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Physicians Sociodemographics and Knowledge, Awareness, Attitude and Practice towards Reporting Adverse Drug Reactions: An Association Study in Jeddah City, Saudi Arabia

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Authors' contributions

This work was carried out in collaboration between all authors. Authors TMAB, SAB, RMAR and MSAG designed the study and wrote the protocol. Author NAQ wrote the first draft of the manuscript and revised it a number of times. All authors managed the literature searches, and data analyses of the study. All authors read and approved the final manuscript.

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ABSTRACT

Background: Adverse drug reactions (ADRs) are considered as one of the most important contributors to significant morbidity and mortality around the world. Currently, ADRs remain a major challenge for healthcare providers, patients, drug industry, and regulators.

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Objective: To determine associations of hospital physicians (HPs) demographics and ADRs variables with their knowledge, awareness, attitude and practice (KAAP), and encountering and reporting ADRs in three general hospitals of Jeddah, Saudi Arabia.
Methods: A7-item self-administered ADR questionnaire was developed and applied in this cross-sectional study. The questionnaire covered seven domains: sociodemographic, the awareness of ADRs program, knowledge about ADR reporting, physicians' attitude towards ADR, practice of ADR reporting, motivators of and barriers against ADRs reporting, and self-perception and intention to report ADRs. From October 2012 to September 2013, randomly selected hospital physicians (HPs) participated in the analytical study.
Results: A total of 337 HPs participated in the study, and the response rate was 87.5%. This study revealed a number of significant associations of physicians' demographic and ADR practice characteristics and self perceptions with KAAP of ADRs and detected and reported ADRs. Physicians were aware of ADRs but their knowledge and attitude was not significantly associated with ever having detected or reported ADRs.
Conclusion: Certain demographics and ADR practice were significantly associated with ADR KAAP scores. The HPs in general hospitals demonstrated low level of knowledge and attitude regarding ADRs reporting, compared to awareness. For improving patient safety and quality of health care advanced education and training in attitude and practice of ADRs reporting, targeting hospital physicians is needed urgently. Further research need to be conducted on several aspects of ADRs in all hospitals of Saudi Arabia.

Keywords: Knowledge; awareness; attitude; practice; adverse drug reactions; general hospital physicians; patient safety; Saudi Arabia.

1. INTRODUCTION

The World Health Organization (WHO) defined ADR as "any noxious, unintended and undesired effect of drugs which occurs at normal doses used in human for prophylaxis, diagnosis, or therapy of diseases, or for the modification or exploration of physiological function or pathological statues of recipient" [1]. Karch and Lasagna [2] defined ADR as any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose. From the perspective of reporting purpose, Food and Drug Administration (FDA) categorized a serious adverse event relating to drugs or devices as one in which the patient outcome is death, life-threatening morbidity, immediate or prolonged hospitalization, significant, persistent, or permanent disability, congenital anomaly in offspring, or one that requires intervention to prevent permanent impairment or damage [3]. Adverse drug reactions and their associated harms are caused directly by the drug at therapeutic doses, and during therapeutic use in any individual. In addition, individual genetic susceptibility and environmental factors such as concomitant diseases could also play a role in their occurrence and prediction [4-6]. Adverse drug reactions differ from side effects of a drug, which are expected and known effects of a drug that are not the component of intended therapeutic outcome [7]. More precisely, side effects are "unintended effects of a pharmaceutical products which occur when the drug is used by a patient in therapeutic doses and which are related to the pharmacological properties of the drug" [8]. Notably, adverse drug event (ADE) is the harm caused by the drug's unexpected reactions, overdosage, and from medication errors [9,10].

ADRs are classified according to severity or type or duration of reactions [11]. Consequently, ADRs have many types; 1) dose-related ADRs that are commonly augmented and predictable effects, related to pharmacological action of the drug and associated with low mortality, 2) non-dose-related ADRs that are, bizarre, unpredictable effects, unrelated to the pharmacological action of the drug and carry high mortality, 3) dose-related and time-related ADR that are chronic, uncommon effects which are due to the cumulative dose, 4) time-related ADRs that are delayed, dose related effects that become apparent after the use of the drug for some time, 5) withdrawal ADRs that are uncommon effects and occur soon after discontinuing the drug, and 6) ADRs due to unexpected failure of therapy are commonly dose–related and often caused by drug interactions [11]. According to Edwards and Aronson [11], suspected drug casualty can be

classified as certain, probable or possible. Rieder and Ferro suggested that serious but rare ADRs need separate causality assessment tools [12]. Notably, suspected drugs causing ADRs should also include complementary and alternative therapies frequently used for patients worldwide [13,14]. According to some researchers, ADRs are classified into type A and Type B [15], and most of their features overlap with aforesaid 5 types of ADRs [11]. Besides other differences, Type A reactions are more common, predictable and can occur in any individual, whereas Type B are uncommon, unpredictable and usually occur among genetically susceptible people [15,16].

Adverse drug reactions have high incidence and prevalence rate and are reported to cause morbidity and mortality, increase in hospital admissions, prolonged hospital stay, noncompliance and cessation of drugs, and financial burden on patients, professionals, industry and regulators due to additional treatment, and occur in all age groups. However, young children and elderly people are preferentially vulnerable to ADRs [17-26]. Most ADRs are preventable and mild and tend to subside when the drug is discontinued or dose is reduced [11,15,16]. The pharmacovigilance system [PVS] and electronic health records (EHRs) help in the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems [27-29]. Furthermore, PVS practices not only help early detection of ADRs, but also facilitate in identifying both risk factors and the mechanisms underlying ADRs. At the same time, the responsible health bodies can reap the benefits from PVS and HER, because these systems detect early the risks of medicinal products and their ADRs, which are associated with great financial burden to the public [3,30-32]. Notably, the ADRs are multifactorial and these factors relate to individual characteristics, environmental conditions, and drug's pharmacokinetic and pharmacodynamic properties. Identification of the causes and reporting of ADRs to surveillance and monitoring system helps develop strategies to prevent the occurrence of ADRs and its adverse consequences. The relevance of this study is that it will shed some light on the associations between individual factors of doctors, their KAAP and ADR variables in Jeddah hospitals. The significance of this research is that the revealed associations between multiple factors and detecting and reporting ADRs will facilitate the development of preventive strategies against ADRs. Overall, this research will contribute to new insights into ADRs and their association with demographic and KAAP of hospital physicians.

1.1 Aim

The objective of this study is to determine associations of hospital physicians' demographic and ADRs variables with their knowledge, awareness, attitude and practice (KAAP), and encountered or detected and reported ADRs in three general hospitals.

2. METHODS AND MATERIALS

2.1 Study Design and Setting

This is a cross-sectional, analytical study, which was conducted in Jeddah for one year, 2012-2013. The estimated mid-year population for the year 2013 was 3.87 million representing 12.9% of the population of KSA [33]. In Jeddah city, there are nine general and specialized hospitals of Ministry of Health (MoH). This study was conducted in three general hospitals namely King Fahd General Hospital, Al-Thaghar Hospital and King Abdul-Aziz Hospital. These hospitals were selected because they serve relatively a large number of patients presenting with ADRs of variable severity [34], and also have different departments including intensive care units and emergency services. The bed capacity of King Fahd General Hospital is 600 beds, Al-Thaghar Hospital 100 beds and King Abdul-Aziz Hospital 450 beds [8].

2.2 Sample Size Determination and the Sampling Technique

The sample size was calculated using specific formulas [35-39] described elsewhere [40]. Subsequently, a proportionate sample from each hospital was defined (Table 1). The total proportionate sample was 269 physicians, and to overcome non-participation, sample size was increased to 385. The actual analysed sample was 337, and the total number of distributed questionnaires among participants was 385 [32,41]. The response rate was 87.5%.

Stratified random sampling technique was used to sub-group departments and job categories (Table 2). Then, systematic random sampling was applied within each stratum to proportionately recruit participants. A sampling frame of physicians and their job categories

was obtained from different departmental administration. Every third physician was selected for participation. In case of absence or refusal to participate, the participant was replaced by the first next physician at the time of questionnaire distribution. Notably, the first starting number was chosen from the table of random numbers by simple random sampling.

2.3 Study Sample

The sample size of this study was 337 and participants including residents, specialists or consultants were selected from three hospitals. Physicians working in administration as managers and medical directors were not included in the study as they are often very busy in their work and have limited time to interview patients. Physicians in diagnostic departments such as radiologists, pathologists and microbiologists were also excluded because they do not directly treat patients. Interns were excluded because they are not hospital employees according to the MOH statistical department's guidelines, and, moreover, they are also not allowed to prescribe medications except under the supervision of senior physicians.

2.4 Instrument

A self-administered questionnaire was developed by five experts after reviewing the pertinent literature (13 references available upon request from TMAB). The questionnaire developers were mainly from hospitals and Saudi Food and Drug Authority (SFDA). The questionnaire's items were aligned with the objectives of the study and the institutional and national guidelines [3]. The final version of the questionnaire comprised of seven parts which are; 1) demographic

Table 1. Proportionate samples of study population by hospitals

Name of hospital	*Total number of study population	Proportionate samples
King Fahd General Hospital	402	133
Al-Thaghar Hospital	120	40
King Abdul-Aziz Hospital	289	96
Total	811	269

Source [42]

Table 2. The stratified physicians'job categories and departments of selected participants

	King Fahd General				AL-Thaghar Hospital				King Abdul-Aziz Hospital				
	Residents	Specialists	Consultants	total	Residents	specialists	Consultants	total	Residents	Specialists	Consultants	Total	Grand Total
Medicine &Home care	13	6	15	34	3	1	2	6	11	7	11	29	**69**
Surgery general and special, ENT	18	16	21	55	2	5	4	11	4	8	9	21	**87**
Emergency	15	5	3	23	9	1	1	11	8	4	0	12	**46**
ICU	2	5	4	11	-	-	-	-	1	1	2	4	**15**
Orthopedics	4	4	4	12	2	1	1	4	3	3	3	9	**25**
Dermatology	2	1	3	6	0	3	1	4	0	2	1	3	**13**
Cardiology & CCU	2	5	3	10	-	-	-	-	-	-	-	-	**10**
Obs &Gyn	-	-	-	-	2	1	2	5	4	2	3	9	**14**
Pediatrics	-	-	-	-	3	2	1	6	9	3	5	17	**23**
Anesthesia	0	6	3	9	0	2	1	3	1	2	2	5	**17**
Nephrology	5	4	3	12	-	-	-	-	1	4	1	6	**18**
The actual No. of physicians	61	52	59	172	21	16	13	50	43	36	37	116	**337**

characteristics: age, sex, nationality, highest qualification, level of practice, department of practice, years of practice, workshops or lectures attended in ADRs reporting and the average number of patients seen daily; 2) the awareness of ADRs program that involved a number of questions including the availability of ADR reporting policy in workplace, and the nearby ADR reporting and monitoring center, and the NPV center at SFDA; 3) knowledge about ADR reporting including the WHO definition of ADRs and which ADRs need to be reported; 4) assessment of physicians' attitude towards ADR reporting using Likert scale; 5) practice of ADR reporting; 6) motivators of and barriers against ADRs reporting and 7) self-assessment and intention consisting of multiple items such as adequate knowledge of ADR, ADR reporting and recommendations for improving ADR reporting.

2.5 Scoring

With regard to scoring of awareness dimension, each item was scored either 1 or zero when answer was correct or incorrect, respectively. The scores of all 8 items were summed up (maximum score 8). Each item on knowledge was also scored similarly. The scores of all the items were summed up; a maximum of 8 score for ADR knowledge, a score of 14 for ADR reporting knowledge, and a score of 22 for the total knowledge. For attitude, the responses from "strongly agree" to "strongly disagree" were scored 5 to 1, respectively. The higher scores indicated positive attitude. The scores of the statements were summed-up, and the total divided by the number of the items, giving a mean score for attitude that ranged from 1 to 5.

2.6 Pilot Study

A pilot study was conducted before data collection. A purposeful sample of 30 physicians was selected from Maternity and Children Hospital in Al-Mosaidiah, which was not included in the study sample. This step was taken to assess questionnaire's clarity, reliability and the coding process along with to resolve any possible field problems. Feedback from the pilot study helped to refine the questionnaire. Reliability of the self-administered questionnaire was good (Cronbach's alpha coefficient 0.7). Cronbach's alpha value of 0.7 or higher indicates acceptable reliability. Hence, the questionnaire was reliable which means all the items on the questionnaire were closely related.

2.7 Data Collection

The first author regularly visited the three hospitals to supervise the data collection from selected physicians. The researcher used to introduce herself and brief the participants about the objectives of the study. Every day the questionnaire was distributed to 20 chosen participants to answer the questions and the researcher was available for any clarification raised by the participants. The questionnaires were collected on completion and the participants who could not complete it due to their duty schedule were asked to complete questionnaires in the afternoon on the same day and return to the researcher. As there was no morning meeting in emergency departments, questionnaires were distributed after endorsement time to the participants and duly filled questionnaires were collected in the afternoon. All collected questionnaires were immediately checked for completeness. In case of an incomplete questionnaire, the concerned participant was asked to complete it instantly and return to the researcher.

2.8 Data Analysis

All collected questionnaires were reviewed and cleaned for logical consistency. Pre-coded data was entered in the computer using Microsoft Office Excel Software program for windows 2010. Data was transferred to the Statistical Package of Social Science (SPSS) Software program, version 16 for analysis purpose. Data were presented in the form of frequencies and percentages for qualitative variables, and means, standard deviation, medians and Inter Quartile Range (IQR) for quantitative variables. Quantitative continuous data were compared using nonparametric Mann-Whitney U or Kruskal-Wallis tests for two and more than two independent samples, respectively, since normal distribution of the data could not be assumed when Kolomogorov-Smirnov and Shapiro-Wilks tests were conducted. Qualitative categorical variables were compared using chi-square test. The p-value <0.05 was considered significant.

2.9 Ethical Considerations

The study protocol was approved by the Council of Joint Program of Family and Community Medicine of Saudi Commission for Health Specialties and the Research Ethical and Scientific Committee of the General Health Affair in Jeddah, Ministry of Health (MOH). The double review process assured the scientific soundness and ethical conformity of the study. The

permission letters to implement the study in four hospitals was taken from the Jeddah General Health Affair. Written informed consent was obtained from individual participants, after clearly explaining the objectives of the study. All physicians were assured that their participation is voluntary and they can withdraw from research at any time. In addition, they were informed about the confidentiality of their personal details and the collected data accessible only to the research team.

3. RESULTS

3.1 Sociodemographic Characteristics

The personal variables of all participants are demonstrated in Table 3. The study comprised of 337 hospital physicians and more than half were male participants. Half of the subjects were adults. Most of them had postgraduate qualification and about one fifth had PhD degree. A little more than one third was general physicians. The majority of physicians were from medical and surgical departments, and a small percentage affiliated to critical care. The majority of the physicians (n=241, 71.5%) had no exposure to training in ADRs. The median age, practice and the number of patients seen daily was 39, 10 and 15, respectively.

The associations between physicians' personal characteristics and their awareness, knowledge, and attitude towards ADRs are shown in Table 4. Notably, with regard to awareness significant associations were observed with age, highest qualification, job category, i.e., being consultant and department, i.e., working in critical care. Participants working in critical care were significantly aware of ADRs but people associated with surgical departments had the lowest awareness about ADRs. Physicians working in emergency department were observed to have significantly favorable attitude towards ADR. Meanwhile, no statistically significant associations were revealed between physicians' knowledge scores and personal characteristics.

There were significant associations between physicians' practice and their awareness of ADRs; however, the number of patients seen daily was not associated with their awareness of ADRs (Table 5). This means that the awareness scores tend to increase with the increasing years of practice, attending training courses in ADRs, and adequate knowledge, feeling of being adequately trained, workplace increasing awareness, and willingness to report ADRs. As for the knowledge, statistically significant associations were observed with the increasing years of practice and willingness to report. Furthermore, statistically significant association was observed between attitude and the feeling that workplace increased the awareness of ADRs.

There were significant associations between physicians who had detected ADRs in their practice and age 40 years age or older, highest qualification, job category and critical care department. The reporting of ADRs was also associated significantly with age, qualification and higher job category (Table 6).

There were statistically significant associations between physicians who had detected ADR in their practice with increasing years of practice, attended ADR training courses, feeling having adequate knowledge of ADRs, reporting of ADRs, and feeling adequately trained in ADRs. The practice of reporting ADRs was significantly associated with longer years in practice, attended ADR training, feeling of having adequate knowledge of ADRs and their reporting, feeling adequately trained in ADR, increasing awareness due to workplace, and willingness to report (Table 7).

Concerning associations between physicians' awareness, knowledge, and attitude towards ADRs and their practice, the only statistically significant associations were between their awareness of ADRs and ever encountering ADR and having reported ADR (Table 8).

4. DISCUSSION

This cross-sectional, analytical study describes a number of associations of physicians' demographic and ADR practice variables with their knowledge, awareness, attitude, practice towards ADRs and reporting of ADRs in three general hospitals of Jeddah. According to this study, physicians' scores of awareness of ADRs and their reporting revealed significant association with age, highest qualification and job category and years of experience. This trend is attributed to interrelations among all the four factors, for example, age and years of experience go together, and furthermore an older age and higher job through promotion often imply a higher qualification and more confidence in work [27]. In other words, the findings are quite plausible since physicians accumulate

unequivocal knowledge, greater awareness and long experience as they progress in age. Moreover, physicians with a higher job may have more opportunities to be involved in administrative work and consequently familiar with hospital policies and procedures. By extension, they also come across patients needing complex medications linked with a high probability of causing ADRs. In the same vein, a study demonstrated that physicians with higher level of qualification had the highest level of self-assessed awareness or knowledge, and informed awareness in practice [43]. In another study, better awareness was found among older physicians attributed to the fact that they are more likely to familiarize themselves with regulations guiding medical practice [44]. Conversely, Gavaza et al. [45] reported an inverse correlation between age and level of knowledge. Other factors in terms of regular training, continuous medical education and higher professional qualification might mediate the relationship between physicians' age and level of knowledge and awareness (related paper on predictors of ADRs reporting forthcoming soon).

Table 3. Sociodemographic and clinical characteristics of the participants (n=337)

Sociodemographic and clinical variables	Frequency (%)
Gender	
Male	220 (65.3)
Female	117 (34.7)
Age (in years)	
-<40	170 (50.4)
-40-<50	102 (30.3)
-≥50	65 (19.3)
Range; Mean±SD; Median & IQR	25-65; 40.1±9.7; 39&32-47
Nationality	
Saudi	181 (53.7)
Non-Saudi	156 (46.3)
Qualification	
Bachelor	94 (27.9)
Specialty Diploma	18 (5.3)
Master	53 (15.7)
Board/fellowship	102 (30.3)
Doctorate	70 (20.8)
Job position (rank)	
General physicians	120 (35.6)
Specialists	102 (30.3)
Consultants	115 (34.1)
Department	
Surgery	126 (37.4)
Medical	146 (43.3)
Critical care (ICU)	23 (6.8)
Emergency	42 (12.5)
Duration of practice	
<5 years	79 (23.4)
5- < 10	71 (21.1)
10 - < 15	53 (15.7)
≥15	134 (39.8)
Range; Mean±SD; Median& IQR	<1 – 39; 13.1±9.4; 10&5 – 20
Patients seen daily	
<10	79 (23.4)
-10 - < 20	130 (38.6)
-≥ 20	128 (38.0)
Range; Mean±SD; Median& IQR	0-50; 18.2±16.8; 15&0-15
Exposure to ADR training	
Yes	96 (28.5)
No	241(71.5)

Table 4. Association between physicians' knowledge, awareness,and attitude towards ADRs and physicians' demographic characteristics (n=337)

Personal characteristics	Awareness score (max 5)	P value	Knowledge score (max 22)	P value	Attitude score (max 5)	P value
	Mean±SD		Mean±SD		Mean±SD	
Age:						
<40	2.3±2.1		12.7±2.3		3.8±0.4	
40-<50	3.5±2.4		12.8±2.2		3.8±0.4	
≥50	3.5±2.5	0.001*#	13.3±2.0	0.18#	3.8±0.4	0.81#
Gender						
Male	3.0±2.5		12.9±2.2		3.8±0.4	
Female	2.7±2.2	0.32$	12.7±2.3	0.68$	3.8±0.4	0.18$
Nationality						
Saudi	2.7±2.2		12.8±2.2		3.8±0.4	
Non-Saudi	3.1±2.5	0.22$	13.0±2.2	0.47$	3.8±0.4	0.68$
Qualification						
Bachelor	2.0±1.9		12.8±2.4		3.8±0.4	
Specialty diploma	3.3±2.4		13.0±2.3		3.9±0.4	
Master	3.3±2.5		13.3±2.1		3.7±0.5	
Board/fellowship	3.0±2.5	0.001*#	12.5±2.1	0.26#	3.8±0.4	0.58#
Doctorate	3.5±2.4		13.0±2.2		3.8±0.4	
Job category						
Physicians/ Resident	2.1±1.9		12.9±2.4		3.8±0.4	
Specialist	3.2±2.6		12.7±2.2		3.8±0.5	
Consultant	3.5±2.4	0.001*#	12.9±2.1	0.64#	3.8±0.4	0.78#
Department						
Surgical	2.7±2.3		12.8±2.3		3.8±0.4	
Medical	3.2±2.4		13.0±2.1		3.8±0.4	
Critical care	3.8±2.8		13.6±1.7		3.6±0.6	
Emergency	2.0±1.8	0.01*#	12.1±2.3	0.14#	3.9±0.4	0.046*#

**Significant, $Mann-Whitney test, #Kruskal-Wallis test*

According to this research, physicians' awareness of ADRs was significantly associated with their work in critical care units. This finding might be attributed to the differences in the settings, the types of patients seen, and the medications used in these hospitals. For example, the use of medications in surgical departments is often limited to antibiotics and pain killers, whereas a wide spectrum of medications is used in the department of critical care. The critical state of the patients may also contribute to physicians' increased awareness of ADRs. Similarly, Robins et al. [46] found that physicians working in medical departments tend to prescribe more medications (polypharmacy) than their surgical counterparts, are more alert to, and encounter a larger number of ADRs. Notably, the risk of serious ADRs is reported to increase among patients prescribed multiple medications, referred to as polypharmacy [47,48]. The findings of this study are also similar to other research, which demonstrated a high awareness of ADRs among physicians working in critical care and emergency settings [44,46,47,49-52].

The present study has also found that physicians' awareness of ADR reporting was significantly influenced by a number of workplace factors such as 'attending training in ADR reporting', having adequate knowledge of ADRs and its reporting, feeling adequately trained in ADR reporting, settings and 'will report ADRs' in future. These findings emphasize the importance of continuing medical education and training in improving physicians' awareness of ADR reporting, consistent with studies that stressed the importance of advanced training in identifying and reporting ADRs, with improvement in health professionals' knowledge, awareness, attitude and practice towards ADR reporting [53]. Furthermore, Stoynova et al. [54] reported that a

training program targeting physicians based on identified needs and knowledge gaps significantly improves their level of knowledge, familiarity with PV and ADR reporting rate, and a positive attitude towards ADRs.

According to this study, physicians' attitude towards ADR reporting was significantly associated with their workplace especially working in emergency department. The physicians need to be aware of and should have positive attitude towards ADRs and ADR reporting. This trend tends to create a culture of patient safety and wellbeing. Eventually, building safe and blame free culture in hospitals ensures long-term improvement in physicians' attitude towards ADR reporting [34,35] that impact patient safety and quality of healthcare [55]. Although physicians working in critical care units had the highest level of awareness of ADRs and their reporting, surprisingly they had the lowest attitude scores. This might be explained possibly by high frequency of ADRs occurring in critical care settings, which may negatively influence their attitudes towards ADRs and their reporting.

According to this study, none of the personal characteristics of hospital physicians was correlated with knowledge of ADRs. Evidently, physicians are found to have low knowledge in ADRs [34,35,44,49,51,56-58], and hence, they less likely to report ADRs to pharmacovigilance system. Notably, the present study has not compared general hospital physicians knowledge (or KAAP) with other professionals, and this may be its limitation. However, physicians' years of

Table 5. Association between physicians' awareness, knowledge and attitude towards ADRs and their practice variables and self-perception (n=337)

Practice and self-perception	Awareness score (max=5) Mean±SD	P-value	Knowledge score (max=22) Mean±SD	P-value	Attitude score (max=5) Mean±SD	P-value
Years of practice						
<5 years	2.0±1.9		12.9±2.2		3.8±0.4	
5- <10	2.3±2.0	0.001*#	12.2±2.4	0.01*#	3.7±0.4	0.72#
10- < 15	3.1±2.5		12.4±2.2		3.8±0.4	
≥15	3.6±2.5		13.3±2.0		3.8±0.4	
Attended training in ADR reporting						
No	2.2±1.9		12.8±2.1		3.8±0.4	
Yes	4.6±2.6	0.001*$	12.9±2.5	0.72$	3.7±0.5	0.19$
No. of patients seen daily						
<10	2.7±2.5		13.1±2.3		3.8±0.4	
10-<20	3.0±2.4	0.56#	13.0±2.1	0.16#	3.7±0.4	0.23#
≥20	2.9±2.2		12.6±2.3		3.8±0.5	
I have adequate knowledge of ADR						
No	2.2±2.1		13.0±2.3		3.8±0.4	
Yes	3.9±2.4	0.001*$	12.6±2.0	0.08$	3.8±0.5	0.75$
I have adequate knowledge of ADR reporting						
No	2.4±2.1		12.9±2.2		3.8±0.4	
Yes	5.0±2.4	0.001*$	12.8±2.1	0.96$	3.7±0.5	0.41$
I feel adequately trained in ADR reporting						
No	2.6±2.2		12.8±2.2		3.8±0.4	
Yes	4.7±2.5	0.001*$	13.0±2.2	0.35$	3.8±0.5	0.92$
My workplace increased my awareness of ADR						
No	2.4±2.2		12.8±2.2		3.8±0.4	
Yes	4.0±2.5	0.001*$	13.1±2.2	0.18$	3.7±0.5	0.01*$
Intention to report						
I will report	3.4±2.4		13.1±2.1		3.8±0.4	
I will try to report	2.2±2.1	0.001*#	12.4±2.4	0.03*#	3.7±0.4	0.32#
I think about reporting	2.4±2.4		12.8±2.2		3.8±0.4	

**significant at p<0.05, $Mann Whitney test, #Kruskal Wallis test*

practice (>15 years) and willingness to report ADRs were significantly associated with their ADR knowledge scores. This relationship is plausible because advancing years of experience probably increase physicians' knowledge in ADR and their reporting. Consequently if physicians are highly knowledgeable in ADRs, they tend to report them to pharmacovigilance system.

According to this research, there was a significant association of physicians' age (40 years and above), qualification, seniority and years of experience and their identification and reporting of ADRs. In addition, hospital physicians encounter a significant number of ADRs in emergency department as compared to their private practice. These findings are compatible with the view that with progressing age, higher awareness and longer years of experience, physicians tend to significantly encounter ADRs and report them to monitoring and surveillance centers. These findings were further supported by revelation of significant correlations between physicians who detected and reported ADRs in their practice with their perception of having adequate training in and knowledge of ADR and its reporting, and feeling sufficiently trained in ADRs. In addition, physicians working in critical care units and emergency settings significantly encounter ADRs but they insignificantly report these ADRs. This finding could be attributed to physicians' higher awareness, the nature of patients seen and medications used in these settings. But they fail to report these ADRs to concerned PV centers because of their busy schedule which is consistent with studies [59]. Hohl et al. [59] demonstrated that ADRs were under-reported in emergency settings in Canada. This important finding might also be explained by the lack of a clinical pharmacist in emergency departments. In a study carried out in the United States, Szczesiul and associates (2009) clarified this heuristic point [60]. From this perspective, the authors of the present study suggest that clinical pharmacists' services need to be integrated into critical care units and emergency departments of general, specialist hospitals in Saudi Arabia. Physicians regularly attending

Table 6. Association between physicians' detection and practice of reporting ADRs and demographic characteristics (n=337)

Personal characteristics	Detected ADR		p-value	Reported ADR		p-value
	Yes (%)	No (%)		Yes (%)	No (%)	
Age						
<40	80 (23.7)	90 (26.7)	0.001*	26 (7.7)	144 (47.2)	0.01*
40-<50	71 (21.1)	31 (9.2)		26 (7.7)	76 (22.6)	
≥50	43 (12.8)	22(6.5)		21 (6.2)	44 (13.1)	
Gender						
Male	129 (38.3)	91 (27.0)	0.59	49 (14.5)	171 (50.7)	0.71
Female	65 (19.3)	52 (15.4)		24 (7.1)	93 (27.6)	
Nationality						
Saudi	99 (29.4)	82 (24.3)	0.25	41 (12.2)	140 (41.5)	0.63
Non-Saudi	95 (28.2)	61 (18.1)		32 (9.5)	124 (36.8)	
Highest qualification						
Bachelor	41 (12.2)	53 (15.7)	0.02*	10 (3.0)	84 (24.9)	0.003*
Specialty diploma	10 (3.0)	8 (2.4)		4 (1.2)	14 (4.2)	
Master	32 (9.5)	21 (6.2)		9 (2.7)	44 (13.1)	
Board/fellowship	64 (19.0)	38 (11.3)		25 (7.4)	77 (22.8)	
Doctorate	47 (13.9)	23 (6.8)		25 (7.4)	45 (13.4)	
Job category						
GP/ Resident	51 (15.1)	69 (24.5)	0.001*	12 (3.6)	108 (32.1)	
Specialist	61 (18.1)	41 (12.2)		21 (6.2)	81 (24.0)	0.001*
Consultant	82 (24.3)	33 (9.8)		40 (11.9)	75 (22.3)	
Department						
Surgical	64 (19.0)	62 (18.4)	0.02*	24 (7.1)	102 (30.3)	0.054
Medical	94 (27.9)	52 (15.4)		37 (11.0)	109 (32.3)	
Critical care	17 (5.0)	6 (1.8)		8 (2.4)	15 (4.5)	
Emergency	19 (5.6)	23 (6.8)		4 (1.2)	38 (11.3)	

**significant at $p<0.05$ (χ^2 test)*

Table 7. Association between physicians' encounter of ADRs, practice of reporting ADRs and their practice characteristics and self-perception

Practice characteristics and self-perception	Detected ADR		P value	Reported ADR		P value
	Yes (%)	No (%)		Yes (%)	No (%)	
Years of practice						
<5 years	30 (8.9)	49 (14.5)	0.001*	8 (2.4)	71 (21.1)	0.001*
5- <10	35 (10.4)	36 (10.7)		12 (3.6)	59 (17.5)	
10- <15	34 (10.1)	19 (5.6)		10 (3.0)	43 (12.8)	
≥15	95 (28.2)	39 (11.6)		43 (12.8)	91 (27.0)	
Attended training in ADR reporting						
No	124 (36.8)	117 (34.7)	0.001*	35 (10.4)	206 (61.1)	0.001*
Yes	70 (20.8)	26 (7.7)		38 (11.3)	58 (17.2)	
No. of patients seen daily						
<10	44 (13.1)	35 (10.4)	0.75	16 (4.7)	63 (18.7)	0.87
10-<20	73 (21.7)	57 (16.9)		30 (8.9)	100 (29.7)	
≥20	77 (22.8)	51 (15.1)		27 (8.0)	101 (30.0)	
I have adequate knowledge of ADR						
No	94 (27.9)	111 (32.9)	0.001*	26 (7.7)	179 (53.1)	0.001*
Yes	100 (29.7)	32(9.5)		47 (13.9)	85 (25.2)	
I have adequate knowledge of ADR reporting						
No	149 (44.2)	130 (38.6)	0.001*	45 (13.4)	234 (69.4)	0.001*
Yes	45 (13.4)	13 (3.9)		28 (8.3)	30 (8.9)	
I feel adequately trained in ADR reporting						
No	159 (47.2)	129 (38.3)	0.03*	50 (14.8)	238 (70.6)	0.001*
Yes	35 (10.4)	14 (4.2)		23 (6.8)	26 (7.7)	
My workplace increased my awareness of ADR						
No	133 (39.5)	103 (30.6)	0.49	39 (11.6)	197 (58.5)	0.001*
Yes	61 (18.1)	40 (11.9)		34 (10.1)	67 (19.9)	
Intention to report						
I will report	112 (33.2)	77 (22.8)	0.78	53 (17.2)	136 (40.4)	0.003*
I will try to report	62 (18.4)	50 (14.8)		13 (3.9)	99 (29.4)	
I think about reporting	20 (5.9)	16 (4.7)		7 (2.1)	29 (8.6)	

** Significant at p<0.05(X^2 test)*

Table 8. Association between physicians' awareness, knowledge, and attitude towards ADRs and their practice

Physician Practice	Awareness score (max=5)	P value	Knowledge score (max=22)	P value	Attitude score (max=5)	P value
	Mean±SD		Mean±SD		Mean±SD	
Ever detected ADR in practice						
No	2.4±2.1		12.7±2.3	0.42◊	3.8±0.4	0.30
Yes	3.3±2.5	0.002*	12.9±2.1		3.8±0.4	
Reported an ADR before						
No	2.5±2.2	0.001*	12.8±2.3		3.8±0.4	0.75
Yes	4.3±2.4		12.9±1.7	0.84◊	3.8±0.5	

** Significant at p<0.05 (Mann-Whitney test)*

training courses in ADRs significantly recognize, encounter and also report ADRs in general hospitals. The implication of this finding is that advanced regular training in ADRs targeting physicians will improve their skills to recognize, encounter as well as reporting ADRs to PV centers and this will result in higher patient safety, again consistent with other studies which recommend scaling up of training in adverse drug reactions [61]. Determining the association

between physicians' awareness, knowledge, and attitude and detected ADR and the practice of ADRs reporting, this study revealed that the physicians' awareness had significant association both with detected and reported ADRs and these results are also supported by other research [45,62].

This study has some limitations. This is a cross-sectional study conducted in three general hospitals and hence the results are not applicable to all the general hospitals of Saudi Arabia. Another caveat of this research is that though the significant associations were found between physicians certain characteristics including KAAP and ADRs detected and reported to surveillance and monitoring agencies, these results are short of being predictors of ADRs encountering and reporting to PV centers (related paper on predictors of ADRs forthcoming soon).

5. CONCLUSION

In summary, this study reported a number of significant associations of physicians' characteristics with KAAP and ADR practice and self-perceptions of ADRs. Similarly, significant associations were found between GPs demographic, ADR practice and detected and reported ADRs. No significant associations were found between GPs knowledge and demographics, ADR practice and self perceptions of ADRs. Attitude scores were found to have significant association with GPs workplace. This research is calling for scaling up training of physicians not only to improve their knowledge, attitudes and practice towards ADRs reporting to pharmacovigilance centers within and outside the general hospitals but also to better recognize ADRs in their practice setting, and this will lead to improvement in patient safety. This study suggests that further research need to be conducted on ADRs in Saudi Arabia.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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