



## Barriers, Facilitators, Strategies, and Predictors for Reporting Adverse Drug Reactions in three General Hospitals in Jeddah, 2013

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### Authors' contributions

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

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### ABSTRACT

**Background:** Adverse drug reactions (ADRs) are the main cause of significant morbidity and mortality worldwide. The identification of barriers, facilitators, strategies, and predictors for reporting ADRs helps in the prevention of ADRs and their potentially harmful consequences.

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**Objective:** This study explored general hospital physicians' opinion to identify the barriers, facilitators, improving strategies, and the most powerful predictors for detecting and reporting of ADRs in three general hospitals of Jeddah city.

**Methods:** Using stratified sampling technique, 337 physicians were selected from three general hospitals and they were asked to complete a 7-part self-administered questionnaire concerning reporting of ADRs. The research variables of physicians' demographics and their knowledge, awareness, attitude, and practice (KAAP) towards reporting of ADRs encountered were entered into the best fitting logistic regression model for finding out the best predictors of detection and reporting of ADRs.

**Results:** Lack of knowledge of ADRs (86.4%) and ADRs reporting process (71.8%), uncertain relationship between ADRs and drug (67.7%), busy schedules and time constraints (53.7%) were the key barriers against reporting ADRs. The important motivators for reporting ADRs were adequate awareness (92.9%), hospital support (89.3%), patient safety concerns (88.1%) and professional responsibility/role (82.5%) of reporting ADRs. Majority of physicians (77.4%) suggested no strategies for improving ADR reporting, and only 16.3% of physicians emphasized on increasing physicians' awareness and knowledge of reporting ADRs through continued training programs. Consultant job and adequate knowledge of ADRs were the most powerful predictors of recognizing ADRs in practice while consultant job, adequate awareness, ample knowledge of ADRs, and training in ADR reporting were the significant predictors of ADR reporting.

**Conclusion:** Besides identifying some motivators and improvement strategies for and barriers against ADR reporting, this study found some independent significant predictors of detecting and reporting of ADR in general hospitals. Continuous training of healthcare professionals in adverse drug reactions is considered the best improvement strategy for identifying and reporting of ADRs. Further research is needed in all the general hospitals of Saudi Arabia to capture other predictors, motivators, and improvement strategies for and barriers against ADRs encountering and reporting.

*Keywords: Adverse drug reactions; detection and reporting; barriers; motivators; predictors.*

## 1. INTRODUCTION

Adverse drug reactions (ADRs) are the cause of significant morbidity and mortality around the world. ADRs are ranked as the fourth to sixth leading causes of death in the USA [1]. The epidemiological studies of ADRs reported variable incidence and prevalence mainly attributed to ADR encountering and reporting trends. In USA, 68% of the licensed pharmacists in community and hospital pharmacies had never reported any ADRs to the Food and Drug Administration (FDA). Furthermore, 93% or more did not report ADRs during the previous 12 months. These low reporting rates were not compatible with their positive attitude towards ADR reporting [2]. In Nepal, the physicians showed positive attitude towards reporting ADRs and pharmacovigilance (PV) programs, yet only 34% of them submitted ADR reports to the regional PV center [3]. Certain facets of attitude such as ignorance, diffidence, lethargy, sense of insecurity, complacency and fear of being held responsible are possible underlying causes of under-reporting of ADRs [4]. In another study, about 90% of primary healthcare professionals encountered suspected ADRs but only 22% of participants reported to PV system [5]. Similarly,

approximately 90% of physicians observed suspected ADRs but only 30% of them reported to the hospital PV center [6].

Despite pharmacists' having high knowledge of ADRs, only 29.3% reported a suspected ADR [7]. Majority of respondents expressed positive attitudes towards the pharmacist's role in PV. The lack of access to a reporting template, remuneration, and time constraints were not perceived as potential barriers against ADR reporting. Conversely, inability to recognize a suspected ADR was considered a barrier by 39.4% respondents in a survey in Qatar [7]. In another study from China, 90% of healthcare professionals including doctors, nurses, and administrators encountered ADRs, and 94% of them believed that these should be reported, and over 60% did not report suspected ADRs. The important barriers against ADRs reporting were unavailability of the report forms when needed, unfamiliarity with the reporting process, and lack of awareness of a national ADR reporting system [8].

In India, 90% of the hospital physicians were aware of ADR reporting and monitoring system, but only 41% had reported suspected ADR to PV

system. Factors that motivated ADR reporting were awareness, acknowledging the receipt of ADRs report, provision of feedback to the reported ADRs and continuous encouragement to reporting ADRs. Barriers against reporting suspected ADRs were time constraints, well known reactions, mild ADRs and immediate management of ADRs [9]. In a study, 81.4% academic medical center physicians suspected an ADR without reporting it, and 40% of them were not aware of various functions and purposes of ADR reporting system. A major determinant of under-reporting of ADRs was 'ADR was considered to be too trivial or too well known' and other factor was uncertainty of types of ADRs. Not reporting well-known ADRs reflects a misconception among physicians about the types of reactions to be reported to PV system [10].

Furthermore, several studies reported that physicians with inadequate knowledge about ADRs and reporting system had low reporting practice, and researchers recommended that physicians need advanced ADRs training programs to bridge this knowledge gap [11,12]. Other studies recommended the continuous training of health professionals and use of skilled-oriented methods known to significantly increase physicians' ADR reporting to PV system, their general awareness and differential effects on attitude towards ADR reporting [8, 13-16]. Both improving ADRs related knowledge and system of reporting ADRs through internet highly motivate hospital professionals including nurses to report ADRs [8,16,17]. Accredited international standards, written policies and procedures further motivate public hospital physicians to spontaneously report ADRs [7]. Obviously, encountering ADRs and its immediate reporting to PV are not convergent as each one is probably affected by a variety of factors including working place, and knowledge, awareness, attitude and practice (KAAP) of healthcare providers.

Under-reporting of ADRs is a worldwide phenomenon [4]; yet reporting ADRs to PV system for ensuring safe use of medicines is the prime responsibility of health care professionals and also patients [13,18,19]. Notably, ADR reporting rate is found to be as low as 6%, and at best it is 18.5% with an average of 10% [20-24]. The underreporting of ADRs is a common feature even in well-established PV programs [25-28]. ADRs reporting rate in Saudi Arabia is about 0.1% [29]. This high rate of under-reporting

delays ADR signal detection and subsequently has a negative impact on public health [6,18,30]. Therefore, it is important to identify the key factors responsible for under-reporting of ADRs to PV systems [31]. Although ADR reporting databases are well established in high income countries, information on encountering, detecting and reporting of ADRs in low-and middle income countries especially in Middle East countries is relatively scanty [32-38]. The relevance of this study is that it will identify barriers, motivators, improving strategies and predictors for ADR reporting in three general hospitals of Jeddah city, Saudi Arabia. The significance of this research is that it will guide educators to tailor advanced training programs to bridge the knowledge and awareness gap of hospital physicians who are at present underreporting ADRs to PV system.

## 1.1 Objective

The objectives of this study were; to identify barriers for reporting ADRs; to determine motivating factors and strategies for improving reporting of ADRs; and to determine the most powerful predictors of ADR detecting and reporting in three general hospitals of Jeddah City.

## 2. METHODS

### 2.1 Study Design and Setting

This is a cross-sectional study, which was conducted in Jeddah, 2012-2013. There are nine public hospitals under Ministry of Health (MoH). This study was conducted in three general hospitals namely King Fahd General Hospital [KFGH] (600 beds), Al-Thaghar Hospital [ATH] (100 beds) and King Abdul-Aziz Hospital [KAAH] (450 beds) [30]. These hospitals were selected because they serve relatively a large number of patients presenting with or without ADRs [6], and also have different departments including intensive care units and emergency services. Full details of methods and materials are described elsewhere [39].

### 2.2 Sample Size Determination and the Sampling Technique

The sample size was calculated using specific formulas [34-38]. Subsequently, a proportionate sample from each hospital was defined. The total proportionate sample was 269 physicians (KFGH

= 133/402, ATH = 40/120, and KAAH = 96/289 [39]. The sample size was increased to 385 in order to overcome refusal to participate in this research. The actual analysed sample was 337, and the total number of distributed questionnaires among participants was 385 [28,40]. The response rate was 87.5%. Stratified random sampling technique was used to include various departments and job categories. Then, systematic random sampling was applied within each stratum (or category) 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 at the time of questionnaire distribution or refusal to participate, the participant was replaced by the next physician on the list. Notably, the first starting number was chosen from the table of random numbers by simple random sampling [39].

### 2.3 Inclusion and Exclusion Criteria

The sample size of this study was 337 and participants were residents, specialists and consultants from three general hospitals. Physicians working in administration as managers or medical directors were not included in the study. These physician-cum-administrators 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 not allowed to prescribe medications except under the supervision of senior physicians.

### 2.4 Instrument

A self-administered questionnaire was developed by 5 experts after reviewing the relevant literature (13 references available upon request from TMAB). The contents of the questionnaire were in tandem with the objectives of the study and the institutional and national guidelines [13]. The questionnaire comprised of seven parts which are; 1) Socioclinical characteristics; 2) the awareness of ADRs program; 3) the knowledge about ADR reporting; 4) assessment of physicians' attitude towards ADR reporting; 5) practice of ADR reporting; 6) motivators of and barriers against ADRs reporting and 7) self-

assessment, intention and recommendations for improving ADR reporting. The present study will focus on motivating factors of, barriers against and strategies for improving the encountering and reporting of ADRs. Full details of the questionnaire development are available here [39].

### 2.5 Pilot Study

A pilot study was conducted before data collection [39]. 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, the coding process, and also to resolve any problems encountered. Feedback from the pilot study helped to refine the questionnaire. Reliability of the self-administered questionnaire was good with Cronbach's alpha coefficient 0.7. Cronbach's alpha value of 0.7 or higher indicates good reliability. Hence, the questionnaire was reliable, and all the items in the questionnaire were closely related. Furthermore, Cronbach's alpha values for the individual sections, barriers (20 items) and motivators (12 items) were 0.9 and 0.8, indicating excellent and good reliability, respectively.

### 2.6 Data Collection

The first author regularly visited the three hospitals to supervise the data collection from selected physicians. The researcher would give a self-introduction and also brief the participants on the objectives of the study. Every morning the questionnaire was distributed to 20 chosen subjects and the researcher was available for any clarification required by the participants. The completed questionnaires were then collected from the participants. Those who were unable to complete the questionnaire because of their busy work schedule were allowed to complete the questionnaires in the afternoon. As there were no morning meeting in emergency departments, questionnaires were distributed after endorsement time and duly filled questionnaires were collected from the participants, in the afternoon. All answered questionnaires were immediately checked for completeness. In case of an incomplete questionnaire, the concerned participant was asked to complete it on the spot and return to the researcher [39].

### 2.7 Scoring

The awareness domain of the knowledge, awareness, attitude and practice (KAAP)

questionnaire had eight items, and each item was scored either 1 or zero for correct or incorrect answer. The scores of all the eight items were summed up and a maximum score of 8 (minimum score 0) was obtained. Similar scoring system was applied to knowledge section too. The knowledge domain had 22 items; eight items for ADR knowledge (maximum score 8) and 14 items for ADR reporting knowledge (maximum score 14). Hence, the maximum score for knowledge domain was 22. For attitude component, the responses ranging from "strongly agree" to "strongly disagree" were scored 5 to 1, respectively. The higher scores indicated positive attitude. The scores of the attitude section were summed-up, and the total divided by the number of the questions in that section, thus, giving attitude mean score with a range of 1-5. Motivators and barriers of ADR reporting were graded as important (score 2), not sure (score 1) and not important (score 0) [39].

## 2.8 Data Analysis

All answered 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, percentages, mean, standard deviation and median for research variables. Best fitting multiple logistic regression model was used to determine the most powerful predictors of detecting and reporting ADRs.

## 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 permission letters to implement the study in four hospitals was taken from the Jeddah General Health Affair. After clearly explaining the objectives of the study, written informed consent was obtained from individual participants. All the participants 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 information and that the collected data would be accessible only to the research team.

## 3. RESULTS

### 3.1 Barriers against ADR Reporting

Table 1 indicates that the most commonly mentioned barriers to ADR reporting were, insufficient clinical knowledge (86.4%) followed by not knowing how to report (71.8%) and the uncertainty of the relationship between ADRs and drugs (67.7%). On the other hand, the least mentioned barriers were those of the misconception that only safe drugs are available in the market (27.6%) and confidentiality issues (38.6%).

### 3.2 Motivating Factors of ADR Reporting

As for the facilitating factors, Table 2 shows that the highest scorers were improving awareness of ADR reporting (92.9%) and taking patient's safety concerns seriously (88.1%). At the other extreme, the least important motivating factors were giving of reward or compensation for ADR reporting (55.2%) and attention drawn to importance of ADR reporting by a publication (59.6%).

### 3.3 Strategies to Improve ADR Reporting

Table 3 demonstrates that the majority of the sample (77.4%) gave no suggestions to improve ADR reporting. However, the most common strategy suggested by 16.3% of physicians was concerning to increasing awareness and knowledge.

### 3.4 Predictors of ADR Encountering

The results of associations of physicians' demographics and ADR practice and KAAP are described in detail elsewhere [41]. In the multivariate analysis, the research variables including age, sex, nationality, qualification, department, experience, training courses, number of patients seen, awareness, knowledge, and attitude scores, having adequate knowledge of ADR reporting, feeling adequately trained in ADR reporting, workplace increased awareness of ADR and intention to report were entered in the model. The results demonstrated that the two variables survived, i.e., being consultant and having adequate knowledge of ADR significantly predicted encountering or detecting ADRs in practice. Each independent predictor increased the probability of encountering or detecting ADR by more than three-folds (adjusted OR = 3.06 & 3.45). The model has a good fit indicated by Hosmer and Lemeshow test (Table 4).

**Table 1. Barriers against ADRs reporting expressed by physicians (n=337)**

Barriers	Important		Uncertain		Not Important		Score (max=2)		
	No.	%	No.	%	No.	%	Mean	SD	Median
Insufficient clinical knowledge of ADRs	291	86.4	33	9.8	13	3.9	1.8	0.5	2.0
Don't know how to report ADRs	242	71.8	38	11.3	57	16.9	1.5	0.8	2.0
Uncertainty relationship between ADRs and drug	228	67.7	87	25.8	22	6.5	1.6	0.6	2.0
No reporting forms available	206	61.1	80	23.7	51	15.1	1.5	0.7	2.0
Busy schedule and lack of time	181	53.7	63	18.7	93	27.6	1.3	0.9	2.0
Fear of loss of patient confidence	172	51.0	75	22.3	90	26.7	1.2	0.8	2.0
Fear of a consequent law suit	172	51.0	94	27.9	71	21.1	1.3	0.8	2.0
Reporting address unknown	170	50.4	99	29.4	68	20.2	1.3	0.8	2.0
Difficulty to admit harm to the patient	165	49.0	118	35.0	54	16.0	1.3	0.7	1.0
Disruption of normal workflow	157	46.6	88	26.1	92	27.3	1.2	0.8	1.0
Time consuming to report	150	44.5	94	27.9	93	27.6	1.2	0.8	1.0
Confidentiality issues	147	43.6	90	26.7	100	29.7	1.1	0.8	1.0
ADR is an expected side effect	146	43.3	101	30.0	90	26.7	1.2	0.8	1.0
Thinking one report doesn't make any difference	144	42.7	94	27.9	99	29.4	1.1	0.8	1.0
Reporting could show ignorance	143	42.4	98	29.1	96	28.5	1.1	0.8	1.0
Conflict of interest	142	42.1	113	33.5	82	24.3	1.2	0.8	1.0
Lack of adequate incentives	133	39.5	137	40.7	67	19.9	1.2	0.7	1.0
The forms are too complicated	131	38.9	143	42.4	63	18.7	1.2	0.7	1.0
Reporting does not influence the treatment scheme	130	38.6	112	33.2	95	28.2	1.1	0.8	1.0
Only safe drugs are available in the market	93	27.6	135	40.1	109	32.3	1.0	0.8	1.0

**Table 2. Motivating factor for reporting ADRs as expressed by physicians (n=337)**

Motivators	Important		Uncertain		Not Important		Score (max=2)		
	No.	%	No.	%	No.	%	Mean	SD	Median
Improving awareness of ADR reporting	313	92.9	15	4.5	9	2.7	1.9	0.4	2.0
Hospital support of ADR reporting	301	89.3	25	7.4	11	3.3	1.9	0.4	2.0
Taking the patient's concern seriously	297	88.1	27	8.0	13	3.9	1.8	0.5	2.0
Part of our professional role	278	82.5	44	13.1	15	4.5	1.8	0.5	2.0
Making ADR reporting as a part of normal workflow	265	78.6	54	16.0	18	5.3	1.7	0.6	2.0
Part of medical care provided	264	78.3	52	15.4	21	6.2	1.7	0.6	2.0
Enforcing rules	263	78.0	50	14.8	24	7.1	1.7	0.6	2.0
Getting more insight into ADR questions in practice	253	75.1	67	19.9	17	5.0	1.7	0.6	2.0
Peer influence	218	64.7	99	29.4	20	5.9	1.6	0.6	2.0
Increasing patient counseling time	214	63.5	84	24.9	39	11.6	1.5	0.7	2.0
Attention drawn by a publication	201	59.6	106	31.5	30	8.9	1.5	0.7	2.0
Some type of reward or compensation	186	55.2	92	27.3	59	17.5	1.4	0.8	2.0

With regard to reporting of ADR, the variables entered in the multiple logistic regression model were age, sex, nationality, qualification, department, experience, training courses, number of patients seen, knowledge, awareness and attitude scores, having adequate knowledge of ADR reporting, workplace increased awareness of ADR, and intention to report. The results showed that the three variables survived the model, i.e., being consultant, having a higher awareness score, and having adequate knowledge of ADR and all three variables significantly predicted reporting of ADRs in practice, while feeling adequately trained in ADR reporting showed a trend towards statistical significance ( $p=0.051$ ). Being consultant was the most powerful predictor as it increased the probability of ADR reporting by more than three-folds (adjusted OR = 3.46). The model has a good fit as indicated by Hosmer and Lemeshow test (Table 5).

**Table 3. Suggestions to improve ADR reporting expressed by physicians (n=337)**

Strategies	Frequency	Percent
None	261	77.4
Increase awareness and knowledge	55	16.3
Make system easier, less complicated forms	12	3.6
More hospital management efforts	4	1.2
Feedback	2	0.6
Clear responsibilities	2	0.6
Clinical pharmacists	1	0.3

#### 4. DISCUSSION

This cross-sectional survey of practicing physicians found some barriers, motivating factors and improving strategies for reporting ADRs in three general hospitals. This research

also found some independent, significant predictors of encountering or detecting ADRs and their reporting in the same settings in Jeddah city. According to this study, the lack of sufficient knowledge of ADRs and the process of ADR reporting, uncertainty about relationship between drug and ADR, unavailability of ADR reporting forms, time constraints and busy schedule were the most important barriers against ADR reporting. According to the physicians, the misconceptions that only safe drugs are available in the market and the confidentiality issues were less important barriers against reporting ADRs. These findings conform to the relationship between low level of awareness and insufficient knowledge of ADRs and unsatisfactory practice of ADR reporting. These results have some implications especially removing barriers by advanced educational strategies may improve spontaneous ADR detection and reporting [42]. Largely, spontaneous reporting of ADRs is the most effective pharmacovigilance method to detect new and serious drug reactions which adversely impact the quality of patient care [43], and also help in monitoring the safety of drugs in post-marketing phase. Similarly barriers including unavailability of reporting forms, high frequency of ADRs, minor ADRs, lack of knowledge of the ADR reporting procedures, underestimating the importance of reporting ADRs, and time constraints were reported in a survey [44]. In a qualitative study of community pharmacists in Malaysia, the major theme concerning barriers to ADR reporting was a lack of knowledge about ADR reporting processes [42] which is consistent with the present study. Evidently, previous studies have also found other reasons for not reporting ADRs to pharmacovigilance systems which are, the negative attitudes and perceptions of healthcare professionals towards ADR reporting, and logistic barriers including unavailability of ADR reporting templates, insufficient knowledge of ADR

**Table 4. Best fitting multiple logistic regression model\* for encountering ADRs**

	Wald	DF	P	OR	95% CI for OR	
					Upper	Lower
<b>Encountering/detecting ADR</b>						
Constant	10.68	1	0.001	0.51		
Job (reference: resident)	15.22	2	0.000			
Job: specialist	3.76	1	0.052	1.74	0.99	3.05
Job: consultant	15.18	1	0.000	3.06	1.74	5.37
I have adequate knowledge of ADR	24.02	1	0.000	3.45	2.10	5.67

\*Nagelkerke R Square = 0.17, Hosmer and Lemeshow Test:  $p=0.281$ , Omnibus Tests of Model Coefficients:  $p<0.001$



**Table 5. Best fitting multiple logistic regression model\* for reporting ADRs**

	Wald	DF	P	OR	95 % CI for OR	
					Upper	Lower
<b>Reporting ADR</b>						
Constant	68.77	1	0.001	0.04		
Job (reference: resident)	12.70	2	0.002			
Job: specialist	0.81	1	0.369	1.46	0.64	3.36
Job: consultant	10.41	1	0.001	3.46	1.63	7.37
Awareness score	10.32	1	0.001	1.23	1.09	1.40
I have adequate knowledge of ADR	6.42	1	0.011	2.24	1.20	4.19
I feel adequately trained in ADR reporting	3.80	1	0.051	2.12	1.00	4.52

*Nagelkerke R Square: 0.25; Hosmer and Lemeshow Test: p=0.18; Omnibus Tests of Model Coefficients: p = 0.001*

reporting process, time constraints, poor awareness about the purpose of spontaneous reporting systems (SRSs), trivial and expected ADRs, lethargy, complacency, fear of legal liability, and ADR reporting not being mandatory [21,45,46]. In a systematic review involving health professionals, the researchers reported that the ignorance, insecurity and indifference were the main obstacles for reporting of ADRs [47].

Notably, the most important factors that could motivate general hospital physicians to report ADRs were improving their awareness and continuing hospital support towards reporting of ADRs. In addition, both taking the patient's concern seriously and reporting ADR being an important professional role were other two factors that might motivate physicians to report ADRs. Conversely, the least important factors to motivate physicians to report ADRs were enforcing rules in the hospitals, rewards or compensation, peer pressure, increase in patient counseling time, and attention drawn by a publication on ADRs. These findings underline the significance of raising physicians' awareness of reporting ADRs and creating a culture of patient safety in the hospital. Similarly, a cross sectional survey of doctors reported that training and knowledge of the reporting system was found to improve ADR reporting. Majority of the doctors (60%) had encountered suspected ADR but only 20% doctors reported using the spontaneous ADR reporting form. The perception for reporting ADRs as a professional responsibility motivates doctors to report ADRs [4]. Detecting ADRs and their reporting do not have linear relationship [39,41]. Furthermore, it is futile setting rules for disciplinary actions to defaulters, and even rewards and compensation fail to motivate physicians to report ADRs, which is not consistent with other studies [42].

However, Hickner and colleagues [48] found that a punitive culture discouraged physicians to report ADRs.

According to this study, majority of physicians did not suggest any method to improve spontaneous ADRs reporting to SRSs. But less than twenty percent reported that enhancing awareness and knowledge of physicians by exposing them to ADR reporting courses will strengthen the reporting of ADRs. In a study, Rehan and colleagues [49] reported that more than 90% of the participants (medical students and prescribers) asked for more training in ADRs and their reporting in order to improve their awareness and practice of ADR reporting. Other studies have reported additional strategies which include integration of ADR reporting into the under - and post-graduate pharmacy curriculum, advanced training programs for enhancing awareness and knowledge, continuing ADR seminars, the implementation of the user-friendly ADR system, and online reporting of ADRs [42,50,51]. Evidently, like online reporting of ADRs [52], multifaceted educational interventions tend to have good impact on ADR reporting to pharmacovigilance system and improvement in the quality of ADR reports as revealed in a systematic review [53].

according to this study, physicians' awareness of ADRs was the most significant predictor of reporting ADR but not of encountering or detecting them. However, physicians' adequate knowledge of ADRs significantly predicted encountering or detecting ADRs. Therefore, it is not merely the awareness that makes the physician able to identify an ADR and consequently increase the likelihood of encountering it, but this needs basic in-depth knowledge about ADR. In fact, the awareness is persons' consciousness and relates to

knowledge about ADRs [54,55]. In addition, physicians feeling of being trained and having adequate knowledge of ADR were found to have an independent, significant impact on ADR reporting. Thus, the act of reporting ADRs needs both awareness and knowledge of ADRs, which are indeed based on advanced, continuing training in ADRs. A recent study from Japan involving hospital workers demonstrated that a problem-based learning program concerning ADR reporting system significantly improve their level of understanding and willingness to report ADRs to pharmacovigilance system [56]. Moreover, a higher job category such as being consultant predicted significantly encountering and reporting ADRs in hospital settings. Consultant physicians are likely to encounter and report ADRs three times higher than the residents. Although specialists' likelihood to report and encounter ADRs was approximately one and a half folds more than that of residents, the difference between them did not reach statistical significance. These findings point that specialists and residents in hospitals need continuing training for increasing their awareness and knowledge regarding identification and reporting of ADRs. Additional significant predictors of ADR reporting are; being older than 60, having prior experience with ADR, having higher specific knowledge of spontaneous reporting of ADRs, and having less concern about the barriers to spontaneous reporting [57].

## 5. CONCLUSION

In summary, this study identified certain barriers which include lack of knowledge of ADRs and ADRs reporting process, uncertainty between ADRs and drug, and busy schedules and time constraints. The important motivators identified for reporting ADRs were adequate awareness, hospital support, patient safety concerns, and professional responsibility of reporting ADRs. The identified improvement strategies for ADR encountering and reporting were increasing physicians' awareness and knowledge of ADR reporting. Consultant job and adequate knowledge of ADRs were the most powerful predictors of recognizing ADRs in practice while consultant job, adequate awareness, ample knowledge of ADRs, and training in ADR reporting were the significant predictors of ADR reporting. These results might help educators in planning ADR training programs for general hospital residents and specialist physicians who have knowledge gaps in detecting and reporting ADRs. Further research is needed to capture

other predictors, motivators, improvement strategies and barriers against ADRs encountering and reporting in all the general hospitals of Saudi Arabia.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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