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Assessment of Hospital Physicians' Knowledge, Awareness, Attitude and Practice of Reporting Adverse Drug Reactions in Jeddah, Saudi Arabia

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Authors' contributions

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

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ABSTRACT

Background: Adverse drug reactions (ADRs) are an important cause of morbidity and mortality around the world. Spontaneous reporting of ADRs is considered an essential component of successful pharmacovigilance (PV). Physicians' unfamiliarity with ADRs and reporting procedures are major factors that lead to sub-optimal reporting of ADRs.
Objective: This study explored knowledge, awareness, attitude and practice (KAAP) of physicians towards ADRs and their reporting.

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Methods: This study was conducted at three general hospitals in Jeddah City. A 7-item, self-administered questionnaire was developed to explore physicians' KAAP.
Results: Majority of physicians had post-graduate qualification (n=243, 72%), were from medical departments (n=146, 43.3%), had long clinical experience (n=258, 77%) and consulted more than 10 patients daily (n=258, 77%). About 72% of physicians were never exposed to ADR training program. More than 60% of physicians were not fully aware of ADR reporting perspectives. Majority of them (75%) knew the correct definition of ADR and adequate knowledge of reportable ADRs (>90%). Majority of physicians depended on textbooks on drugs and therapies (31.2%) and drug package inserts (22.3%) as sources of ADR information. The majority of respondents (>90%) showed positive attitude towards ADRs and ADRs reporting and monitoring system. About 57.6% of physicians had come across ADRs in practice but only 21.7% reported these reactions. Most of physicians agreed to improve KAP towards ADRs reporting.
Conclusion: The preliminary findings of this study suggest that though majority of physicians had good awareness and positive attitude towards ADR and ADR reporting, but needed correct knowledge in some areas of ADRs and their reporting system. Majority of physicians were not exposed to ADR training courses. Physicians certainly need ADR training programs in order to further enhance their KAAP towards ADRs and ADR reporting.

Keywords: Adverse drug reactions; physicians, knowledge; awareness; attitude; practice; general hospitals; pharmacovigilance.

1. INTRODUCTION

This is an era of modern medicines that can relieve people suffering, improve health and enhance quality of life [1]. Although, medications primarily have therapeutic applications in health and disease, some unfavorable reactions tend to occur with their use [2]. These are known as adverse drug reactions (ADRs) which tend to present serious health problems across the world. Furthermore, ADRs need to be identified not only during clinical trials but also in clinical practice and healthcare settings but this is not happening [3,4]. The World Health Organization (WHO) defined ADRs as "any noxious, unintended and undesired effect of drugs which occurs at normal doses used in humans for prophylaxis, diagnosis, or therapy of diseases, or for the modification or exploration of physiological function or pathological states of recipient" [5]. ADRs are an important cause of morbidity and mortality worldwide [6]. Their incidence is about 7%, and 6.7% of them are ranked as serious and 0.3% are fatal [7,8]. Mortality rate among those patients who develop ADRs increases by 19.18% [9]. Individuals suffer from ADRs irrespective of age and gender [10-12]. ADRs adversely affect public health, and are associated with huge economic burden on the healthcare system around the world [1,13]. It is estimated that 6.25% of hospital admissions are due to ADRs [6]. ADRs are responsible for 4% of bed occupancy [6] and longer length of stay (LOS) in hospital [9]. In addition, the indirect cost resulting from absenteeism and lost productivity is reported to exceed the medications cost [14].

The research on ADRs is relatively scanty in the Kingdom of Saudi Arabia (KSA). In one study, Al-Olah found that 14.7% of patients admitted to the hospital from the emergency department were attributed to drug-related problems, and 24.5% of them were due to ADRs [13]. Additional studies reported 5.5% incidence rate of ADRs in medical departments [15]. The estimated monthly expenditure on ADRs was about 860, 000 Saudi Riyals (SR) per hospital. The average LOS for a patient admitted through the ED due to DRPs was 5.74 days [13]. Notably, 80% ADRs are Type A and they are preventable, predictable, and attributed to many factors including drug doses and pharmacokinetics, and they lead to multiple adverse consequences [6,12,13] if their occurrence is not proactively prevented. Conversely, Type B ADRs, more serious than Type A, account for less than 20% of reported drug reactions, occur unpredictably in genetically susceptible people, and are mostly immunologically-mediated drug reactions [6]. ADRs tend to occur both in inpatients and outpatients settings [16], and can be prevented using cost-effective strategy of pharmacovigilance (PV) [12]. The post-marketing surveillance by PV program is crucial for monitoring and evaluating ADRs, [3,17] for example, spontaneous reporting of ADRs has contributed significantly to the success of PV system [3,18,19]. In this context, physicians, being the front-line healthcare providers, are the

key healthcare professionals who can instantaneously report most ADRs [4,20-22]. Furthermore, the physician's bedside evaluation of patients plays the fundamental role in detecting ADRs [23]. ADRs reporting rate is as low as 6%, and at best 18.5% with an average of 10% [17,24-27]. Even with well-established PV program in place, underreporting of ADRs is a common trend [28-31]. In Saudi Arabia, the ADR reporting rate is about 0.1% [32], which is relatively very low. In fact, the high rate of underreporting tends to delay signal detection, and consequently impacts the health outcome negatively [1,33,34]. Therefore, it is important to explore the KAAP of medical professionals in order to identify the key factors associated with under-reporting of ADRs, which adversely affect the performance of PV system [20]. The literature on ADRs is vast in high income countries compared to low and middle income countries [35-37]. In this regard, the Gulf countries especially Saudi Arabia is no exception [12,13,38,39]. This study is aimed at exploring the knowledge, awareness, attitude and practice of physicians towards ADRs and their reporting in Jeddah City. The rationale for conducting this study in Saudi Arabia was underreporting and paucity of research on ADRs especially physicians' KAAP. The significance of this research is that it would help activate ADRs reporting system in hospitals, together with the reduction in morbidity, mortality and cost associated with ADRs. Furthermore, the study results are expected to represent baseline data of physicians' KAAP regarding ADRs reporting in general hospitals. The collected data may help the decision makers and planners in both Ministry of Health (MOH) and Saudi Food and Drug Agency (SFDA) for better response to prevention and management of ADRs.

1.1 Objective

The objective of this study was to explore hospital physicians' knowledge, awareness, practice and attitude towards reporting of adverse drug reactions in Jeddah city.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This is a cross-sectional, explorative/descriptive study, which was conducted in Jeddah city from October 2012 to September 2013. Jeddah is the largest and most vital city in Makkah Al-Mukarramah province, and is considered a gateway to the two holy mosques in Makkah Al-Mukarramah and Medina Al-Munawwara. Its estimated mid-year population for the year 2013 was about 3.87 million which represent 12.9% of the population of KSA [40]. 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 represent the largest health organizations, and serve relatively a larger patient population with ADRs of variable severity [41]. Furthermore, these hospitals have several departments including general surgery, ear, nose and throat, orthopaedic and obstetrics & gynaecology, general medicine, paediatrics, 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 [42].

2.2 Sample Size Determination and the Sampling Technique

The sample size was calculated using the following equation: $n = \frac{z\alpha^2 \times p \times q}{\delta^2}$. Where n is the sample size, $z\alpha$ is the z-value for the selected level of confidence (1-α) = 1.96, p is the expected frequency of the outcome = 0.1. Based on the assumption that the average ADR reporting rate is 10% [17,24-27], q= (1 – p) = 0.9, δ=the maximum acceptable error = 0.03. The sample size for infinite is: $n = \frac{(1.96)^2 \text{X } 0.1 \text{ X } 0.9}{(0.03)^2} = 384$. Then, adjusted sample size was calculated as $\text{correction for population size} = \frac{n}{1+(\frac{n}{\mathcal{N}})} = \frac{384}{1+(\frac{384}{811})} = 262$ .Where n is the calculated sample size, $\mathcal{N}$ is the total number of physicians in the three hospitals. Finally, proportionate samples were calculated for each hospital as: proportionate sample = $\frac{\text{adjustedsample}}{\mathcal{N}} = \frac{262}{811} = 0.32$. Where $\mathcal{N}$ is the total number of physicians in the three hospitals. Thus by calculating the sample size, 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 analyzed sample was 337, and the total number of distributed questionnaires among participants was 385 [43,44]. The response rate was calculated as 337\385 × 100 and was 87.5%.

Stratified random sampling technique was used to sub-group departments and job titles/ 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 and Selection Criteria

The sample size of this study was 337 and participants were selected using some exclusion and inclusion criteria. Physicians working in administration as managers and medical directors were not included in the study. They are often very busy in managerial work and have limited time to interview patients. Physicians in diagnostic departments represented by mostly radiologist, pathologist and microbiologist etc were also excluded because they do not directly treat patients, and they have only indirect contact with patients. Interns were not included because they are not hospital employees according to the MOH statistical department's guidelines. Furthermore, they are also not allowed to prescribe any medication except under the supervision of senior physicians.

2.4 Instrument Development

A self-administered questionnaire was developed by 5 experts after reviewing the pertinent literature [28,33-35,38,46-53]. The panel of experts consisted of community medicine, clinical

Table 1. Proportionate samples by hospitals of study population

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 [45]*

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

	King Fahd General Hospital				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

pharmacy and PV professors taken from hospitals and SFDA. The questionnaire' items were aligned with the objectives of the study and the institutional and national guidelines [34]. The panel of experts again reviewed the questionnaire in accordance to feedback of 30 participants' who participated in the pilot study. Based on the panel's recommendations and pilot study participants' suggestions, minor modifications were made in the questionnaire. This revision exercise entailed appropriateness in interpretative, linguistic and content terms in the questionnaire. Finally, all experts also agreed 100% on all items of the questionnaire. The time allotted for filling out one questionnaire was 10 minutes. Most of questions were close-ended and were pre-coded prior to data collection to facilitate data entry and analysis. On the other hand, the open-ended questions were coded after data collection. For each question, a set of possible answer options were given; "yes", "no" or "don't know". The final version of the questionnaire comprised of seven parts which are;1) Socioclinical characteristics**:** age, sex, nationality, highest qualification, level of practice, department of practice, years of practice, workshops/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 any recommendations for improving ADR reporting.

2.5 Pilot Study

A pilot study was conducted before starting data collection. A purposeful sample of 30 physicians was selected from Maternity and Children Hospital in Al-Mosaidiah, which is not included in the study sample. The objectives of the pilot study were: 1) to test questionnaire's clarity, feasibility and applicability, reliability and the coding process, and 2) to identify and resolve any possible field problems. Feedback from the pilot study helped to further refine the self-administered questionnaire, and finalize the version to be used in the study. Reliability of the self-administered questionnaire was measured using Cronbach's Alpha test. The internal consistency analysis of the questionnaire revealed Cronbach's alpha coefficient that ranged from 0.65 to 0.88. Cronbach's alpha value of 0.6 or higher indicates good reliability. Hence, the questionnaire was reliable and accepted for use.

2.6 Data Collection

The first author regularly visited the three hospitals to supervise the data collection from department/unit physicians. A written permission was taken from each head of medical department to attend the morning meeting session. The researcher introduced herself and explained to the participants the objectives of the study on daily basis. Every day the self-administered questionnaire was distributed to 20 chosen participants who were requested to answer the questionnaire. The researcher was available for any clarification raised by the participants during the process. The questionnaires were collected on completion. Those participants could not complete the questionnaires in the same sitting because of 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 selected participants and completed questionnaires collected in the afternoon on the same day. All collected questionnaires were immediately checked for completeness on the spot. In case of an incomplete questionnaire, the concerned participant was asked to complete it immediately and return to the researcher.

2.7 Data Management and 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 (SD), medians and interquartile range (IQR) for quantitative variables.

2.8 Ethical and Administrative Considerations

The study protocol was submitted to the Council of Joint Program of Family and Community Medicine of Saudi Commission for Health Specialties for ethical approval. In addition, the research proposal was also presented to the Research Ethical and Scientific Committee of the General Health Affair in Jeddah, Ministry of Health for review in order to access MOH settings for data collection. Both committees approved the research protocol for this study without recommending any changes in the proposal. The double review process assured the scientific soundness and ethical conformity of the study. Finally, permission to implement this study was obtained from the General Health Affair in Jeddah, Ministry of Health. For this purpose, an official letter from the Council of Joint Program of Family and Community Medicine was submitted to the general health authority of Jeddah and consequently permission was granted. Subsequently, General Health Affair issued separate letters to the four targeted hospitals including the hospital where pilot study was conducted to ensure cooperation from hospital administration and participants. Written informed consent was obtained from individual participants, after clearly explaining the objectives and benefits of the study. All physicians were assured that their participation is voluntary and they have can withdraw from research at any time. Participants also were informed about the confidentiality of their personal details, and the collected data was only accessible to the research team.

3. RESULTS

The sociodemographic variables of all participants are demonstrated in Table 3. The study comprised of 337 hospital physicians and the male participants were 220 (65.3%). Half of the subjects were less than 40 years of age. Most of them had postgraduate qualification (n=243, 72%) including about 21% had PhD degree. With regard to job, 120 (35.6%) were general physicians.

The majority of physicians were from medical (n=146, 43.3%) and surgical departments (n=126, 37.4%), and a small percentage affiliated to critical care (n=23, 6.8%). Notably, the majority of the physicians (n=241, 71.5%) did not have exposure to training in ADRs (Table 4).

With regard to physician's awareness about ADRs (Table 5), about 61% (n=206) of physicians had no idea about ADR reporting policy in their settings. Of those who had reported having a policy, 61.1% (n=80) read it and only 22.6% (n=76) have seen the ADR reporting template. An equal number of physicians (n=10/56, 17.8%) knew about ADR reporting program through colleagues and MoH officials. About one half of physicians (n=155, 46%) did not know to whom to report ADRs. Only 8.9% physicians had awareness of nearby ADR reporting center. Another 16.6 % of physicians

Table 3. Sociodemograhic characteristics of participants (n=337)

Sociodemographic 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)
Age–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 - General physicians	120 (35.6)
- Specialists	102 (30.3)
- Consultants	115 (34.1)

were aware of National PV center of SFDA. Notably, 15.1% of physicians (n=51) were not aware of any elements of ADR reporting, while only 8.9% (n=30) were aware of all its elements. The remainders (n=256) were aware of some of its items.

In general, the knowledge of ADR (Table 6) shown by all physicians was low on all its items except 'definition of ADRs', 'serious ADRs are known before a drug is marketed' and 'ADRs can be reported anonymously'. The correct definition of ADR was known to

Table 4. Distribution of job characteristics of physicians (n=337)

Job variables	Frequency (%)
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	0-150, 18.2±16.8, 15 & 0-15
Exposure to ADR training - No	241(71.5)

Table 5. Distribution of physicians' awareness of ADR reporting (n=337)

Awareness items	Frequency (%)
Is there an ADR reporting policy:	
Yes	131 (38.9)
No	65 (19.30)
Do not know	141 (41.8)
Have you ever read ADR reporting policy? Yes	80 (61.1)
Have you ever seen ADRs reporting forms? Yes	76 (22.6)
ADRs are reported to:	
Head of department	57 (16.9)
Hospital management	12 (3.6)
Hospital pharmacy	78 (23.1)
Ministry of health (MOH)	7 (2.1)
Drug company	4 (1.2)
Saudi Food and Drug Authority (SDFA)	7 (2.1)
More than one choice	17 (5)
Do not know	155 (46)
Is given ADR info satisfactory? Yes	91 (27)
Do you update your own info on ADR? Yes	130 (38.6)
Are you aware of nearby ADR reporting & monitoring center? Yes	30 (8.9)
Are you aware of the NPV at SFDA? Yes	56 (16.6)
Have you previously contacted any of the 2 centers? Yes	14 (25)
Knew about ADR reporting program through (n=56):	
Conferences/symposia	5 (8.9)
Colleagues	10 (17.8)
MOH officials	10 (17.8)
Read about it	12 (21.4)
Drug company representatives	4 (7.1)
SDFA staff	4 (7.1)
More than one source	7 (12.5)
Missed	4 (7.1)

Table 6. Distribution of knowledge of ADR reporting by physicians (n=337)

Knowledge items	*Frequency (%)
ADR definition	253 (75.1)
ADRs should not be reported if uncertain about the product caused event	95 (28.2)
ADRs should be reported only if all details of event are available	120 (35.6)
All serious ADRs are known before a drug is marketed	157 (46.6)
ADRs can be reported anonymously	140 (41.5)
Adverse experiences with cosmetics are not to be reported	42 (12.5)
Adverse experiences with nutritional products are not to be reported	45 (13.5)
One case of ADRs reported does not contribute much to knowledge on drug risks	103 (30.6)
Reportable ADRs:	
Suspected reactions (suspected drugs is uncertain)	168 (49.9)
Certain/sure reactions	290 (86.1)
Reaction causing hospitalization	325 (96.4)
Reaction causing persistent disability or incapacity	325 (96.4)
Reaction causing death of the patient	334 (99.1)
Life threatening reaction	326 (96.7)
Slight reactions such as vomiting & diarrhea	169 (50.1)
Reactions to old drugs	217 (64.4)
Reactions to newly introduced drugs in the market	310 (92)
Only proved ADRs	118 (35)
Unexpected/Unusual reactions	269 (79.8)
Possible interaction with other drugs	248 (73.6)
Teratogenic phenomena	288 (85.5)
Any reaction in special population, e.g. children	294 (87.2)

**Correct answer*

253 physicians (75.1%).12.5% of physicians (n=42) and other 13.5% of participants (n=45) correctly knew the reporting of adverse experiences with cosmetics and nutritional products, respectively. Most physicians were abreast of all reportable ADRs except 'proved ADRs' (n=118, 35%), 'suspected reactions' (n=168, 49.9%), and 'mild reactions' (n=169, 50.1%).

Table 7 demonstrated that physicians mostly depended on textbooks on drugs and therapies (31.2%) and drug package inserts (22.3%) as sources of information about ADRs. On the other hand, only 4.7% of them had the SDFA as a source of information.

Regarding physicians' attitudes towards ADR reporting (Table 8), more than 90% of them agreed upon the importance of ADRs as a problem in medical practice, importance of monitoring drug safety by PV, and the benefit of ADR reporting and monitoring system. In the same vein, high percentages of physicians disagreed upon negative statements regarding the belief that all drugs are safe to be sold in the market (70%) and ADRs reporting may increase malpractice (67.4%).According to physicians' opinions, the highest responsibility for reporting ADRS was on pharmacists (30%) followed by physicians (29.1%). Meanwhile, 35.9% of them gave more than one choice (Fig. 1). Furthermore, 57.6% of physicians (n=194) had encountered ADRs in their practice.

Table 7. Sources of information about ADR reporting by physicians (n=337)

Sources of information about ADRs (n=337)*	Frequency (%)
Textbooks on drugs & therapies	105 (31.2)
Drug package insert sheet	75 (22.3)
Scientific journals (ADRs articles)	55 (16.3)
Medical representatives	20 (5.9)
Saudi Food and Drug Authority (SFDA)	16 (4.7)
Other sources:	
Internet	8 (2.4)
Smart phone applications	5 (0.3)
Up-to-date pharmacology	3 (0.9)
Hospital policy	2 (0.6)
BNF	1 (0.3)
MEDI	1(0.3)
Other books	1(0.3)
Royal college magazine	1(0.3)
Missing	44 (13.1)

**Not mutually exclusive*

Table 8. Physicians(n=337) attitude towards ADR reporting

Attitude	Strongly agree / agree (%)	Uncertain (%)	Strongly disagree/ disagree (%)
I believe any safe drug needs to be in the market	66 (19.6)	35 (10.4)	236 (70)
ADRs are an important problem in medical practice	304 (90.2)	16 (4.7)	17 (5)
The science of monitoring drug safety (PV) is important	327 (97)	6 (1.8)	4 (1.2)
An ADR reporting and monitoring system benefits the patient	316 (93.8)	18 (5.3)	3 (0.9)
ADRs reporting may increase malpractice risk	55 (16.3)	55 (16.3)	227 (67.4)
Confidentiality is not essential in ADR reporting	115 (34.1)	84 (24.9)	138 (40.9)
I want to be sure the ADR is related to the drug before reporting	248 (73.6)	39 (11.6)	50 (14.8)
Consulting colleagues is important before reporting an ADR	229 (68)	60 (17.8)	48 (14.2)

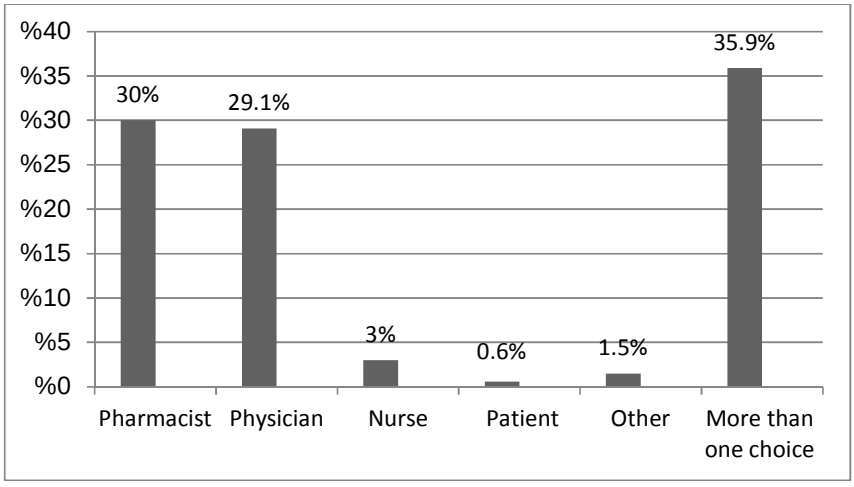

Fig. 1. Physicians' opinions regarding the responsibility of reporting ADR

About one-fifth of physicians (n=73, 21.7%) had previously reported ADRs, and 74% of them (n=54/73) reported ADRs during last year (Table 9). Most physicians (n=37, 50.7%) reported ADRs by verbal means, followed by using forms other than SFDA template (n=28, 38.4%). Most of physicians (n=31, 42.5%) reported ADRs to hospital pharmacy, followed by head of department (n=12, 16.4%).

Concerning physicians' self-perceptions and intentions, only 39.2% of them (n=132) perceived having adequate knowledge of ADR, and 17.2% physicians (n=58) had adequate knowledge of ADR reporting. Additionally, only 14.5% of physicians felt to have adequate training in ADR reporting. With regard to the intention to report ADRs, more than half of the physicians (n=189, 56.1%) expressed the will to report, while one-third of physicians (n=112, 33.2%) mentioned they will try to do so (Table 10).

4. DISCUSSION

This study explored hospital physicians' knowledge, awareness, practices and attitude towards ADRs and their reporting in three hospitals of Jeddah city. The findings generally indicated hospital physicians' low levels of awareness and knowledge with the exception of definition of ADR as well as practice of ADRs and their reporting; however, most of them demonstrated positive attitude and strong willingness to improve their practice as most of them were not exposed to ADR training program. These diverse results might be

explained by physicians' sociodemographics, job characteristics, and healthcare settings.

Table 9. Physicians (n=337) practice of reporting ADR

Items	Frequency (%)
Have reported an ADR before:	
No	264 (78.3)
Yes	73 (21.7)
Have reported an ADR last year (n=73):	
No	19 (26)
Yes	54 (74)
Reporting mode (n=73):	
Verbally	37 (50.7)
On reporting form other than SFDA	28 (38.4)
On SFDA form	4 (5.5)
SFDA online	4 (5.5)
Reported to (n=73):	
Hospital pharmacy	31 (42.5)
Head of department	12 (16.4)
Hospital management	8 (11)
Drug company	4 (5.5)
SFDA	2 (2.7)
Ministry of health (MOH)	1 (1.4)
Others	3 (4.1)
More than one choice	12 (16.5)

Table 10. Physicians' (n=337) self-perception of and intention to report ADR

Self-perception items	Frequency (%)
I have adequate knowledge of ADR	132 (39.2)
I have adequate knowledge of ADR reporting	58 (17.2)
I feel adequately trained in ADR reporting	49 (14.5)
My workplace increased my awareness of ADR	101 (30)
Intention to report:	
I will report serious ADRs that I encounter	189 (56.1)
I will try to report serious ADRs that I encounter	112 (33.2)
I think about reporting serious ADRs that I encounter	36 (10.7)

According to this study, important findings revealed major deficiency in staff development activities related to continuous training of physicians about ADRs and ADR reporting and monitoring systems. This tends to have a negative impact on their knowledge, awareness, attitude, and practice. Evidently, the literature strongly suggest that various types of interventions such as skill-based training [54], self-training using educational tools, [21] and on job continuing educational programs supported by handouts [55] not only positively improve attitudes but also knowledge, awareness, practice and attitude towards adverse drug reactions and their reporting to concerned pharmacovigilance centers within as well as outside hospital. This study is calling for continuous ADR training programs targeting physicians in all general hospitals in Jeddah city and by extension all hospitals in Saudi Arabia.

Another important finding of this study is that majority of physicians were not aware of ADR reporting policy and procedures in their workplaces, which was attributed to physicians' lack of interest or reluctance to know about administrative policies, especially about reporting adverse drug reactions. Nonetheless, more than 80% of the physicians were aware of ADR reporting system. Conversely, other studies have reported low awareness of ADR reporting system [56]. Overall, all concerned physicians should have awareness of ADR related policies and also of reporting and monitoring system to which all ADRs need to be reported instantly. In this context, hospital administration and quality management team might be game changers in improving physicians' awareness of ADR related policies and procedures and reporting and monitoring system.

Furthermore in a related context, only approximately one-fourth of physicians reported having seen ADR reporting template. This finding might be explained by the fact that not every physician needed to report an ADR. However, it is surprising that physicians are not acquainted with all the forms required to be used in their workplace. Ideally, physicians should be made aware of the ADR template as a routine by the quality control team. The reported rate in the present study is even lower compared with that found by Chopra and associates [57] in a teaching hospital in India. Notably, in other study 47% of doctors were acquainted with their institute's ADR system and forms for reporting adverse drug reactions [57]. The current study found that half of physicians were not aware about ADR reporting center or national PV and also to whom to report ADRs. Moreover, only less than one-tenth of physicians were aware of the complete protocol of ADR reporting. These findings present a dismal scenario of physicians' awareness of ADRs reporting and, thus, health care professionals need constant updating of knowledge and awareness in this area as also suggested by other researchers from Asia [35].

This becomes even more important as information about ADRs changes on a daily basis.

According to this study, physicians' attributed the responsibility for reporting ADRs almost equally to pharmacists and physicians. This may reflect their willingness to share this task with pharmacists and not taking on the whole responsibility. More importantly, majority of physicians assigned this responsibility to several members of healthcare team, which implies that ADRs and their reporting is a shared responsibility which needs collaboration of all the team members. In a study in Turkey, Nazli and associates (2010) reported similar findings and in addition emphasized the greater role of nurses in PV and ADRs reporting [1].

A small number of physicians (n=2, 0.6%) opined that patients have a role or responsibility in reporting ADRs. However, to be able to achieve this role, patients must be aware of the potential ADRs of the prescribed or dispensed medications, and this is possible through their healthcare provider physicians. Hence, if physicians' awareness about ADR reporting is low and they do not offer relevant ADR information to patients, the patient's ability to report ADRs is questionable. An Australian study also reported low awareness of ADRs and related reporting system among patients [58] consistent with the present study. However, slightly less than half of those patients who experience ADRs tend to report ADRs to their family physicians. Thus, the role of family physicians becomes crucial as regard monitoring and reporting of ADRs. Conversely, Lorimer and colleagues [59 highlighted that patients did not feel that reporting ADRs was their responsibility, and recommended encouraging them to report ADRs by increasing their awareness]. Notably, this is possible through an interactive educational program administered by the primary care physicians to their patients, as was demonstrated in a randomized clinical trial [60]. Nonetheless, the role of patients in reporting ADRs is still controversial. In a study from Malaysia, Ahmad and colleagues (2010) suggested that reporting of ADRs by health consumers could improve PV programs [61]. In another study from India, Kamtane and Jayawardhani [35] stated that patient reporting of ADR in low-income countries is a complimentary process that helps to increase the level of ADR reporting. The contribution of patients to reporting of ADRs is also widely variable. In a review of published literature, Blenkinsopp and associates [62] stated that patient reporting of ADRs contributed a small percentage of total reports to pharmacovigilance. A study from the Netherlands, de LJ et al. [63] revealed that the involvement of patient as a source of ADR reporting to PV system is feasible and they could contribute significantly to the reliability of PV.

Although approximately three-fourth of physicians in the present study had a correct knowledge of the definition of ADR, only few of them had correct, detailed knowledge of other ADR related issues, such as reporting adverse experiences with cosmetics and nutritional products, reporting when uncertain, and anonymity of the report. These findings indicate that majority of physicians possibly had only superficial knowledge about ADRs. On the contrary, Rehan and colleagues [56] demonstrated that only 35% of the physicians in their study gave a correct definition of the ADR but they had better knowledge of what to report to ADR reporting system. Concerning the reporting of ADR of natural health products such as cosmetics and nutritional supplements, and consistent with our results, another study from Canada also found low related knowledge and practice [64]. This must be taken into consideration in any ADR educational programs aimed at raising physicians' knowledge in ADRs and their reporting since natural products and supplements have been regulated two decades ago. In fact, in 1994, the Dietary Supplement Health and Education Act amended the Federal Food, Drug, and Cosmetic Act to set up a distinct regulatory framework for dietary supplements. The act gives the US Food and Drug Administration authority to regulate and take action against manufacturers of supplements or supplement ingredients that present safety problems, are presented with false or misleading claims, or are adulterated or misbranded [65]. In general, the low level of knowledge among physicians might be due to deficient graduate or postgraduate training in the area of dietary supplements. In fact, physicians in the present study depended mostly on textbooks on drugs and therapies and drug package inserts as sources of information about ADRs. Moreover, only a few of them considered SFDA as a source of information despite of the fact that SFDA has Saudi Drug Bulletin, which is published online in order to update KAAP of physicians across Saudi Arabia. In this context, it has been stated that the undergraduate training in PV is either inadequate or insufficiently delivered to future physicians

who will take on the task of monitoring and reporting ADR in their practice [35].

According to this research, a high proportion of physicians were able to discern and recognize the most common reportable ADRs. This might be due to the fact that these physicians may have high perceptions of medications' risks. On the contrary, lower percentages of participants had correct knowledge regarding reporting not only proved, but also suspected, and minor ADRs. This might be attributed to the view possibly held by physicians that only the life-threatening reactions causing hospitalization and death is reportable. On the other hand, reporting of suspected ADRs is debatable. Consistent with this finding, in a study involving Bulgarian physicians Stoynova et al. [21] identified uncertainty concerning the relationship between the suspected drug and the ADRs as the most common reason for non-reporting ADRs by physicians.

There is no direct relationship between having knowledge in ADRs and ADR reporting. According to this study, majority of physicians had variable knowledge on several items of ADRs but reporting of ADRs was relatively low. These results based on assessing physicians' knowledge were further confirmed by the results of physicians' perception of their knowledge, which revealed even lower percentages of perceived adequate knowledge of ADR and of ADR reporting. However, the finding is not unique to this study setting as several international studies have also reported low knowledge of ADRs and their reporting in Nigeria [17,33], European countries, [29,41,66,67] and Asia [48,56,68].

The assessment of participating physicians' attitude towards ADR reporting is important because this attitudinal element influence practice. Evidently, the consistent ADR reporting by healthcare professionals needs full integration into their daily practice [48]. Arguably, physicians' positive attitude is typically the most important triggering factor in reporting adverse drug reactions [52]. According to this study, majority of physicians' agreed with the importance of ADRs reporting in medical practice, and the benefits of their reporting to the patient. At the same time, majority of participants disagreed upon misconceptions 'that all drugs in the market are safe'. Thus, physicians showed positive attitude towards ADR reporting, which is consistent with other studies [21]. A study in Bulgaria revealed that approximately 83% of the studied physicians had positive attitude towards reporting ADRs, and considered it an obligation towards their patients [21].

According to this study, more than 50% of physicians encountered ADRs in their practice, but less than half of them self-reported ADRs. This means that four out of ten ADRs were reported only. Furthermore, 50% of these ADRs were reported verbally, which is not the proper method of reporting ADRs. Moreover, ADRs were reported to multiple authorities. Overall, these findings not only indicate low practice of ADR reporting but also inappropriate and inadequate reporting, which are consistent with other studies [21,57]. Chopra and associates [57] found that only 30% of physicians reported ADRs. While Stoynova et al. [21] reported that 25.2% of physicians had actually reported ADRs. In fact, under-reporting of ADRs has been signaled as a major problem in medical practice [69]. Mandatory training courses in ADRs should be in place for all physicians in hospitals, and this strategy will not only enhance their KAAP but also reporting of ADRs to PV system. As a result, the patients will be relatively safer in knowledgeable hands.

Finally, the self-reporting practice of ADRs was low in the present research, which may be influenced by the "self-image" bias associated with self-reporting. Some respondents may over-report self-reporting of ADRs in order to enhance their image. In a study from India, 46% of physicians self-reported the practice of ADR reporting, but the screening of records surprisingly did not identify any reported ADRs [56].

This cross-sectional study has some limitations. It is a descriptive study and, therefore, its result do not give any sound idea about cause-effect relationship in terms of what factors impact physicians' knowledge, awareness, attitude and practice. Furthermore, the results have limited power to be generalized to many other hospitals in the Kingdom of Saudi Arabia. This study has not specifically described ADR reporting by job position, i.e., general physician, specialist, and consultant and, hence, this remains undetermined who should be the main target for training in ADR reporting. Another relevant point is that the radiologists need to be included in this study, because they come across many patients who develop hypersensivity reactions to contrast material used in radiological setting around the world. This exclusion criterion introduced small bias in the selection of sample. However, this

study has some strengths. Evidently, this study involved a heterogeneous sample of adequate number of physicians with diverse sociodemographic background from different departments and healthcare settings. This kind of sample tends to increase representativeness of physician population, and consequently increases the external validity of the study and the possibility of making fair inferences from its results. Other strength is that such diverse sample enables the process of investigating the impact of independent variables on physicians' knowledge, awareness, attitude, and practice of reporting ADRs (related paper is forthcoming soon). Moreover, although the study was based on a self-administered questionnaire as a data collection tool, the response rate was approximately 88%. This high response rate adds to the credibility of the study findings since a high non-response rate is often associated with non-response biases [70-72].

5. CONCLUSION

The preliminary findings of this study suggest that though majority of physicians had good awareness and positive attitude towards ADRs and ADR reporting, they had correct knowledge only in some areas of ADRs and their reporting system. As majority of physicians were not exposed to ADR training courses, hence they certainly need mandatory ADR training programs in order to further enhance their KAAP towards ADRs and ADR reporting. Further research on ADRs and their reporting is needed especially to explore which drugs are potentially liable to cause ADRs among patients with particular diseases.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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