2%) in the study among clinicians in a teaching hospital in the United Arab Emirates (UAE), however the sample size was small (n = 42) for comparison and it was only conducted in one teaching hospital where the level of knowledge is expected to be better (John et al., 2012a).

Nearly all physicians in the present study exhibited excellent attitude toward reporting ADRs. Such findings are in line with those in other studies (Gupta and Udupa, 2011; Iffat et al., 2014; Alsaleh et al., 2017; Bakhsh et al., 2016). However, when it comes to the thought about considering ADR reporting a professional obligation, significantly more government hospital physicians had the notion that this task is outside the scope of their job responsibilities. This might reflect a lack of well-defined job responsibilities among physicians in the government hospitals and call for the relevant stakeholders to fulfil this gap.

Regarding reporting ADRs, physicians in the private and governmental sectors in this study attributed the responsibility for reporting ADRs to physicians followed by pharmacists. In a previously published study, when pharmacists from government

hospitals in Kuwait were asked the same question, they stated that pharmacists were responsible for reporting ADRs followed by physicians. (Alsaleh et al., 2017). Such discrepancy between the physicians' opinions in this study to that of the pharmacists (Alsaleh et al., 2017) highlights the fact that HCPs in Kuwait lack the perception that ADR reporting and the subsequent patient safety optimization is a shared responsibility among all medical professionals who should equally take role in reporting ADRs. In comparison to the data from Kuwait, physicians in a study in Saudi Arabia attributed the reporting responsibilities almost equally to doctors and pharmacists which reflected their willingness and preparedness to share this task (Bakhsh et al., 2016). Perhaps the difference between Kuwait and Saudi Arabia is associated with the fact that Saudi Arabia has developed PV and ADR reporting systems that are supported by the SFDA, which may have increased awareness of ADR reporting among HCPs in this country.

Regardless the good attitude toward reporting ADRs, a considerable number of physicians in the present study never reported ADRs, which is in line with physicians in other studies (Iffat et al., 2014). The most commonly reported reason cited by most physicians in both sectors was not knowing how to report, again in line with previous reports (Iffat et al., 2014; Alsaleh et al., 2017). However, physicians in the private sector reported ADR incidents significantly more frequently than the government hospital physicians (42.4% vs 29.6%). These results are consistent with the assessment of physicians' attitudes where a higher proportion of private hospital physicians thought that reporting ADRs is part of their job. Such results can be accredited to the fact that physicians in the private sector were seniors with more years of experience, hence could have more confidence in reporting any suspected ADRs. Previous studies revealed that under-reporting of ADRs is a worldwide phenomenon and a problem in medical practice (Williams and Feely, 1999; Hazell and Shakir, 2006; Lopez-Gonzalez et al., 2009; Nichols et al., 2009). In line with this, the multivariate stepwise logistic regression analysis in our study showed that ADR reporting practice among physicians was significantly associated with their knowledge on "what" ADRs should be reported and "where" to report them. Therefore, targeting these modifiable variables with education and training could help improving the ADR reporting practices. Accordingly, obligatory education and training courses on the science of PV and ADR reporting should be designed for physicians and other HCPs during and after graduation (Lopez-Gonzalez et al., 2015).

The current study also aimed to explore the perceived barriers that exist in both sectors against establishing an ADR reporting system. Some of these barriers included lack of training and education, lack of communication between private and government sectors, lack of governing legislation and reporting system by the MOH. These observations suggest that raising awareness about ADRs and providing ongoing training, as part of continuing medical education (CME) or continuing professional development (CPD), could help both hospital administrators and physicians increase ADR reporting, as documented in other studies (Herdeiro et al., 2012; Bisht et al., 2014; Lopez-Gonzalez et al., 2015). In fact, the KDFC is striving to stimulate and encourage ADR reporting and is ready and willing to provide targeted training to HCPs in Kuwait to support them in this endeavor. However, MOH should have more governing role in supporting and establishing a national system across the country in line with other countries in the region and worldwide.

5. Study strengths and limitations

This study is the first to be conducted among physicians in Kuwait and it includes all government general hospitals, as well

as all private hospitals, except one which refused to take part in the study. Taking the very good overall response rate into account (83.8%), results can be considered to represent the target population of physicians across private and government general hospitals.

There are some limitations to our study. Although the questions used in the study questionnaire were derived from previously validated tools, the current questionnaire was not retested for reliability in this specific population. Moreover, some of the questions were dependent on the respondents' ability to recall information, such as any identified ADRs during their practice years, which may have led to response bias (Smith, 2006). Many challenges were faced during the data collection procedure in both sectors. In the private hospitals, the researchers were not allowed to distribute the questionnaires to the physicians by hand, rather human resources personnel in the hospital undertook this role, so no clarification for any of the questions by the researcher, if any needed, were possible and that could have affected the participant response to the questions.

6. Implications for clinical practice and future recommendations

Results from the current study call for the need of a national PV center to be established in the country. The MOH should monitor and govern the PV center by setting clear legislation and policies on how and what to report which in turn should improve physicians' reporting practices in the country. Furthermore, the HCPs should be supported and provided with constant updating of knowledge and awareness in this area for effective ADR reporting and monitoring, as suggested by other researchers. Regardless, having a reporting system and proper training does not necessary warranty receiving adequate ADRs reports unless a blame-free environment is created in hospitals where HCPs are able to report errors without fear of reprimand or punishment. Therefore, the concept of "safety culture" should also be taught and emphasized to all HCPs starting from the undergraduate level and later on in their clinical practice.

7. Conclusion

The findings generally indicate that physicians in private and general government hospitals have good level of knowledge regarding ADRs and PV, and demonstrate excellent attitude and strong willingness to improve their practice. Regardless, the majority of them do not know to whom ADRs should be reported and that reflected negatively on their reporting practices.

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Conflict of interest

The authors have no conflicts of interest that are related to the content of this study.

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